BMC Medical Ethics

RESEARCH Open Access

Evaluation of the surgical informed consent for elective and emergency surgeries in obstetrics and gynaecology in Saudi Arabia

Maryam Al-Meshkhas[1], Zahraa Alakrawi[2*] and Sumaiah Alrawiai[2]

Abstract

Background Informed consent (IC) represents one of the fundamental rights of patients in healthcare. An essential aspect of the IC process is providing patients with equal access to information to enable them to make the right decisions. However, failure to obtain IC undermines patient autonomy, lowers patient satisfaction, increases risks, and negatively affects the patient's trust in healthcare providers. This study aims to evaluate the surgical informed consent (SIC) process from the patient's perspective both for emergency and elective surgeries in obstetrics/genecology in Saudi Arabia.

Methods This is a quantitative cross-sectional study. The study population included all hospitalized female patients who had undergone obstetric or gynaecological surgeries, from February 2021 to March 2021. The total sample size was 156 female patients.

Results Most of the participants were married (96.2%) and unemployed (80.1%). The most performed surgery was caesarean Sect. (84%). Most of the patients were satisfied with their SIC experience which represents over 85%. No significant difference has been found between the elective and emergency surgeries. However, person-in-charge of SIC administration and the time provided to sign the IC were deemed to be significant predictors.

Conclusion Based on the findings, it is recommended that physician take responsibility for the SIC administration rather than an unknown provider. It is also recommended to provide the patients with adequate time to understand the SIC. Furthermore, ensuring the availability of emotional support is critical for enhancing the patient experience.

Clinical trial number Not applicable.

Keywords Informed consent, Patient experience, Surgical consent, Emergency surgery, Elective surgery, Gynaecology, Medical ethics

*Correspondence:
Zahraa Alakrawi
zalakrawi@iau.edu.sa
[1]Maternity and Children Hospital, Dammam 34212, Saudi Arabia
[2]Health Information Management and Technology Department, College of Public Health, Imam Abdulrahman Bin Faisal University, Dammam 34212, Saudi Arabia

Background

Overview and definitions

Informed consent (IC) is a legal and ethical document that represents one of the fundamental rights of patients in health care. Informed consent "is probably the most revolutionary, the most rudimentary, the most misunderstood and misused term in all of health law and bioethics" [1]. The patients' rights movement has been working on establishing an intercorrelated relationship between patients and healthcare providers (HCPs) to ensure that patients are aware of health-related information, receive the required education, and are familiar with their social rights [2]. Moreover, patient rights emphasize equal access to healthcare by all patients as well as compliance of the HCPs with ethical standards in the required care provided to patients [3]. This includes having patients' rights standards based on the type of service provided by the health care facility. For example, if there is no surgery unit, a consent form will not include a section for this service [3].

The general concept of patient IC involves "voluntary authorization, by a patient or research subject, with full comprehension of the risks involved, for diagnostic or investigative procedures, and medical and surgical treatment" [4]. IC guarantees patient autonomy in choosing the preferred treatment with adequate knowledge regarding the surgery to be performed [5–7]. The process of obtaining IC should ensure that the patients understand the treatment, care, services, and procedures they will have to undergo [8]. Furthermore, IC is considered as a legal document that protects HCPs from legal liability [9].

This study focuses on surgical informed consent (SIC) as a distinct type of the IC and its role in enhancing patients' experience, improving patient satisfaction, and improving the quality of services [6, 10]. The SIC is defined as "a client's right to receive adequate and pertinent information that allows the client to fully understand the proposed surgery, including possible benefits and complications" [7].

Although SIC has been extensively studied in literature, the actual implementation is still lagging [7, 11, 12]. Information provided by the HCPs should be in a common and clear language and sufficient time should be allocated to allow the patients and/or their guardians to discuss unclear steps or information regarding the surgery [9]. A well-executed SIC signed by a patient who has been properly informed is essential to every surgical intervention [8].

Failure to obtain SIC undermines patient autonomy, lowers patient satisfaction, increases risk, and negatively affects the patient's trust in the surgeon [12, 13]. If the surgical procedure results in an undesired outcome, the patient-physician relationship may deteriorate which could lead to an assault or battery [13, 15]. In addition, a lack of proper documentation of SIC may result in a physician being sued for disciplinary actions [4, 9, 14].

On a national level, the Patient Experience Centre in collaboration with the Patient Safety Centre in Saudi Arabia has published an IC manual for Saudi healthcare settings [16]. The ethical elements of IC information sharing involve ensuring that a patient understands the treatment plan, is aware of all available options, understands the importance of their opinions, and is an integral part of the team in shared decision making [16].

Surgical informed consent

Existing literature on SIC has reported smaller proportions of patients who feel that physicians provide them with all necessary information about their surgery [17, 18]. One study found a significant difference between physicians and patients reports of the amount of information provided regarding the surgery [18]. In this study, patients were asked for their opinions on the information they received during the outpatient visits before the surgery [18]. In fact, patients' view before the surgery could affect their ability to evaluate the surgery information. However, this study has not reached a conclusion regarding the real quality of the entire SIC process [12].

The knowledge provided for the IC differed from one setting to another. Variations in the amount of information provided for surgery have been reported in previous studies. Kirane et al. (2015) and Weckbach et al. (2016) reported that little information was provided to patients regarding the surgery while Hallock et al. (2017) and Yildirim et al. (2014) reported that a large amount of information was provided [5, 19–21].

In other studies, patients reported receiving better verbal explanations about the planned surgery [22–24]. Ochieng et al. (2015) have concluded that even if the physician gives good verbal information about the surgery, only 50% of the physicians allocate a suitable time during the discussion to answer patients' questions [23]. Furthermore, researchers have found that only 50% of the patients read the SIC form thoroughly [22]. Two studies have found that a high percentage of the patients could not recall the information provided to them [22, 25]. In addition, some patients reported they did not have sufficient time to sign the SIC given within 24 h before the surgery [22].

In obstetrics and gynecology, a study has reported that only 53% of the physicians discussed possible alternative treatments with the patient [26]. Although 94% of the physicians asked the patients whether they had any questions, only 32.7% confirmed that the patient understood the information by asking them to repeat it [26]. Furthermore, 90% of trainee physicians were not sure about the surgical risks involved when discussing the SIC with

patients. However, most of the participants in this study were female physicians, which affects the generalization of the result from a gender perspective [26]. In general, physicians may be biased when they explain the benefits and potential risks of the proposed surgery [27].

Several studies have reported that only a low number of patients were dissatisfied due to physicians not explaining the required information [5, 22, 23]. In addition, one study reported a significant association between the information and awareness of SIC and the success rate of the operation and patient satisfaction [5]. Shemesh et al. (2019) have reported an association between high levels of education and employment status to patient satisfaction. However, no associations were identified between patients' demographic characteristics and satisfaction in these studies [28].

A qualitative study by Gabay & Bokek-Cohen (2020) stated that patients prefer personalized information tailored to their needs [17]. While they argue that there is time available for discussion, it was found that physicians' behavior regarding explanations was below expectation, both in terms of time and emotion [7, 24, 29, 30]. All these studies reported the importance of time spent on the SIC process. Other factors found to have effects on the SIC process are patient participation and parents' involvement [24], patient education [24, 30], the environment, and the opportunity for clarification for the patient [7], and the amount of information provided [5, 29].

