THE UNDERSTANDING AND RECOLLECTION OF INFORMED CONSENT BY LABOURING WOMEN AFTER AN EMERGENCY CAESAREAN SECTION

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DECLARATION

I would like to certify that Candice Johnson, student number: 0309348E, is the first author of this paper. She is responsible for the content of the paper. She has written the protocol, collected the data, and written up this manuscript.

By signing this declaration, I agree to the use of the article by the student as part of her research report.

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ABSTRACT

Background

Informed consent is a regulatory and ethical requirement in medical practice. It forms the ethical basis of a patient-centered approach. In order to give informed consent, the user should be well informed and participate in the decision making. There is contention on whether women in labour can give a valid informed consent.

Objectives

To evaluate the understanding and recollection of informed consent after emergency caesarean section.

Methods

A cross- sectional study at Chris Hani Baragwanath Academic Hospital between May and October 2016. English speaking women older than 18 years were invited to participate. Previous caesarean section, maternal or neonatal complications were exclusion criteria.

Results

One hundred women were interviewed. The mean age was 26.5 years (SD±5.76). All the women recalled the indication for the caesarean section and 90 understood this. Seventy-eight said that risks and complications were discussed, eight said they were not, eleven could not remember and 3 did not know if they were discussed. When women were prompted, the recollection of the risks and complications was better. Seventy-four women wanted full disclosure of all the risks and complications. Eighty-four were satisfied with the information and 93 felt they took part in decision-making without being pressurised.

Conclusion

This study indicates that labouring women can recall indications and mostly understand the reason for the caesarean section. Their recall of complications was poor but better when prompted with specific questions. Most women would like to know about all the risks and complications.

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This project is dedicated to my late mother, Agnes Johnson. Her undivided love and guidance as a mother and healthcare worker will be remembered. May her beautiful soul rest in peace.

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LIST OF ABBREVIATIONS

CHBAH: Chris Hani Baragwanath Academic Hospital

C/S: Caesarean section

SA: South Africa

HPCSA: Health Professional Council of South Africa

MOU: Midwife Obstetrics Unit

WHO: World Health Organisation

USA: United States of America

SECTION 1: Protocol and extended literature review

1.1 Introduction

Informed consent is a regulatory and ethical requirement in medical practice.[1] It forms the ethical basis of a patient-centered approach, whereby a patient can make decisions on behalf of themselves, based on their own values and beliefs.[1] The National Health Act no 61 of 2003,[2] states that " before a user can consent to treatment, they should have full knowledge, and participate in the decision making. The knowledge should include a description of their health status, a range of possible treatments, the benefits, the risks and consequences associated with the treatment and the right to refuse together with the implications of such refusal." Informed consent is based on respect for a patient's autonomy, which is one of the four ethical principles in biomedical ethics, set out by Beauchamp and Childress.[3] Clinicians have an obligation to respect and protect the patient's health through beneficence. Only the patient has the freedom to decide what should happen to his or her body without coercion from others.[3]

Participation in decision making means that there has to be an understanding of the health status and the proposed management plan. Failure to adhere to these requirements is a violation of the patient's rights, and doctors may be held liable for harm.[2] There is contention on whether women in labour can give a truly valid informed consent. There are many reports on the recall and understanding of the informed consent for surgical procedures across various specialties. But not enough literature is available on how much information is understood and recalled by labouring woman.

Regarding informed consent in clinical research, there are many studies on the quality of informed consent, however studies to assess the quality of informed consent in clinical practice are lacking. Furthermore pregnant women are a vulnerable group and are underrepresented in clinical research. Regarding labouring women's voluntariness to consent, Van Lier and Roberts highlighted that labouring women's voluntariness can be undermined by being easily coerced because they fear they might be abandoned or treated unfairly if they refused to participate in clinical research. They suggested that labouring women are

vulnerable subjects that need special protection because researchers may "unknowingly" abuse the vulnerable state of labouring women."[4]

Chris Hani Baragwanath Academic hospital (CHBAH) is a busy tertiary hospital which delivers approximately 23000 women annually and it has a caesarean section (C/S) rate of 40%. Most of these C/S's are emergencies (Departmental statistics). The consenting procedure is performed by doctors of different seniority and experience. This study was performed to evaluate the understanding and recall in labouring women who had an emergency C/S. We also asked women about their perceptions regarding the consent process.

The informed consent process is governed by three elements according to Beauchamp and Childress which are in place to protect the patient's autonomy.[3] The three elements are as follows: threshold, information and consent.

1.1.1 Threshold elements

The threshold elements consist of the following characteristics:[3]

- Voluntariness: There should be an ability to make a free and voluntary informed choice without coercion.

- Decision-making capacity: A demonstration of understanding and the ability to communicate such understanding.

Assessing the women's capacity to consent is important and it forms part of the threshold element.[3] Studies concerning labouring women's decision-making capacity are few and it is believed that factors such as time constraints, pain, exhaustion and analgesia may affect their capacity to make an informed choice.[5] For that reason there is disagreement on whether they have the capacity to give consent. One of the concerns alluded to by Salmeen et al, is that pregnant women are prone to being anxious and are easily distracted during the painful labouring process.[5] This may then influence their capacity to make an informed choice to have an emergency C/S.[5]

Studies concerning labour epidurals demonstrated that labouring women's decision-making capacity are not affected by factors such as pain, anxiety and opioids[6,7,8,]

The study done by Jackson et al, found that labouring women have the capacity to consent because most of them wanted to know all the risk associated with labour epidurals, and knowing the risk would not have discouraged them to have an epidural. This was from a cohort of 60 labouring women who rated they pain scores as high as 7.5/10 and anxiety levels as high as 7.2/10.[6]

A study in the United States of America (USA) revealed that the degree of pain did not influence 101 women's ability to recall epidural risks when ask within 24 hours after giving consent. They assessed the women's capacity by the number of risks they could recall after delivery. All the women were in active labour and had not received any form of pain medication. They found that women with low, moderate and severe pain scores on a visual analogue scale had no difference in the number of risks recalled. Furthermore, they could recall 2.0 ± 1.3 risk spontaneously which improved to 3.5± 1.1 when prompted with a list of possible complications. The study concluded that the risks labouring women could recall was comparable to that of non-labouring women.[7]

And a survey done on 448 anaesthesiologists still in the USA found that 68% of doctors believed that actively labouring women are able to give informed consent for labour epidurals, while another 86% of the doctors also believed that antenatal anaesthesia consultations are not necessary for pregnant women who would prefer epidural when in labour.[8]

The time taken to provide information about the C/S during labour may also be too brief to give enough information. In a retrospective chart review, the study looked at the amount of time it took in obtaining informed consent in 90 labouring women who underwent an emergency C/S. The study demonstrated that the informed consent discussion was too short (less than 50 minutes) and further reduced to less than 30 minutes in 56% of women who underwent C/S for foetal heart rate indications as compared 13.8 % of women who had a C/S for non-foetal heart rate indications (<.001). There was no literature or published guidelines on what the optimal informed consent time should be as it may vary in different patients. It was concluded that short consent time may result in poor understanding and recall of information.[5]

Assessing women's capacity to consent is an important part of the consenting process, which is usually determined by the doctor.[9] There are no standard guidelines on how to assess capacity and a woman is presumed to be competent unless there is suspicion, in which case the doctor should seek further help by involving family members, translators, use of communication tools, or consulting with a psychiatrist.[10,11]

Doctors are guided by the criteria set out by the Health Professions Council of South Africa (HPCSA) where a patient is presumed to be competent if they demonstrate understanding, believe the information, appreciates the consequences of the situation and reach a decision.[11]

Labouring women can change their minds at any time and doctors should assess it regularly by encouraging ongoing sharing of information at various points before having an emergency C/S. It is also not good practice to judge a woman as not being capable to consent because doctors fail to agree with her decision. Other factors such as language barriers, medication, use of technical medical terms may affect their understanding and ultimately lead to poor decision, portraying the women as incompetent.[11] Information given to competent women may still not be clear enough because their understanding may vary according to their needs, values and expectations.

