Measurement of Patients' Satisfaction Regarding Informed Consent in Surgical Intervention.

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ABSTRACT

Background: Surgical Informed consent is the process by which valuable written data about a surgical procedure is given to the patient or his family. It is a worldwide practice in both developed and developing countries. The present work aimed to detect the satisfaction of patients regarding informed consent in surgical intervention. **Methods:** A cross-sectional study was done through a questionnaire to know the patient's perception of informed consent. The operated patients were interviewed after their operation and were asked certain questions by the interviewer to calculate their perception of consent. **Results:** The study showed that the average age was 44.87 years and the majority was married (68%), 50.7% had elective surgery while the rest had emergency surgery, the surgical team was known and popular with 46.4% of patients, 40.7% of the operated patients declared a good perception of consent, and they elucidated that education, verbal communication, elective surgery type, the timing of consent concerning the date of operation, and the physician-patient relationship all affect the patient's good perception of consent. Patients also expressed their desire to be informed about the surgery and anesthesia's potential complications, activity levels, and date of return to work. **Conclusion:** The study emphasizes the need for better communication and training for physicians regarding informed consent. Overall, the findings underscore the importance of informed consent and highlight areas that require improvement to ensure patients' perceptions of informed consent are positive.

Keywords: Consent; Informed; Perception; Relationship.

I: INTRODUCTION

The way by which a medical professional informs a patient of the risks, benefits, and alternatives of a particular procedure or operation is known as informed consent. The patient must have the mental capacity to voluntarily consent to the procedure or intervention (Slim& Bazin, 2019; Shah et al. 2022).

Leclercq et al. (2010) said that one of the most important rules of medical ethics is to get the patient's permission before doing anything to him or her and to include the patient in the decision-making process regarding his treatment modality.

It is the responsibility of the provider to make the patient's participation in the decision-making process explicit and to prevent the patient from feeling coerced into agreeing with the provider (Edwards, 2019).

The acute and vulnerable state of patients, the rapidity of the actions that must occur, the high technological advances, and the variety of crucial elements of the procedure that can cause major harm to the patient all contribute to the high degree of criticality

that characterises surgical IC. Therefore, it becomes more challenging for the patient to learn about and weigh all of these factors, as well as any potential alternatives to the surgery (Ochieng et al. 2015).

Perception of consent means how the patient sees the legality, scope, and importance of consent before surgery. This can be good if the patient is aware of consent, or it can be bad, which makes it hard for the patient and the surgical team to make decisions and affects satisfaction with consent (Gebrehiwot et al. 2022).

To document that a patient has provided informed consent for a procedure, hospitals generally utilise paper-based consent forms on which the procedure, its potential advantages and risks, and the patient's and clinician's signatures appear. Several healthcare organisations scan consent forms and preserve them in an electronic document repository (John et al. 2021).

This study aimed to detect the satisfaction of patients regarding informed consent in surgical intervention.

II: SUBJECTS AND METHODS

The study design:

A cross-sectional descriptive study was carried out at Fayoum University Hospital. The survey was conducted over a period of six months, between June 2022 and December 2022.

Ethical approval and consent to participate:

All procedures performed in the study were according to ethical standards of the Faculty of Medicine Fayoum University. The ethical committee approved the research protocol, under the code R388/ 101/12/2022. Informed consent to research participation was obtained from all participants included in the study.

The study population;

The study looked at 300 people who had surgery at Fayoum University Hospital, either elective or emergency surgery. Patients over 18 years old who had surgery and gave written permission to be in the study were included. The study excluded younger patients and children. All patients were interviewed using a structured questionnaire between the second and fifth day after surgery. One 3rd-year undergraduate medical school student who did not know the patients interrogated the subjects after explaining the purpose and method of the study to the main investigator. The gathered information and responses were kept strictly confidential.

The study tool;

The goal of this study was to find out what patients in all of Fayoum University Hospitals' surgical departments thought about informed consent. So, we can figure out if they agree with informed consent, what factors affect how they see the consent if the format used needs to be changed, or how healthcare workers act when people sign consent forms. We can also find out what they want or what should be on the consent form.

