

## Original Article

# Patients' Perception of Informed Consent for Surgical Operations in Kuwait

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## Abstract

**Background** Informed consent is part of every surgeon's daily practice. Surgical patients often need accurate information about their operation. The most important goal of informed consent is to inform patients about risks, benefits and expectations of the operation and help the patients make the final decision about their healthcare.

**Objective:** To assess the patients' perception of informed consent for surgical operations and to determine their expectations about the information given in Kuwait.

**Methods:** A cross-sectional study was conducted from January to June 2016 in all six governmental general hospitals and two private hospitals in the state of Kuwait. 805 adult patients hospitalized in surgical departments participated in the study by completion of self-administered questionnaires about their perception of informed consent.

**Results:** The mean age of participants was 35.6 years, males constituted 48.3% of the sample, 49.2% were Kuwaiti residents, 79.2% were secondary or higher educated and 73.4% were married. 69.9% of patients believed that it was a legal requirement. While, 37.0% thought that signing the consent meant waiving their rights to any compensation, 72.3% thought that the consent form protects the patient's rights. 72.9% believed that signing the consent form confirms that the operation and its effects have been explained to them. 76.4% signed the consent form so that they can undergo the required operative procedure. 82.0% believed that consent forms are necessary, while 59.5% believed that consent forms protect the doctor against being sued. Many of the patients (78.5%) thought that, a relative could sign on their behalf, if they can't sign the consent form, 57.6% of the patients were happy to allow doctors to determine their treatment but they wanted to know about their condition, the treatment and the important side effects. 26.5% wanted to make final decision themselves after discussion of pros and cons of the treatment. Only 15.9% trusted their doctor to take the right decision and did not think that detailed explanation was necessary.

**Conclusion:** The findings of this study show that informed consent was perceived differently by patients, which seems that consent procedures appear inadequate and hence consenting in its current form is not informed and should be re-evaluated to achieve patient autonomy.

**Key words:** Informed consent, Patients' perception, Patients' Rights

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**Suggested Citations:** Alazmi SF. Patients' perception of informed consent for surgical operations in Kuwait. JHIPH. 2018;48(2):92-96.

## INTRODUCTION

Informed consent is a legal requirement for all patients before medical interventions (surgical and non-surgical procedures), it is an authorization obtained from the patient. Informed consent was defined by most studies as a process of getting permission before conducting a health care intervention on a patient. It serves to recognize and respect a patient's best concern by giving each patient the prospect to decide autonomously what his or her best interests are. So, it acts as a safeguard to ensure the preservation of individual rights. <sup>(1)</sup> The right of patient to decide and make decisions about his medical management is called patient's autonomy, which is an important issue in health care. <sup>(2, 3)</sup> Some research studies designed to assess understanding of patients

towards informed consent have shown that patients are often poorly informed, and informed consent can be seen as nothing more than a patient's signature. Furthermore, some patients who gave written consent reported that they do not read and understand the consent. In contrast to Western cultures, which adhere to more individually oriented philosophies, traditional cultures place more value on the collective role of family in decision making. Due to this reason, most often patients are given inadequate information about their surgery before operation. <sup>(4)</sup> In cases where the patient is provided insufficient information to inform a reasoned decision, serious ethical issues arise. Despite this general observation, there is limited research study available in Kuwait about the usual practice of Pre-operative informed consent. Informed consent requires that the procedures be properly explained that

the patient understands the procedures and their risks, and agrees to undergo them voluntarily.<sup>(5)</sup> One reason for taking informed consent is that it provides assurance that patients and others are neither deceived nor coerced.<sup>(6)</sup> Hence, the process of obtaining consent is as important as the contents. Successful surgery depends on a relationship of trust between the patient and the doctor. To establish this, the patient's right to autonomy must be respected, even if his decision results in harm or death. Surgery is technically an assault, unless the patient has given permission for this to occur after provided adequate information necessary to make informed decisions.<sup>(7, 8)</sup> Therefore, the aim of current study was to assess the patients' perception and understanding of informed consent for surgical operations in Kuwait and to determine their expectations about the information given.