In his review article Hoener P remarked that "Factual knowledge is used, not as an end in itself, but as a means to extent the patient's own understanding in such a way as to meet his or her own unique priorities, needs, concerns, beliefs and fears so that they may come to a decision about their care in the manner they make similar choices."[12]

Informed consent is only valid when it is obtained from a well-informed patient who made a free and voluntary informed choice. According to Beauchamp and Childress "A person acts voluntarily to the extent that he or she wills the action without being under the control of another's influence."[3] The definition of voluntariness is that it is a choice made of a person's free will.[13] Women's voluntary choice should be given freely without pressure from family, friends and doctors. However some women have misconceptions about the true meaning of voluntariness.

Some studies demonstrated that women think they have no free choice to decide for themselves, most women felt pressurised and felt consent was there to protect hospitals.[14-15] This was demonstrated by Akkad et al, study where they investigated 734 women's recall, experience and overall satisfaction with the consenting procedure. Four hundred and ninety-nine women had elective surgery and 233 had emergency surgery. Compared to the women who had elective surgery they found that most women undergoing emergency surgery felt scared and pressurized to sign the consent form and some felt they had no choice but to sign the form. They were also less likely to be satisfied with the overall consenting process And in both groups most women felt that detailed information provision regarding the procedure were important. [14]

In another study by Akkad et al, 732 women's view on their experience of written informed consent were explored after having an elective or emergency surgery in obstetrics and gynaecology. Only 41% of the women were of the opinion that the consent form made their wishes known. The study found that 46% thought the main function of the consent form was to protect the hospital and up to 68% thought that giving consent gave the doctors control over what should happen to them.[15]

The same sentiment was shared by Habiba et al, where 20 women also felt the primary purpose of the consent form was to serve the interest of the hospital and up to 6 women who underwent emergency surgery felt that it was forced on to them and they had no say in the matter. Another 3 who did not want to have the surgery felt that they eventually had to give in to the decision made by the doctor. This was from a cohort of 25 women where their experience on the consenting process after undergoing an elective or emergency gynaecogical or obstetrics procedure was explored.[16]

However some patients feel that that doctors should decide what is best for them. This finding was demonstrated in an observational cross-sectional study done in India. The study indicated that 69.2% of the 500 participants felt that the doctor should decide the treatment for them.[17]

1.1.2 Informational elements

Informational elements are comprised of the following characteristics:[3]

- Disclosure of information: An explanation of the proposed intervention and the benefits, risk, prognosis and alternative treatment choices including no treatment.

- Recommendations: An explanation of the nature of the illness and a recommendation of a treatment plan.

- Understanding: A demonstration of understanding of what has been recommended before consenting.

The World Medical Association Declaration of Lisbon said that patients everywhere have the right to information and choice.[18] The courts standard of disclosure of information varies between different countries and no agreement exists on how much information should be given to a particular patient prior to surgery. Doctors should be aware that the amount of information disclosed to the patient may vary according to their individual needs, and it is their responsibility to determine how much the patient understands and wants to know.

There should be disclosure in order for the patient to be a part of the decision making process. Most countries including South Africa (SA) apply the reasonable person standard as opposed to the reasonable doctor standard. According to the reasonable patient standard the doctor has a duty to disclose all "material risks" to a patient. A "material risk" being "anything a reasonable person in a patient's position, if warned of the risks, would attach significance in his or her decision making process."[11] Even if some risks associated with the surgery are rare but important to the patient, they should be discussed, especially if their occurrence carried serious consequence such as death.

However these requirements set out by the Health Professional Council of South Africa (HSPCA) seemed contrary to what Chima has found in his study conducted in KwaZulu Natal.[19] He evaluated whether the quality of informed consent obtained by 168 doctors is consistent with international standards and local regulations. The study revealed that only a

few doctors (35) disclosed all the "material risks" and 97 doctors were still in favour of the reasonable doctor standard of disclosure,[19] while 54.9% of the 102 doctors in a Nigerian study felt that not enough information are given to patients when consenting them for a surgical procedure.[20]

These finding are concerning because most women want full disclosure of information during the consenting process, which was demonstrated in 2 previously mentioned studies by Jackson A, et al in the USA[6] and Akkad A et al in the United Kingdom.[14]

The Royal College of Obstetricians have issued guidelines on what information doctors should give woman undergoing C/S's.[21] The guidelines include a comprehensive list of incidences of risks, serious and frequently occurring risks and on extra procedures that may become necessary during the procedure. Table 1 below explains the serious and frequent risks and their incidences.[21]

Table 1. Risk associated with caesarean section.

Serious risk includes:	
Maternal • Emergency hysterectomy,7-8/1000 (uncommon). • Need for further surgery at a later date, including curettage, 5/1000 (uncommon). • Admission to intensive care unit (highly dependent on reason for caesarean section), 9/1000 (uncommon). • Thromboembolic disease, 4-16/1000 (rare). • Bladder injury, 1/1000 (rare). • Ureteric injury, 1/10000 (rare). • Death, 1/12000 (rare).	Future Pregnancies • Increased risk of uterine rupture during subsequent pregnancies/deliveries, 2-7/1000 (uncommon). • Increased of antepartum stillbirth,1-4/1000 (uncommon). • Increased risk of subsequent pregnancies of placenta praevia and accrete, 4-8/1000 (uncommon).
Frequent risk includes:	
Maternal • Persistent wound and abdominal discomfort in the first few months after surgery, 9/100 (common). • Increased risk of repeat caesarean section when vaginal delivery attempted in subsequent pregnancies, ¼ (very common)	Fetal Lacerations, 1-2/100 (common

• Readmission to hospital, 5/100 (common). • Haemorrhage, 5/1000 (uncommon). • Infection, 6/100 (common).	

Extra procedures which may become necessary during the procedure include:

- Hysterectomy
- Blood transfusion
- Repair of damage to bowel, bladder or blood vessels.

C/S is a common procedure with risks and complications, it is therefore important that women be told about all the risks, especially risks with serious consequences. Information may not necessarily have to be too extensive unless the women have a desire to know all the risks involved. Doctors should be aware that "reasonable" labouring women's needs and expectations for disclosure of information may vary according to the amount of information they want to know.