To reach its goals, this study used a carefully made and tightly designed questionnaire that participants filled out on their own. The questionnaire was created after a thorough search of the literature. The questionnaire is divided into four sections:

The first part was made to find out how patients felt about consent. It was based on a Likert scale, which gave a result between 0 and 40 (Mbonera & Chironda, 2018). The result was either good (20 points or more) or bad (less than 20 points), depending on the subscales that were made to measure the legality of the consent (5 questions), the applicability of the consent (5 questions), and the relevance of the consent (10 questions). The second part collects information on specific demographic characteristics, types of surgery, and the physician-patient relationship. The third section was constructed to collect information regarding consent from the

patient's point of view. The fourth part was used to know the general information on the consent form, while the fifth part was used to classify the patient-physician relationship as either good (six points or more on a scale of 10) or bad (less than six points on that scale) according to certain questions given to each patient and the answer being yes or no. The questions were, Do you trust your physician?" and "Do you owe an attitude to your physician?" Do you think your physician does you a favor?" Do you think your physician listens to your concerns and respects your feelings?" Do you respect your physician's opinion?

Also, a pilot sample of 10% of the people who were supposed to fill out the questionnaire was used to clear up any confusion and make sure it was easy to understand. The pilot testing allowed for certain changes to specific questions, either by restructuring or omitting certain questions, in order to achieve optimal internal consistency and reliability (Cronbach's $\alpha = 0.80$ for the perception of the consent). The pilot sample was not included in the final sample for the study.

Statistical analysis:

The collected data were organised, tabulated, and statistically analysed using SPSS software, version 28 (SPSS Inc., USA). Categorical data were presented as numbers and percentages. Bivariate and multivariable logistic regressions were done to identify the statistically significant association between the covariate and outcome variables. In the multivariable analysis, the odds ratio with 95% CI was used to determine the strength of association. For the interpretation of results, significance was assumed at $P \leq 0.05$.

III: RESULTS

Regarding the sociodemographic characteristics of the studied patients, table (1) revealed that the average age was 44.87 years and the majority was married (68%). They were composed of 63.3% males and 36.7% females. 45% of them were college graduates, 19% were illiterate, and the remaining 36% were adult patients who finished their education at the primary or secondary school level. 47% of the population lives in urban areas, while the remaining 53% live in rural areas.

Table (1) Sociodemographic characteristics of surgical patients in Fayoum University Hospitals.

Variables		N	%
Gender	Males	190	63.3
	Females	110	37.7
Education	High	135	45
	Secondary	65	21.6
	Primary	53	14.4
	illiterate	47	19
Marital status	Married	204	68
	Single	46	15.4
	Divorced	32	10.6
	widow	18	6
Residence	Rural	159	53
	urban	141	47

N: number of patients (300 patients).

Table (2) demonstrated that 50.7% had elective surgery while the rest had emergency surgery. Most patients (41.6%) were admitted for a general surgical procedure, 26% had orthopedic surgery, and the remaining had ENT, ophthalmic, or gynecologic operative interference. The surgical team was known and popular with 46.4% of patients. 44.8% said that they read the content of the consent, and the rest didn't do. 45.6% said that they were subjected to verbal information regarding the operation, and the rest said they were not. 45.6% said that the person who made them sign the consent form was one of the surgery team, and the rest said that he was not from the surgery team. 49.3% had signed the consent form just before the operation or in the operation theatre, while the remaining signed

it the day before or two days before. 43.7% declared a good relationship with the surgeon; the remaining had a bad relationship.

Table (2) Relationship with physician and factors related to informed consent in Fayoum University Hospitals.