## METHODS

A descriptive cross-sectional survey was conducted from January to June 2016 in the state of Kuwait. All six governmental general hospitals and two randomly selected private hospitals out of 11 were included in the study. The study population was patients 18 years old and above who attended to the surgery departments in the selected hospitals. Sample size for study participants was calculated by a web based freely accessible sample size calculator, Raosoft (Raosoft, 2013).<sup>(9)</sup> Based in the formula for sample size and margin of error from Raosoft, the estimated sample size for participants was 910 participants. Structured self-administered questionnaires were distributed to the patients hospitalized in surgery departments of Kuwaiti hospitals; who were counseled before their elective surgery and signed their consent forms. The questionnaire was derived from different published studies dealing with the same topic, as well as from our personal experience. It took 15-20-minutes to be filled. To increase the response rate repeated visits was sometimes necessary to collect completed questionnaires from the patients. It consisted of four sections. The first section collected information on personal and demographic characteristics (age, gender, nationality, education status, and marital status). The second section included questions about perception and understanding of informed consent and the legal issues. The third section included the expectations of patients about the information given during the consent sessions to determine what they needed to know about their treatment. The fourth section included opinion of patients regarding their role in decision making about treatment. The questionnaire was pilot tested on 30 patients prior to being finalized. The investigators reviewed feedback from the pilots, and, where appropriate, questions were modified accordingly.

### Statistical analysis

The data were analyzed using Statistical Package for Social Sciences (SPSS) version 21. Simple descriptive

statistics was used (mean  $\pm$  standard deviation for quantitative variables, and frequency with percentage distribution for categorized variables).

### Ethical considerations

All ethical issues related to research were addressed according the standard and universal research ethical guidelines. Ethical review and approval was sought from the Research Ethical Committee of Kuwait Ministry of Health. Permission to conduct the study was obtained from the respective hospital administrations. Informed verbal consent was obtained before recruitment of any participant into the study. To maintain confidentiality, questionnaires were made anonymous.

## RESULTS

Of the 910 patients approached, 61 patients refused to participate and 44 were discarded during data analysis due to lack of internal consistency and the remaining were 805 patients. The response rate was 88.5%. The mean age of participants was 35.6 years, males constituted 48.3% of the sample, 49.2% were Kuwaiti residents, 79.2% were secondary or higher educated and 73.4% were married (Table 1).

**Table 1: Characteristics of study sample of surgical patients in Kuwait**

Background characteristics	Surgical patients (n=805)	
	No.	%
<b>Age group</b>		
<30	233	28.9
30-	352	43.7
40-	129	16.0
50+	91	11.3
<b>Mean<math>\pm</math>SD</b>	35.6 $\pm$ 3.5	12.4 $\pm$ 4.1
<b>Gender</b>		
Male	389	48.3
Female	416	51.7
<b>Nationality</b>		
Kuwaiti	396	49.2
Non-Kuwaiti	409	50.8
<b>Educational status</b>		
below intermediate school	167	20.7
secondary level	274	34.0
Higher than secondary	364	45.2
<b>Marital status</b>		
Single	168	20.9
Married	591	73.4
Divorced	24	3.0
Widowed	22	2.7

Patients' perception and understanding of informed consent and their legal issues was shown in (Table 2). It revealed that 69.9% of patients believed that it was a legal requirement; while, slightly more than one third of respondents (37.0%) thought that signing the consent meant removing their rights to compensation. Slightly less than three quarters (72.3%) thought that

consent form was to protect the patient's rights. Another 72.9% believed that signing the consent form confirms that operation and its effects have been explained to them. About two thirds (65.8%) of the patients under study thought that they had the right to change their minds after signing the consent. Many of the patients (39.1%) believed that they would be left to die if they had not signed the consent. 76.4% signed the consent form so that they can undergo the required operative procedure. On the other hand, 82.0% believed that consent forms are necessary, while 59.5% believed that the consent form was to protect the doctor against being sued. Many of the patients (78.5%) thought that their relative could sign on their behalf, if they can't sign the consent form.

Most patients were interested to know the reason for operation (93.5%), the duration of the operation (80.6%), possible risks (82.6%) and complications involved if they undergo the operation (79.1%), chances of successful operation (87.2%) and cost of treatment (83.6%). About 88% were interested to know what will be done during the operation and a similar proportion was interested to know information about postoperative care. Moreover, 85.7% were interested to know after how many days they should resume their work. 88% of patients were interested to know any special precautions to be taken after operation. About 87% were interested to know any special dietary advice to be considered after operation (Table 3).