However, IC research is scarce in Saudi Arabia [31, 32]. One study found that 37% of the patients perceived IC to be a shared decision; 50% believed that it is to inform the patient; 45% think that it is to help the patient to decide; and 40% believe that it is to ensure that the patient understands the surgery [32]. However, the participants in this research scored their experiences within six months of having surgery. This can be viewed as a limitation of this study since such a long timeframe could affect the accuracy of patients' recall of their experience. In a different study, researchers have found that only 54% of patients were satisfied with their experience, and almost 50% evaluated the quality of IC as poor [31].

Elective versus emergency surgery

Several studies found some differences in the SIC process for elective and emergency surgery. First, the overall quality of SIC was affected by the urgent nature of the surgery required [28]. Second, patients who undergo emergency surgery have less understanding than those who have elective procedures due to the urgency, the life-threatening nature of the patient's condition, and the little time allocated for patient discussion [28, 30]. In Lemmu et al. (2020), most of the patients had had emergency surgeries, and there was no clear statistical comparison between the two groups [30]. The patients' ability to recall the SIC process, and to read the SIC form, and patient satisfaction were low with emergency surgeries [29, 33].

One of the earliest studies comparing elective and emergency surgery patients was conducted by Khan in 2012 [29]. However, the surgery performed in the two groups differed, which affected the comparison due to the differences in the information obtained. Two studies conducted in obstetrics and gynecology settings found contradictory results [7, 34]. Teshome et al. (2019) found no statistical difference between emergency and elective cases [7], while Perić et al. (2018) had the opposite result [34]. Researchers identified patient illness, analgesic medication, and fatigue as factors associated with low patient comprehension in emergency surgeries [33, 34].

The previously discussed literature shows how SIC is currently practiced nationwide and on an international level. Furthermore, it shows that patients desire to be more involved in SDM. However, there is a clear gap between the information provided and the amount of information the patients want, as well as the level of involvement they prefer versus their actual level of involvement [17]. In Saudi Arabia, the literature seemed sparse, with only a few articles that discuss some aspects of the SIC process [31, 32, 35–37]. None of these articles addressed SIC for surgery in the inpatient setting. Obstetrics and gynecology settings are complex environments [38]. Thus, they should be examined.

This study explores and evaluates SIC for elective and emergency surgeries in the obstetrics and gynecology setting. This study will enrich the literature on SIC in Saudi Arabia. In addition, it will help to identify the weaknesses in the implementation of these concepts in practice. Finally, the study will guide improvement planning, based on the findings and that of other research in the local area in the obstetrics and gynecology field, which may differ from what has been found in other settings and countries.

This study focuses on the SIC process in obstetrics and gynecology settings. These topics were evaluated from the patients' perspective. For the SIC, the issues discussed in the following section were considered.

These research data were obtained by eliciting patients' recall of their experience during the SIC process for obstetric and gynecologic operations, which is considered to be an effective method to judge the SIC process [8]. The obstetrics and gynecology setting was selected because it has not been widely covered in the literature, compared to other specialties. Furthermore, this specialty may be different because of the urgency of some operations, such as under conditions that are considered to be potentially life-threatening to the patient or the fetus during pregnancy and delivery [39]. This study aimed to assess the experience of the SIC process from

the patient's perspective both for emergency and elective surgeries in obstetrics/gynecology in Saudi Arabia.

Methods

Research design

The study design is a quantitative cross-sectional study. The null hypothesis examined in this study is that there was no differences between the patients experience undergoing elective surgery and those who had emergency surgery. The data used to answer the study questions are primary data, gathered with an electronic questionnaire from the patients who met the study inclusion criteria. The data were analyzed by calculating the frequencies and percentages to describe the data and chi-square to compare the study variables. The independent variables in this study are patient nationality, age, level of education, employment status, marital status, surgery title, and type of surgery. The dependent variables were divided into many domains, starting with factual and procedural questions; reading and understanding the consent form; physical and emotional status of the patient at the time of SIC form signing; patients' agreement to signing the SIC; and patients' view on the importance of particular issues in the SIC process.

Study setting

The study was conducted in a specialized governmental maternity hospital in the eastern region of Saudi Arabia. The hospital has a 400-bed capacity. Different types of obstetric and gynaecologic surgeries are performed in the study setting, based on the patient's diagnoses and conditions. The average number of major Obstetrics and Gynaecology surgeries performed in the hospital in a year is around 2200 surgeries. The surgeries were scheduled for all the elective cases, while emergency surgery would be decided on and performed based on the patient's condition.

Participants

The study population included all hospitalized female patients who had undergone obstetric or gynaecologic surgery, whether elective or emergency. The participants were aged 18 years old and above. All hospitalized patients scheduled for major obstetric or gynecology surgery in the study period had an equal opportunity to participate in the study. The following patients categories were excluded from this study: (1) non-Arabic speakers, (2) critically ill patients, and (3) isolated patients. It was made clear to all participants that participation in the study was anonymous and voluntary, answers would be treated confidentially, and participation would not affect their hospital treatment plan.

Sample size

The sample in this study was all patients who underwent surgery during the data collection period (1 February 2021 to 17 March 2021). All hospitalized patients for major obstetric or gynecology surgery in the study period had an equal opportunity to participate in the study. All of them were asked if they would like to participate and the study participants included all those who agreed to participate and who were within the criteria included in the study. The sampling technique used was a convenient sample, including all patients who met the inclusion criteria and would voluntarily complete the questionnaire [40]. This resulted in a sample size of 156.

Data collection methods

Instruments

The data were collected with an electronic questionnaire using a tablet, which consists of three main parts. The first section involved the patients' data. The second contained questions on the informed consent process and the importance of the process to the patient.

The first part of the questionnaire was developed based on similar topics and questionnaires in the literature. The second part was derived from a previous study that examined the differences between the patient experience in elective and emergency surgeries [34]. This questionnaire was chosen because it was comprehensive and covered many aspects of the informed consent process. The original questionnaire used in the Perić et al. (2018) study [34] was developed based on research conducted by Akkad et al. (2004), which was created with panelist participation and piloted before starting the actual data collection [41]. The last part was derived from another study, and it focused on patients' involvement in the decision-making process for their treatment plan [42]. This part was tested for internal reliability and face validity in two stages, and it was translated from German to English by two language experts [42]. The final version of the questionnaire used in this study can be found in the supplementary material.

Validation process

As the questionnaire was intended for distribution to patients who use Arabic as their first language, there was a need to translate it from English to Arabic. Two experts in the English and Arabic languages did the translation. The translation process consisted of two steps. The first step was translating the original English questionnaire to the Arabic language by one of the experts. The new Arabic version was then sent to the second expert via email to translate it back to English to validate the translation and ensure that the language was correct and understandable. Independent reviews of the original and the

re-translated version were performed to ensure the accuracy of the wording.

Content validity

The content validity of the questionnaire was assessed by eight experts who were considered acceptable for a content validity assessment [43]. The participating experts were from both academic and healthcare backgrounds. The validation instrument consisted of two main sections. The first part contains questions for the expert regarding the relevance of the questions in the questionnaire to the study purpose, the clarity of questions, and the ease of responding. The second part contained an open-ended question requesting the expert's comments on the tool, the sequence of the questions, the length of the tool, and any other comments on how to enhance the benefits of the tool. In addition, the scale-level (S-CVI), item-level (I-CVI), and average deviation mean index (ADm) were assessed [44, 45].

