

Importance of Informed Consent in Clinical Practice

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ABSTRACT

Introduction: This study aims to determine the experiences and opinions of physicians on informed consent practices, to research their awareness of their legal responsibilities, and to provide solutions to the problems encountered in practice.

Methods: This research is a descriptive field study. One hundred and eighty-four physicians working in a state hospital in İstanbul participated in this study between January 15 and February 15, 2018. The questionnaire form was used as a data collection tool. After the participants were informed about the purpose and method of the research, their consent was obtained, and they were asked to fill in the questionnaire forms. The analysis of the data was performed using the SPSS 18.00 program. The significance level was accepted as $p < 0.05$.

Results: One hundred and eighty-four physicians working in a state hospital in İstanbul participated in this study. 69% (n=127) of the physicians participating in the study were male and 31% (n=57) were female. 35.3% (n=65) of the participants were from the 30-39 years old age group. 96.7% (n=178) of the physicians in the study stated that they personally informed their patients before the surgical interventions. 83.7% (n=154) of the physicians think that the lawsuits filed against the physicians due to medical malpractice affect the health services provided by the physicians to their patients. 61.4% of the participants (n=113) think that they have not received enough education in their medical education processes regarding the rights and obligations of the physicians.

Conclusion: Considering the current situation in Turkey, the informed consent process is not yet at the level it should be. Since human rights are in the process of development in the world, informed consent and many more patient rights will gain importance with studies on this subject. Therefore, training, and studies should be increased to inform physicians and patients about informed consent and to make them a behavioral model physicians.

Keywords: Informed consent, physician, patient rights

Introduction

Informing patients and obtaining their consent are both legal and ethical requirements within the framework of contemporary medical practice. Before any medical practice, it is one of the basic rights of patients to be informed about their diseases in accordance with their sociocultural background so that they can provide their informed consent. This process is an important element of the current medical approach in legal and ethical terms as a requirement of the principle of respecting the autonomy of the individual and the responsibility of the physician (1,2).

In the third section of the Patient Rights Regulations, which entered into force in Turkey on August 1, 1998, the right of patients to obtain information about their own health status is regulated. According to the regulations, patients have the right to request verbal or written information about the possible causes of the disease and how it will progress, by whom, how and for how long the medical intervention will be performed, alternative treatment methods, benefits and risks of

treatment, possible complications and consequences in case of refusal of treatment (3).

Previous studies on informed consent have noted that patients who were adequately informed in the preoperative period and had a detailed preparation for surgical intervention had a more successful process (4-6).

Recently, the concept of informed consent has begun to be further discussed in legal and medical circles in Turkey. Moreover, the awareness of both healthcare professionals and patients on this issue has increased. This process has also led to lawsuits against physicians for allegations that the patient was not adequately informed, or that the information obtained did not provide the appropriate conditions. Compared to the past, there are many more cases concerning only alleged deficiencies in the application of the right of informed consent.

With advanced technological applications becoming frequently used in the field of medicine, physicians have become able to perform riskier



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interventions. Additionally, the expectations of patients from these applications have increased. Physicians face more complaints due to these high expectations and increased awareness. If physicians are familiar with the legal regulations in their fields, manage the informed consent process correctly, show sufficient care, and spend sufficient time on patients in the process, the problems in this area will be minimized.

The aim of this study is to determine the experiences and opinions of physicians on informed consent practices, to research their awareness of their legal responsibilities, and to provide solutions to the problems encountered in practice.

Methods

This research is a descriptive field study designed to determine the experiences and opinions of physicians on informed consent practices and to investigate their awareness of their legal responsibilities.

One hundred and eighty-four physicians working in a state hospital in İstanbul participated in this study between January and February 2018. The questionnaire form was used as a data collection tool. After the participants were informed about the purpose and method of the research, their consent was obtained, and they were asked to fill in the questionnaire forms.

The questionnaire form consisted of four parts. The first part consists of 6 questions about the sociodemographic characteristics of the participating physicians. The second part consists of 11 questions about the physicians-way of obtaining informed consent, whether they received training on informed consent and their opinions on the legal consequences of informed consent. The third part consists of 8 questions about the attitudes of physicians during the informed consent process. The fourth and final part consists of 9 statements about their views on informed consent.