There is considerable literature available regarding the recall and understanding of the informed consent process for surgical procedures across various specialties. Most of the studies found that patients' understanding and recall of information following a medical or surgical procedure is generally poor.[22,23] A study done by Barret et al in the Free state found that 13 out of the 53 transfused patients could not recall being told about any risk related to blood transfusion, while 9 felt they did not received enough information about the risks.[22] In Uzzaman et al, study 19 patients could not recall any complication associated with open inguinal repair. And only a few could recall the possible long term complications i.e. chronic pain (2 patients), numbness (10 patients) and testicular complications (10 patients). The study investigated 86 patients' understanding and recall of the consenting procedure after having an elective open inguinal hernia repair.[23]

Various factors have been shown to contribute to poor transfer of information, which leads to poor understanding and recall. Among these are doctors that underestimate the informational needs of women they consent. In both developed and under developed countries, studies found that doctors especially junior doctors are deficient in most aspects of the surgical informed consent.[24,25]

A study in Pakistan demonstrated that junior doctors perform more poorly than senior doctors, and most of them assigned the responsibility in obtaining informed consent to junior doctors or nurses.[24]

A study in the Netherlands looked at current informed consent practices of 453 doctors which consisted of 157 surgical residences in training and 296 surgeons. The study also found that the surgical residents fared worse than the surgeons. In addition, only 55% of the 453 doctors knew all three basic elements (threshold, informational and consent) for a valid informed consent. Only 62% of the doctors knew about assessment of threshold elements, but 92% knew about informational elements and only a few (12%) knew about consent elements.[25]

Some studies demonstrated that patients understanding and recall of information may be influenced by a patient's age and education level.[26,27] Hekkenberg et al, found that age and education are important determinants of recalling information in 54 patients that underwent head and neck surgery. The overall recall rate of risk and complications was 48%, younger patients recalled over 50% of the complications and patients with a higher level of education recalled better.[26] Similar findings were demonstrated in an orthopedic study done in Turkey, the recall of complications was better in the educated group and poor in the advanced age group.[27]

Some studies have shown that patients undergoing emergency procedures are more likely to have poor understanding and recall of the informed consent process compared to those undergoing elective procedures.[14,27-29] The degree of urgency was a consistent contributory finding in all the studies, which led to poor transfer of information.

Regarding elective procedure, patients have plenty of time to participate in the decision making process. In contrast patients undergoing emergency procedures are unprepared and may have no prior knowledge. This finding was demonstrated in an audit that was done to compare the recall of the consent process and desire for information between 40 trauma and 41 elective orthopedic patients. Of note the elective patients received information leaflets as well as a verbal explanation of the procedure. The trauma patients only received verbal information. The study concluded that the overall recall of complications was poor in both groups but that the trauma patients fared worse (62% v/s 22%, $P<0.001$).[28]

Similarly, another orthopaedic study that was previously mentioned found that out of the 142 patients, the rate of recall of potential complications was worse in the emergency trauma group (56.9%) compared to 25.7% in the elective group.[27] And Odumosu et al compared the level of recall and understanding of the risk associated with C/S 24 hours after having an emergency or elective caesarean section in 554 women. The study found that women undergoing emergency caesarean section had poor recall of risk compared to the elective group (70% v/s 95.6%, P<0.001). The study concluded that women undergoing emergency caesarean section had poor recall and understanding of the informed consent process.[29]

Doctors in a South African study mentioned earlier also identified time constraints as a major challenge in obtaining a valid informed consent.[19] They also identified language barriers, work load, lack of education and lack of administrative support e.g. translators as major challenges in obtaining consent.[19]

1.1.3 Consent elements

- Decision: An informed decision based on what was explained and this could also be a refusal of the treatment plan.

- Authorisation: there is authorisation or refusal to the proposed treatment.

C/S is more often an emergency procedure in SA that is undertaken when a mother or baby's lives are at risks.[30] It may be defined as a surgical incision through the abdominal wall and uterus, performed to deliver a fetus. [31]

C/S rates vary among countries with the highest rates in developed countries, but there has been a steady increase in developing countries over the last decade.[32] In 1985, The World Health Organisation (WHO) suggested an upper limit of 15% for C/S rates globally because they found that rates as high as 10% can improve neonatal outcomes.[32,33] CHBAH is a tertiary hospital in SA, which is the 3rth largest hospital in the world that had a C/S rate of 38.90% in 2015. (Departmental statistics)

C/S is a common procedure performed worldwide and is associated with immediate and delayed complications as well as implications for future pregnancies. Complications may be minor and less commonly severe. When there is poor consent this may have medico-legal implications.[2] In the context of worldwide increasing C/S rates and its high litigious nature obtaining written informed consent is therefore important.

Consent to treatment can be expressed or implied. Expressed consent can either be given verbally or in writing.[11] The HPCSA states that written consent should be taken if the procedure involves significant risks or side-effects, it is important to take written consent for a common procedure such as a C/S because it carries risks.[11] However, the signature does not prove that the patient is fully informed and verbal consent may be difficult to prove in court if there is a subsequent dispute.[34]

Many obstetrics organisations state that informed consent is more than simply getting a patient to sign consent.[11,35] But in practice some doctors still give importance to a signature on a consent form. In a study done in the Netherlands there where 69% of the 453 doctors who were of the opinion that a signed consent represents a valid informed consent.[25] And in Nigeria they found that 70.6% of the 102 doctors felt that the most important reason for obtaining informed consent was for medico-legal reason.[20]

Some patients have little understanding of the true nature of the consent form. In a cross-sectional study done on 500 patients, the majority (75.2%) believed that if they don't sign consent, the operation will not be done and they may die. Another 71.6% thought that signing protects the doctor from being sued and up to 75% thought signing is a legal requirement. And up to 88% thought they could not change their minds after signing, while only 25.8% believed signing protects their rights.[17]

1.2 Problem statement and Justification of the study

Informed consent in labouring women is thought to be affected by factors such as time constraints, pain, exhaustion and analgesia.[5] And for that reason there is disagreement on whether they have the capacity to give consent.
Literature regarding labouring women's decisional- making capacity is lacking.

Only a few studies are of the opinion that labouring women have decisional making capacity.[6,7] In a study done in Canada the authors found that most of the labouring women wanted to know all the risk associated with labour epidurals and based on these findings they concluded that labouring women have the capacity to consent.[6] A study in the USA found that the women were able to recall labour epidural risks, although poor it was comparable to that of non-labouring women.[7]

The prevalence of C/S's at CHBAH is much higher than the C/S rate that the WHO recommends.[33] It is common and is more often an emergency procedure in SA.[30] In view of the fact that it is a major open abdominal procedure that carries risk, labouring women should therefore be fully informed about possible risk and complications. This study will determine whether labouring women at CHBAH understand the information provided and if they are capable of recalling what they have been told. We will also determine their perception of the consenting process.

1.3 Aims & Objectives

- To determine women's recall of the indication for a C/S.
- To determine women's understanding of the indication for a C/S.
- To determine women's recall of the risks and complications for a C/S.
- To determine women's understanding of the risks and complications for a C/S.
- To determine women's perception of the informed consent process.

1.4 Methods

1.4.1 Study setting

This study was conducted in the Department of Obstetrics and Gynaecology at CHBAH which is a tertiary hospital in the Gauteng Province. It is a major referral hospital serving four Midwife Obstetrics Units, a district hospital and two regional hospitals in the southern part of Gauteng. The hospital delivered 20 324 women in 2015. The C/S rate was 38.90% in 2015.

1.4.2 Study population

The study population was labouring women who required an emergency C/S. Once the decision is made and consent given, the midwife assists the woman in filling in a "layman's form". They explain in their own words what they have been told. The "layman's" form is used at CHBAH to check women's understanding after signing the consent form.

The doctor who operates on the woman is usually different from the one who has made the decision for C/S. This is because the maternity unit is extremely busy and the doctors who are allocated to the obstetrics theatre are, in most cases, different from the doctors allocated to the labour ward.

1.4.3 Inclusion criteria

- Women who are able to speak English.
- Women older than 18 years.
- Women with a term pregnancy and who had consented whilst in labour.
- Women with an uncomplicated C/S.

1.4.4 Exclusion criteria

- Women with a previous C/S.
- Women with babies admitted to Neonatal intensive care unit or with Still birth's
- Women who are unwilling to participate in the study.
- Women with severe complications such as severe pre-eclampsia.

1.4.5 Study design

This was a cross sectional descriptive study conducted from May 2016 to October 2016. The questionnaire was piloted on 10 women to identify any problems with the questionnaire.