Variables		N	%
Relationship with Physician	Bad	169	56.3
	Good	131	43.7
Responsible for consent	Surgical team	137	45.6
	Other person	163	55.4
Time of consent	Hours before surgery	148	49.3
	One day	64	21.4
	≥ two days	88	29.3
Verbal information	Given	137	45.6
	Not given	163	54.4
Content of consent	Comprehensible	134	44.8
	Incomprehensible	166	55.2
Surgeon name	Known	139	46.4
	Unknown	161	53.6
Surgery type	Emergency	148	49.3
	Elective	152	50.7
Specialty	General	125	41.6
	Orthopedic	78	26
	ENT	33	11
	Gynecology	27	9
	Ophthalmology	37	12.4

N: number of patients (300 patients).

In bivariate analysis, Table (3) revealed that variables such as high education, male gender, married or single marital status, good patient-physician relationship, responsibility for letting the patient sign the consent, urban residence, verbal information to the patient regarding operation and consent content, elective type of surgery, and signing the consent at least two days prior to the operation are all predictors of good perception of informed consent. In addition, applying multivariable binary logistic regression to the aforementioned variables revealed a worthy association with a good perception of consent at a p-value less than 0.05. Also the table demonstrated that 40.7% had a good perception regarding consent, and the remaining had a bad perception regarding informed consent.

Regarding the information that should be included in the consent form from the patient's perspective, Table (4) revealed that more than 80% of the study participants agreed that the consent form should include the reason for the operation, the time required to be discharged from the hospital, the complications of the operation, and anaesthesia, whereas less than 20% of the study participants disagreed. The inclusion of the return-to-work date on the consent form was supported by all participants in the study, who were unanimously in favour. About 60% of the participants in the study disagreed with the inclusion of detailed

information about the operation and the surgeon's name on the consent form, while 30% agreed and 10% were unsure. Half of the study participants agreed with the inclusion of special precautions and information about diet and alternative procedures on the consent form, while the other half disagreed.

Table (3) Factors associated with good perception of informed consent for surgical procedures of surgical patients in Fayoum University Hospitals.

Variables		Perception				COR (95%CI)	AOR (95%CI)
		Good		**Poor**			
		N	**(%)**	**N**	**(%)**		
Gender	Males	91	30.3	99	33	2.34(1.42-3.88)	3.6(0.47-28.6)
	Females	31	10.4	79	26.3	1	1
Education	High	88	29.4	47	15.6	11.64(5.026.22)	39.4(2.83-549.7)*
	Secondary	17	5.6	48	16	2.1(.85-5.4)	2.6(0.21-32.6)
	Primary	9	3	34	11.4	1.62(.56-4.6)	7.8(0.37-161.7)
	illiterate	8	2.3	49	16.3	1	1
Marital status	Married	106	35.4	98	32.6	3.32(1.56-7.064)	6.07 (1.569-23.541)
	Single	20	6.7	26	8.7	1	1
	Divorced	3	1	29	9.6	0.37(0.094-1.48)	0.861(0.104-7.143)
	widow	11	3.7	7	2.3	5.65(1.74-18.38)	14.70(2.08-103.69)*
Residence	Rural	35	11.6	124	41.4	1	1
	urban	87	29	54	18	5.143(3.11-8.49)	3.855(1.72-8.597)*
Relationship with Physician	Bad	25	8.3	144	48	1	1
	Good	97	32.4	34	11.3	0.6(.034-.108)	0.02(0.0-0.172)*
Responsible for consent	Other person	25	8.3	138	46	1	1
	Surgical team	97	32.3	40	13.4	13.38(7.6-23.5)	21.93(6.92-69.476)*
Time of consent	Hours	18	6	130	43.3	1	1
	One day	28	9.3	36	12	0.123(.056-.269)	0.707(.069-5.2)
	≥ two days	76	25.4	12	4	0.022(.01-.048)	0.006(.00-.048)*
Verbal information	Given	100	33.3	37	12.3	0.058(.032-.104)	0.0(0.00-0.023)*
	Not given	22	7.4	141	47	1	1
Content of consent	Comprehensible	84	28	50	16.8	5.65 (3.42-9.364)	13.28(3.48-50.676)*
	Incomprehensible	38	12.6	128	42.6	1	1
Surgeon name	Known	91	30.4	48	16	7.95(4.70-13.441)	4.56 (1.59-13.054)*
	Unknown	31	10.3	130	43.3	1	1
Surgery type	Emergency	31	10.3	117	39	1	1
	Elective	91	30.3	61	20.4	6.15(3.66-10.338)	18.93(0.86-413.403)*
Specialty	General	44	14.6	81	27	0.37(.17-.78)	0.248(.02-2.40)
	Orthopedic	25	8.4	53	17.6	0.32(.14-.72)	0.11(.009-1.41)
	ENT	19	6.4	14	4.6	0.925(.35-2.39)	0.409(.013-12.5)
	Gynecology	12	4	15	5	0.54(.2-1.48)	0.326(.008-13.0)
	Ophthalmology	22	7.4	15	5	1	1

