



Quality of informed consent at King Abdullah Medical Complex in Jeddah, Saudi Arabia: A cross-sectional study

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Abstract: -

Background: Care provided to patients can be enhanced by their awareness and understanding of informed consent process. This study aims to evaluate and measure the quality of informed consent at King Abdullah Medical Complex, Jeddah, Saudi Arabia (KAMCJ).

Methods: A cross-sectional study using a valid and reliable survey to assess informed consent. Hospital-admitted patients (n=399) were randomly selected during 1-31/03/2022 in (KAMCJ).

Results: There were 54.1% (n=216) females and 45.9% (n=183) males with a mean age 41.67 (± 16.8). Illiterates formed 1.3% (n=5), high schoolers 29.8% (n=119), and university-degree patients 49.9% (n=199). Significant associations were found between understanding the consent and educational level. University-degree patients reported higher percentages regarding consent clarity, needing help understanding it, and how easy to understand it was ($p < 0.05$).

Conclusion: Both patients and physicians should be provided with skills and tools to enhance the informed consent process. Improvement of readability, easiness, and understanding of informed consent forms can enhance patients' experience.

Keywords: informed consent; education; professional-patient relationship; health care delivery; public health.

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1. Introduction:

Informed consent, as a term, was introduced in 1957 in California Appeals Court. It stated that the patient must be told sufficient information to equilibrate the risks and the benefits before consenting to a surgical or a medical procedure (1). Thus, providing treatment to a patient without consent is considered a battery, whilst treating a patient with incomplete informed consent constitutes negligence (2). This practice has changed the emphasis from the classic medical paternalism into a duty to respect and honor patient autonomy (3).

Informed consent for patients undergoing a medical procedure is not only crucial for ethical or legal reasons (4). It is also essential to improve the quality of care delivered to the patients. Patients' comprehension allows for better cooperation, results, and satisfaction while also helps in preventing medical errors (5). Though in reality, complex decisions, such as invasive treatment or surgery, require a talk about the uncertainties of the procedure. Although informed consent is a well-known and well-established practice, it sometimes fails to meet its defined purpose (6).

Since most patients lack the necessary medical knowledge to help them make autonomous decisions and opinions about their care, they trust their treating physicians to provide accurate information to choose between several treatment options and then decide in their best interest (7). Unfortunately, many patients do not fully comprehend or simply forget the information they were told (8). Too frequently, they are not aware of their treatment option and/or do not fully understand the benefits and risks associated with each option (9). Researchers have extensively explored the deficiencies of informed consent practice and noted that patients' education; low health literacy; impairment in vision, hearing, and cognitive function; stress and anxiety; the complexity of the subject contribute to a lack of informed decision when consenting to a medical procedure (10-16).

2. Materials and Methods:

2.1 Study Design and Population:

The present study has adopted the cross-sectional design and was done using 399 patients undergoing different surgeries from most of the King Abdullah Medical Complex departments at Jeddah (KAMCJ), Saudi Arabia. These departments include Oral and Maxillofacial Surgery, Obstetrics and Gynecology Surgery, Endoscopic Surgery, Neurosurgery, Cardiac Surgery, Ophthalmic Surgery, Orthopedic Surgery, General Surgery, Ear, Nose, and Throat Surgery, and Internal Medicine.

2.2 Data Collection:

The study utilized a valid and reliable patient survey to evaluate informed consent provided by Agency for Healthcare Research and Quality (AHRQ), United States Department of Health and Human Services (17). The survey can be taken by the patients or their family members who were asked to consent to treatment or procedure. The survey asks about informed consent and how it was delivered. It asks about unanswered concerns or questions, the satisfaction of the consent discussion, and the form of the consent (17).

2.3 Study Settings:

The study was done in KAMC, Jeddah, Saudi Arabia. The KAMC

is considered one of the largest serving hospitals in the city and the whole western region. It is a 500 beds hospital complex that runs under the supervision of the ministry of health. It provides elective surgical and medical services. KAMC has a well-equipped trauma center, laboratories, and outpatient clinics. Consent was acquired from all the patients who participated in this study. The study went per the hospital guidelines and regulations.

2.4 Statistical Analysis:

The data were analyzed using Excel 2019 (Microsoft Corporation, Seattle, WA, USA) and SPSS version 28 (SPSS Inc., Chicago, IL, USA). Apart from the descriptive analysis, the Chi-square test was used to compare the different responses. P-values of <0.05 were considered statistically significant.