**Table 2: Surgical patients' perception of informed consent in Kuwait**

Perception items	Surgical patients (n= 805)					
	Yes		No.		Don't know	
	No.	%	No.	%	No.	%
Consent forms are necessary	660	82.0	65	8.1	80	9.9
Signing the consent form is a legal requirement	563	69.9	117	14.5	125	15.5
Signing the consent form removes your right to compensation	298	37.0	365	45.3	142	17.6
Consent form protects the doctor from being sued	479	59.5	206	25.6	120	14.9
Consent form protects the patient's rights	582	72.3	110	13.7	113	14.0
Signing the consent form confirms that operation and its effect have been explained to me	587	72.9	142	17.6	76	9.4
I have signed the consent form so that I can undergo the operative procedure	615	76.4	110	13.7	80	9.9
The patient has the right to change his mind after signing the consent form	530	65.8	136	16.9	139	12.3
If the patient can't sign the consent form, his relative can sign on his behalf	632	78.5	90	11.2	83	10.3
If the patient is not able to sign the consent form, the operation cannot take place, even if this means he could die	315	39.1	335	41.6	155	19.3

**Table 3: Patients' expectations of information that needs to be given during informed consent sessions in Kuwait**

Expected Information	Surgical Patients (n= 805)					
	Yes		No		Don't know	
	No.	%	No.	%	No.	%
Reason for operation	753	93.5	26	3.2	26	3.2
Operation procedure	712	88.4	49	6.1	44	5.5
Duration of operation	649	80.6	69	8.6	87	10.8
Possible complications due to operation and risk of recurrence	665	82.6	59	7.3	81	10.1
All complications	637	79.1	97	12.0	71	8.8
Information about post-operative care	707	87.8	47	5.8	51	6.3
After how many days patient can go back to work	690	85.7	41	5.1	74	9.2
Chance of successful operation results	702	87.2	50	6.2	53	6.6
Special precautions needed after operation	708	88.0	42	5.2	55	6.8
Special diet needed after operation	699	86.8	53	6.6	53	6.6
Cost of treatment	673	83.6	71	8.8	61	7.6

More than half of the patients (57.6%) were happy to allow doctors to determine their treatment but they wanted to know about their condition, the treatment and the important side effects. About 26.5% of the patients

wanted to make final decision themselves after discussion of pros and cons of the treatment. Only 15.9% trusted their doctor to do the right thing and did not think detailed explanation was important (Table 4).

**Table 4: Opinion of surgical patients regarding their role in decision making about treatment in Kuwait**

Opinion	Surgical patients (n=805)					
	Yes		No		Don't know	
I do not want to know anything but will do what doctor recommends	128	15.9	611	75.9	66	8.2
I want to know about my treatment but will do what doctor recommends	464	57.6	278	34.5	63	7.8
I should make final decision after discussion of pros and cons of the treatment	213	26.5	544	67.6	48	6.0

## DISCUSSION

Informed consent is a legal and ethical term defined as the consent by a patient to a proposed medical treatment or procedure. In order for the consent to be informed the patient must first achieve a clear understanding of the relevant facts, risks and benefits, and available alternatives involved. Informed consent requires legal documentation. The concept of informed consent originated with the recognition that individuals have rights to autonomy and human dignity. Patients possess these rights and cannot be denied their rights due to mental health status or condition. Several studies have shown that written information has beneficial effects. Patients who were given written information have better understanding and postoperative recall of information.<sup>(10,11)</sup> The present study revealed that about (70.0%) of patients believed that it was a legal requirement. In another study conducted by Rajesh et al. 2013, indicated that (75.0%) of patients falsely believed that it was a legal requirement. In the same study, 68.8% thought that signing the consent meant waving their rights to any compensation however, in our study a lower percentage was reported (37.0%). Other studies revealed that most of the patients (88.0%) thought that they had no right to change their minds after signing the consent.<sup>(12)</sup> Similar observations were also made by another study from Egypt.<sup>(13)</sup> In the current study, a lower percentage of patients (65.8%) thought the same. It was found in this study that most of the patients (80.6%) were interested to know about duration of the operation, possible risks and complications (82.6%) involved if they undergo the operation, chances of successful operation (87.2%) and cost of treatment (83.6%). Our findings were consistent with other studies.<sup>(13,14)</sup> This study revealed that some patients have limited legal knowledge

towards signing or not signing the consent forms. Akkad et al 2006, also made similar observations.<sup>(15)</sup> Some patients want their doctor to make the final decision about their care.<sup>(16,17)</sup> In this study, 15.9% of patients do not want to know anything and they will do what the doctor recommends, while 57.6% of patients want to know about their treatment, but will do what the doctor recommends, moreover, about 26.5% reported that they should make a final decision after discussion of pros and cons of the treatment. Our findings were consistent with other studies conducted by Beresford and colleagues 2001.<sup>(18,19)</sup>

## CONCLUSION & RECOMMENDATIONS

The findings of this study show that informed consent was perceived differently by patients. The difference in perception and limited knowledge of the legal implications of signing or not signing consent form indicates that consent procedures appear inadequate and hence consenting in its current form is not informed and should be re-evaluated to achieve patient autonomy.

**Conflict of interest:** None to declare.

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