Reliability and validity result

Eight experts participated in the content validity study; four are in an academic field and four are employed in a hospital. The S-CVI score was 0.9, which is acceptable according to Lynn, (1986) [45]. Three questions in the I-CVI that scored 75% or less were removed. The clarity of the questions was also evaluated. Fifteen out of 36 questions were modified, based on the clarity scoring [43]. To evaluate the interrater agreement for the Likert-scale items, ADm was calculated, and this calculation resulted in acceptable scores (for questions with 1 answer > 0.1, 2 answers > 0.3, 3 answers > 0.5, and 4 answers > 0.69) as maximum [44].

Internal consistency

The internal consistency was performed with Cronbach's alpha to measure the reliability of the study instrument. The Cronbach alpha test was performed on the study instrument to test the reliability of each scale to measure what it was intended to measure. The questionnaire had three scales (reading and understanding the SIC; and the importance of the SIC process to the patient. The result of the Cronbach alpha test for the first scale was 0.8, indicating a good level, 0.69 for the second scale, indicating an acceptable level, and 0.8 for the third scale [46].

After ensuring the validity and reliability of the questionnaire, the data collection phase commenced. Eligible patients were approached, and after they had read the study consent form and agreed to participate in the study, they were asked to complete the questionnaire after the surgery to ensure that they had undergone the SIC process experience. Moreover, the questionnaire had to be completed within 14 days of signing the surgery consent form. The participants were asked to read and answer the questions by themselves, or the researcher would read the questions and record the answers.

Ethics and limitations

Ethical approval (Number IRB- PGS-2020-03-432) was obtained from the institutional review board at the Imam Abdulrahman bin Faisal University. A limitation was the time constraint, which resulted in collecting the data in a shorter time and effect the sample size as well as using convenient sampling as a sampling methodology.

Data analysis

For the statistical analysis of the data, the Statistical Package for Social Sciences (SPSS) program was used. For the univariate analysis, the frequency and percentage were used for all the categorical data. For the bivariate analysis, the chi-square test was used to test the association between the categorical variables The statistically significant cut-point to compare differences between variables was P-value = < 0.05.

Results

Demographic characteristics

The data collection period was from 1 February 2021 to 17 March 2021. During this period, 181 patients were contacted. Out of the 181, three patients were excluded because they were not Arabic speakers, and 14 others were excluded because of serious medical conditions, which brought the total to 164 patients. Eight patients chose not to participate in the study. Therefore, the total number of participants is 156 patients. The response rate was 95%. A summary of the demographic characteristics is provided in Table 1.

The highest percentage of the participants 30.1%, were aged between 31 and 35 years old, followed by 22.4% in the age group 26–30, and 21.8% in the 36–40 age group. The majority of patients were Saudi (87.2%). A high percentage of the participants (42.3%) had a high school educational level, followed by a bachelor's degree level (32.1%), and 10.3% of the participants had little or no education. The majority of the participants were unemployed (80.1%) and married (96.2%). The most performed surgery was cesarean sections (CS) (84%).

Patient experience with the SIC process

The majority of the patients were satisfied with the SIC process (85.9%). Figure 1 represents the patient satisfaction with the SIC between elective and emergency surgeries in Gynecology. Most of the time, SIC was given by another physician (38%). However, data shows different distribution across elective vs. emergency surgeries. Approximately, 48% of elective SIC were given by the surgeon compared to only 15% of their emergency counterparts. Details are shown in Fig. 2. Regarding patients'

Table 1 Demographic characteristic

Demographic variables		*N* (%)	Demographic variables	*N* (%)
Citizenship status (156)	*Citizen*	136 (87.2)	Resident	20 (12.8)
Age (156)	*18–25*	25 (16)	*36–40*	34 (21.8)
	26–30	35 (22.4)	*41–45*	11 (7.1)
	31–35	47 (30.1)	*46–50*	2 (1.3)
	56 - and above	2 (1.3)		
Level of education (155)	*Elementary or less*	16 (10.3)	*Diploma*	11 (7.1)
	Intermediate	11 (7.1)	*Bachelor*	50 (32.1)
	High school	66 (42.3)	*Master or upper level*	1 (0.6)
Employment status (156)	*Employee*	31 (19.9)	*Not-employee*	125 (80.1)
Marital status (156)	*Single*	1 (0.6)le	*Widow*	2 (1.3)
	Married	150 (96.2)	*Prefer not to tell*	1 (0.6)
	Divorce	2 (1.3)		
Type of surgery (156)	*Elective*	52 (33.3)	*Emergency*	104 (66.7)
Surgery name (156)	CS	131 (84)	Hysterectomy	5 (3.2)
	CS & fallopian ligation	1 (0.6)	Myomectomy	4 (2.6)
	D&C	4 (2.6)	Ovarian Cystectomy	3 (1.9)
	D&E	1 (0.6)	Salpingectomy	4 (2.6)
	E&C	3 (1.9)		

emotional status, 85% of the patients felt reassured when signing the SIC. This looks consistent across all surgeries. More information is provided in Fig. 3. The overall patient satisfaction with the SIC was 85.9%, as shown in Table 2.

In general, higher percentages of patients who were satisfied with their experience were scheduled for elective surgeries, given consent by the surgeon in more than 24 h, and had emotional support as shown in Fig. 4. In contrast, patients who had a negative experience of the SIC, were mostly given less than 24 h to sign the consent and had no emotional support. Further details are shown in Fig. 5.

Reading and recalling the SIC

In general, only 36.5% of the participant reported remembering at least some of the information provided to them in the SIC form. 61% of the elective cases were able to recall at least some SIC information, compared to 24% of the emergency cases. Only 23.7% of the participants had read at least some of the written information in the form. Only 34.6% of the patient reported that it easy for them to understand the written information in the form which is similar to the number of patients who read the form. It was found that between the participant 42% of the elective cases read and understood the handwritten section, compared to 14.4% of the emergency cases. Further details are presented in Table 3.

The association between the participants' demographics and the importance aspect of SIC

There were significant differences in the perception of the importance of SIC based on the demographics data as shown in Table 4. The importance of having someone check patient understanding was found to differ significantly between age groups, with $X^2 = 21.7$ and p-value of 0.001. In addition, participants' opinions about the