1.4.6 Data collection

A hundred women were recruited in the post-natal wards. This was a convenience sample and participants were recruited on the researcher's intake or post intake days. Five women were recruited on any day between 06h00 and 08h00 in the morning. One woman from every cubicle was chosen. They were approached at least 24 hours after the C/S and informed about the study verbally and if they agreed to participate, they were given an information sheet (Appendix A) and consent form (Appendix B). They were interviewed in one of the private rooms. All the women agreed to participate after being told about the study.

The questionnaire (Appendix C) had 2 parts. The first part pertained to demographics, antenatal history and stage of labour when consent was taken. The second part dealt with their understanding, recollection and perception of the informed consent process.

Variables: age, parity, gestation, education level, indications, income, were obtained from the file and questionnaire. Women's understanding, recall and perception of the consenting process was obtained using the questionnaire.

1.4.7 Statistics

Categorical variables were described using frequencies and percentages. Continuous variables were described using means with Standard Deviations (SD) and/or medians with Interquartile Range (IQR) depending on the distribution of the data. Responses to open questions were analysed using themes.

1.4.8 Ethics approval

Ethics approval was granted by the University of the Witwatersrand HREC (M161188) (Appendix D). Permission to do this study was granted by the Chief Executive officer at CHBAH (Appendix E). Informed consent was obtained from every participant prior to the interview after providing them with an information leaflet and explaining the research project.

1.4.9 Funding

All costs incurred were borne by the researcher.

1.4.10 Intention to disseminate

The research will be presented at academic meetings and there is an intention to publish research in medical journals.

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SECTION 2: Journal Guidelines

This chapter outlines the authors' guidelines for the South African Journal of Bioethics and Law, which is the intended journal of publication.

Structured abstract

- This should be no more than 250words, with the following recommended headings:
  - **Background:** why the study is being done and how it relates to other published work.
  - **Objectives:** what the study intends to find out
  - **Methods:** must include study design, number of participants, description of the research tools/instruments, any specific analyses that were done on the data.
  - **Results:** first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
  - **Conclusion:** must be supported by the data, include recommendations for further study/actions.
  - Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors. It should be able to be intelligible to the reader without referral to the main body of the article.
  - Do not include any references in the abstracts.

- A max of 20 - 25references

- Embed/include each table in the manuscript Word file - do not provide separately as supplementary files.
- Number each table in Arabic numerals (Table 1, Table 2, etc.) consecutively as they are referred to in the text.
- Tables must be cell-based (i.e. not constructed with text boxes or tabs) and editable.
- Ensure each table has a concise title and column headings, and include units where necessary.

SECTION 3: Submissible Article

This section outlines the journal formatted according to the authors' guidelines as described in section 2 above.

MMED SUBMISSIBLE FORMAT

THE UNDERSTANDING AND RECOLLECTION OF INFORMED CONSENT BY PATIENTS, FOLLOWING AN EMERGENCY CAESAREAN SECTION

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Keywords: Caesarean section, Informed Consent, Understanding, Voluntariness

Abstract

Background

Informed consent is a regulatory and ethical requirement in medical practice. It forms the ethical basis of a patient-centered approach.[1] In order to give informed consent, the user should be well informed and participate in the decision making. There is contention on whether women in labour can give a valid informed consent.

Objectives

To evaluate the understanding and recollection of informed consent after emergency caesarean section.

Methods

A cross- sectional study at Chris Hani Baragwanath Academic Hospital between May and October 2016. English speaking women older than 18 years where invited to participate. Previous caesarean section, maternal or neonatal complications were exclusion criteria.

Results

One hundred women were interviewed. The mean age was 26.5 years Standard deviation(SD±5.76). All the women recalled the indication for the caesarean section and 90 understood this. Seventy-eight said that risks and complications were discussed, eight said they were not, 11 could not remember and 3 did not know if it was discussed. When women were prompted, the recollection of the risks and complications was better. Seventy-four women wanted full disclosure of all the risks and complications. Eighty-four were satisfied with the information and 93 felt they took part in decision-making without being pressurised.

Conclusion

This study indicates that labouring women can recall indications and mostly understand the reason for the caesarean section. Their recall of complications was poor but better when prompted with specific questions. Most women would like to know about all the risk and complications.

Background

The National Health Act no 61 of 2003,[2] states that "before a user can consent to treatment, they should have full knowledge and participate in decision making. The knowledge should include a description of their health status, a range of treatments, the benefits, the risks and consequences."[2] The informed consent process is governed by three elements which are in place to protect the patient's autonomy.[3] These include: threshold elements (voluntariness and capacity), informational elements (disclosure, recommendations and understanding) and consent elements (decision and authorisation).[3]

Assessing the woman's capacity to consent is important and it forms part of the threshold element.[3] Studies concerning labouring women's decision-making capacity are few and it is believed that factors such as time constraints, pain, exhaustion and analgesia may affect their capacity to make an informed choice.[5] For that reason there is disagreement on whether they have the capacity to give consent. Affleck et al, found that irrespective of the 101 labouring women's pain thresholds there were was no difference in the number of labour epidural risks recalled, which further improved when prompted. The study concluded that labouring women have the capacity to consent which was comparable to that of non-labouring women.[7]

The informational element requires that all 'material risks' should be disclosed.[10] "Material risks" being "anything a reasonable person in a patient's position, if warned of the risks, would attach significance to the decision-making process."[10]
Consent is the third element and can be expressed or implied.[10] Expressed consent can either be given verbally or in writing.[10] But mostly written consent is required for a C/S because it is a common procedure that involves significant risks.[10] But, a signature does not prove that the patient is fully informed and verbal consent may be difficult to prove in court if there is a subsequent dispute.[34] Akkad et al, in their evaluation of women's recall and satisfaction with consent for emergency vs. elective surgery found that most women undergoing emergency surgery felt scared and pressurised to sign and some felt they had 'no choice.'[14] The same authors in a subsequent study found that more than half of the women felt that their wishes were not considered and that the consent was to protect the hospital.[15]

The findings in studies that considered recall and understanding in patients undergoing elective vs emergency surgery were inconsistent.[17,23] A study of 524 elective cases done in

India, reported that patients understanding of information was as low as 17%.[17] Another prospective study demonstrated poor recall and understanding for elective inguinal hernia repair.[23] CHBAH is a busy tertiary hospital with a C/S rate of about 40%. This study was performed to evaluate the understanding, recall and perceptions in labouring women who had an emergency C/S.

Methods

This study was conducted in the Department of Obstetrics and Gynaecology at CHBAH which is a tertiary hospital in the Gauteng Province. It is a referral hospital serving 4 MOU's, a district hospital and two regional hospitals in the southern part of Gauteng. The maternity unit treats approximately 60 000 patients per year and 80% are high risk women however some are self-referrals or low risk referred by MOU's. The hospital delivered 20 324 women with a C/S rate of 38.90% in 2015.

The study population was 100 labouring women who required an emergency C/S. Once consent is given, the midwife assists the woman in filling in a 'layman's' form. The 'layman's' form is used at CHBAH to check women's understanding after signing the consent form.

The doctor who operates on the woman is usually different from the one who has made the decision for C/S. This is because the maternity unit is extremely busy and the doctors who are allocated to the obstetrics theatre are, in most cases, different from the doctors allocated to the labour ward.

This was a cross sectional descriptive study conducted from May 2016 to October 2016. Women who spoke English and were older than 18 years, with a term pregnancy who had consented whilst in labour where included.

