RESEARCH ARTICLE

Gaps in Informed Consent Process Among Women Who Have Undergone Elective Caesarean Section at AIC Kijabe Hospital, Kiambu County Kenya

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Submitted 03rd October 2022, Accepted 02nd November 2022 and Published 23nd November 2022

ABSTRACT

Informed consent for elective C-sections is both a legal and ethical requirement. It includes the patient's decision-making capacity, provision of adequate information, and voluntary consent. The aim of the study was to examine the informed consent process for elective C-sections at Kijabe Hospital with a focus on identifying gaps. The study design was cross-sectional and a structured questionnaire assessing 15 recommended elements of the informed consent process was administered to 137 women post-surgery. Descriptive statistics were used for sociodemographic data. The 15 elements of informed consent were aggregated and expressed in frequencies. Data were analyzed using Microsoft Excel and STATA. The results demonstrated excellent compliance with 100% of files having a signed consent form. However, documentation of the informed consent discussion(s) was not done in all cases. Infrequently addressed elements were; the benefits of surgery, post-surgery briefing and implications on future pregnancy at 59.1%, 57.7% and 67.9% of participants respectively. The average time spent obtaining consent was ten minutes. Of note is that patients' questions and concerns were addressed in 97.1% of participants. In conclusion, all other elements of the informed consent process were frequently addressed except, documentation of the process, benefits of surgery, post-operative briefing, and implications of the surgery on future pregnancy.

Key Words: elective cesarean section, gaps, informed consent

I. INTRODUCTION

Informed consent is an essential component of good quality medical practice worldwide. It is both an ethical and a legal requirement that emanates from the ethical principle of autonomy (Beauchamp, 2011). A valid informed consent essentially consists of the presence of three aspects; the decision-making capacity of the patient, adequate information delivered in a comprehensible language and manner with ascertainment of comprehension, and voluntariness in the permission to intervention(s) where coercion or undue influence from family, friends, and healthcare workers is absent (RCOG, 2015). The informed consent process should elicit the patient's values, beliefs, preferences, and healthcare needs and address them. This is captured in the fifteen elements of informed consent recommended by ACOG (ACOG, 2019) and NICE (NICE, 2021). This, therefore, requires the clinician obtaining consent to be knowledgeable about caesarean section and also have the ability to properly communicate risk, educate patients on available treatment options, and support patients' preferences as part of the consenting process.

The scarce literature available on the informed consent process for caesarean section suggests the presence of gaps. Lubansa in Zambia concluded that only about half of the participants adequately consented, this suggests gaps in the other half (Lubansa, 2010). Another cross-sectional study in India concluded that patients were well informed about the procedure and related consequences (Latika et al., 2015). This conclusion however missed the other elements of informed consent following the guidelines update. Ntonjira in Kenya while assessing the consent process for elective surgeries, in general, found that the nature and indication for surgery were adequately addressed but alternatives, risks and benefits of surgery were inadequately addressed (Ntonjira, 2012). With the increasing world population and availability and access to better obstetric care, the informed consent process for elective cesarean section ought to be comprehensive since the caesarean section is the most performed surgery worldwide (Sung & Mahdy, 2020). Gaps in the informed consent process may lead to poor medical decisions by patients, poor adherence to treatment, and patient dissatisfaction with the care as offered which in turn leads to an increase in litigations. The aim of this study was to determine if there were gaps in the informed consent process for elective cesarean section at AIC Kijabe hospital by assessing the patients' recollection of information about the informed consent process based on their immediate experience. The objective of this study was to evaluate which of the recommended elements of the informed consent process for elective cesarean section were frequently or infrequently addressed