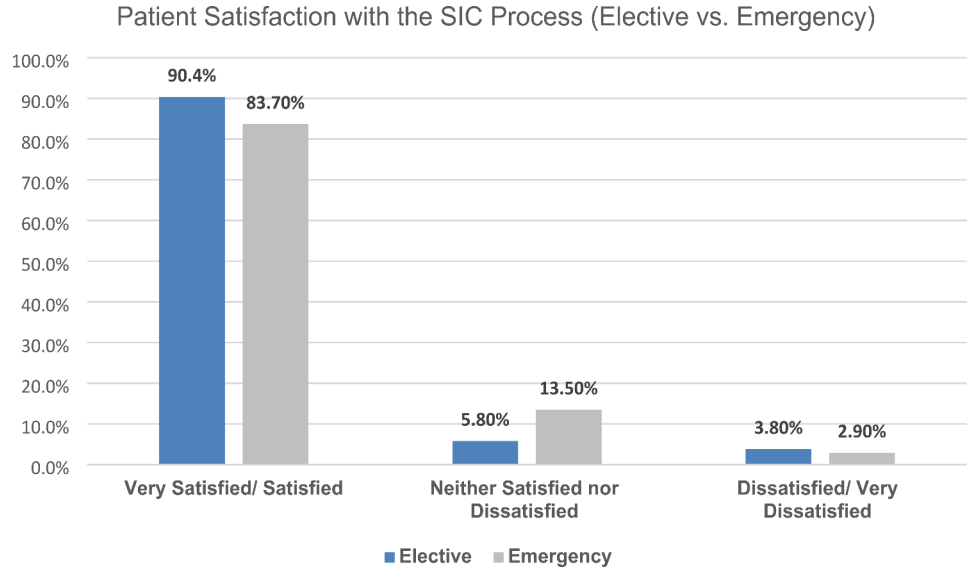

Fig. 1 Patient satisfaction with the SIC process between elective and emergency surgeries

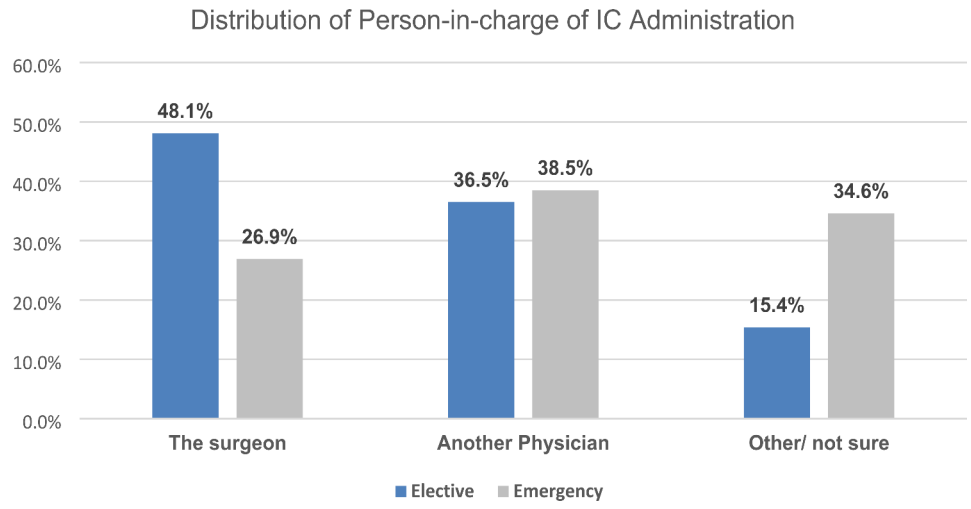

Fig. 2 Person-in-charge of the SIC administration

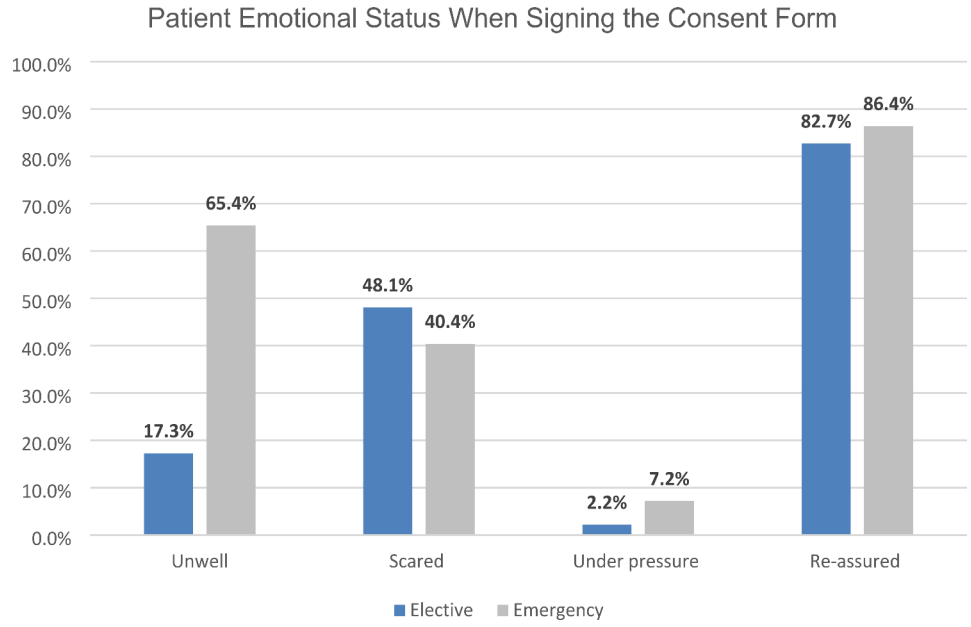

Fig. 3 Patient emotional status when signing the SIC

importance of having an opportunity to ask questions showed significantly different scores according to education ($X^2 = 19.5$, p-value of 0.002), employment status ($X^2 = 4.8$, p-value of 0.02), and nationality ($X^2 = 5.1$, p-value of 0.02).

Significant predictors of SIC experience

The result shows that more than half of the participants (34% and 37.8%) reported that the SIC process was done by their surgeon or another physician, respectively, and 28.2% said that another HCP had done the SIC process with them. The educational background of the HCP with-ier physician or nurses who did the SIC process with the patient showed a significant difference between elective and emergency surgery, with $X^2 = 9.14$ and a p-value of 0.02. It was shown from this finding that a high number of patients with emergency surgery get the SIC with nurses and other staff rather than the physician.

In general, 62.2% of the patients reported they were given the SIC to read it and sign it in less than 24 h before the surgery time. Of the emergency cases, 76.9% signed the SIC within 24 h before surgery, and 83.7% of the elective cases signed the SIC between 1 and 14 days before the surgery, which means a significant difference between elective and emergency surgery of $X^2 = 72.6$ and p-value of 0.0001. The patients also expressed that the time allocated to think about the consent form before signing it was enough for 75.6% of the total participants. Only

Table 2 Patient experience in both elective and emergency surgeries (bivariate analysis)

