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Assessing the Quality of Receiving Patients' Informed Consent in the Surgical Wards of Hospitals Affiliated to Zanjan University of Medical Sciences

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Abstract

Background: Informed consent is the cornerstone of medical ethics and is related to four out of ten articles of the patient's legal charter, aimed at supporting the patient and clarifies ethical principles in the physician-patient relationship.
Objectives: The purpose of this study was to assess the quality of receiving patients' informed consent in the surgical wards in Zanjan University of Medical Sciences.
Methods: In this descriptive cross-sectional study, all patients, admitted to surgical wards of public hospitals in Zanjan, were selected through stratified random sampling method. Data were collected after admission and before surgery, using a questionnaire designed according to library studies and considering Sheikh Taheri et al.'s study in two sections: general and specific. Mann-Whitney and Kruskal-Wallis tests were used to analyze the results. The content validity method was used to determine the validity, and the reliability of the questionnaire was evaluated by internal reliability using Cronbach's alpha coefficient.
***Results*:** The number of patients was 400 (211 males and 189 females) and their mean age was 33.78. The results showed that 24% of the samples rated as "appropriate" the process of signing the consent form, and 19% of them considered the status of information submission appropriate. Three percent of the respondents regarded the comprehensibility of the questionnaire, and 12% considered the voluntary nature of obtaining the informed consent, as well as 19% found the relationship between the physician and the patient as appropriate. Other findings revealed that there was no significant relationship between sex and marital status with the sum of the questionnaire dimensions, but there was a significant relationship between the type of hospitalization and how to submit information consent and the process of signing the consent form, and also between the number of hospitalizations. Moreover, the type of job was found to be statistically significant with the form signature process variable.
Conclusion: This study found that there were some shortcomings in the process of obtaining a surgical informed consent. Therefore, considering the role of the patient in the process of obtaining informed consent, providing sufficient information on physician's treatment, training physicians and providing the patient with the opportunity to choose the treatment method can be effective in improving the quality of obtaining an informed consent.

Keywords: informed consent, patient, surgery

Introduction

Informed consent is the cornerstone of medical ethics. In Iran, four of the ten articles of the patient's legal charter specifically address the issue of informed consent. At the age of essential change in the structure of the medication system, informed consent marks one of the cornerstones of offering information to the patient in connection with treatment and decision making [1]. The objective is supporting the patient and

clarifying the moral principles of relationship between the physician and the patient [2]. The word consent should be interpreted as the patient's autonomy, indicating his/her freedom of choice to accept or reject the procedure, no matter it will end up with dangerous consequences, if any [3]. The word informed also means providing the patient with information and answering his/her questions. Since majority of the surgical procedures are complicated and whose dangers and advantages are unknown to the patient, s/he undergoing surgical operation needs to be provided with more information and guidance on the operation. Though being ordinary and simple for the physician, the surgical operation information is new and puzzling for the patient; therefore, it will be necessary to provide the patient with diagnosis and treatment information, the surgical procedure and its advantages or disadvantages as well as treatment alternatives [4].

Previous studies have suggested a relationship between getting informed consent and right clinical results–take for instance the opportunity to check symptoms of diseases and pain, promotion of the patient's mental health, his/her better performance, and ensuring the physiological standards. The practice is expected to result in the patient's more active contribution to the medication process and higher level of his/her satisfaction with the kind of treatment thus offered [5,6]. Based on the Clinical Affairs Council guidelines for designing informed consent, any information consent sheet should include easy to understand and non-technical jargons and lexicon, and the writer should be cautious not to use such statements as "The physician will be free to choose any method of treatment s/he deems right for the patient" because court considers these types of statements very broad and non-technical. A study conducted in 2000, involving 540 patients in the US hospitals, revealed that informed consents were designed mostly to relinquish the legal responsibility of hospitals and physicians. Hence, the study concluded that the informed consents are devoid of sufficient content to meet the legal and moral standards of obtaining informed consent [7].