*Statistically significant, COR: crude odds ratio, AOR: adjusted odds ratio, and 1: reference category. N: number of patients (300 patients). %: Percent. Bivariate and multivariable logistic regressions were used.

Table (4) Information that should be included on Fayoum University Hospitals' surgical patients' informed consent forms, based on patient opinion.

Information	Frequency of agreement	Percent of agreement
Reason for operation	250	83.3%
Time of discharge out	241	80.3%
Complications of the operation	245	81.6%
Complications of anesthesia	240	80%
Time needed to return work	300	100%
Operation procedure	85	28.3%
Duration of operation	94	31.3%
Name of surgeon	86	28.6%
Precaution after the operation	152	50.6%
Diet after the operation	154	51.3%
Operation alternatives	155	51.6%

IV: DISCUSSION

The patient has the right to be supplied with information, whether or not they decide to get a medical or surgical intervention in the end. Thus, the patient has the right to know everything about his health problem, even if a diagnostic-therapeutic decision doesn't have to be made right away. So, informed consent gives the right to do procedures on a patient when they know all the facts about the treatment and are not being forced to do so (Varkey, 2021).

The current study revealed that 50.7% of patients had elective surgery while 49.3% had emergency surgery. Consent was obtained just a few hours before surgery in 49.3% of the patients, while the remaining patients consented before the surgery date. The result is completely accepted as the emergency presentation of patients necessitates swift decisions in order to save their lives, and assent is signed just prior to surgery. This contradicted the findings of McKeague & Windsor's (2003) study, which found that 70% of patients underwent elective surgery and consented prior to the operation date in 43% of cases. In addition, Akkad et al. 2006 reported that 68% of patients underwent elective surgery, with 42% of patients consenting to the procedure the day before the procedure. Moreover, Basukala et al. (2023) found that 84.3% of patients underwent elective surgery, and consent was received in 49.1% of cases several hours before operation. The difference between these results and those of these studies may be attributable to the number of study groups, the type of medical care provided, and the location of the facility, which determines the types of cases presented.

Consistent with the findings of Agozzino et al.'s 2019 study, we found that a lack of knowledge about the content of consent was associated with a negative perception of IC in 55.2% of cases, despite the fact that the vast majority of participants could read and write. One probable explanation for this result is that the permission process took place too close to the time of operation, meaning that neither the patient nor their legal guardian had time to read it carefully.

Second, when asked how they felt comfortable reading and understanding the IC, 54.3% of cases said they hadn't received any verbal instruction concerning the procedure or the content of the IC. Third, the language used in a written consent form may be too advanced for them. Fourth, some patients sign the consent without reading it or understanding what it says because they are so afraid that the surgeon won't do the necessary operation for them or won't do it right if they don't. In contrast to the current findings, Basukala et al. (2023) revealed that the permission form was understood by 95.4% of patients. This disparity might be attributable to the kind of hospital and the patients' degree of education.