Patient experience		Total *N* (%)	Elective *N* (%)	Emergency *N* (%)	X^2	*P*-value =>0.05	Adjusted *P*-value
Overall satisfaction with the process of giving consent (156)	Very satisfied/ satisfied	134 (85.9)	47 (90.4)	87 (83.7)	2.16	0.339	0.678
	Neither satisfied nor dissatisfied	17 (10.9)	3 (5.8)	14 (13.5)			
	Dissatisfied/ very dissatisfied	5 (3.2)	2 (3.8)	3 (2.9)			
Who asked you to sign the consent form (156)	The surgeon	53 (34)	25 (48.1)	28 (26.9)	9.14	**0.010***	**0.02***
	Another Physician	59 (37.8)	19 (36.5)	40 (38.5)			
	Other/ not sure	44 (28.2)	8 (15.4)	36 (34.6)			
When did you sign the consent form (156)	> 24 h before operation	97 (62.2)	10 (19.2)	40 (76.9)	72.6	**0.000***	**0.000***
	< 24 h before operation	50 (32.1)	87 (83.7)	10 (9.6)			
	Not sure	9 (5.8)	2 (3.8)	7 (6.7)			
Was the amount of time you had to think about the consent form before you signed (156)	Enough	118 (75.6)	49 (94.2)	69 (66.3)	14.8	**0.002***	**0.004***
	Not enough	28 (17.9)	2 (3.8)	26 (25)			
	Too long	3 (1.9)	0	3 (2.9)			
	Not sure	7 (4.5)	1 (1.9)	6 (5.8)			
Did you have a partner/ relative/ friend with you when you signed the consent form (156)	Yes	34 (21.8)	22 (42.3)	12 (11.5)	19.2	**0.000***	**0.000***
	No	122 (78.2)	30 (57.7)	92 (88.5)			
Emotional and physical factors							
Feeling in pain, unwell, drugged, tired, or exhausted at the time of signing the consent form	**Yes**	**77 (49.4)**	**9 (17.3)**	**68 (65.4)**	32.05	**0.000***	**0.000***
	No	79 (50.6)	43 (82.7)	36 (34.6)			
Feeling scared or frightened by signing the consent form	**Yes**	**67 (42.9)**	**25 (48.1)**	**42 (40.4)**	0.83	0.360	0.72
	No	89 (67.1)	27 (51.9)	62 (59.6)			
Feeling under pressure by signing the consent form	**Yes**	**8 (5.6)**	**1 (2.2)**	**7 (7.2)**	1.5	0.220	0.44
	No	135 (94.4)	45 (97.8)	90 (92.8)			
Feeling re-assured by signing the consent form	**Yes**	**132 (85.2)**	**43 (82.7)**	**89 (86.4)**	0.37	0.539	1.078
	No	23 (14.8)	9 (17.3)	14 (13.6)			

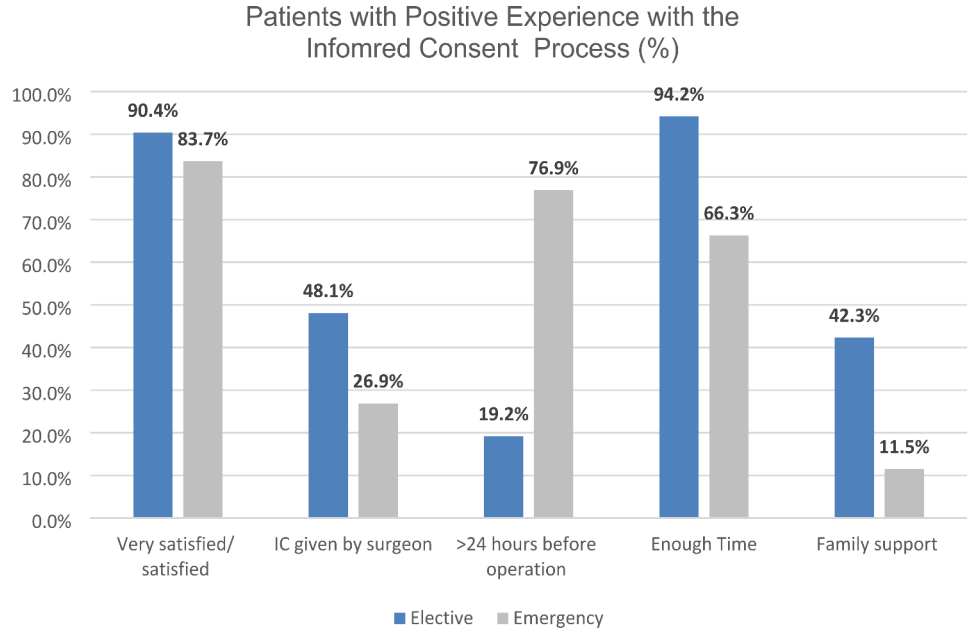

Fig. 4 Patients with positive SIC experience (%)

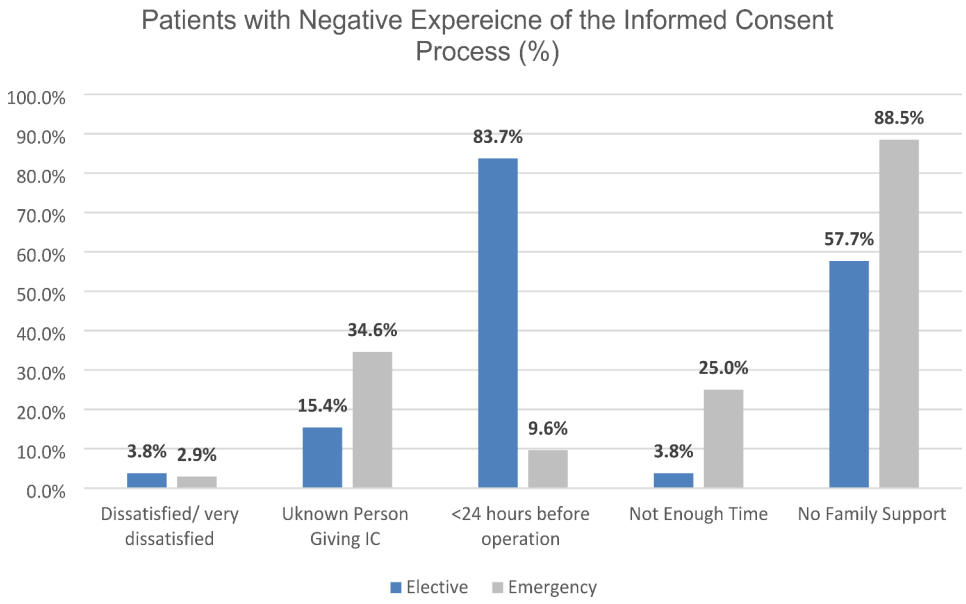

Fig. 5 Patients with negative SIC experience (%)

Table 3 Reading and understanding the SIC

Reading and understanding the SIC		Total *N* (%)	Elective *N* (%)	Emergency *N* (%)	X^2	*P*-value =>0.05	Adjusted *P*-value
Remember at least something about signing consent form	Yes	57 (36.5)	32 (61.5)	25 (24)	21.02	**0.00***	**0.00***
	No	99 (63.5)	20 (38.5)	79 (76)			
Read at least some of consent form—handwritten part	Yes	37 (23.7)	22 (42.3)	15 (14.4)	14.8	**0.00***	**0.00***
	No	119 (76.3)	30 (57.6)	89 (85.6)			
Found handwritten part of consent form easy to understand	Yes	37 (23.7)	22 (42.3)	15 (14.4)	14.8	**0.00***	**0.00***
	No	119 (76.3)	30 (57.7)	89 (85.6)			
Found printed part of consent form easy to understand	Yes	54 (34.6)	30 (57.7)	24 (23.1)	18.3	**0.00***	**0.00***
	No	102 (65.4)	22 (42.3)	80 (76.9)			

Table 4 The association between the participants' demographics and the importance aspect of SIC (the items presented here is the one that shows significant result)

Important topics to patient	Demographic characteristics					
	X^2	P-value = > 0.05/ Adjusted	X^2	P-value = > 0.05 Adjusted	X^2	P-value = > 0.05 Adjusted
importance of having someone check patient understanding	Age					
	21.7	0.001 0.008				
importance of having an opportunity to ask questions	*Education*		*Employment status*		*Nationality*	
	19.5	0.002 0.012	4.8	0.02 0.04	5.1	0.02 0.04
interest in knowing the details of the surgery	*Nationality*					
	3.7	0.05 0.1				
knowledge of the possible complications	Age					
	15.1	0.01 0.08				
importance of having time alone before signing the SIC form	*Education*		*Nationality*			
	14.3	0.01 0.06	5.1	0.02 0.04		

3.8% of the patients who had undergone elective surgery described that the time to think about the procedure before signing the SIC form was not enough, compared to a quarter of the patients who had had emergency surgery, with $X^2 = 14.8$ and a p-value of 0.004.