The informed consents obtained from patients are valid depending on its signatory. If s/he is not qualified to voice consent to the medical treatment, only eligible individuals (or the patient's legal guardian) would be right to ink the sheet. Kabirzadeh et al, surveying the records of 540 patients in Iran's northern province of Mazandaran, showed that about 74% of the informed consents lacked any validity. For instance, in majority of cases the hospital officials had asked the person close to the patient, who was in right sense, conscious and in good physical position at the time of the informed consent signing, to ink the sheet [8]. Sheikh Taheri et al. (2007) scrutinized the ways informed consent was received in the educational hospitals in the city of Kashan in Iranian province of Isfahan. The study findings suggested that signatories of the informed consent, including the patients signing the sheets, who were more literate, were more satisfied with the ways related informed were provided in the specialized hospitals. The study proposed taking necessary measures to provide the less literature patients, including those in general hospitals, with more information. While pointing to dissatisfaction of 41 percent of the patients with the surgical operation that at times resulted in adverse consequences, the study showed that 88.7 percent of the group of patients undergoing the research believed that the physical or surgeon should have explained the adverse consequences and possibility of death as a result of the operation. It said 66.3 percent of the patients the informed should have been provided to the patient herself/himself [9]. For the time being in Iran the signatories are required to sign the informed consent sheet only. This deprives the signatory of any opportunity to be provided with specific information concerning the surgical operation, leaving the patient with limited chance to study the form. The form is provided by (not well trained) staff of the hospital's reception department while the reception procedure is underway [8].

The informed consent forms' structural content is diversified with regards to the hospital it is provided. Since certain medication centers and hospitals provide an informed consent form, which bears the kind of statements which

relinquish the physician and hospital staff from any legal responsibility towards outcomes of surgical operations and regarding study of a corpus of documents available in data bases, it seems that there are rare studies on receipt of informed consent in Iran. Only Amini et al. conducted a study to that effect in Tehran pertaining to a BSci thesis. Since the study's sample size was small, it has limited power of generalization [10]. Regarding the fact that only the wise and valid informed consent, obtained from patients based on the ethical and legal standards, will serve as the basis of medical ethics and since patient's share in the decisions made in connection with his/her treatment is proved to be influential in expediting the medication process and also since researches have over recent years been witnessing failures to observe standards and patients' rights code, this research is done to explore perceptions of patients on the way informed consent prior to surgical operation is received in Zanjan. It is hoped that this research will open a horizon to qualitative improvement of informed consent sheets and qualitative pre-surgical operation informed consent receipt in Iranian hospitals.

Methods

This study has the endorsement (A-11-764-1) of Zanjan University of Medical Sciences Research Ethics Committee as the researcher tried his/her best the data collection process will not cause any discrepancy in the patients' treatment. This study is cross-sectional in nature, conducted in the general surgery, men and women orthopedic surgery, neurosurgery, urology, eye and ear surgery wards of educational hospitals, affiliated to Zanjan University of Medical Sciences. 400 patients, or their envoys, admitted to Zanjan educational hospitals (except psychiatric hospital) in 2017 to undergo surgical operation and were assigned an appointment with the physician, underwent this study. The number of patients decided to be involved in this survey was in proportion to the extent of the hospitals they were hospitalized. The samples were selected on stratified random sampling method when they were admitted to the hospital in different times (morning and evening) of the week based on the timetable the patients were admitted to the surgical operation ward in each of the hospitals under investigation. The sample selection process was this way: The sample size required for this study was decided initially and then the patients undergoing operation in each ward a day were taken into consideration for the purpose of sampling. Then samples were drawn from the population of patients in the surgical center. (The patient samples were taken in proportion to those referring to the center to undergo surgical operation). The next phase of this survey marked interviews for several days with all the patients at the time of discharge. The informed consent signatories, who were parents or legal guardians of the patients falling under the 18 years of age and thus not yet qualified to fill up and sign the informed consent sheet, and of those not being in psychologically good mood, being mentally retarded and devoid of any sense, were asked to fill up the questionnaire. The consenting persons were excluded from the survey if were absent. The instrument for collection of data was questionnaire, designed based on library studies and with respect to the study of Sheikh Taheri et al [1] and Amini et al. [11]. It fell into two parts: General and specialized. The general part sought demographic and background information of the patients like age, sex, number of hospitalization, marital status, job, education status and the quality of hospitalization, while the specialized part included 40 questions presented in five sections. Six questions asked about the informed consent signing process, 14 about the degree of information sharing with the patient, three asked about the degree of the informed consent form's understandability and six items asked about physician's communication with the patient.

To ensure validity of the questionnaire, the researcher used methods for assessment of content validity: Two surgeons, two ethics specialists, two patients and four members of the board of instructors in the field were asked to express opinion on the content of the questionnaire. Cronbach's alpha coefficient was used to check the internal reliability of the questionnaire. To ensure internal reliability of the questionnaire, it was distributed among twenty patients before the main phase of the study and after data collection, the data were analyzed through SPSS software. The data thus obtained showed that Cronbach's alpha coefficient was at the level of 0.85. The figure suggested that the questionnaire was both

reliable and valid. The questions were developed based on the Likert scale and after scoring, the scores were divided into five categories: highly inappropriate, inappropriate, average, appropriate and very appropriate. The questionnaire was cleared of any ambiguity with respect to the answers given by the patients. Then the time for distribution of the questionnaire among the respondents was decided. The questionnaire was given to the patient or the consenting body after the patient's admission to the ward and before surgery and was returned back instantly once filled up in presence of the researcher. The questions of the questionnaire were explained well to the respondent on demand. The responses were rated as "Very Inappropriate" with a score of zero, "Inappropriate" with a score of 1, and "Medium" with a score of 2. It also received a "good" score of 3 and a "very good" score of 4. The questionnaires filled up by the respondents were interpreted by the SPSS software version 19. The mean value, the 95% confidence interval and standard deviation of scores for all five dimensions of the informed consent were estimated. An acceptable score of four was set for each question. Thus, the total number of questions related to submitted information was 56 points, comprehensibility of 12 points form, 24 points voluntary, 44 points interaction and communication and the process of signing consent form was 24 points. Average scores falling below 25% were rated as poor, those within the range of 25% to 50% were considered as moderate, those within the range of 50 to 75% were taken as good, and those within the range of 75% or more were regarded as excellent. The questionnaires filled up by the group were analyzed using such descriptive statistics indices as frequency distribution tables, charts, percentages, averages, etc.; various tests were used in accordance with the levels for measurement of the (nominal, sequential, interval and relative) variables: Pearson test was used to analyze the correlation of variables; Kolmogorov-Smirnov test was used to check the normality of the data and the non-parametric tests of Mann-Whitney and Kruskal-Wallis were used for path analysis and structural equations.

Results

A total of 400 people filled up the questionnaire. They fell with the age range of 20 and 72. Their age average was 33.78. Table 1 shows other demographic information of the group.

Table 1: Demographic information of the participants

Background Features		Number	Frequency
Sex	Male	211	53%
	Female	189	47%
Marital Status	Married	240	60%
	Single	160	40%
Education	Primary or Under Diploma	156	39.8%
	Diploma or Post-Diploma	138	34.5%
	Graduate or higher	106	26.5%
Type of Hospitalization	Emergency	216	54%
	Ordinary	184	46%
Number of Hospitalization	Without Precedence of Hospitalization	232	58%
	Twice	92	23%
	Three Times	42	10.5%
	More than three times	34	8.5%

Table 2 illustrates information on the five dimensions of the informed consent process. Based on the data, 24% of the samples considered the procedure for signing of the informed consent as “appropriate”; moreover, 19% considered that the way the information was offered was “appropriate”; 3% of the individuals believed that the voluntary nature of informed consent receipt was “appropriate” and 19 percent said communication between physician and patient was at the “appropriate” level. They knew. A total of 24 patients (6%) had signed the informed consent themselves, while the forms for 336 others (84 percent) were signed on their behalf by the spouse; for 22 (5.5%) patients, however, the forms were signed by their father or parents and

for 18 patients (4.5%) other individuals had signed the forms. Investigation of each part of the questionnaire showed that 32% of patients were embarrassed and anxious when filling up the informed consent form; 45% of patients considered that the medical explanations regarding the surgical complications were at the "moderate" level and 30% of the respondents evaluated the explanations as "inappropriate." Sixty percent of patients rated the understanding of the technical jargons of the informed consent form as "inappropriate" and 47% of the individuals believed that physician-patient contribution and cooperation in various stages of the treatment was "inappropriate." Furthermore, 30% of the patients believed that their choice of treatment was at the moderate level, while 45% took it as "inappropriate." 85% of the patients were interested to receive comprehensive information on their disease and their treatment by the physician and 15% were reluctant to receive the information. Twenty percent of the samples believed that understandability of the physician's explanations on the treatment process were at "appropriate" level and 53% said they were at the "moderate" level.

The results showed no significant relationship between sex and marital status and overall score of the questionnaire dimensions but there was a significant relationship between the type of hospitalization and the type of information and the process of signing the consent form (Mann-Whitney test). This means that the average satisfaction with the information provided in the normal hospitalization group was higher than that in the emergency one. According to Kruskal-Wallis test, there was a statistically significant relationship (p value being less than 0.001) between the number of hospitalizations and the type of occupation and the form signing process. This is while the people with the precedence of hospitalization for three or more times and the staff group were more satisfied with the informed consent form signing process. There was a statistically significant relationship between the score given to comprehensibility of the questionnaire (0.006), voluntary consent process (0.002) and the relationship between the variables of the physician-patient communication and the educational level (0.005). This means that the mean of the dimensions mentioned was higher in the group holding the bachelor's and higher educational degrees.

Table 2: Frequency Distribution of Responses Given to Questionnaire in Proportion to Dimensions of the Questionnaire

		Type of Answer						
		Very Appropriate	**Appropriate**	**Neither Inappropriate Nor Appropriate**	**Inappropriate**	**Highly Inappropriate**	**Average**	**Variance**
Dimensions of the Questionnaire	**Informed Consent Signature Process**	25	72	153	15	35	2.69	1.58
	Information Submission	18	61	143	96	82	2.32	1.63
	Level of Understandability of the Informed Consent Form	1	11	76	143	169	1.88	1.97
	The Degree of Voluntariness of the Process for Receipt of Informed Consent	1	50	104	125	120	2.15	2.34
	Physician-Patient Communication Level	29	49	106	135	86	2.43	2.41

Discussion

This study revealed that inappropriate information is provided to the patients on filling up the informed consent form prior to surgery. Patients do not consider the informed consent form comprehensible and the choice of treatment as

voluntary. They also believe that the type of relationship between the physician and the patient is "inappropriate". The findings fall in line with results of similar research [1,8,10,11].

This research proved that there is no relationship of significance between age and sex and marital status and collection of the rates given to different dimensions of the questionnaire. However, San showed that there is a relationship of significance between the degree of the provided information and the age and sex of the patient [12]. Howlader (2004) proved that patients younger than 60 are more willing than the older patients to be informed of the complications and possibility of death; however, there was no difference of significance between the willingness [13]. Amini et al. (2009) showed that there is direct relationship between the marital status of the patients and the degree of information of the informed consent form given to the patients: The married patients were more informed than the singles in filling up the informed consent [11]. Regarding the degree of information provided to the patients differentiated by type of their hospitalization (ordinary or emergency), Amini et al. believed that the emergency and non-emergency patients were equal and similar in terms of their information.

One more component influential in informed consent is "extension of enough information" on the type of the disease and its importance, likely benefits and consequences of the proposed surgery to the extent that any refusal to provide enough information will serve as the root cause of many post-surgery complaints against the physicians at the judicial and legal courts [14]. The results of this study also showed that 45 percent of the patients considered the explanations given by the physician on the surgery consequences as "moderate", while 30 percent took it as "inappropriate." Furthermore, 85 percent of the patients were willing to receive enough information on the disease and the method of medication on part of the physician. Therefore, the component was not in an appropriate level and most of the patients were not well provided with enough information on the type and importance of their disease as well as the likely benefits and adverse consequences of the suggested surgery. The patients, holding bachelor's degree and higher had been provided with more information and were more interested to receive the information. The finding was in line with that of San et al. (2000) [14]. Taghadossinejad et al. (2018) believed that offering informed consent related information to the patients prior to surgery was not well done [15]. In the same vein, Mirbagher Ajorpaz et al. (2019) showed that the extent of information, provided to the patient on the choice of surgical operation, did not seem enough and the patients needed to receive enough information [16].

Sixty percent of the patients considered the comprehensibility of the technical jargons in the informed consent form as "inappropriate" and 53 percent of the respondents rated comprehensibility of physician's explanations on the treatment procedure as falling in the "moderate" level. The informed consent form was not understandable for 97 percent of the patients and had relationship of meaningful significance with the variable of the level of education. This means that this dimension of the group was higher in average than that in the group holding bachelor's and higher degrees. Those distinguished with educational degrees below bachelor's degree imagined that understanding the informed consent form content was more difficult for them. Another study confirmed non-comprehensibility of the informed consent forms [3]. Sheikh Taheri et al. (2010) showed that it was more difficult for those holding degrees blow diploma to understand the forms. Sometimes the signatories signed it irrespective of its content [9]. This research also observed evidences of difference of significance between the age and educational status and understandability of the informed consent form to the extent that the brochures provided helped the patients (and their envoys) to find the informed consent form more understandable. Overall, the "comprehensiveness and understandability" of the informed consent form was not in an appropriate position. The following factors seem to influence understandability of the informed consent forms: The literacy level of the consenting individuals; careful study of the form; transparency of the explanations; and explanation of the contents by an informed individual. Therefore, it is necessary to encourage patients to study the informed consent form and provide them (especially those less literate) with enough information. Moreover,

introducing other sources of information (including brochure) will provide more information, leading to better understanding of the form.

Thirty percent of the patients involved in this study rated their voluntary choice of treatment as "moderate" and 45% as "inappropriate." Therefore, the informed consent was at a "poor" level considering its voluntary nature and patients viewed the choice of treatment as "less voluntary." Other studies also point to the patients' unawareness of other kinds of treatment and their benefits and side effects [1]. The undergraduates and those, who used supplemental resources, and those receiving information from non-physicians and surgeons also believed the process of obtaining informed consent is more voluntary. Simon et al. (2019) believe that compared to adults, who consent to themselves, the parents, who consent to their children, receive more information about voluntary participation and exclusion from the study. The finding is inconsistent with findings of the present study [17]. The results of this study showed that 47% of the respondents considered the physician-patient contribution and participation in different stages of treatment as "inappropriate" and overall, it seems that the voluntary participation in research is more important for the specialists than the treatment.

Therefore, physicians and surgeons need to pay more attention to this issue. This study also revealed that there was no good relationship with patients in the studied hospitals while obtaining informed consent, but other studies reported a good physician-patient relationship [8,12].

The patients, who benefited from complementary information sources, reported that they had better encounter with them. As said earlier, the crowding of the public hospital is likely to result in less time allocation for the patients. Therefore, providing alternative methods such as pre-recorded audio tapes or written brochures as sources of awareness raising prior to signing of the informed consent form seem to be helpful in this regard.

The mean time interval for submission of information in the public hospitals and filling up of the questionnaires was one to seven days. There is a long time span between offering of information in Zanjan's public hospitals and the surgery date. This might be due to the fact that this study only included the patients who had been admitted for surgery; therefore, majority of them were provided with information prior to reception and mainly at the physician's office or hospital clinic. Possibly the long waiting list added to the time span. Therefore, it seems necessary to take necessary measures to raise awareness of the patients on public hospitals. The information can be provided through right resources or appropriate brochures published for the purpose. This study also came up with the finding that 32 percent of the patients were fearful and embarrassed while filling up the information consent form. Scholars consider the following factors are involved in the process of failure to offer information under discussion: Inability of the patient to understand the information; patient's disinterest in contribution to the treatment; fear, anxiety and wrong decision [18].

Another study found that request of the patient's family (18%), time constraint (16%), the possibility of the patient's depression (11%), and patient's reluctance to receive information (7%) were the most important factors that physicians considered as impediments to receipt of information [19]. Another study showed that physicians believed that emotional stability and acceptance of reality in the incurable patients as an obstacle to telling of the truth [20]. As far as patient's reluctance is concerned, this study showed that 15% of patients were reluctant to receive complete information about the disease and its treatment. Other studies, however, have shown that patients are reluctant to receive further information [10,11]. A study in Tehran revealed that only eight percent of patients thought that information, provided to them, was sufficient and majority of patients desired receiving maximum amount of information on different fields [5]. Howlader et al (2004) showed that 81% of patients held that they needed receiving more information if were to do the same again [13]. This study was performed on all types of diseases and the researchers had no questions regarding diagnosis of the patients' disease. The methods taken by physicians for treatment of patients may vary depending on the type of disease and the conditions that cause the disease. Therefore, further studies need to be conducted in this concern. There were cases (3 persons) that

consent was obtained from persons under 18 years of age. Furthermore, 68 of the women taking part in this survey required receiving the consent of their husband; however, 45 individuals were not required to receive consent of their husband. Patient decision-making competence (both legally, such as age, person authorized to consent to the patient, and capacity to receive information and decision making) is one of the important aspects of obtaining consent that was not part of the objectives of this study; therefore, further studies in this regard are recommended to be made. Also, due to the lack of complementary statistical methods, the possible relationships between variables have not been investigated, which should be considered in future studies. Additionally, only certain factors relating to informed consent were studied in this research and the selected patients were people with lower socio-economic status based on existing policy in Iran; therefore, the results thus gained cannot be generalized to all segments of the target population. In addition, a group of patients were reluctant to participate in the development and filling up of the questionnaire because of the post-surgery complications such as the post-surgery pain. As for other limitations of the study, reference should be made to the low number of the informed and knowledgeable legal, financial and judicial experts available to comment on the subject of informed consent. The researchers tried their best to compensate for the failure through seeking help of the social medicine team and forensic experts.

This study proved that patients are willing to receive more information; furthermore, the study revealed that there is a disagreement between physicians and patients regarding the type of information provided. This should be considered when providing information to patients. So, appropriate measures need to be adopted to raise awareness of patients, especially making those less literate and general hospital patients more aware. Due to prolongation of the time span between presentation of information and surgery, future studies are suggested to present the sources of pre-surgery information such as distributing leaflets to patients and updating their information. Providing other sources of information (like brochures) will ensure a positive impact on the three dimensions of voluntary receipt of information on the informed consent; comprehensibility of the consent form, and the patient-physician communication. The breakthroughs can be considered as appropriate strategies of the awareness raising process. As the final word, offering complete and balanced information as well as raising awareness of patients seems to leave negative impact on concern of the patient.

This study surveys different dimensions of receiving pre-surgery informed consent from a group of patients in a city; therefore, more studies need to be conducted. Furthermore, it is recommended to conduct a study to cover other aspects of the voluntary informed consent and the competency of the patients in making related decisions.

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Conflict of interest

The authors of this article confirm that there is no conflict of interest with regards to present study.

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