



Cross-sectional Study

Obtaining informed consent from patients hospitalized in the surgical wards as a major legal challenge

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ABSTRACT

Background and objectives: Informed consent (IC) is the process of establishing communication between the physician and the patient or an alternative decision that leads to the agreement or rejection of the patient and/or their legal representative to perform specific medical procedures. In this study, we evaluated the level of awareness and patient participation in IC in the surgical wards of the general hospital in northern Iran in the 2019–2020 years.

Patients and methods: This study is cross-sectional research that was performed during the 2019–2020 years. The statistical population includes patients admitted to the surgical wards of the general hospital in northern Iran in 2019–2020. The Cochran's formula was used to determine the sample size and the statistical sample size was 385 patients. The sampling method is stratified random. The method of data collection was through questionnaire tools. The software used was SPSS 21 with an independent *t*-test and one-way ANOVA.

Results: Our data showed that the frequency of men was significantly higher ($P < 0.001$). Individuals with a higher education group have a significantly higher level of awareness ($P < 0.001$). The Pearson's Correlation (PC) test showed that there was no significant correlation between age and patients' awareness score (PC = -0.007, $P = 0.887$).

Conclusion: The current study showed that individuals with higher education had a significantly higher level of awareness, and there was no significant correlation between age and patients' awareness score. Therefore, senior university administrators are suggested to improve IC processes in accordance with the patients' rights charter and internationally accredited standards, and assist health care providers with legal implications in the courts.

1. Introduction

Informed consent (IC) is the process of establishing communication between the physician and the patient that leads to the agreement or rejection of the patient and/or their legal representative to perform specific medical procedures. The concept of IC for certain aspects of medical treatment is a relatively new concept in medical ethics that has evolved over the last century. As a result, the patient's rights are the

observance of a set of duties that are applied by the members of the group in order to meet legitimate and reasonable needs in accordance with the standards, rules, and regulations of the medical center [1].

According to the World Health Organization (WHO), the patients' rights charter means access to appropriate care and treatment, access to information, confidentiality of information, IC, independence, education, complaint, and compensation [2]. The process of IC is an opportunity that allows the patient to identify complex problems, correct

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misconceptions, and consult with other sources [3].

IC consists of three basic components: information sharing, decision-making ability, and the ability to make free and voluntary choices. Previously, medical decisions were made under a model that assumed that physicians, given their expertise, could show what was good for their patients without consulting them. This model has been criticized for failing to address facts such as the fact that there is often more than one reasonable treatment option for patients, patients may choose different options based on their values, and that physicians may not be able to evaluate each patient's [4]. IC is the free (and revocable) consent of an eligible person (patient or legal guardian) to participate in treatment (or research) decisions following knowledge of its nature, purpose, and requirements, believing in the influence of this participation on the selection of effective and useful treatment methods [5].

IC is one of the main components of patient rights in health care centers and the basis of medical ethics. IC requires six conditions: information, understanding, volunteering, competence to decide, written consent form (or verbal consent) license and factors related to the interaction and communication between physician and patient. IC and the participation of patients in their own decisions can accelerate their recovery. In this regard, various studies have been conducted worldwide, some of which have reported the status of obtaining consent as positive and some have mentioned problems in this area. There are a few studies in Iran, some of which have raised problems such as non-compliance with the patient's rights to identify the diagnosis and treatment in 19% of cases, choice of treatment method in 23% of cases, and rejection of treatment in 32% of cases.

Observance of the standard process of obtaining IC from the patient in the treatment and research process not only has a direct effect on sustainable growth and patient satisfaction during the treatment and research process, but also is effective in reducing complaints from physicians and other medical teams. The result will be a reduction in legal and disciplinary interventions. Resolving problems related to obtaining IC requires recognizing factors such as the patient's inability to understand information, the patient's reluctance to participate in treatment, fear, anxiety, the possibility of depression, incorrect decisions, the patient's family request, time limit, obtaining consent from inexperienced people, deficiency of personnel, and acceptance of the patient are discussed. Most studies have examined only the provision of information to patients, and there is little information about other dimensions of IC [6].

In addition, this does not underestimate the importance of respecting patients as independent individuals, which in medicine involves trying to allow patients to choose what happens to their bodies. However, in the mid-1980s, this model gave way to one that valued efforts to respect patient independence. Ideally, this model is based on effective communication and dialogue with the patient and offers different treatment options and, ultimately, the patient's decision based on their values and preferences. However, the idea of involving the patient as a call to allow patients to choose any treatment they want, without consulting a physician, is due to concerns that such counseling may adversely affect the patient and hence disrupt the patient's independence, misinterpreted [7].