II. METHODOLOGY

This was a cross-sectional study in which a structured questionnaire was administered to 137 women in the AIC Kijabe hospital's postnatal ward who met the inclusion criteria and gave both verbal and written consent to the study. The eligible women were consecutively recruited. Those who were 18 years and above, had an elective cesarean section, and understood and spoke either English or Swahili well were included, while those with arising emergency cesarean section or postoperative complications were excluded. The interview was conducted on a postoperative day two or three following an elective cesarean section in Kijabe hospital when the woman was not in significant pain. The study questionnaire was adapted from two published studies by Lubansa and Latika. It was also peer-reviewed by two local experts and pretested among a few patients who met the inclusion criteria. The questionnaire had two parts. Part I captured the sociodemographic data while part II captured the recommended elements of

informed consent. The patient's record file was used to corroborate her responses. Data was collected using RedCap (a data collection application) and was then exported to Excel and STATA formats. Information gaps in the informed consent were measured as an aggregate score (0 to 15) and expressed as frequencies/percentages. The estimate of the time taken to obtain informed consent was expressed in minutes while the chance to address all patients' questions and concerns were expressed as Yes and No. A series of bivariate linear regression analyses were used to examine the association between the sociodemographic characteristics and the aggregate score on the informed consent process Data was analyzed using software for statistics and data science (STATA) and Microsoft Excel. A P-value of < 0.05 was considered statistical significance. Ethical approval was sought from all the relevant research ethics committees including Kabarak University, NACOSTI and AIC Kijabe hospital research committees before the commencement of the study.

III. RESULTS

Sociodemographic characteristics of participants of the 137 women who participated, most were between 26-35 years of age (97), had tertiary education (103), were married, (130) had 2 to 4 previous deliveries (122), lived in medium-density towns (79), and understood and spoke both English and Swahili well (131). The scoring category was up to 14 out of the 15 elements because the documentation of the informed consent process in the patient's file was not done at all. The P-values as shown below suggested that none of the sociodemographic characteristics had a statistically significant effect on the aggregate score either as a characteristic or within its category.

Table 1:

Sociodemographic Characteristics and the Association with the Aggregate Score on the Informed Consent Process

Sociodemographic Characteristic	Score Category		
	<14 (n=127,92.7%)	14 (n=10,7.3%)	P-value
Age (years), median (IQI)	32.0 (29.0; 35.0)	31.5 (26.8; 33.3)	0.29
Age category (years), n (%)			
18 - 25 years	7 (87.5)	1 (12.5)	
26 - 35 years	89 (91.8)	8 (8.2)	
Above 35 years	31 (96.9)	1 (3.1)	0.53
Level of education, n (%)			
Primary	4 (80.0)	1 (20.0)	
Secondary	29 (100.0)	0 (0.0)	
Tertiary	94 (91.3)	9 (8.7)	0.15
Marital status, n (%)			
Single	6 (85.7)	1 (14.3)	
Married	121 (93.1)	9 (6.9)	0.47
Parity after this caesarean section, n (%)			
<2	10 (90.9)	1 (9.1)	
2 to 4	113 (92.6)	9 (7.4)	
>4	4 (100.0)	0 (0.0)	0.83
residence, n (%)			
High density	38 (90.5)	4 (9.5)	
Medium-density	75 (94.9)	4 (5.1)	
low density	14 (87.5)	2 (12.5)	0.47

Understands and speak either Swahili or English well? n (%)			
Yes	121 (92.4)	10 (7.6)	
A little	6 (100.0)	0 (0.0)	0.48
When did the discussions begin? n (%)			
ANC Visits	123 (92.5)	10 (7.5)	
Night to operation	4 (100.0)	0 (0.0)	0.57

All the other elements of informed consent were frequently addressed except the benefits of cesarean section to both the mother and the baby (59.1%), post-operative briefing (67.9%), implication of the surgery on future pregnancy (57.7%) and documentation of the informed consent process in the patient's record file as shown below:

Table 2:

Frequencies of the Elements of Informed Consent as Addressed at Kijabe Hospital

Elements of Informed Consent	Response/Frequency	
	Agree	Disagree
	n (%)	n (%)
Was the consent process documented?	0 (0.0)	137 (100.0)
Were you told the name of your operation?	116 (84.7)	21 (15.3)
Were you told what the operation entails? i.e., it is a delivery of the baby via	115 (83.9)	22 (16.1)
Were you told why you needed to have the operation?	130 (94.9)	7 (5.1)
Were you informed of the benefits of the planned caesarean section for you and your baby?	81 (59.1)	56 (40.9)
Did you understand and feel that the operation to deliver your baby was necessary?	136 (99.3)	1 (0.7)
Were you told that the planned caesarean operation has some potential risks?	119 (86.9)	18 (13.1)
During the informed consent process, did you have all your questions and concern	133 (97.1)	4 (2.9)
Did you feel like you had the right to accept, refuse, or defer the caesarean operation	129 (94.2)	8 (5.8)
Were any extra procedures that might become necessary during your elective caesarean section discussed with you?	98 (71.5)	39 (28.5)
Were you informed of the available anaesthesia and post-operative analgesia options?	109 (79.6)	28 (20.4)
Was the implication of this planned caesarean section on your future pregnancy and delivery option?	79 (57.7)	58 (42.3)
Were you briefed on the outcome of your operation afterwards?	93 (67.9)	44 (32.1)
Was there any alternative(s) to the planned caesarean section discussed with you?	45 (32.8)	92 (67.2)

About 97.1% of participants had their questions and concerns answered before undergoing a cesarean section. This demonstrated respect for maternity care and attention to the uniqueness of each participant's beliefs, values, preferences and wishes.

IV. DISCUSSION

There are multiple ethical challenges that could arise when offering obstetric care, especially regarding sharing of information in order to obtain informed consent for elective caesarean section. This study set out to determine if there were gaps in the informed consent process for elective caesarean section at AIC Kijabe Hospital.

First, to describe the sociodemographic characteristics of the women who underwent elective caesarean section, this study found that most (70.8%) of the participants were between the age of 26 to 35 years with a mean age of 32 years. Only 5.8% of participants were under 25 years of age. 75.2% of the women had a tertiary education followed by secondary education at 21.2%, least was primary education at 3.6%. 94.9 % of the participants were married. These findings were almost similar to those of both Lubansa and Latika's studies (Latika et al., 2015; Lubansa, 2010). Only 5.1% were single. None was separated or widowed. Most, 89.9% had two to four previous pregnancies carried to term and delivered. 8% had fewer than two pregnancies and only 2.9% of the participants had more than four previous pregnancies. 57.7% of the participants came from smaller towns, 30.7% came from Nairobi city, and only 11.8% came from a village. Despite the hospital being located in rural Kiambu, only 11.8% came from a village. This could be due to the lower population in the village or the higher cost of care at Kijabe hospital which is unaffordable for the villagers in as much as such cost was affordable for urbanites. Residence described where the participants lived at the time of the study. Most of the participants (95.6%) spoke and understood both English and Swahili very well. Only 4.4% had little comprehension of the two languages. This could be attributed to the high levels of literacy in Kiambu county and its environs as well as most urban or semi-urban regions in the region where most of these patients came from.

None of these sociodemographic factors had statistically significant associations with the aggregate score on the gaps in informed consent. This is unlike Lubansa's study which noted that the age of the participant was associated with the overall adequacy of informed consent (Lubansa, 2010). This was also unlike a literature review finding which concluded that patients' level of education (literacy) and language competency were important determinants to fully provide informed consent (Sherlock & Brownie, 2014). Although most of the participants in this study read and understood English and Swahili well, the difference in their level of education had no influence on the aggregate score. Each patient is unique with unique needs, preferences, values, and expectations hence addressing her uniqueness by answering her questions and responding to her concerns probably mattered more than any of these sociodemographic characteristics.