A high number of the participants (78.2%) reported that they signed the SIC form alone. The study also shows that there was a significant difference between the percentage of patients who had a partner with them at the time of signing the SIC, based on the surgery type, 42.3% for elective cases and 11.5% for emergency cases, with $X^2 = 19.2$ and p-value of 0.000. Half of the patients expressed that they were experiencing pain or felt unwell, drugged, tired, or exhausted when signing the SIC; most of this half had emergency surgery, with $X^2 = 32$ and a p-value of 0.00 between the two surgery types. Although 42.9% reported that they felt scared or frightened when signing the SIC, 85.2% felt reassured, and only 5.6% felt pressured.

Discussion

Obtaining SIC has been recognized as a fundamental part of informing the patient about the surgery. This study examined the SIC process and the elements affecting it, including the process and the discussion time. The null hypothesis in this study is that there are no differences between obtaining SIC for elective and emergency surgeries. The study found that 85.9% of the patients reported that they were satisfied with the overall SIC process, and 75.6% reported that enough time was allowed for reading and signing the consent form. The study also found that 64.5% of the patients received a verbal explanation regarding the surgery, 49.4% of the patients reported suffering pain during the SIC process, and only 34.6% of the patients had read and understood the SIC form.

Patient demographic characteristics were found to be affecting factors related to evaluating the SIC. Patient education is one of the demographic characteristics that play a positive role in the quality of the delivered SIC and the patient comprehensiveness to the surgery knowledge [23, 24, 28, 30]. At the same time, a younger patient's age was found to be a significant predictor of the quality of SIC [31]. In a study conducted by Ochieng et al. (2015) found even more demographic characteristics that affect the patient perception of the SIC as the region of the country where the patient lives and the socioeconomic factors together with age and education [23]. Our study also examined the effect of patient nationality and employment status and found a relationship between them and the SIC important aspect.

The HCPs who provide the required information about the surgery to the patients should have appropriate knowledge regarding the reasons for, benefits of, possible complications of, and alternatives to the proposed treatment. A physician should discuss the patient's condition with them and propose all possible solutions, rather than only presenting information relevant to the option preferred by the physician [18]. In this study setting, although 71.8% of the patients had done the SIC process with either the treating physician or the surgeon who performed the surgery, which indicates that a reasonable level of information was provided, 28.2% of the patients still received the SIC process from nurses or other staff, who were not recognized by the patients. This indicates that in this study physicians and surgeons showed more involvement compared to other studies [10, 34]. The study also found that there is a significant difference in the job title of the HCP who gives the SIC form between elective and emergency surgeries, indicating that the physicians depend on nurses or other HCPs to provide the patient with surgery information in emergencies which may result in receiving less information than elective surgery. A contradictory result was found in one study that was performed in Bosnia and Herzegovina which found that 83% of the patients do the SIC process with the nurses [34]. While in two other studies, a high percentage of the patients did not recognize the staff member who did the SIC process with them, 76.3% by Ochieng et al. (2015), and 51% in a study by Dogan (2015) [10, 23].

More than 60% of the patients (62.2%) in our study declare signing the SIC form less than 24 h before surgery; out of these patients, only 19.2% were elective cases, while the majority (76.9%) were emergency surgeries. A similar result was found in a study conducted in an obstetrics and gynecology setting where elective and emergency surgeries are performed, which found that 66.8% of the patients signed the SIC within 24 h before surgery [24]. Talking about time, our study found that 75.6% of the patients reported having enough time to read and sign the SIC form. However, some patients who underwent emergency surgery felt that the urgency of their cases justified the limited time allowed for the SIC process. The nature of an emergency condition due to a life-threatening condition, can affect the process and shorten the processing time [30]. This may result in the patient ignoring the time inadequacy and assuming that the SIC is just a tool for informing the patient about the selected treatment by the physician, as was found in one study where 50% of the patients reported that their decision was not valuable since the physician made the treatment decision [31]. The short time allocated by the HCPs implies that the SIC process did not receive the appropriate attention in execution, especially in emergency cases. A recent qualitative study that explored the patient's preferences before the surgery stated that patients tend to think that, although there is sufficient time available for a physician to discuss the issue with them, they did not

receive the required information [17]. Another aspect of patient experience in this current study, is that only 21.8% of the patients had an accompanying partner to discuss their decision with them, which is due to the hospital temporary policy at the time of the study aimed to minimizing the risk of spreading the COVID-19 infection by asking patients to attend without their partners. In general, patients in this study setting had a similar experience during the SIC process to what was found by Perić (2018) [34].

Furthermore, the study shows that patients undergoing emergency surgery were in more need of an accompanying partner or a relative to be involved in the decision-making and were less demanding in asking questions, which differed significantly from those who underwent elective surgery. Al Abdullah et al. (2017) reported that SIC was important for different aspects, and of the participants, 75% agreed that it was important to understand the surgery information, 62.1% to explain the diagnosis, and 61.4% to disclose the risks of an operation [35].

The HCPs should discuss possible complications and alternatives with patients in the outpatient setting, which will help to reduce the knowledge gap for emergency cases. With almost nine months for a normal pregnancy, the result of patients having knowledge, understanding, discussing, being involved in the treatment plan, and choosing their preferred treatment plan should result in a higher score than for patients with acute conditions in other medical specialties. Increased efforts to involve patients in their treatment plans were recognized in the literature to positively contribute to higher patient satisfaction [27, 47, 48].

Study limitations

This study had some limitations which might affect the external validity of the research and the generalizability of the findings. Since most of our patients had CS sections, findings might not be generalizable to other obstetrics and gynaecology patients with different types of surgeries and medical interventions. Other factors that could further affect the external validity and generalizability of this study's findings also include the smaller sample size and the brief data collection period.

In addition, since this study was conducted in a governmental hospital, the patient demographics may have affected the results, so a further investigation should be undertaken to identify possible differences between patients in government and private hospitals because patients' economic status treated in governmental hospital may vary from those who seek a private hospital. A further observational study should be done to examine the extent of the information provided to the patient by the physician, based on the SIC standards.

Conclusions

This study was designed to explore SIC in the obstetrics and gynecology specialty from patients' perspective. The study examined the SIC process and explored possible differences between patients' experiences in elective and emergency surgeries. In general, the study found that the written information is not essential to some patients as they did not read it while they still satisfied, highlighting that patient-physician communication is critical for the SIC process. Regardless, the SIC form should contain all the surgical information necessary to guide the physician in providing the required knowledge for the patients [49–51]. The study found that the type of surgery, elective or emergency, affects many aspects of the patient experience. The patients undergoing emergency procedures had less attention during the process of obtaining the SIC in terms of who discuss the surgery to the patient, the time period of receiving the information before the surgery, the adequacy of time needed to read and sign the SIC and the need for family support. However, patients' medical conditions should not be a barrier to providing them with the required information for SIC. The study also found that the highest education and the younger patient age were associated with a higher need for more quality process in obtaining the SIC. The study findings, however, have limited generalizability due to the smaller sample size, brief data collection period, and type of setting where the study was conducted.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12910-024-01159-0.