The concepts of IC and confidentiality are more complex if the patient is an adolescent. This is especially true when the needs and wants of adolescents are at odds with those of their parents. The rules governing consent and confidentiality in adolescent health care vary from country to country. In the United States, they vary from state to state. The specific provisions of the consent and confidentiality laws are also different and not the same [8].

Physicians are legally and ethically responsible for providing sufficient information to the patient so that they can process the information and make appropriate decisions. An educated patient is beneficial to the physician both in terms of cooperating with the planned intervention and in reducing complications in the event of complications [9]. A physician who trains and responds carefully to the patient enters the

medical decision process, addresses the patient's concerns, and creates reasonable expectations about the treatment outcome. Therefore, this study was conducted to investigate the level of awareness and patient participation in IC in the surgical wards of a general hospital in northern Iran in 2019–2020.

2. Patients and methods

The present study is cross-sectional research which has been conducted on patients who were admitted to a teaching hospital (Imam Khomeini) in Mazandaran Province, northern Iran in 2019–2020. The statistical population consisted of patients admitted to the surgical wards. The Cochran's formula was used to determine the sample size. The statistical sample size was 385 patients. The sampling method is stratified random. The method of data collection was through questionnaire tools. The software used was SPSS 21 with an independent *t*-test and one-way ANOVA.

The data collection tool for this research was a questionnaire that was used by Amini et al. (2009). The method of data collection was through study and the library, using electronic resources and questionnaire tools.

The questionnaire used in this study was based on the international codes of medical ethics and the IC was divided into two general and specific sections. The general part included demographics characteristics of patients and the specific section consisted of 19 questions, 17 of which were compiled based on the Likert scale, including very low (with value 1), low (with value 2), medium (with value 3), high (with value 4) and very high (with value 5), and 2 other questions in the specific part of the questionnaire were developed using a different test method but different from the Likert scale, and the researcher tried to analyze them according to the Likert scale.

After collecting the questionnaire data, it was evaluated using the reliability test of SPSS 21 software. Cronbach's alpha for these research tools was about 0.85, which indicates the suitable capability of the questionnaire in terms of reliability. Data analysis in this study was performed in two parts; descriptive and inferential statistics. In the descriptive statistics section, demographic information was shown using frequency distribution tables (Tables 1–4), and first the Kolmogorov-Smirnov test was performed to check whether or not the distribution of research data was normal. According to this test, if the distribution of research data is normal, parametric statistical tests will be used, and if it is abnormal, non-parametric statistical tests will be used. Inclusion criteria included patients elective admitted to the surgical wards of the hospital, and exclusion criteria included patients emergency, homeless, and unconscious. Also, the amount of error accepted in the research is 0.05. The work has been reported in line with the STROCSS criteria [10]. This study is registered with the Research Registry, and the UIN is research registry 7195

<https://www.researchregistry.com/register-now#home/registratordetails/615577d17fa285001ee43f7c/>

Table 1

Frequency and percentage of frequency of gender, marital and educational status, number and type of hospitalization.

		Frequency (%)
Gender	Male	226 (58.70)
	Female	159 (41.30)
Marital status	Single	157 (40.78)
	Married	228 (59.22)
Classification of education status	High school and diploma	197 (51.17)
	Technician and bachelor	154 (40.00)
	Master's and higher degrees	34 (8.83)
Number of hospitalization	Less than 3 times	239 (62.08)
	3 to 6 times	83 (21.56)
	More than 3 times	63 (16.36)
Type of hospitalization	Normal	167 (43.38)
	Emergency	218 (56.62)

Table 2
Mean and standard deviation of patients' age.

	Mean	SD	Minimum	Maximum
Age	51.62	14.48	22	78

3. Results

According to the findings of this study, the number of cases studied was 385 patients. 226 (58.7%) were male and 159 (41.3%) were female. The Chi-square test showed that the frequency of men was higher significantly ($P < 0.001$), 228 cases (59.23%) were married. 197 patients (51.17%) had high school and a diploma, 154 (40%) had technician and bachelor's degrees, and 34 (8.83%) had master's and higher degrees. 239 patients were hospitalized (62.08%) less than 3 times, 83 patients (21.56%) 3 to 6 times, and 63 patients (16.36%) more than 6 times. The most patients were admitted to the emergency department (56.62%). The mean age of patients was 51.62 ± 14.48 years, with a minimum age of 22 and a maximum age of 78 years. Tables 1 and 2 show the mentioned results.