3. Results:

3.1 General characteristics of the patients:

(Table 1) highlights the detailed patients' bibliographic characteristics. It show that a total of (n=399) patients were recruited; among them, 54.1% (n=216) were females and 45.9% (n=183) males; most of the participants, 49.9% (n=199) had a university education, 29.8% (n=119) had secondary education, 5% (n=20) had intermediate education, 5.2% (n=20) had elementary education, 5% (n=20) cannot read or write, and one participant had a diploma.

Table 1. General characteristics of the patients

Variable	% (No)
Gender	
Male	45.9% (183)
Female	54.1% (216)
Age	
18-29 years old	27.8% (111)
30-39 years old	24.6% (98)
40-49 years old	13.8% (55)
50-59 years old	33.8% (135)
Mean (Standard Deviation)	41.67 (± 16.8)
Education Level	
University and above	49.9% (199)
Secondary	29.8% (119)
Intermediate	5% (20)
Elementary	10% (40)
Diploma	0.3% (1)
Cannot read or write	5% (20)

3.2 Type of surgeries and their distributions among the hospital departments

It is clear from the results derived from (Table 2) that the highest percentage of operations 38.8% were performed in the General Surgery Department, then 17.8% in the Obstetrics and Gynecology Surgery department, 9% in the Orthopedic Surgery department, 7.5% in the Endoscopic Surgery department, 7% in the Neurosurgery department, 3.5% in the Eye surgery department, 2.8% in the Ear, Nose and Throat Surgery department, and 1.5% in the Oral and Maxillofacial Surgery department.

Table 2. Distributions of the procedures among the hospitals' department and their type

Variable	% (No)
Type of Surgery	
Minor	51.1% (204)
Major	48.9% (195)
Department	
Oral and Maxillofacial Surgery	1.5% (6)
Obstetrics and Gynecology Surgery	17.8% (71)
Endoscopic Surgery	7.5% (30)
Neurosurgery	7% (28)
Cardiac surgery	6.5% (26)
Eye surgery	3.5% (14)
Orthopedic Surgery	9% (36)
General Surgery	38.8% (155)
Ear, Nose, and Throat Surgery	2.8% (11)
Internal Medicine	5.5% (22)

3.3 Clarity of the consent form

(Table 3) shows the clarity of the consent forms based on the participants' answers. When asked about the clarity of the consent form, 48.9% (n=195) answered it was clear. While 4.3% (n=17) said some of the items of the form were not understood, and a similar number of participants were not able to understand the form. Interestingly, about 41.1% (n=164) said they did not look at the consent form. 14.8% (n=59) said they were required to read the form and assisted by hospital staff. While 3.3% (n=13) asked a family member or friend to help them read the form. 45.4% (n=181) read it without assistance, and 36.6% (n=146) required no help as they did not read it. On the easiness of the consent form, 40.9% (n=163) said it was easy to read, 41.9% (n=167) signed the consent without reading it, 11.3% (n=45) stated it was difficult to read, 2% (n=8) said it was somewhat easy to understand, and 4% (n=16) said it was too hard to understand.

Table 3. Answers to the questions about the clarity of the consent form

Question	% (Answer)
Was the consent form you were asked to sign for the test, treatment, or operation clear?	
Yes	48.9% (195)
No, there were some terms that were not understood	4.3% (17)
No, I couldn't understand it	4.3% (17)
I was not asked to sign a form	1.5% (6)
Have not taken a look at it	41.1% (164)
Has anyone helped you read the form?	
Yes, someone in the hospital read it to me	14.8% (59)
Yes, of my family member or friend	3.3% (13)
No, read with no help	45.4% (181)
No, have not read it/ None help me to read it	36.6% (146)
How easy is the form to understand?	
Too hard to understand	4% (16)
Somewhat easy to understand	2% (8)
Somewhat difficult to understand.	11.3% (45)
I signed, but I did not read the form	41.9% (167)
Easy to read and understand	40.9% (163)

3.4 Patients' education levels

(Table 4) demonstrates the significant associations between the level of education of the participants and the clarity or understanding of the consent form items. Regarding consent form clearness to the participants, 60% (n=117) of higher education individuals said yes, while 4% (n=87) individuals with lower education said yes. It should be noted that 70.6% participants (n=12) of lower education participants said they could not understand the form, compared to 29.4% (n=5) of the higher education participants (p-value<0.05). Moreover, 61.9% (n=112) university-educated participants required no help in reading the form, compared to 38.1% (n=69) lower-education participants (p-value<0.05). As for the easiness of the consent form, 64.4% (n=105) of the university-educated participants answered that it was easy to read, compared to 35.6% (n=58) of the lower education participants (p-value<0.005).