Supplementary Material 1

Author contributions

Authors have contributed equally to the development of this manuscript. Maryam: literature review, SPSS and tables, discussion; Summaya: methodology, and data analysis plan, discussion, conclusion and general supervision and direction; Zahraa: data analysis, interpretation, write-up and figures, discussion and general supervision and direction. All authors reviewed the manuscript.

Funding

This research received no external funding.

Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the institutional review board at the Imam Abdulrahman bin Faisal University (Number IRB- PGS-2020-03-432)>.

Informed consent

Informed consent was obtained from all subjects involved in the study.

Institutional review board statement
This study was approved by Imam Abdulrahman bin Faisal University Institutional Review Board.

Competing interests
The authors declare no competing interests.

Received: 4 March 2024 / Accepted: 25 December 2024
Published online: 12 March 2025

References

1. Lantos JD. The Lazarus Case: life-and-death issues in neonatal intensive care. Johns Hopkins University; 2001.
2. Roscam Abbing HDC. Twenty Year who principles of patients' rights in Europe, a common Framework: looking back to the future. Eur J Health law. 2014;21(4):323–37. https://doi.org/10.1163/15718093-12341331.
3. Sperling D, Pikkel RB. Promoting patients' rights through hospital accreditation. Isr J Health Policy Res. 2020;9(1):47–47. https://doi.org/10.1186/s13584-020-00405-1.
4. Leclercq WK, Keulers B, Scheltinga MRM, Spauwen PHM, Wilt GJ. v. d. (2010). A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. *World journal of surgery*, *34*(7), 1406–1415. https://doi.org/10.1007/s00268-010-0542-0
5. Hallock JLMD, Rios RPD, Handa VLMDMHS. Patient satisfaction and informed consent for surgery. Am J Obstet Gynecol. 2017;217(2):181.e181-181.e187.
6. Jahan F, Roshan R, Nanji K, Sajwani U, Warsani S, Jaffer S. Factors affecting the process of obtaining informed consent to surgery among patients and relatives in a developing country: results from Pakistan. East Mediterr Health J. 2014;20(9):569–77. https://doi.org/10.26719/2014.20.9.569.
7. Teshome M, Wolde Z, Gedefaw A, Asefa A. Improving surgical informed consent in obstetric and gynaecologic surgeries in a teaching hospital in Ethiopia: a before and after study. BMJ open. 2019;9(1):e023408–023408. https://doi.org/10.1136/bmjopen-2018-023408.
8. Pathak S, Odumosu M, Peja S, McIntyre K, Selo-Ojeme D. Consent for gynaecological procedure: what do women understand and remember? Arch Gynecol Obstet. 2013;287(1):59–63. https://doi.org/10.1007/s00404-012-2518-9.
9. Firdouse M, Wajchendler A, Koyle M, Fecteau A. Checklist to improve informed consent process in pediatric surgery: a pilot study. J Pediatr Surg. 2017;52(5):859–63. https://doi.org/10.1016/j.jpedsurg.2017.01.023.
10. Dogan HH, Işik E, Vural E, Vehid H, Brezis M. Quality and extent of informed consent for invasive procedures: a pilot study at the institutional level in Turkey. Int J Qual Health Care. 2015;27(1):46–51. https://doi.org/10.1093/intqhc/mzu093.
11. Hall DE, Prochazka AV, Fink AS. Informed consent for clinical treatment. Can Med Association J (CMAJ). 2012;184(5):533–40. https://doi.org/10.1503/cmaj.112120.
12. Schenker Y, Meisel A. Informed consent in Clinical Care: practical considerations in the effort to achieve ethical goals. JAMA: J Am Med Association. 2011;305(11):1130–1. https://doi.org/10.1001/jama.2011.333.
13. Leclercq WKG, Keulers BJ, Houterman S, Veerman M, Legemaate J, Scheltinga MR. A survey of the current practice of the informed consent process in general surgery in the Netherlands. Patient Saf Surg. 2013;7(1):4–4. https://doi.org/10.1186/1754-9493-7-4.
14. Ethics ACo. ACOG Committee Opinion 439: informed consent. Obstet Gynecol (New York 1953). 2009;114(2 Pt 1):401–8. https://doi.org/10.1097/AOG.0b013e3181b48f7f.
15. Ogburn T. Shared decision making and informed consent for Hysterectomy. Clin Obstet Gynecol. 2014;57(1):3–13. https://doi.org/10.1097/GRF.0000000000000003.
16. Alhosawi A, Altareqi I. (2019). الدليل السعودي لإذن الطبي. Saudi Arabia: Ministry of health Retrieved from https://www.moh.gov.sa/Ministry/MediaCenter/Ads/Pages/Ads-2019-12-09-001.aspx
17. Gabay G, Bokek-Cohen Y. What do patients want? Surgical informed-consent and patient-centered care – an augmented model of information disclosure. Bioethics. 2020;34(5):467–77. https://doi.org/10.1111/bioe.12703.
18. Jukic M, Kozina S, Kardum G, Hogg R, Kvolik S. Physicians overestimate patient's knowledge of the process of informed consent: a cross-sectional study. Medicinski Glasnik. 2011;8(1):39–45.
19. Kirane AG, Gaikwad NB, Bhingare PE, Mule VD. Informed consent: an audit of Informed Consent of Cesarean Section Evaluating Patient Education and Awareness. J Obstet Gynecol India. 2015;65(6):382–5. https://doi.org/10.1007/s13224-014-0651-z.
20. Weckbach S, Kocak T, Reichel H, Lattig F. A survey on patients' knowledge and expectations during informed consent for spinal surgery: can we improve the shared decision-making process? Patient Saf Surg. 2016;10(1):15–15. https://doi.org/10.1186/s13037-016-0103-z.
21. Yildirim G, Cetin A, Aksu M, Altiparmak S, Guler N. The effects of the informed consent given for cesarean section on anxiety and knowledge. Clin Exp Obstet Gynecol. 2014;41(1):62.
22. Agozzino E, Borrelli S, Cancellieri M, Carfora FM, Di Lorenzo T, Attena F. Does written informed consent adequately inform surgical patients? A cross-sectional study. BMC Med Ethics. 2019;20(1):1–1. https://doi.org/10.1186/s12910-018-0340-z.
23. Ochieng J, Buwembo W, Munabi I, Ibingira C, Kiryowa H, Nzarubara G, Mwaka E. Informed consent in clinical practice: patients' experiences and perspectives following surgery. BMC Res Notes. 2015;8(1):765–765. https://doi.org/10.1186/s13104-015-1754-z.
24. Sulaiman A, Ayyuba R, Diggol I, Haruna I. Knowledge, attitude and perception of patients towards informed consent in obstetric surgical procedures at Aminu Kano Teaching Hospital. Nigerian J Basic Clin Sci. 2015;12(1):45–50. https://doi.org/10.4103/0331-8540.156688.
25. Zethof S, Bakker W, Nansongole F, Kilowe K, van Roosmalen J, van den Akker T. Pre-post implementation survey of a multicomponent intervention to improve informed consent for caesarean section in Southern Malawi. BMJ open. 2020;10(1):e030665–030665. https://doi.org/10.1136/bmjopen-2019-030665.
26. Propst K, O'Sullivan DM, Ulrich A, Tunitsky-Bitton E. Informed Consent Education in Obstetrics and Gynecology: a Survey Study. J Surg Educ. 2019;76(4):1146–52. https://doi.org/10.1016/j.jsurg.2018.12.005.
27. Sutherland J, Harris I. Surgery-risks, benefits, and the value of shared decision-making. Anaesth Intensive Care. 2016;44(3):338.
28. Shemesh S, Sidon E, Heller S, Cohen N, Kosashvili Y, Dovrat R, Burg A. The quality of informed consent obtained for orthopedic surgeries—elective versus trauma: a prospective interview-based study. J Orthop Surg. 2019;27(2):2309499019847021–2309499019847021. https://doi.org/10.1177/2309499019847021.
29. Khan SK, Karuppaiah K, Bajwa AS. The influence of process and patient factors on the recall of consent information in mentally competent patients undergoing surgery for neck of femur fractures. Injury Extra. 2012;43(10):104–104. https://doi.org/10.1016/j.injury.2012.07.293.
30. Lemmu B, Megersa A, Abebe E, Abebe K. Knowledge and perception of Ethiopian Surgical patients to Informed Consent Practice for Surgical procedures. Open Access Surg (Auckland). 2020;13:65–70. https://doi.org/10.2147/OAS.S268009.
31. Abolfotouh MA, Adlan AA. Quality of informed consent for invasive procedures in central Saudi Arabia. Int J Gen Med. 2012;5:269–75. https://doi.org/10.2147/IJGM.S29599.
32. Hammami MM, Al-Jawarneh Y, Hammami MB, Qadire A, M. Information disclosure in clinical informed consent: reasonable patient's perception of norm in high-context communication culture. BMC Med Ethics. 2014;15(1):3–3. https://doi.org/10.1186/1472-6939-15-3.
33. D'Souza A, Pasquini M, Spellecy R. Is 'informed consent' an 'understood consent' in hematopoietic cell transplantation? Bone Marrow Transplantation (Basingstoke). 2014;50(1):10–4. https://doi.org/10.1038/bmt.2014.207.
34. Perić O, Mišić M, Tirić D, Penava N, Bušić D, Tomić V. Patients' experience regarding informed consent in elective and emergency surgeries. Medicinski Glasnik. 2018;15(2):179–85. https://doi.org/10.17392/957-18.
35. Al Abdullah HA, Al-Sultan AS, Alabdulsalam AM, Alkahtani AS, Alhawaj AM, Hafizallah AB, Almutairi FF. Knowledge, opinions and attitude of surgeons in Saudi Arabia toward Informed Surgical Consent. Egypt J Hosp Med. 2017;69(4):2232–7. https://doi.org/10.12816/0041522.
36. AlHaqwi AI, AlDrees TM, AlRumayyan A, AlFarhan AI, Alotaibi SS, AlKhashan HI, Badri M. Shared clinical decision making. A Saudi Arabian perspective. Saudi Med J. 2015;36(12):1472–6. https://doi.org/10.15537/smj.2015.12.13682.
37. Aljaffary A, Alhuseini M, Rayes SA, Alrawiai S, Hariri B, Alumran A. The OPTION scale: measuring patients' perceptions of Shared decision-making in the Kingdom of Saudi Arabia.(ORIGINAL RESEARCH). J Multidisciplinary Healthc. 2020;13:1337–46. https://doi.org/10.2147/JMDH.S273340.