Table 4, was shown the mean and standard deviation of patients' awareness scores by gender, marital and educational status, and the number and type of hospitalization. An independent *t*-test and one-way ANOVA were used for comparison between groups. These tests showed that individuals with a higher education group have a significantly higher level of awareness ($P < 0.001$). In other cases, no significant difference was observed between the groups ($P > 0.05$). Also, the Pearson correlation test showed that there is no significant correlation between age and patients' awareness score (Pearson's correlation = -0.007 , $P = 0.887$).

4. Discussion

The results showed that individuals with higher education had a significantly higher level of awareness ($P < 0.001$). In the study, Mohammad et al., about 76% of patients did not know that there was a patient charter. The mean score of patient rights awareness in this study was 7.2 ± 2.71 from 14. Patients' education was significantly related to their information score. The majority (98.1%) of the questioned patients were certain that the medical team did not inform them about the available treatment options [11]. This study was consistent with our research. In clinical settings, having IC is important for decisions. However, consent practices vary in different institutions and countries. In medicine, the concept of IC has become a moral turning point in the last 60 years and is based on information sharing, compliance and

licensing [12,13]. Awareness of consent is embedded in a process of agreement between a patient and a physician called "joint decision." The requirements of the IC process vary as a set of risks of trials or treatments. Disabled or unconscious patients need alternative decision makers to consent or decline on their behalf [14,15].

In our results, there was no significant correlation between age and patients' knowledge score. Weithorn et al. studied 9, 14, 18, and 21 years old using hypothetical treatment problems and concluded that 14 years old did not differ from adults in terms of decision competence. At the age of 16 years old, a young person can be treated as an adult and their decision capacity can be assumed. Juveniles less than 16 years old may be able to make decisions depending on their ability to understand. It was previously thought that the age of written consent for surgical treatment was 18 years [16].

In our study, more than half of the patients were men. The mean age of patients was about 52 years old. About 60% were married, more than half of patients had a high school, diploma, and most patients were hospitalized less than 3 times, most of whom were admitted as

Table 4
Mean and standard deviation of patients' awareness score by gender, marital and educational status, and the number and type of hospitalization.

		Mean \pm SD	P-value
Gender	Male	2.64 \pm 0.63	$P < 0.303$
	Female	2.71 \pm 0.64	
Marital status	Single	2.61 \pm 0.62	$P < 0.142$
	Married	2.71 \pm 0.64	
Classification of education status	High school and diploma	2.50 \pm 0.51	$P < 0.001$
	Technician and bachelor	2.76 \pm 0.67	
	Master's and higher degrees	3.71 \pm 0.18	
Number of hospitalization	Less than 3 times	2.65 \pm 0.64	$P < 0.421$
	3 to 6 times	2.64 \pm 0.59	
	More than 3 times	2.76 \pm 0.67	
Type of hospitalization	Normal	2.72 \pm 0.64	$P < 0.155$
	Emergency	2.63 \pm 0.63	

Table 3
Frequency and percentage of frequency of answers to the questionnaire.

	Very Low	Low	Moderate	High	Very High
The level of reading consent form	133 (34.55%)	127 (32.99%)	37 (9.61%)	38 (9.87%)	50 (12.99%)
The level of understanding after reading the consent form	36 (9.35%)	43 (11.17%)	45 (11.69%)	137 (35.58%)	124 (32.21%)
Physician's use of incomprehensible words	138 (35.84%)	123 (31.95%)	38 (9.87%)	39 (10.13%)	47 (12.21%)
General understanding of the disease and treatment methods	31 (8.05%)	159 (41.3%)	146 (37.92%)	26 (6.75%)	23 (5.97%)
The amount of reminder of the Physician's words	31 (8.05%)	153 (39.74%)	163 (42.34%)	16 (4.16%)	22 (5.71%)
Awareness of treatment costs	135 (35.06%)	126 (32.73%)	26 (6.75%)	45 (11.69%)	53 (13.77%)
Physician's response to patients questions	25 (6.49%)	19 (4.94%)	29 (7.53%)	159 (41.3%)	153 (39.74%)
Awareness of having the right to reject prescription treatment	116 (30.13%)	145 (37.66%)	35 (9.09%)	54 (14.03%)	35 (9.09%)
Awareness of one's disease	28 (7.27%)	28 (7.27%)	22 (5.71%)	145 (37.66%)	162 (42.08%)
Awareness of the treatment methods	24 (6.23%)	147 (38.18%)	170 (44.16%)	21 (5.45%)	23 (5.97%)
Awareness of medications used	0 (0%)	95 (24.68%)	135 (35.06%)	122 (31.69%)	33 (8.57%)
Awareness of the outcome of the treatment	140 (36.36%)	121 (31.43%)	46 (11.95%)	36 (9.35%)	42 (10.91%)
Patient participation in clinical decisions	127 (32.99%)	134 (34.81%)	43 (11.17%)	37 (9.61%)	44 (11.43%)
Awareness of the success and failure of treatment	129 (33.51%)	132 (34.29%)	42 (10.91%)	46 (11.95%)	36 (9.35%)
Awareness of the side effects of treatment	112 (29.09%)	149 (38.7%)	45 (11.69%)	37 (9.61%)	42 (10.91%)
Awareness about medical staff	131 (34.03%)	130 (33.77%)	40 (10.39%)	35 (9.09%)	49 (12.73%)
Awareness of other treatments	140 (36.36%)	121 (31.43%)	36 (9.35%)	41 (10.65%)	47 (12.21%)
Awareness in decisions	127 (32.99%)	134 (34.81%)	31 (8.05%)	47 (12.21%)	46 (11.95%)
Awareness of surgery results	135 (35.06%)	126 (32.73%)	46 (11.95%)	37 (9.61%)	41 (10.65%)