Women who were excluded were those with a previous C/S, whose babies were admitted to the Neonatal Intensive Care Unit, stillbirth's and severe complications such as pre-eclampsia.

Women were recruited in the obstetrics postnatal wards and were approached at least 24 hours after the C/S. The study was explained to them and an information sheet and consent form was provided. A questionnaire was given to all women who consented to participate.

The questionnaire had 2 parts. The first part pertained to demographics, antenatal history and stage of labour when consent was taken. The second part dealt with their understanding, recollection of information and perception of the informed consent process.

The following variables were obtained from the file and questionnaire: age, parity, gestation, education level, indications, income. The women's understanding, recall and perception of the consenting process were obtained using the questionnaire.

Permission to do this study was granted by the Chief Executive Officer at CHBAH and the University of the Witwatersrand HREC (M161188).

Categorical variables were described using frequencies and percentages. Continuous variables were described using means with Standard Deviations (SD) and/or medians with Interquartile Range (IQR), depending on the distribution data. Responses to open questions were analysed using themes.

Results

There were 100 participants and hence the frequency and percentage are the same. We reported the frequency and percentage when the denominator was not 100.

Demographic factors

One hundred questionnaires were completed by all the women in the study, with no missing data. The mean age was 26.5 years (SD±5.76) and the median age was 25 years (IQR=21.5-30; range=19-39). Fifty eight women was nulliparous and 42 was multiparous. The Rhesus

blood group was negative in one woman. All women were RPR negative. Fifteen women were HIV positive.

All the women had some form of formal education. Seventeen had a primary school education, 60 had a secondary education and 19 had a tertiary education. The number of women who were employed was 46, 50 were unemployed and 4 were still attending school or studying. The mean monthly income was R7241.17 (SD±6930.45) and the median was R5000 (IQR=2100-9500; range=1000-20000).
Thirty-eight women's main source of income was from their own salary, 29 received an income from their partners, 20 received an income from a relative and 5 received a government grant. Sixteen were married, 72 never married (but cohabitating) and 12 were single.

The mean gestation at delivery was 39.6 weeks (SD±1.21) and the mean gestation at delivery was 40 weeks (IQR=38.5-40.6; range =37.3-41.2).

The Seniority of the doctor who took the consent.

Most of the consent was taken by interns (76) followed by 23 registrars and 1 consultant.

Phase of labour when consent was taken

Consent was obtained in the latent phase of labour in 52 women, in the active phase of labour in 47 women and in the second stage of labour (Failed vacuum delivery) in one woman.

Indications for Caesarean section

The number of indications did not add up to 100 because there were women who had more than one indication. The indications are illustrated in figure 3.1 below.

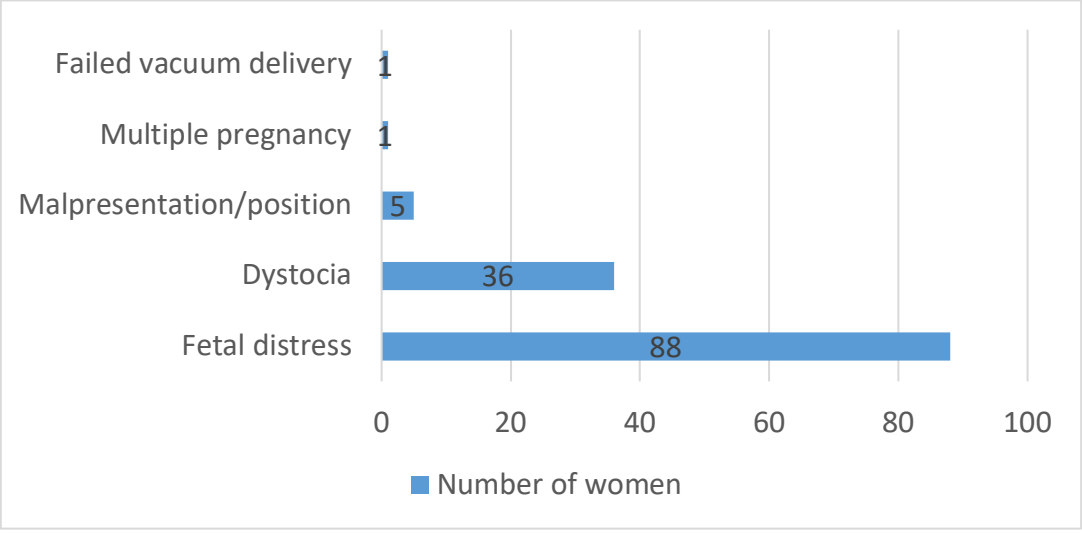

Figure 3.1. Indications for an emergency caesarean section.

Information disclosure

The majority of women (88) said the doctor gave them the most information and 12 said the midwife. Information provided to the women included the indication, risks and complications of having a caesarean section.

Women's recall of the indication for an emergency caesarean section.

The 88 women who had a C/S for foetal distress were told that the C/S was performed for foetal reasons. The way it was explained was that the "baby was tired," the "heart rate was abnormal," there was "meconium stained liquor, " the "babies condition was not good."

The exact phrases of some of the women were:

- "The doctor was scared the baby will get more tired and because of my age."

- “They said that the baby was exhausted.”

Some of the exact words alluding to the abnormal heart rate was:

- “The babies heart was going to stop.”
- “They showed me that machine that showed that the babies heart was not fine.”

In those women where meconium stained liquor was given as a reason, the exact words of some of the women was:

- *“*They told me yellow stuff was coming out of my vagina.”
- “They said that the baby pooped inside of me.”

Other reasons that related to the baby was:

- “My child was suffocating.” “The baby could not take the pain anymore.”
- “Because the baby cannot breathe.”

Other explanations that women were given:

- “I was having hard pain and the pain was so long, for 2 days.
- “I had infection in my womb.”

Of the 40 women who had an emergency caesarean section for dystocia the explanation was that the cervix was not dilating, that they did not have adequate contractions, or that there was no engagement.

Some of the exact words of the women were:

- “They told me the water they broke did not help, and I was stuck at 6cm’s.”
- “It’s been 24 hours that I am not dilating properly.”

Some alluded to the fact that they were not having adequate contractions:

- “They said that I was forcing the baby to come down and it was not helping.”
- “The pains was not adequate even when they gave me strong medication through the drip. They said I would not deliver.”

In some women the explanation appeared to be that there was poor engagement:

- “The baby was lying far.”

- "They said the baby was taking too long to move down and I was not progressing.

Other reasons were:

- "The baby did not want to come out."

Of the 5 women who had an emergency caesarean section for malpresentation/position the general theme was that they could only deliver when the baby's head presents. This is what 2 of the women said they were told:

- "They said I won't give normal birth because the baby cannot come out with its bums."
- "They said that the baby will not come out with its face."

Only one patient in the study had delayed second stage (Failed vacuum delivery) and this is what she was told:

- "They said the baby had a cord around its neck and they used a vacuum 3 times but nothing happened."

Women's understanding about the reason for having an emergency caesarean section.

Most women (90) said they understood the explanation of the reason for caesarean section, some of the women's exact words as shown in Table 3.1.

Table 3.1: Women's understanding of the reason for a caesarean section.

Clarity of information	**Clear n=90**	**Partly clear n=8**	**Unclear n=2**
Comment by participant	"They explained well, that the babies heart was beating fast. I decided to have the caesarean section for my baby."	"She just said the baby is not responding. They did not go into detail. They explained nothing even when they were preparing me."	"They did not really explain everything to me. Why was my labour so long then?"
	"Even at the clinic things was not fine with my baby. Then here they explained it again and made me understand."	"Like I said, that I gave natural birth with my first child who they said was bigger than this one. So why a caesarean section."	"Because I could have delivered. I was almost full. So I don't get why they wanted me to do the caesarean section."