Table 4. Clarity of the consent based on the education level.

Question	University Education and Higher	Below University Education	p-value
Was the consent form you were asked to sign for the test, treatment, or operation clear?			
Yes	60% (117)	40% (78)	<.001
No, there were some terms that were not understood	41.2% (7)	58.8% (10)	
No, I couldn't understand it	29.4% (5)	70.6% (12)	
I was not asked to sign a form	66.7% (4)	33.3% (2)	
Have not taken a look at it	40.2% (66)	59.8% (98)	
Has anyone helped you read the form?			
Yes, someone in the hospital read it to me	42.4% (25)	57.6% (34)	<.001
Yes, of my family member or friend	15.4% (2)	84.6% (11)	
No, read with no help	61.9% (112)	38.1% (69)	
No, have not read it/ None help me to read it	41.1% (60)	58.9% (86)	
How easy is the form to understand?			
Too hard to understand	37.5% (6)	62.5% (10)	<.001
Somewhat easy to understand	37.5% (3)	62.5% (5)	
Somewhat difficult to understand.	44.4% (20)	55.6% (25)	
I signed, but I did not read the form	38.9% (65)	61.1% (102)	
Easy to read and understand	64.4% (105)	35.6% (58)	

Figure 1) displays the trend in the size of the gap change when participants' perceptions of the ease, clarity, and readability of the consent form were associated with their level of education.