The study was approved by the Acibadem Mehmet Ali Aydınlar University Local Ethics Committee (approval number: 2018-1-37, date: 11.01.2018).

Statistical Analysis

Data were analyzed using the SPSS 18.0 package program. Statistical analyses were conducted with frequencies, percentages and the χ^2 -test. A p-value less than 0.05 was accepted as significant.

Results

One hundred and eighty-four physicians working in a state hospital in İstanbul participated in this study between January and February 2018. 69% (n=127) of the physicians participating in the study were male and 31% (n=57) were female. The age groups of the participants were analyzed in five groups- 25-29, 30-39, 40-49, 50-59, and 60+ years old. Thirty-39 years old age group was the largest group. 35.3% (n=65) of the participants were from the 30-39 years old age group. Of the physicians participating in the study, 72.8% (n=134) were specialists, 25.5% (n=47) were residents and 1.6% (n=3) were general practitioners. The years of work experience of the participants were analyzed in four groups-0-10, 11-20, 21-30, and 30+ years. Participants were most commonly within the 0-10-year group, with 41.8% (n=77), in terms of working time in the

profession. The sociodemographic characteristics of the participants are in Table 1.

96.7% (n=178) of the physicians in the study stated that they personally informed the patients before the surgical interventions. The behavior of the physicians when having patients sign the consent form is shown in Table 2.

The views of the physicians on the implementation of the informed consent procedure are shown in Table 3.

52.2% (n=96) of the physicians believe that obtaining informed consent from the patients before surgical interventions will protect the

Table 1. Sociodemographic characteristics of the physicians participating in the study

	n	%
Gender		
Male	127	69
Female	57	31
Age		
25-29	51	27.7
30-39	65	35.3
40-49	47	25.5
50-59	17	9.2
60+	4	2.2
Title		
Specialist	134	72.8
Resident	47	25.5
General practitioner	3	1.6
Years of work experience		
0-10	77	41.8
11-20	59	32.1
21-30	23	12.5
30+	7	3.8
Specialty		
Department of surgical sciences	96	52.2
Department of medical sciences	85	46.2
Department of basic sciences	2	1.1

Table 2. The behavior of the physicians about having patients sign the consent form

	n	%
Please mark the appropriate option for you below		
I read the consent form out loud to patients, patients sign it themselves.	50	27.2
I have patients read the consent form, patients sign it themselves.	107	58.2
I have nurses read the consent form out loud to patients, patients sign it themselves.	2	1.1
I have patients sign the consent form without having it read.	12	6.5
I have relatives of patients sign the consent form instead of patients themselves	1	0.5
Other hospital staff have the consent form signed	9	4.9

Table 3. The views of physicians on the implementation of the informed consent procedure

	n	%
Do you think the informed consent procedure is implemented correctly in Turkey? If not, what do you think is the reason for this?		
I think the procedure was implemented correctly.	34	18.5
I don't think informed consent procedure was implemented.	64	34.8
Reasons:		
Adverse working conditions		
Insufficient number of existing health personnel	48	26.1
Healthcare professionals not showing the necessary diligence	41	22.3
Not having enough information about informed consent	31	16.8
patients not caring informed consent	25	13.6

healthcare personnel from medical practice errors. 83.7% (n=154) of the physicians think that the lawsuits filed against the physicians due to medical malpractice affect the health services provided by them.

13.6% (n=25) of the physicians participating in the study have a lawsuit or an investigation filed against them regarding alleged medical malpractice. When asked what they would do if they took action that would fall within the scope of medical malpractice, 51.1% (n=94) of the physicians gave the answer-I will immediately report this situation to the hospital management-For the same question, 25.5% (n=47) of the physicians answered-I share this situation with the patient- 12% (n=22) of them answered as "I only share this situation with my close friends/family- and 7.6% (n=14) of them answered-I do not share this situation with anyone-

61.4% of the participants (n=113) think that they have not received enough education in their medical education processes regarding the rights and obligations of the physicians. The attitudes of the surgeons toward the content of informed consent are shown in Table 4. The agreement of the physicians with the statements about informed consent is shown in Table 5.