Most women (77) thought that the explanation given was sufficient. Some of the women's exact words on whether the information was sufficient or not is shown in Table 3.2 below.

Table 3.2: The women's perception of adequacy of information

Perception of information	Sufficient n=77	Too much n=7	Too little n=16
Comment by participant	"After he explained to me. I understood that my baby is not doing well. And if I give natural birth my baby may die."	"There was too many people around me. They were confusing me and I was in too much pain to understand the explanation."	"I did not understand why I was 6cm's for a long time. I wanted to know why."
	"I was once on the internet and also saw that if the bums are in front you must get an operation. It was clear."	"I did not expect it. I thought everything is fine and then they told me too many things."	"I did not understand fully because I wanted to wait. They could not explain why my baby was getting tired."

Women's recall about the risks and complications.

Seventy-eight women said that risks and complications were discussed, 8 said it was not discussed, 11 did not remember and 3 did not know if it was discussed. Some women remembered that they were told that the caesarean section may be dangerous.

Some of the exact words were as follows:

- "If things don't go well during the caesarean section I may lose the baby."
- "It may happen that I may die or the baby may die." "They said it is dangerous."

Of those women who were told there may be contiguous damage, the exact words were:

- "They said they could damage my organs but if it happens they will fix it, but most of the time caesarean sections are successful."
- "If anything ruptures in me, they can fix it." Figure 3.2 below depicts the risks and complications as remembered

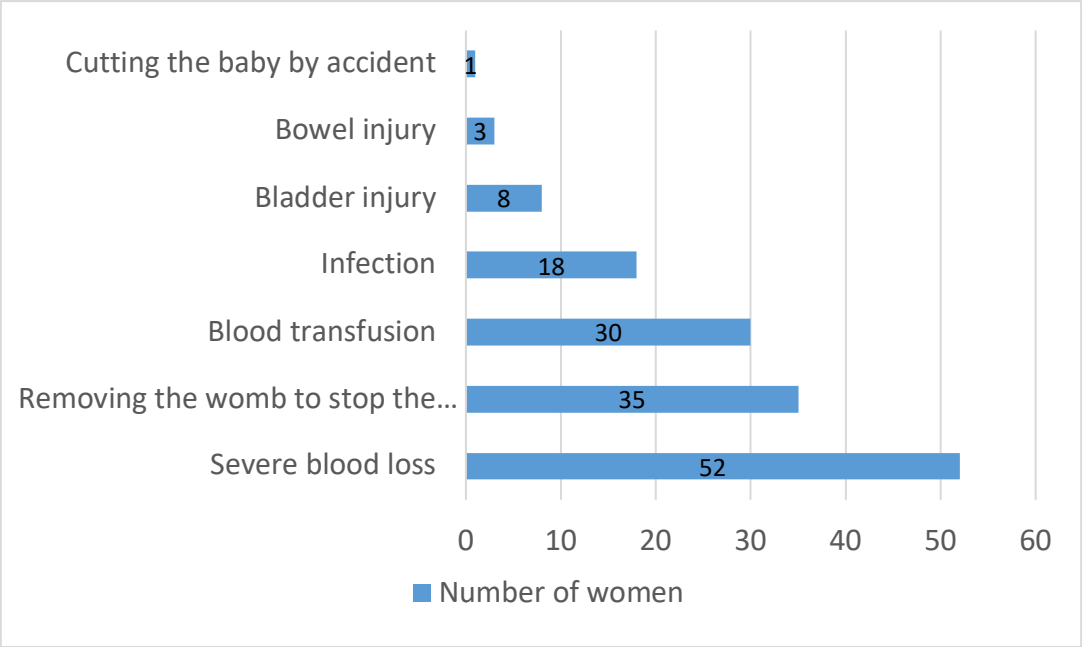

Figure 3.2 Illustrates the risks and complications women recalled the doctor told them.

Women were then asked specifically about known complications. Most women did not recall the risks for subsequent pregnancies. Five women were told about uterine rupture, 5 about adhesion formation and 0 about placenta praevia. Figure 3.2 below is the recollection when women were asked about the specific risks and complications, which may occur with caesarean section.

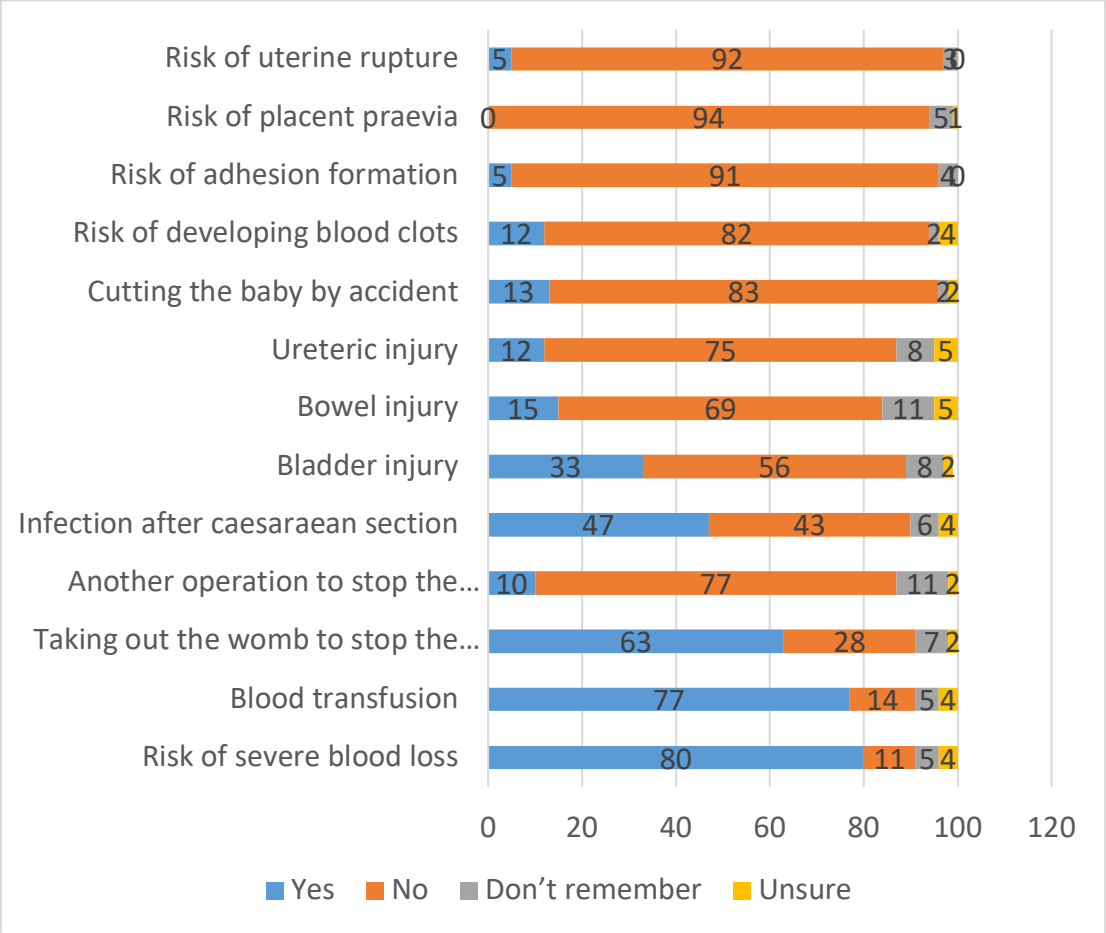

Figure 3.3 An illustration of the specific risks and complications women could recall when asked, e.g. do you recall being told about the risk of severe blood loss.