38. Declercq ER, Cheng ER, Sakala C. Does maternity care decision-making conform to shared decision- making standards for repeat cesarean and labor induction after suspected macrosomia? Birth (Berkeley Calif). 2018;45(3):236–44. https://doi.org/10.1111/birt.12365.
39. Lovell J. (2018). Mum and baby saved from rare condition in emergency operation: Woman developed life-threatening complication during pregnancy. *Hull Daily Mail* Retrieved from https://library.iau.edu.sa/newspapers/mum-baby-saved-rare-condition-emergency-operation/docview/2040061517/se-2
40. Taherdoost H. Sampling Methods in Research Methodology; how to choose a sampling technique for Research. Int J Acad Res Manage. 2016;5(2):18–27.
41. Akkad A, Jackson C, Kenyon S, Dixon-Woods M, Taub N, Habiba M. Informed consent for elective and emergency surgery: questionnaire study. BJOG: Int J Obstet Gynecol. 2004;111(10):1133–8. https://doi.org/10.1111/j.1471-0528.2004.00240.x.
42. Kriston L, Scholl I, Hölzel L, Simon D, Loh A, Härter M. Development and psychometric properties in a primary care sample. Patient Educ Couns. 2010;80(1):94–9. https://doi.org/10.1016/j.pec.2009.09.034. The 9-item Shared Decision Making Questionnaire (SDM-Q-9).
43. Polit DF, Beck CT, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. Res Nurs Health. 2007;30(4):459–67. https://doi.org/10.1002/nur.20199.
44. Burke MJ, Dunlap WP. Estimating interrater agreement with the average deviation index: a user's guide. Organizational Res Methods. 2002;5(2):159–72. https://doi.org/10.1177/1094428102005002002.
45. Lynn MR. Determination and quantification of content validity. Nurs Res (New York). 1986;35(6):382–6. https://doi.org/10.1097/00006199-198611000-00017.
46. Ursachi G, Horodnic IA, Zait A. How Reliable are Measurement Scales? External factors with indirect influence on reliability estimators. Procedia Econ Finance. 2015;20:679–86. https://doi.org/10.1016/S2212-5671(15)00123-9.
47. Page AE. Safety in surgery: the role of shared decision-making. Patient Saf Surg. 2015;9(1):24–24. https://doi.org/10.1186/s13037-015-0068-3.
48. Akgün M, Boz İ. Women's decision-making processes and experiences of vaginal birth after caesarean birth: a phenomenological study. Int J Nurs Pract. 2019;25(6):e12780. https://doi.org/10.1111/ijn.12780.
49. Driever EM, Stiggelbout AM, Brand PLP. Shared decision making: Physicians' preferred role, usual role and their perception of its key components. Patient Educ Couns. 2020;103(1):77–82. https://doi.org/10.1016/j.pec.2019.08.004.
50. Lamb CC, Wang Y, Lyytinen K. Shared decision making: does a physician's decision-making style affect patient participation in treatment choices for primary immunodeficiency? J Eval Clin Pract. 2019;25(6):1102–10. https://doi.org/10.1111/jep.13162.
51. Niranjan SJ, Wallace A, Williams BR, Turkman Y, Williams CP, Bhatia S, Rocque GB. Trust but Verify: exploring the role of treatment-related information and patient-Physician Trust in Shared decision making among patients with metastatic breast Cancer. J Cancer Educ. 2020;35(5):885–8. https://doi.org/10.1007/s13187-019-01538-x.

Publisher's note