Discussion

Informing patients in accordance with their sociocultural background and then obtaining their consent for medical intervention is a basic patient right, which is included in national and international regulations (1,2). Nowadays, the awareness of patients in this field and their expectations from physicians have increased with the developing technology. This has led the physicians to face legal problems recently in Turkey.

It is very important that physicians are adequately knowledgeable about their legal rights and obligations. Since obtaining informed consent is a legal obligation and a condition for the respect of the autonomy of patients, physicians must be familiar with the law. Additionally, physicians should know about the content of informed consent and when and from whom it should be obtained. Therefore, physicians should be educated about their legal responsibilities-both during their medical education and while practicing their profession (7). In the study, 61.4% (n=113) of the physicians stated that they did not receive sufficient education regarding the rights and obligations of the physicians in the

Table 4. The attitudes of the surgeons toward the content of informed consent

	n	%
Before the surgery, I informed the patient in detail about the disease that caused the patient to undergo surgery		
Yes	89	97.8
No	2	2.2
Before the surgery, I inform the patient about the problems he/she may encounter in case of not having surgery		
Yes	90	98.9
No	1	1.1
If the patient agrees to undergo surgery, I inform him/herest about the possible risks of the surgery		
Yes	87	95.6
No	4	4.4
Before the surgery, I informed the patient about the available alternative treatment methods		
Yes	82	90.1
No	9	9.9
Before the surgery, I inform the patient about how long he/she will stay in the hospital after the surgery, the issues to be careful about after the surgery, and when he/she will return to his/her normal activities after the surgery		
Yes	85	93.4
No	6	6.6
Before the surgery, I introduce the surgical team to the patient		
Yes	7	7.7
No	84	92.3
I use medical terminology while informing the patient		
Yes	14	15.4
No	77	84.6
I inform the patient about the risks that are very unlikely to occur		
Yes	62	68.1
No	29	31.9

medical education process. In another study, when physicians were asked about the adequacy of the education they received regarding their rights and obligations, 85.9% of them stated that education was inadequate (6). In the study by Yaşar Teke et al. (8), this rate was found to be 82.4%. As seen in the studies conducted, physicians generally do not find the education they receive in this field sufficient. If physicians had sufficient knowledge in this field, this would enable them to fulfill their legal obligations, and this will be in the interest of patients. With the provision of graduate and post-graduate training, the concept of informed consent has become more known. Physicians have begun to make more efforts to inform patients about their diseases, to provide the conditions for obtaining their consent based on the information provided, and to manage this process correctly.

In our study, 83.7% (n=154) of the participating physicians are of the opinion that the lawsuits brought against the physicians due to medical malpractice affect the health service provided by them. Physicians may turn to defensive medicine practices under the pressure of medical malpractice (9,10). In the study of Yıldırım et al. (11), when

Table 5. The agreement of the physicians with the statements about informed consent

	n	%
Obtaining informed consent before a surgery is a legal right		
I agree	175	95.1
I do not agree	4	2.2
I have no idea	2	1.1
Obtaining informed consent is an indicator of respect for the patients' autonomy		
I agree	171	92.9
I do not agree	6	3.3
I have no idea	5	2.7
It is correct to obtain informed consent from the patients before every surgery		
I agree	175	95.1
I do not agree	4	2.2
I have no idea	3	1.6
The physician makes the best decision in planning the treatment of the patients, including the surgeries		
I agree	102	55.4
I do not agree	57	31
I have no idea	23	12.5
Physicians should inform the patients about even the smallest risks that may occur during surgery		
I agree	119	64.7
I do not agree	36	19.6
I have no idea	23	12.5
The consent given by the patient when he/she just comes to the hospital remains valid for all medical interventions to be applied to that patient		
I agree	68	37
I do not agree	89	48.4
I have no idea	24	13
The patient has the right not to get information from the physician if he/she requests		
I agree	69	37.5
I do not agree	83	45.1
I have no idea	25	13.6
Even if the patient has information about the health problem he/she has, the physician should provide information		
I agree	142	77.2
I do not agree	24	13
I have no idea	15	8.2
If the physician believes that the patient will be adversely affected if the patient is informed, she may not inform the patient, in this case, this information was retained with the relatives of the patient		
I agree	76	41.3
I do not agree	85	46.2
I have no idea	21	11.4