Women's understanding of the risk and complications associated with caesarean section.

Fifty-eight women understood what they have been told, as depicted in table 3.3. The table also shows the women's actual thoughts as to why they understood.

Table 3.3: Description of women's understanding of risks and complications.

Clarity of information	Clear n=58	Partly clear n=20	Unclear n=22
Comment by participant	"Because the doctor took her time and she was patient. Even while I was screaming of pain she would wait for me to calm down and continue explaining."	"Because I was not listening. I was more worried about my baby."	"I really don't remember, I think they never told me."
	"Because it was repeated a lot to me, so I got the impression that it was important."	"They only told me about my womb being removed, not the other things you just asked me about now."	"Like I said they did explain but I was not caring anymore. I had too much pain."

Women's opinion as to what they think they should have been told about the risk and complications.

Most of the women (74) wanted all the risks and complications associated with the surgery disclosed, while 26 wanted to know only some of the risks and complications.

Of the 74 women who wanted more information, the general theme was that they felt they would be able to make an informed choice in case anything happens, this is some of their exact words:

- "I would have blamed them if there were any problems."
- "I wish they could explain everything, but due to time I understood.

Some alluded to the fact that they wanted information on implications for future pregnancies.

- "They must tell me also what happens after the caesarean section."
- "This is my first child. I heard from people that I can only have three pregnancies after caesarean sections."

Pain seemed to have been the main reason why 26 of the women felt they wanted less explanations. This is what some said:

- "It would be better not knowing everything. You already stressed, imagine knowing all the dangers, it will make you stress more."
- "I'd rather be told after the operation, so that I don't get scared. The things you just told me now are scary."

Involvement in the decision making process

Ninety-three women felt they took part in the decision making process. The main theme was that they felt they could ask questions and the common sentiment was, that they felt it is very important to decide what should happen to their bodies and not blame the hospital if anything happens. The remaining 8 women who said no, the theme was that they felt that they had no choice because the caesarean section was going to happen either way and the most common sentiment was "that the doctor knows best."

When asked whether they were given an opportunity to discuss it with a family member or friend, most of the women (74) said no, while 24 said yes, one could not remember and one did not know. Sixty women would have liked to discuss it with someone. Forty-nine women said they were not given enough time to ask questions, the general theme was that they felt everything was rushed.

Sixty-three women were happy with the role they played in making a decision and 37 were not happy. Eighty-four women were satisfied with the information provided.

Discussion

This study found that labouring women had good recall and understanding of indications but poor recall and understanding of the risks and complications associated with C/S. Even though their recall and understanding improved when prompted with specific questioning it still was not absolute.

Most of the women were able to recall more than one indication and could explain what the indication was in their own words. The way the women explained it, may have been attributed to the use of different ways of explaining 'foetal distress' and 'dystocia.' This

highlights that foetal distress diagnosed with cardiotocography has grades of severity and is explained differently by health workers. The use of the 'layman's' form may have further contributed to their good recall. As previously mentioned, the 'layman's' form is used to reinforce women's understanding. However, the 'layman's' form just considers the indications.

There are no standard guidelines to assess capacity to consent in the literature and it is usually determined by the doctor.[9] Affleck et al, assessed 101 women's capacity by the number of labour epidural risks they could recall after delivery. The women could recall risks spontaneously which improved when prompted with a list of complications. The study found that the risks labouring women were able to recall, although poor were comparable to that of non-labouring women.[7]

Our study showed similar results, the three frequently recalled complications were, severe blood loss (52 women), removing of the uterus to stop the bleeding (35 women) and blood transfusion (30 women). Their recollection improved further when prompted. An example in our study can be seen with severe blood loss where recall improved to 80 women when prompted.

A competent patient should be told about all the "material risks" associated with a procedure. Even if some risks are rare or its occurrence has serious consequences such as death.[11]
Most of the women in our study (74) wanted to know all the risks.
Similar findings were demonstrated in the study by Jackson et al, on the risks associated with epidurals, where most of the labouring women wanted to know all the risk and knowing would not have discouraged them to have the epidural.[6]

Various factors have been shown to contribute to poor transfer of information. Among these are doctors that underestimate the informational needs of women. In the study by Chima, only 35 out of the 168 doctors disclosed all the "material risks" to their patients.[19] And a Nigerian study found that most doctors felt that they did not provide patients with sufficient information and the most important reason for obtaining consent was for medico-legal reasons.[20]

In our study the poor understanding and recall of risk and complications could perhaps have been because consent was mostly taken by junior doctors. A study in Pakistan also demonstrated that the junior doctors performed worse than the senior doctors.[24]

The degree of urgency may also be a contributory factory to poor transfer of information since C/S is more often an emergency procedure and this may explain the poor understanding and recall in our study.[28,29] Odomuso et al, concluded that time constraints may be a contributory factor for the poor recall of risks for emergency C/S compared to elective C/S.[29] Similar findings were also demonstrated in Bhangu et al, study.[28] Doctors in a South African study also identified time constraints as a major challenge in obtaining a valid informed consent.[19]

The use of medical terms may not be understood by the patient and the HPCSA advises against it.[10] In a South African study, most of the patients felt that information was provided in non-technical terms[22] and in our study the use of the 'layman's' form may have contributed to the women's good recall of indications.

Surprisingly 84 women in our study were satisfied with the information provided which is not in keeping with other studies.[14] We think perhaps it may be because the women were happy their babies were well and because 93 women felt they took part in making the decision for C/S themselves.

In Akkad et al, study they found that compared to the elective surgery patients only 144/732 of women undergoing emergency surgery was satisfied with the overall consenting process because they felt that they did not receive all the information.[14]

Limitations

Teenagers were excluded from this study and form an important group of women who are consented for C/S. The study excluded women who did not speak English. This study was done in one public hospital and therefore may not be generalised to other public hospitals.

Conclusion

This study highlighted that despite the difficulties encountered during labour, labouring women want to be told about all the "material risks" and can make an informed choice. The small number of women whose recall and understanding was poor should not be forgotten and there should be more study on this group. Another important factor is that labouring women want to participate in decisions regarding their management in labour

RECOMMENDATIONS

Even though our study showed that most labouring women have the capacity to make an informed choice and wanted to know all the risk and complications. We acknowledge that there were still a small number of women in our study where the quality of the consent was poor due to the stressful nature of labour. It may not always be possible to obtain a valid consent in those rapidly evolving emergencies where time may be too short and the patient is too distressed to focus. We should therefore focus on giving women information antenatally about possible intrapartum complications that may warrant a C/S. This approach will enable women to exercise their right to enquire more and become fully informed prior to the onset of labour.

Furthermore labouring women's ability to take in information and make an informed choice whilst in labour can vary. In these circumstances consent should be sought during the early stages of labour when the woman are more comfortable and the interval between contractions allow for explanation and discussion. Information should be provided between contractions so that the patient can focus on the request.
The term "foetal distress" and counselling pertaining to its varying applications, significance and implication need to be explored to find a way that best describes "a foetus in trouble."

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CHAPTER 4: Appendices

APPENDIX A: INFORMATION SHEET

Good day, my name is Dr Candice Johnson. I am a doctor training to be a specialist in obstetrics and gynaecology here at Chris Hani Baragwanath Hospital. I am conducting research in order to obtain a master's degree (MMed). My research looks at labouring woman's understanding and recall of the informed consent after an emergency caesarean section.

The findings will help understand current knowledge regarding the informed consent process in labouring woman. If the findings can improve the consent process.