emergency. In the study of Erkan et al. (2017), half of the patients were male and the other half were female, and most of the patients were in the age range of 18–39, which was less than in our study. In this study, 80.4% of the patients did not have a university degree and had a high school and diploma. Also, 56.8% of the patients were unemployed or retired [17].

In the present study, most of the patients had read the consent form very little or little, but the patients' understanding was acceptable after reading it. Our results showed that the physician's use of incomprehensible words and expressions was low and the general perception of patients about the physician's words and the treatment process was acceptable, which can be effective in patients' understanding of the consent form. Moreover, the level of awareness of the cost of treatment and the success and failure of treatment, having the right to reject the prescribed treatment, possible results and complications of treatment, patient participation in clinical decisions, knowledge of the medical team (especially physicians), awareness of other treatment processes, awareness of decisions, and about the person responsible for the consequences and results of surgery were low among most patients. Also, results showed that the physician's response to patients' questions and their awareness of their disease and medications was acceptable. In addition, patients' awareness of the treatment process was moderate.

Consent is generally given in writing, but in some cases it may be verbal, especially for interventions that are non-invasive and relatively safe [17]. In a study (2011), where they consciously assessed the level of knowledge of surgical patients, it was found that the majority of patients (70.2%) did not have sufficient knowledge about this issue, which confirms our results [18]. In another study (2010) of 106 patients, found that only 38% of patients experienced preoperative IC, which was similar to our results [19]. In the study by Erkan et al., when asked about IC, only 39 patients (38%) did not have sufficient knowledge [17].

In another study (2005), 89.9% of patients stated that they were told why they should have surgery, but 74.2% of them did not find this explanation satisfactory [20], which was similar to our results. Of course, in our study, most patients had little or no study of the IC form. In the present study, patients' knowledge of gender, marital and educational status was evaluated. In these cases, only individuals with higher education groups had significantly higher levels of awareness and, in other cases, no significant difference was observed between the groups. In our study, there was no significant correlation between age and patients' comprehension. This finding in the present study suggests that individuals with higher education are more aware of the potential risks; they think that complications may occur as a natural result of the intervention, and could better diagnose the correlation between these diseases and treatment.

Analysis of the results of our study regarding the level of awareness and patient participation in IC in surgical wards showed that people with higher education had a significantly higher level of awareness and there was no significant correlation between age and patients' awareness score. Most patients had read the consent form little or very little, but the patients' understanding after reading it was acceptable. Also, in most patients, the rate of reading the consent form, awareness of the cost of treatment, having the right to reject the prescribed treatment and the result of treatment were low.

5. Conclusion

The patients' rights charter is the observance of a set of duties performed in order to meet legitimate and reasonable needs in accordance with international standards, regulations, and laws. Therefore, hospitals should explain the process of obtaining IC to service recipients and help health care providers with legal consequences in the courts. As a result, physicians should obtain IC for any surgery from the patient and their first-degree relatives after explaining the type of disease and surgery and complications during and after the operation.

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Ethical approval

The protocol of the study was reviewed and approved by the Ethics Committee of Mazandaran University of Medical Sciences (NO: IR.MAZUMS.REC.1399.5301).

Consent

Not applicable.

Author contribution

S K G and H R D designed the study, wrote the manuscript. M K analyzed and interpreted the data. M S, M H K and B M S were involved in writing, editing and preparing the final version of the manuscript. Z Z involved in interpretation and editing the manuscript. All the authors reviewed the paper and approved the final version of the manuscript.

Trial registry number

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Availability of data and materials

The authors are responsible for data. Access to all relevant raw data will be free to any scientist.

Declaration of competing interest

The authors have no conflicts of interest to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.amsu.2021.103053>.

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