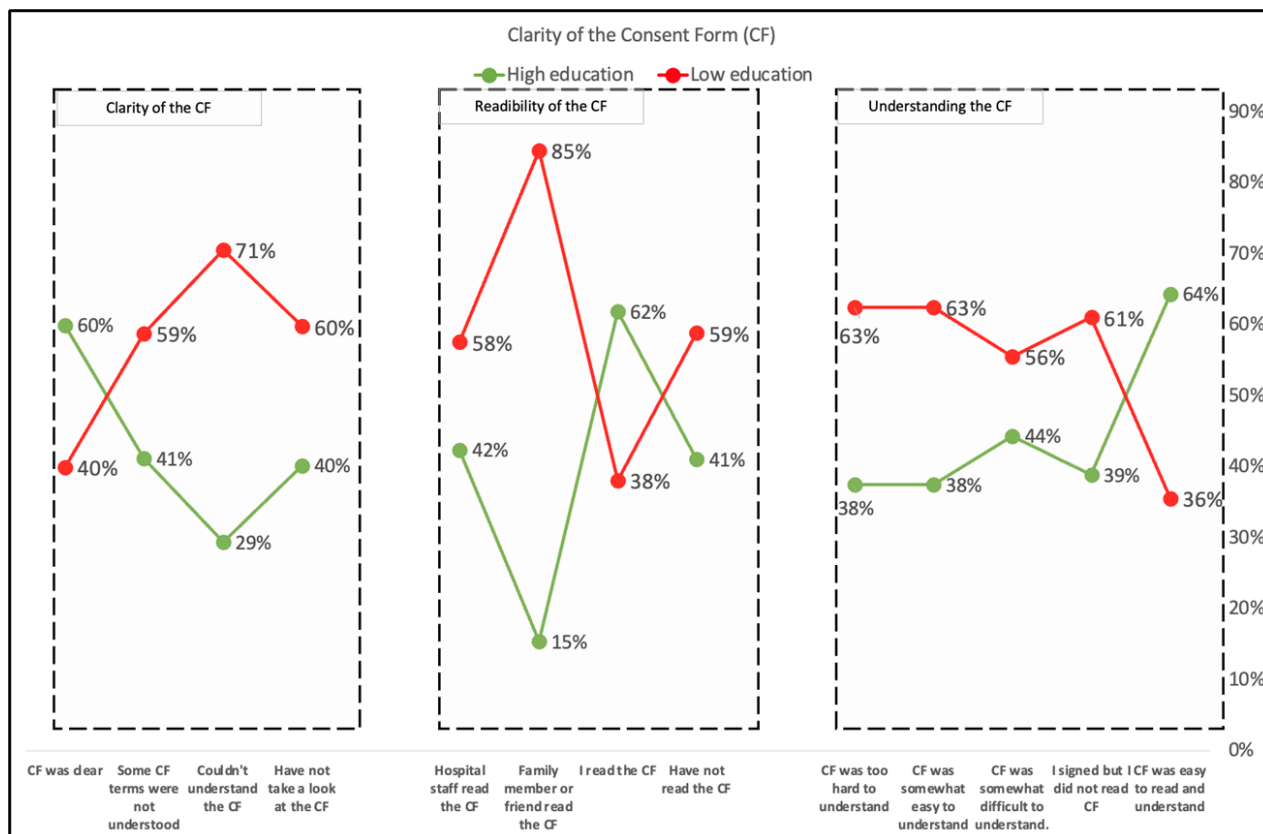


Figure 1. Clarity of the Informed Consent Form (CF) based on the participants' levels of education.

4. Discussion:

Informed consent is mandatory for all clinical trials involving human beings. The consent process must respect the patient's ability to make decisions and adhere to the individual hospital rules for clinical studies. The patient must be competent to make a voluntary decision to undergo the procedure or intervention. It is an opportunity to promote the patient's understanding and voluntary rights regarding medical procedures or research projects (18). Studies have demonstrated that the practice of informed consent to reach an informed decision is variable among different demographics of patients (10-16). It has also been shown that health literacy or low levels of education is associated with suboptimal communication between the health provider and the patient. Consequently, resulting in decreased patient compliance, poorer health outcomes, and increased hospitalization (19, 20).

We reported significant associations between the clarity of consent forms, readability of the consent form, and easiness of the items in the consent forms with the level of education of the patients or the participants (p -value <0.05). The results of the present findings showed the trends in the size of the gap changed when participants' perceptions of the easiness, clarity, and readability of the consent form were linked to their level of education. This could affect the efficiency of the consent forms when presented to individuals with below university education. It has been reported that individuals with lower Intelligence Quota (IQ) handle the consenting process worse than the ones with higher IQ (21). Patients with lower education could be more affected by a reported practice of physicians restricting the information given to the patients based on the bias that too much information will increase the patient anxiety (22) (thus, declining the procedure), though such a bias has not been reported to be valid (23).

In the United Kingdom (UK), the law explicitly explains the importance of the previous items. It stated that for informed consent to be legal, it must contain the following three items: 1) the patient being competent enough to give the consent; 2) consent should be given voluntarily; 3) adequate information should always be given (24). This issue has been called out previously to enhance the practice of informed consent. Moreover, these studies examined and tested the quality of the informed consent and challenged its ability to tell the patients prior to their treatment, surgery, or procedure (7, 25-27). Thus, new ways of enhancing the consent forms have been reported with success. Examples include delivering consent with computer agents to patients with lower health literacy (10). Other examples include providing the consent through smartphones or smart tablets (28, 29). The advantage of using technology to give the consent form is that a supplementary explanation through audio or a video outlet can be utilized (30). It has been reported that such a method has received acceptance from patients in various medical specialties such as spinal surgery (31), gastroenterology (32), ophthalmology (33), urology (30), vascular surgery (34), and foot and ankle surgery (35).

Such tools can be implemented to facilitate better patient care and overall patient experience within the hospital. Supplementary aids for a better understanding of a treatment, test, or procedure can be leveraged to gain better patient cooperation and allow them to make an informed decision about their preferred route of action in managing their health. Moreover, such tools should be tailored to

fit different demographics, languages, and levels of health literacies.

4.1 Study Limitations

A few limitations have been recognized in the present work, which include the small sample size, short duration, limited demographic variable analyzed, and performance of this study in a single center. However, these limitations can be overcome by doing this study on a larger scale and multi-center. But despite the limitations, the current study provides valuable data on the quality of informed consent in Saudi Arabia.

5. Conclusion:

Patients reported positive answers to the questions, mainly statements like a chief person who spoke to patients to describe their other options, provided assistance in making decisions, spent enough time with patients, encouraged you to ask questions, and other statements. Significant association with the education of the patients and easiness of understanding the consent form.

Improving the consent, in terms of readability and easiness, could be a starting point that will enable hospitals and other providers to evaluate and improve the quality of informed consent in Saudi Arabia. Redesigning consent forms, which will likely include more educational documentation, is a promising strategy for achieving ethical mandates for informed consent and encouraging joint decision-making.

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Disclosure of interest:

The authors of this manuscript report there are no competing interests to declare.

Availability of data and material

Data can be obtained from the corresponding author on a reasonable request.

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