The current study demonstrated a lack of communication and insufficient information between patients and their treating surgeons. Similar results were reported by Joshi et al. in 2021. On the other hand, Metwally et al. 2021, observed that enough information was recognized in the majority of patients in Mansoura University Hospital- Egypt (63.8%), but no consent was obtained, either written or oral, in 11.4% of patients.

Ghulam improved written IC through structured conversations can help doctors build relationships with their patients, make documentation easier, and provide both patients and doctors with reliable legal evidence of the accuracy of the information provided (Ghulam et al. 2006).

Finding the correct balance in informed consent is critical to maintain the ideals of nonmaleficence and autonomy. It is vital for healthcare practitioners to provide adequate data that permits patients to settle on informed choices without overloading them with needless details or creating unjustified anxiety. Maintaining such a delicate balance guarantees that patients may express their liberty while simultaneously safeguarding them from expected harm (Agozzino et al. 2019).

The surgeon was responsible for obtaining the patient's consent in 45.6% of cases, which is approximately the same as what Arshad et al. (2022) discovered, namely that the consultant was responsible for obtaining the patient's consent in 40% of cases. On the contrary, Basukala et al. (2023) found that consent was obtained by the operative surgeon in 12.6% of patients.

Regarding the patient's perception of consent, the current study revealed that education, verbal communication, elective surgery, good relationship with the surgeon, and the time of consent in relation to the date of operation affect the good perception of informed consent; similar results were found in the studies conducted by (Amir et al. 2009 and Gebrehiwot et al. 2022).

In accordance with Gebrehiwot et al.'s (2022) findings, this study demonstrated that the patient-physician relationship and marital status interact with and influence the perception of informed consent. The plausibility of our findings improves with the level of patient education and surgeon-provided information on the surgical procedure the patient would endure prior to the surgery, as in cases of elective surgery. This induces a sense of comfort and reassurance in the patient towards the surgeon, resulting in a favourable impression of signing the assent. This connection shows that well-informed patients are more likely to appropriately describe their surgical

encounters and outcomes. Furthermore, it emphasizes the value of excellent communication between surgeons and patients in order to guarantee a thorough awareness of the surgery and its potential consequences.

Interaction between physicians and their patients can be influenced by numerous variables. Importantly, compliance with therapy is increased when patients feel flexible and involved in decision-making and when their personal circumstances are sufficiently considered (Otero et al. 2022).

There are three widely accepted principles for judging the sufficiency of information release. The first is the 'professional standard', which is decided by nearly all of the profession's practice. The second level is the 'reasonable person' standard, which is based on what an acceptable or sensible person would need. The third type of standard is the 'subjective standard,' which is decided by what each individual patient desires. The information must be presented to the patient in such depth and in a way that is understandable, using suitable language, that the patient may make an educated decision (McKeague & Windsor, 2003). Based on the former fact, the current study recognized a good perception of IC when the responsible person for taking the consent was one of the surgical team. This ensures providing the necessary data in the appropriate way for the patient to understand.

On the other hand, the current study revealed that patients with low levels of education and illiteracy had a negative perception of informed consent. This conclusion is extremely logical, as their inability to read prevents them from comprehending what is written in the consent and from understanding the necessary medical procedures and methods of treatment; consequently, they cannot make an informed decision regarding the participation of the treating physician. This conclusion is supported by Mares et al. 2022, who reported that patients with limited health literacy are less likely to participate in healthcare decision-making. Literacy was discovered to be an essential factor in determining a patient's ability to give fully informed consent. In line with the current findings, Elsehrawy et al. 2021 found that 31.2% of patients had an unfavorable view of IC; however, this figure was reduced to 22% by increasing health literacy.

Less than half (table 3) 40.7%, of the patients in the current study had a positive perception of informed consent, similar to those found in the study conducted in Ethiopia (Gebrehiwot et al. 2022), but in contrast to studies conducted in Saudi Arabia (Abolfotouh & Adlan, 2012) and Rwanda (Mbonera &Chironda, 2018), in which 76% of patients had a positive perception of informed consent. Their disagreements may stem from distinct study groups, insurance, financial aid, and may be the consent was written in a way that is difficult to understand. Similarly, Basukala et al. (2023) found that Almost three-quarters of the patients were unconcerned about IC. The proportion of satisfied persons was somewhat greater than the number of unhappy individuals.