Second, to describe the elements of informed consent that were frequently addressed and those that were infrequently addressed. In all cases, documentation of the informed consent process discussions was not done when the patients' record files were checked. However, the consent forms were signed and recorded in all cases. Only words like 'consent signed', 'consent form signed', and 'signed consent form' were found in the patient's file record. This closely compared with Lubansa's study in Ghana, in which 14% of cases, documentation of the informed consent process was well done but consent forms were properly filled in only 56% of cases (Lubansa, 2010). The signing of the consent form is just one aspect of documentation,

documenting discussions held with the patient is the other important aspect. Signing the consent form is not adequate consenting (Ricketts et al., 2019). Alternatively, a consideration for a more comprehensive consent form specific to each surgery documenting the quality and duration of each element of informed consent is important. The generic consent form at AIC Kijabe hospital only addressed the name of the procedure, indication, any extra procedures that might become necessary during surgery, anesthesia options (unspecified) but lacked alternatives to surgery, benefits of surgery among others that are recommended for documentation (Shah et al., 2020). The lack of documentation could have been attributed to time constraints and a lack of knowledge of the ethical and legal obligation to document discussions held while obtaining informed consent. The assumption that filling and signing the consent form was adequate could also have contributed to the lack of documentation of the discussions held before signing the consent form.

The name, nature of the procedure, indication, and agreement on the necessity of the procedure by the patient were frequently addressed in 84.7%, 83.9%, 94.7% and 99.3% of cases respectively, this was relatively similar to the findings in other studies (Latika et al., 2015; Ntonjira, 2012; Lubansa, 2010). These elements were part of the current consent form and that might have contributed to their frequent address. The benefits of the caesarean section to both mother and baby were addressed in 59.1% of cases only, this was much lower compared to a previous Kenyan study done at Kenyatta National Hospital (KNH) in which 89.4% of patients who underwent elective surgeries in multiple specialties were informed of the benefits of their surgical procedure (Ntonjira, 2012). It is possible that the benefits of the procedure were confused with the indication for the procedure. Once patients understood and agreed to the indication, some clinicians may have forgotten to discuss the benefits of the procedure. Also, some clinicians might have been unaware of the benefits of caesarean section to the mother and baby as opposed to vaginal delivery and that is why it was not frequently discussed. The balance between the success of the planned caesarean section and complications or risks from the surgery is better calculated by the patient when discussions about benefits versus risks of the procedure are held hence its importance (Anderson & Wearne, 2007).

Risks of the planned caesarean section were discussed in 86.1% of cases. This was almost similar to findings by Ntonjira at KNH in which 78.8% of patients had discussions about potential risks or complications of the scheduled elective surgery. Our findings were much better than similar studies by Lubansa and Latika in which only 7.3% and 32% of participants respectively had discussions about risks (Latika et al., 2015; Lubansa, 2010). Most clinicians and nurses working in the obstetrics department were taught and dealt with these complications often and that might have contributed to the frequent address. Also, the current generic consent form at AIC Kijabe hospital had risks of surgical procedure included hence they were less frequently missed. The most commonly discussed risks were; death, excessive bleeding, injury to adjacent organs and infection. Any extra procedures that might become necessary during caesarean section such as blood transfusion, hysterectomy were addressed in 71.5% while patients outwardly expressed any unwanted procedures during caesarean section in 7.3% of cases. The most unwanted procedure during surgery by all these participants was bilateral tubal ligation (BTL). This stemmed from discussions initiated by clinicians either in the ANC clinic or when signing the consent form on the wards whether the woman wanted the BTL procedure for contraception or not. These two elements were part of the update to the guidelines.

The available anesthesia options and the recommended ones were discussed in 79.6% of participants. This was almost similar to Ntonjira's findings at KNH in which anesthesia options were discussed in 76.7% of patients. This finding was however far much better than findings in similar studies by Lubansa, Teshome, and Latika in which it was only discussed in 4.7%, 11.7%, and 19.64% respectively (Latika et al., 2015; Lubansa, 2010; Teshome et al., 2018). Intraoperative and postoperative analgesia option was an update to the guidelines too and as such had not been reported previously. AIC Kijabe hospital is a training site for anesthesia for registered nurses and consenting for anesthesia and analgesia is part of their training. This could have contributed to the higher frequency of addressing this element of informed consent. Most consenting for analgesia and anesthesia actually happened in the operating room.

