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INFORMED CONSENT FOR CAESAREAN SECTION AT A NIGERIAN UNIVERSITY TEACHING HOSPITAL: PATIENTS' PERSPECTIVE

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ABSTRACT

Background: Caesarean section is one of the commonest obstetrics surgery and has become increasingly safer compared with the early 20th century. The practice of informed consent has also become universally adopted for surgical procedures. However, with increasing knowledge about ethics and rights, issues on consent isone of the frequent grounds for litigation and malpractice claims.

Aims and Objectives: To audit the process of informed consent for emergency and elective caesarean section in a Nigerian tertiary health care setting.

Methodology: This was a descriptive cross-sectional study involving 150 patients who had caesarean delivery at the study site within the study period.

Results: The mean age of the respondents was 32±1.8 yearswith 118(79%) of the surgeries being emergency Cesarean sections. The consent for CS were mostly given by the patients (96, 64.0%) and husbands(43, 28.6%). Majority of the respondents 123(81.5%) had the consent obtained in the labour ward with profuse bleeding (86.0%) and blood transfusions (88.7%) being the most commonly discussed risks. Many of the respondents expressed satisfaction with the consent form and felt it was well written(75.3%), attractive (76.0%) and simple to read (75.3%).

Conclusion: This study found out that although patients were satisfied with the consent process for caesarean section, only information about major risks was commonly discussed. There is therefore the need for customized and detailed consent formsto be adopted for different surgical procedures.

Keywords: *Caesarean section, Informed consent, patients' perspective, risk*

INTRODUCTION

Historically the Hippocratic Oath which dates back to the 5thcentury is one of the earliest documented guidelines for medical standards. The oath, although paternalistic in nature, with decisions based solely on the physician had the core objectives of doing no harm and also protecting the confidentiality of patients. Over the past two millennia, there has been a paradigm shift in the physician-patients role in decision making towards the patient, accompanied with several modifications of the Hippocratic Oath.[1]

Major events in the last century accelerated the various codes of ethic, which is now in place in several countries. The atrocities committed by German Nazi doctors during the 2nd world war where medical treatments were experimented on prisoners and the Tuskegee study where ethnic

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minorities were used in trying to describe the natural progression of syphilis infection, are some of the black spots in medical practice. Since then concerted efforts had been put in place to protect the rights of human subjects in research resulting in the development of the Nuremberg code (1947), the World Medical Association's Helsinki declaration (1964) and Belmont report (1978).[2-5] Theseethicscodes emphasized the need for voluntary consent in research and treatment, confidentiality, protection from harm, freedom of withdrawal from research and the protection of vulnerable groups. This gave birth to the concept of informed consent.

In addition to ethics, legal consideration and quality of care has also played a role in the attention being given to informed consent. A physician-patient relationship can be likened to a contractual agreement where there is duty of care and effective communication is very essential for this relationship not to be breeched.[6,7]There have been various litigations regarding consent in medical care and informed consent is now required by law before any diagnostic or therapeutic medical procedure can be carried out on patients.[8,9]Patients' understanding of informed consent improves cooperation, results, satisfaction and prevents errors.[10]

Informed consent can be recognized as the legal adoption of the concept of each person's right to decisions regarding his/her wellbeing including health.[11]Although there is no consensus on all the constituents of an informed consent, some are consistent in the literature and some institutions had adopted standardized pro-forma. For consent to be valid there must be disclosure about the treatment, risks, benefits, complications and alternative treatments, in a manner that can enable an ordinary person make a reasonable decision about its acceptance and rejection.The patient must be able to understand the information, consent and withdraw freely.[12]Informed consent can be verbal but preferably written especially for surgical intervention and in research. Where written, there must be clarity and the language should be simple.[13]

It is difficult to obtain consent in all situations such as in children, during certain emergencies, in unconscious patients and where the capacity to think has been impaired by medical illness or medications. There are various guidelines to advice in the above scenarios. Other challenges to obtaining informed consent include cultural diversity, illiteracy and political will.[14]

Major progress in the principle of informed consent had been made in in the practice of surgery. The decision to surgically intervene could arise in emergencies or electively following clinical diagnosis and or with ancillary investigations. These decisions are made mostly in the perceived best interest of the patient.