Regarding the information required to be included in the consent form as perceived by the patient, the present study revealed that

the patient placed the most importance on the time required to return to work and daily activities, followed by the cause for the operation and anticipated complications. This was similar to McKeague & Windsor's (2003) study, which found that the patient's awareness of complications and the time required for recovery and revision are the two most important factors. In contrast, Alazmi (2018) reported that the most pressing need of the patients was the reason for the operation. This controversy may be a result of the need to satisfy the fundamental needs of the study population and the lack of insurance support.

V: CONCLUSION

Informed consent must be provided written form to ensure that patients have the necessary information to make an informed decision and consent to treatment. Education, verbal communication, elective surgery, and the time of consent in relation to the date of operation affect the good perception of informed consent. Patients' satisfaction with IC was hampered by a lack of communication between them and their treating surgeons.

VI: RECOMMENDATIONS

Oral communication is not always conveyed clearly for patients, so we must provide physicians with training on how to effectively interact with patients. Respecting the education and culture of the patients, the current form of informed consent should be reformulated so that it is readily understood.

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IX: CONFILICT OF INTEREST

NONE.

قياس رضا المرضى فيما يتعلق بالموافقة المستنيرة في التدخل الجراحي.

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المقدمة: الموافقة المستنيرة الجراحية هي العملية التي يتم من خلالها إعطاء بيانات مكتوبة قيمة حول إجراء جراحي للمريض أو عائلته. إنها ممارسة عالمية في كل من البلدان المتقدمة والنامية.

الهدف من البحث: تهدف هذه الدراسة إلى الكشف عن مدى رضا المرضى فيما يتعلق بالموافقة المستنيرة.

الطرق: أجريت دراسة وصفية مقطعية في مستشفى جامعة الفيوم. وتم إجراء الاستطلاع على مدى ستة أشهر، بين يونيو 2022 وديسمبر 2022. أجريت الدراسة على 300 شخص خضعوا لعملية جراحية في مستشفى جامعة الفيوم، سواء كانت جراحة اختيارية أو طارئة. تم تضمين المرضى الذين تزيد أعمارهم عن 18 عامًا والذين خضعوا لعملية جراحية وأعطوا إذنًا كتابيًا بالمشاركة في الدراسة. استبعدت الدراسة المرضى الأصغر سنا والأطفال. وتمت مقابلة جميع المرضى باستخدام استبيان منظم بين اليوم الثاني والخامس بعد الجراحة.

النتائج: أظهرت الدراسة أن 40.6٪ من المرضى الذين خضعوا للجراحة أفادوا بإدراك جيد للموافقة ، وأوضحوا أن التثقيف والتواصل اللفظي ونوع الجراحة الاختيارية وتوقيت الموافقة بالنسبة لموعد العملية والعلاقة بين الطبيب والمريض. كلها تؤثر على تصور المريض الجيد للموافقة. من وجهة نظر المريض ، يجب أن تُعلم الموافقة المريض بشكل أساسي بتاريخ العودة إلى العمل والنشاط والمضاعفات المتعلقة بالجراحة والتخدير.

الخلاصة: كان هناك نقص في المعلومات التي تصل المرضى قبل التوقيع على الموافقة. يحتاج الأطباء إلى تدريب حول أهمية التواصل اللفظي مع المرضى والموافقة المستنيرة.

التوصيات: لا يتم دائمًا نقل التواصل الشفهي بوضوح للمرضى، لذلك يجب علينا تزويد الأطباء بالتدريب على كيفية التفاعل الفعال مع المرضى. مع احترام تعليم وثقافة المرضى، يجب إعادة صياغة الشكل الحالي للموافقة المستنيرة بحيث يتم فهمه بسهولة.