the participants were asked what impact the concern of being sued for malpractice would have on healthcare, 66.7% of them stated that it would be harmful. When the physicians were asked whether they behaved

recessively in the intervention due to the concern of malpractice, 69.7% of them answered yes (11). This situation actually does not benefit the patients. It is critical to conduct studies to minimize errors in the health system and to organize vocational training and meetings regarding the legal processes in practice.

The physician must inform the patient about the disease, its treatment process of the disease and treatment options. This information should be made in a clear, understandable language and in accordance with the sociocultural background of the patient. Whether the patient understands this information should be checked and their consent should be obtained. During the informed consent process, the physician and patient should be actively involved in the process and patient should decide with his/her free will. In our study, 96.7% (n=178) of the physicians stated that they personally informed the patients before the surgical intervention. In the study of Turla et al. (12), 64.7% of the physicians stated that they obtained consent from their patients before all professional practices. In the study of Jukic et al. (13), just 38% of the physicians stated that they were completely informed about the process of obtaining consent. In our study, 94% of the physicians stated that they informed patients in detail about diseases that caused patients to have surgery before the operation, 96.2% of them stated that they informed patients about the problems they might encounter in case of not having surgery, 94% of them stated that they inform patients about the possible risks of the surgery if the patients agree to have surgery, 85.3% of them stated that they informed patients about the available alternative treatment methods before the surgery, 90.8% of them stated that they informed the patients about how long they will stay in the hospital after the surgery, the points they should be careful after the surgery and when they will return to their normal activities after the surgery. However, 10.9% of the physicians stated that they introduced the surgery team to the patients before surgery, and 15.8% of them stated that they used medical terminology while informing the patients. Nowadays, the awareness of physicians has increased due to the discussions of the issue on different platforms and the legal problems encountered. It can be observed that they care about informing their patients personally and in detail. However, it also appears that there are deficiencies in terms of introducing the surgical team and explaining them in an understandable language without using medical terminology.

In the study, although the participating physicians stated that they informed patients in person and in detail, only 18.5% of them believed that the informed consent procedure was implemented correctly in Turkey. An insufficient number of existing health personnel (26.1%), adverse working conditions (34.8%), healthcare professionals not showing the necessary diligence (22.3%) and patients not caring informed consent (13.6%) are mentioned as possible reasons for this. In a study conducted on healthcare professionals, 47.6% of the interviewees partially agreed that the process of informed consent was applied correctly. In the same study, the reason why informed consent was not implemented at the desired level was attributed to the insufficiency of the number of personnel (33.6%) and adverse working conditions (23.8%). Furthermore, it was seen that 56.6% of the participants considered consent as an assurance of proof, and 62.2% of them shared the opinion that the responsibility for obtaining informed consent belongs to the whole

team (11). In the study by Turla et al. (12), 84.3% of the physicians spent less than 10 min to inform their patients. Among the reasons for this, it was stated that the number of personnel was insufficient.

Study Limitations

Our study has no limitations.

Conclusion

Considering the current situation in Turkey, the informed consent process is not yet at the level it should be. Since human rights are in the process of development in the world, informed consent and many more patient rights will gain importance with further studies on this subject. Therefore, training and studies should be increased to inform physicians and patients about informed consent and to make this a behavioral model for physicians. It is critical to define the problems regarding informed consent, which is one of the basic elements of patient rights, and to develop strategies for solving these problems. The awareness of healthcare professionals about informed consent should be increased, and continuous educational activities should be emphasized to make standard practice a behavioral model.

Ethics Committee Approval: The study was approved by the Acıbadem Mehmet Ali Aydınlar University Local Ethics Committee (approval number: 2018-1-37, date: 11.01.2018).

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