The implication of the current caesarean section on the woman's future pregnancy and delivery options if she still desired pregnancy was discussed in 57.7% of the participants. In as much as this was among the less frequently addressed elements of informed consent in AIC Kijabe hospital, still, it was better than what similar studies previously by Lubansa and Latika found (18% and 32.1% respectively). Most patients were having repeat cesarean sections and so most clinicians may have assumed that most women already knew their next mode of delivery. Also, some clinicians might have assumed that the woman was done having babies or that since the next pregnancy and delivery were far away, there was no need to discuss it in that sitting. Regarding postoperative briefing on the events and outcome of the elective caesarean section, 67.9% of the participants were briefed. This study's findings were better than in similar studies by Latika and Lubansa in which post-operative briefing was only done in 7.1% and 7.4% of participants respectively. The post-operative briefing was done either in the operating room, post-operative recovery unit (PACU) or in the ward. Arising emergency cases in between the scheduled elective cases interfered with the immediate post-operative briefing (i.e., in PACU) for some patients as the operating surgeons were urgently needed elsewhere. Also, during that period renovations were ongoing in theatre and the obstetrics and gynecology team only had one operating room and one operating team at ago which meant surgeries were back-to-back leaving little room for immediate postoperative briefing. However, due to the importance of post-operative briefing and despite such challenges, the operating team sometimes handed over the briefing to the ward team or would debrief the patients after they were done with surgeries for the day.

Alternative(s) to the planned cesarean section was discussed in more than 32.8% of participants as reported. However, the reason it was reported as infrequently (32.8%) addressed was that most women had more than one previous scar as an indication for the caesarean section and thus had no other option of delivery mode, hence their response of 'disagree' was not necessarily because it was not discussed but it meant that there was no alternative. Commonly discussed alternatives to caesarean section were regular vaginal delivery and vaginal birth after caesarean section (VBAC) both of which were available at AIC Kijabe hospital. All patients' questions and concerns were addressed in 97.1% of the participants before the operation. This was much better than the previous findings by Ochieng' et al, Latika, and Lubansa in which 56.1%, 26.8% and 24.7% of the patients had all their questions and concerns addressed before surgery respectively (Latika et al., 2015; Lubansa, 2010; Ochieng et al., 2015). About 90.3% of patients in a study by Perić reported that having the opportunity to ask questions was important to them (Perić et al., 2018). The chance to ask questions and have concerns addressed was a great

marker of respect for the participant's autonomy in the informed consent process. It gave the patient room to express her values, preferences, beliefs and wishes. Addressing this element was considered most dignifying in the informed consent process in this study.

V. CONCLUSION

The fifteen elements of the informed consent process recommended by the ACOG and NICE guidelines only benefits of surgery, post-operative briefing, implications on future pregnancy and documentation of the informed consent process in the patient's record file were infrequently addressed at AIC Kijabe hospital. There is a need to emphasize training clinicians who obtain consent to document the discussions held beyond having the patient's signature on the consent form. Further research to understand why the benefits of cesarean section and post-operative briefing are not addressed in nearly half of the cases is necessary.

VI. RECOMMENDATIONS

Policy recommendations

- Develop a comprehensive informed consent form specific to each surgical procedure.
- Train all clinicians to document the informed consent process discussions in the patient's record file.

Recommendations for further research

- A qualitative study to explore why the benefits of elective caesarean section, post-surgery briefing and documentation of the informed consent process are infrequently addressed.
- A quantitative study to assess clinicians' knowledge of the informed consent process for elective cesarean section at AIC Kijabe Hospital.

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