One of such surgical interventions is the Caesarean section (CS) which dates back to320BC[15]. It is a common obstetric procedure performed and accounting for between 9.1% and 36.4% of births in Nigeria.[16-20]The common classification of CS is into elective and emergency types depending on the indication. Some other authors have adopted elective, scheduled, urgent and emergency types of CS.[21,22]As with other surgical operations, informed consent is vital for caesarean delivery since obstetric practice is one of the fields with high insurance premium and malpractice litigation claims in developed countries.[23]Moreso these suitsfrequently revolve around consent and adequate documentation.[24,25] Information on imminent surgical procedures to patients has proved helpful in coping with a perceived threatening procedure,[26] although patients still have the right of refusal even in the face of looming danger to her life or her unborn child.

Consent and documentation in emergencies is challenging to both doctors and patients.Patients

have different capacities to make decisionswhen stressed and recall of information given during informed consent has been shown to be poorer with emergency surgeries compared to electives.[27] Some have even reported a feeling of fright in signing the consent form; sometimes preferring to defer such an important action to their husbands. The doctor has to be faced with the task of explaining the need for the surgical intervention while at the same time thinking of the urgency for intervention. Comprehensive and detailed informed consent forms had been adopted in most institutions in developed countries in order to avoid omission.

Informed consent is gaining importance because of the rise in literacy level, increase in women empowerment, and awareness of fundamental human rights in patient management. Also recently in the Nigerian media there are increased publications related to complaintson medical malpractice and litigations involving caesarean sections. Some have attracted sanctions by the Medical and Dental Council of Nigeria (MDCN) which is the regulatory body of Medical practice in Nigeria, while others are still in court awaiting hearing and judgement.[28]Ironically, despite this alarming trend, various hospitals are still maintaining the "status quo" using unstructured pro-forma or forms with scanty information to obtain consent for surgery.

In consideration of the importance of these developments, this study was designed to audit the process of obtaining informed consent using a University Teaching Hospital as a pilot study. The quality of information given during the consent and patients' perception of the informed consent procedure was also assessed.

METHODS

This was a cross-sectional study of the consent procedure from patients who had Cesareansection (CS) at the Obstetrics unit of the University College Hospital (U.C.H), Ibadan. The study was done over a period of three months. A total of 150 participants were enrolled for this study. The U.C.H Ibadan is an850-bedded tertiary referral specialist hospital located in Ibadan, in the South West region of Nigeria. The obstetric unit records a birth of approximately 2500 babies annually.

The labour ward theatre unit of the hospital is used to carry out each CS. Consent for surgery is normally obtained in the lying-in wards for elective cases while foremergencies, they are mostly obtained in the labour ward. The practice is for patients for elective CS to be admitted at least the day prior to surgery and consent obtained in the lying-inward.

The survey instrument was a questionnaire developed from information in the literature. The audit standards contained within the Royal College of Obstetricians and Gynaecologist (RCOG) Guidelines[29]were used to assess the written information on each consent form. The questionnaire was interviewer administered and contained 42 open- and closed-ended questions. It was divided into four sections related to their socio-demographic characteristics, obstetric history, the informed consent procedure and the respondents' perceptions. A pilot study among 10 patients was done during the design of the questionnaire and subsequently adjusted to include some of the missing information.

Two of the investigators administered the questionnaires to the patients within 24 hours of undergoing a CS. This was done in the in-patient post-natal ward. In cases where consent was not given by the patients, the person who gave consent for surgery was contacted and the questionnaires administered.

Prior to the commencement of the study, ethical approval was obtained from the State's Research

Ethical Review Committee and informed consent was obtained from the patients before enrolment into the study.

The data were entered and analyzed using Microsoft excel and Statistical package for Social Scientist (Version 17).

RESULTS

During the study period, 173Caeserean Section(CS) were performed in the labour ward complex of U.C.H,Ibadan and 150 patientsconsented to the study.

Table 1 shows the Socio-demographic data of the repondents. The mean age was 32±1.8 years. The modal age group was 30-34 years which consisted of 80 respondents (53.3%). Most of the respondents were unskilled workers 63 (42.0%) with tertiary level of education 85(56.7%).The highestproportion of respondents 93 (62.0%) were Christians.Majority, 122, (81.3%) of the respondents were Yoruba.

An equal proportion of respondents booked in UCH or in other hospitals 74(49.3%), 72(48.0%) respectively. One hundred and eighteen (79%) of the surgeries were emergency CS. Majority of the indications for CS were medical. (This is shown in Table 2)

Of the medical indications for CS the common ones were prolonged labour(15.1%),previous CS and suspected fetal distress each being 13.7% as well as poor progress in labour (12.3%). (This is depicted in Figure 1).A large proportion (74.5 %) who had previous CS,had only one previous .

Most of the time, consent was given by the patients (96,64.0%) and husbands (43, 28.6%). One hundred and six(70.5%) of the respondents were not sure ofthe cadre of doctors who administered the consent, while most of the others 27(18.0%) were obtained by registrars.The highest number of personel witnessing the consent procedure were nurses72(48.0%) and relations 70(46.7%). Majority of the respondents 123(82.0%) had the consent obtained in the labour ward, while 18(12.0%) was donein the lying-in ward.Patient counseling occured more in the evening 56(37.3%) and afternoon 46(30.7%).Most counseling were done in English language 76(50.6%) while48(32.1%) was in the native languageand mostly over a period of 10-30mins(55.3%).(See Table 3).

Patients were frequently informed of the risks of excessivebleeding(86.0%) and blood transfusions(88.7%) while otherswere less frequently discussed with patients.Postoperative care wasless emphasized torespondents. These included commencement of oral intake (25.3%),andsuture removal (18.7%).(Depicted in Table4).

Many of the respondents expressed satisfaction with the consent form and felt it was simple to read and well written in113(75.3%) patients respectively as well as beingattractive to read in114(76.0%) patients..Over all, 137(91.3%) respondentswere satisfied with the information provided,while 128(85.3%) said the consent procedure was helpful indecision making(See table 5).More of the respondents(37.5%) preferredcounseling in the native language compared to English (43, 28.8%) or both languages (51,33.8%).A hundred and forty(93.7%) patients described the consent session as being informative .

DISCUSSION

Informed consent may be inthe written or verbal form.At the study site, a mixture of the two formats modelled after the RCOG Clinical Governance advice for obtaining valid consentwas employed. Also the same consent form is adopted for all surgical sub-specialties, althoughadditional verbal information is expected to be passed to patients scheduled for surgery.

In this study, in most instances, consent for CS were

given by patientsthemselves, or by their close relations, majority of whom expressed satisfaction with the process of informed consent.It is not clear what factor motivated the respondent, but prior experience for those that havehad a previous CS might have contributed to the high level of satisfaction.

Consent forms in most institutions, if not all, are designed in English language and this study has shown that despite the fact that most of the participants completed at least the primary level of education, a significant number still preferred to be counselled in their native language or a mixture of English and native language. Communicating in a comfortable language helps in minimising the use of technical terms.

The information passed during the consent process is equally important because it must be comprehensive for patients to reasonably make an informed choice. Ethicists[18] generally agree that a clinical informed consent must have, at a minimum, four content elements which are information about the procedure, risks, benefits and alternatives.These were covered verbally in the information given to the patients. The RCOG Guidelines on consent for CS also recommended that in addition to the common risks, women are to be informed of the serious maternal risks of CS such as hysterectomy, yet only a few of the questionnaires audited documented these risks. Very little information was made available to patients in terms of what to expect post operatively.This may be due to most of the cases being emergencies and the urgency of the situation. It further demonstrates the shortcoming of verbal consent as important information may be omitted.Also, if not documented patients may deny being told verbally in medico legal tussles.

Although risks should be discussed in the context of promoting the ethical principle of autonomy, how much information to be given is still debatable. Some researchers have suggested risks below 1% are non-significant and need not be discussed except any clinical situation increases the risk. Therefore, as an example, discussing the risk of hysterectomy which occurs in <1% of cases will only be necessary in the presence of several previous CS, placenta praevia and so on. A few other researchers found out that some patients desire to be informed of "significant" risks, no matter how rarely they occur[15]and a hysterectomy following CS would be considered a "significant" risk.

Caesarean section also has attendant risk to the fetus such as fetal lacerations especially during emergency CS compared with elective CS.[30] This study has further confirmed the poor communication of fetal risk to patients. To prevent omission of all the risks involved with CS, the recent trend is the adoption of customized consent per surgical procedure in the form of a simple check list. This has been made mandatory by some colleges and the same should be adopted in the Nigerian environment. It will also reduce the litigations associated with complications of CS.

The majority of respondents in this survey remembered the medical personnel who explained the procedure to them, although they seemed not to pay attention to the cadre of doctors. It was also possible the doctors only introduced themselves without mentioning their designation. The cadre of the doctors is also important especially since more of the consent was obtained by junior residents.

It may be reasoned that the more experience a doctor has in a surgical specialty, the better they are at administering informed consent and answering patients' questions concerning outcome following surgery.The onus falls on specialists to ensure that their patients have informed consent obtained by suitably qualified doctors or the operating surgeon.[31]Consent procedure must be properly handled to avoid complaints, which

frequently occurs when the task is delegated to trainees who are not fully conversant with the details of the intended procedure, the likely outcome and the risks.[31]Most cases of litigation have been shown to be due to doctors failing to communicate adequately.[24]The import of the finding of this study is that there is a significant risk of litigation with our current practice, since from our study younger doctors obtained consent.

The good ability to recall is reassuring because normal reasoning will expect the opposite since majority of the cases were emergencies and occurred during the night. Emergency CS respondents probably would likely be less informed than elective CS considering the stressful situation involved while obtaining informed consent. This consideration is why the RCOG Clinical Governance advice guidelines recommended explaining the procedure and obtaining consent in between contractions.[31] In a study on informed consent prior to the introduction of epidural analgesia in labour, the majority of women reported that written consent would help them "remember and appreciate the different anaesthetic options, risks, and procedures".[32]

The most striking finding of this audit, however, is thatinformed risks were few or the ability to recall risks was poor. It is difficult to know how this recall can be improved, particularly in an emergency setting, but clearly this area needs more attention and perhaps doctors and nurses should spend more time during the antenatal period discussing the potential complications associated with different modes of delivery.Given the emergency situation,one of the main reasons for poor information was time constraints and the more tense situation in the labour ward compared to the lying-in ward or antenatal clinic.

The possible limitation of this study is the sample size and the questionnaire being in English. This exposes respondents who could not read or write to communication difficulties.The type of analgesia used for the CS may also affect their ability to recall information.

In conclusion, adequate communication is essential in all aspects of Medicine and this audithas highlighted the deficiency incommunication and documentation, particularly in relation to the consent of women undergoing CS delivery. Proper guidelines should be made available in conjunction with regular staff education and training.[33]Given that the purpose of informed consent is to ensure that patients fully understand, and agree to, the proposed medical intervention, the findings presented here suggest that written consent is more likely to result in better comprehension of the risks and benefits involved.

Finally, consideration should be given to development of standardized consent forms for common obstetric procedures.

Table 1: Frequency Table Showing Socio-Demographic Characteristics Of The Respondents

Category		N=150	Percentage (%)
Age group (years)	15-19	2	1.3
	20-24	15	10.0
	25-29	24	16.1
	30 -34	80	53.3
	35- 39	23	15.3
	40-44	4	2.7
	>44	2	1.3
Occupation	None	7	4.7
	Unskilled	63	42.0
	Semiskilled	52	34.7
	Skilled	28	18.6
Educational Level	Arabic	2	1.3
	Primary	15	10.0
	Secondary	46	30.7
	Tertiary	85	56.7
	Post-graduate	2	1.3
Religion	Islam	57	38.0
	Christianity	93	62.0
Tribe	Yoruba	122	81.3
	Hausa	4	2.7
	Ibo	22	14.7
	Others	**2**	**1.3**

Table 2: Frequency Table Showingobstetrics History of the Respondents

Category		N=150	Percentage (%)
Booking status	Booked (UCH)	74	49.3
	Booked (Other hospitals)	72	48.0
	Mission home	4	2.7
Type of caesarean section	Planned (Elective)	32	21.3
	Emergency	118	78.7
Indication for surgery	Maternal request	4	2.7
	Medical indications	**146**	**97.3**

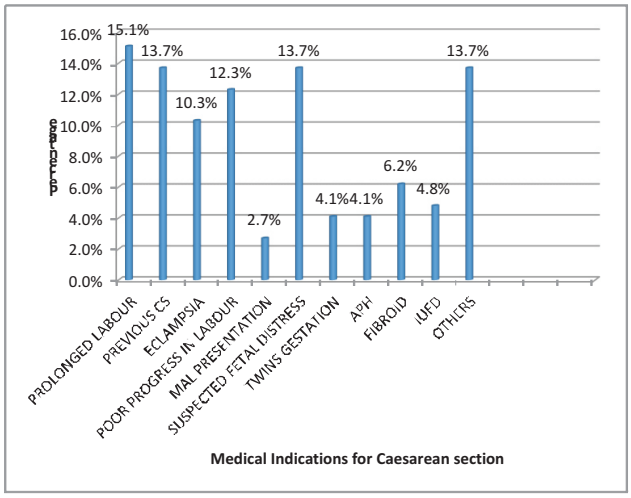

Figure 1 Medical indications for Caesarean Section

Table 3: Frequency Table Showing Consent Procedure For Caesarean Section.

Category		N=150	Percentage (%)
Relationship of the person who gave consent	Patient	96	64.0
	Husband	43	28.6
	Relation	7	4.7
	No response	4	2.7
Cadre of doctor who obtained consent	House officer	6	4.0
	Registrar	27	18.0
	Senior registrar	4	2.7
	Consultant	7	4.7
	Not sure	106	70.6
Personnel who witnessed the consent procedure	Nurse	72	48.0
	Medical student	6	4.0
	Relation	70	46.7
	Paediatrician	2	1.3
	Anaesthetist	-	-
Consent location	Lying in ward	18	12.0
	Antenatal clinic	5	3.3
	Casualty/emergency room	4	2.7
	Labour ward	123	82.0
Counseling period	Morning	44	29.3
	Afternoon	46	30.7
	Evening	56	37.3
	No response	4	2.7
Counseling language	Native	48	32.1
	English	76	50.6
	Both	26	17.3
Counseling duration (Minutes)	Less than 10	56	37.3
	10-30	83	55.3
	>30 – 60	**11**	**7.4**

Table 4: Frequency Table Showingthe Information Given During Consent For Caesarean Section

Category of information		n	(%)
Risk	Infection	41	27.3
	Bleeding	129	86.0
	Blood transfusion	133	88.7
	Bladder or intestinal injury	26	17.3
	Laceration to the baby	9	6.0
	Hysterectomy	17	11.3
	Tubal ligation	6	4.0
	Retained placenta	2	1.3
	Repeat caesarean section	21	14.0
	Death	24	16.0
Post-operative care	Oral intake Commencement	38	25.3
	Bladder catheter removal	20	13.3
	Wound dressing removal	23	15.3
	Suture removal	28	18.7
	Ambulation Commencement	24	16.0

***Multiple Responses**

Table 5: Respondents Perception Of The Consent Form And Procedure

	Description	*Frequency	Percentage (%)
Consent form	Language simple to read	113	**75.3**
	Well written	113	**75.3**
	Attractive to read	114	**76.0**
Consent procedure	Surgical procedure written on the form prior to signature	119	**79.3**
	Satisfaction with information	137	**91.3**
	Helpful in decision making	128	**85.3**

***Multiple Responses.**

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