I invite you to partake in my research. All I require is information regarding your background and questions relating to your understanding, knowledge and recall of the informed consent process. I will not perform any examinations or tests on you. I assure you that your personal information will be kept highly confidential. Only your study number will appear on the forms which will be kept by me and my supervisor Professor Adam. Your file number will not appear on my research. The data sheet will not contain any identifiable information and will be destroyed once data analysed.

You will not receive any remuneration or reward for partaking in study. You may change your mind at any point even if you have signed. Your treatment and care shall not be jeopardized in any way if you decide not to participate in my study. Ethics approval has been obtained from the University of Witwatersrand and the Human Research Ethics Committee.

You may contact me at any time concerning my research. My cell number is 0790891584.

Human Research Ethics Committee contact details:

Prof P Cleaton Jones, Tel 011 717 2301, email: peter.cleaton-jones1@wits.ac.za

Ms Z Ndlovu/ Mr Rhulani Mkansi/ Mr Lebo Moeng at the Administrative Officers Tel: 011 717 2700/ 2656/ 1234 /1252 email: zanele.ndlovu@wits.ac.za; Rhulani.mkansi@wits.ac.za; and Lebo.moeng@wits.ac.za

APPENDIX B: INFORMED CONSENT FORM

If you are willing to partake in my study, please kindly sign that you have understood all that has been explained to you.
Thank you for your participation.

Participant……

Witness……

Researcher……

Date……

APPENDIX C: QUESTIONAIR

Date:

Study number:

Information from patients file:

1. Age ……..

2. Booking bloods:

1. RPR	2. RH	3. RVD

3. Parity:…… …….

4. Gestation at delivery (best estimate):……..

5. Indication for caesarean section:

1. Fetal distress.
2. Malpresentation e.g. breech presentation.
3. Cephalopelvic disproportion.
4. Prolonged labour.
5. Multiple pregnancy.
6. Delayed second stage of labour.
7. Other.

Explain……

6. When was informed consent taken from the patient?

1. Not in labour.	2. Latent phase of labour.	3. Active phase of labour.	4. Second stage of labour.

Specify in hours……

7. The seniority of the Doctor who consented the patient.

1. Consultant.	2. Registrar.	3. Medical Officer.	4. Community service.	5. Intern.
6. Other.				

Explain……..

8. Analgesia given whilst in labour:

1. Pethidine.	2. Morphine.	3. Epidural.	4. No Analgesia.	5. Not applicable.

Explain……

9. The time at which the analgesia was given before obtaining consent:

……

Participant's information:

10. Highest education achieved:

1. None.	2. Primary School.	3. Secondary education.	4. Higher education.	5. Tertiary education.	6. Other.

Explain……..

11. Employment:

1. Full-time.	2. Part-time.	3. Unemployed.	4. Still at school.	5. Other.

Explain……

12. How much money do your family make in total in a monthly basis?

……

13. What is your main source of income?

1. Child maintenance.	2. Partner.	3. Own salary or wages.	4. Relative.	5. Government grant.

14. Relationship status:

1. Married.	2. Never married.	3. Divorced.	4. Separated.	5. Widowed.	6. Cohabitating.	7. Other.

Explain……

15. Did you sign the consent form to give permission for the caesarean section?

1. Yes.	2. No.

Explain……

16. What was the reason for your emergency caesarean section?

……

17. I would like you to choose one of the following with regards to the explanation given to you about the caesarean section and explain your choice.

1. Explanation was sufficient.	2. Explanation was too much.	3. Explanation was too little.

Explain…….....

18. Who gave you the most information about the reason on why you are having an emergency caesarean section?

1. Doctor.	2. Midwife.	3. Other.

Explain.....

19. Did you receive an explanation about the risks and complications from caesarean section?

1. Yes.	2. No.	3. Don't remember.
4. Don't know.	5. I think so.	

Explain…….

20. I am now going to ask you whether the doctors or midwifes explained some risks to you. It is not always necessary that they tell you these because some are really uncommon.

20a. Were you told that there is a risk of severe blood loss?

1. Yes.	2. No.	3. Don't remember.	4. Unsure.

20b. Were you told that you may require blood transfusion if you bleed a lot?

1. Yes.	2. No.	3. Don't remember.	4. Unsure.

20c. Were you told that they may have to take out your womb to stop the bleeding?

1. Yes.	2. No.	3. Don't remember.	4. Unsure.

20d. Were you told that you may have to have another operation after the caesarean section in the event of any complications?

1. Yes.	2. No.	3. Don't remember.	4. Unsure.

20e. Were you told that you may develop an infection after having a caesarean section?

1. Yes.	2. No.	3. Don't remember.	4. Unsure.

Can you please explain in your own words what they said about infection?

…….

20f. Were you told that the following injuries can happen during the operation.

• Bladder injury.	1. Yes.	2. No.	3. Don't remember.	4. Unsure.
• Bowel injury.	1. Yes.	2. No.	3. Don't remember.	4. Unsure.
• Ureteric injury	1. Yes.	2. No.	3. Don't remember.	4. Unsure.

(The tubes that transport urine to your bladder).				

20g. Were you told that you may develop blood clots in your legs or your chest.

1. Yes.	2. No.	3. Don't remember.	4. Unsure.

20h. Were you told that you may be at risk of developing the following problems during your next pregnancy?

• Adhesion formation (scar tissue will make the next caesarean section difficult.	1. Yes	2. No.	3. Don't remember.	4. Unsure.
Because of your previous operation the scar tissue may cause the placenta to attach at the	1. Yes.	2. No.	3. Don't remember.	4. Unsure.

wrong area and it may cause bleeding before the baby comes out.				
• The possibility of uterine rupture.	1. Yes.	2. No.	3. Don't remember.	4. Unsure.

21. Was the explanation on the risk and complications from caesarean section clear to you?

1. Explanation was clear.	2. Explanation was partly clear.	3. Explanation was unclear.

Explain……

22. Would you have wanted more explanations regarding the risks and complications?

1. Yes.	2. No.

Explain……

23. Would you have wanted less explanations regarding the risk and complications?

1. Yes.	2. No.

Explain……

24. Did you feel that you were part of the decision making process?

1. Yes.	2. No.

Explain……

25. On a scale of 1-5 with 5 being the most involved, how involved did you feel?

1.  2.  3.  4.  5. 

26. Were you given an opportunity to discuss it with a family member or friend first?

1. Yes.	2. No.	3. Don't remember	4. Don't know

27. Did you feel that you were given enough time to ask questions?

1. Yes.	2. No.

Explain……

28. Did you understand the reason for the emergency caesarean section?

1. Understanding was clear.	2. Understanding was partly clear.	3. Understanding was unclear.

Explain……...

29. Did you understand the risk and complications associated with caesarean section?

1. Understanding was clear.	2. Understanding was partly clear.	Understanding was unclear.

Explain……...

30. Are you satisfied with the explanation given to you about your caesarean section?

1. Yes	2. No

Explain……..

31. Are you satisfied with the role you played in making a decision for a caesarean section?

1. Yes	2. No

Explain……

32. Would you like to add anything to the way that the consenting procedure is carried out?

…….

R14/49 Dr CA Johnson

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M161188

NAME: (Principal Investigator)	Dr CA Johnson
DEPARTMENT:	Obstetrics and Gynaecology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	The Understanding and Recollection of Informed Consent by Labouring Women after an Emergency Caesarean Section
DATE CONSIDERED:	25/11/2016
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Yasmin Adam
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	03/02/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 301, Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193. University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in November and will therefore be due in the month of November each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date 100217

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES