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Evaluating the Efficiency of the Informed Consent Forms of the Patient Files Which Were Notified of Erroneous Medical Intervention

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ABSTRACT

If a medical intervention was lawfully performed, a criminal liability does not exist under any circumstances. Only liability arising from an erroneous medical intervention can be related with the concepts of penal law, obligations law, and compensation liability of the administration. Likewise, disciplinary practices of trade bodies such as Medical chambers can be brought to agenda due to erroneous medical intervention. Therefore, it is vitally important to ensure the existence of legal bases before any medical intervention. "Informed consent" is the most important document ensuring that a medical intervention is legal. When the understanding of patient-oriented health services was adopted in North American and European countries in the twenty-first century, the views supporting the patients' making their own medical decisions about themselves started to replace the provider-oriented approach. In order for the persons to take part in the decisions made regarding their health, they must be fully informed about their medical statuses and the treatment options. The informed consent is important for patient rights, as well as for the physicians' right in case of a complication. The purpose of this study is to determine whether the legal requirements of the informed consent process in the erroneous medical practices that were reflected on the Istanbul Medical Chamber, and set forth the medical and legal results on the files with no Informed Consent Form. In the study, 1528 patient files regarding erroneous medical practice that were informed to the Istanbul Medical Chamber between 2009 and 2014 by the victim or the victim's relatives were examined, it was observed that 72.2% of the files had no informed consent form, whereas 27.8% of them had one. It was observed that 44.9% of the existing Informed consents were printed but inadequate, 54.1% of them were printed and adequate, 0.7% of them were specially written for the patient but inadequate, and 0.3% of them were specially written for the patient and adequate.

Keywords: Patient Rights, Erroneous Medical Intervention, Informed Consent

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INTRODUCTION

Contrary to what was believed in during the antique ages, it is not possible for the physician to directly communicate with God. Therefore, physicians cannot promise their patients that they can heal them completely, or keep them alive. They can only promise them that the patient will be benefited from the up-to-date standard medical opportunities with skill and attention. Health system is a sector that is consumed as it is generated, directly related with human life, and labor- and technology-intensive. As a result of these features, it contains within itself many risk factors during the generation and presentation stages[1]. Schimmel identified in 1964 that 20% of the 240 patients who applied to a university hospital were exposed to negative medical practices, and 20% of this 20% had serious and fatal physical damages[2]. A study based on the records of approximately 20,000 patients that were hospitalized in California in 1974 revealed that 4.5% of the patients experienced undesirable incidents, and 1% of them experienced incidents which occurred as a result of neglect[3]. Steel revealed in 1981 that 36% of the patients that applied to a training hospital were harmed, 25% of the patients harmed faced death risk, and in 50% of these cases the errors were made during the application of the drugs[4]. Gropher determined in 1989 that an average of 1.7 errors were made per patient [5]. It was expressed in Harvard Practice Study in 1991 that 4% of the hospital applications in New York state resulted in physical damage; however, 69% of them were preventable[6]. It was expressed in the famous report, "To Err is Human", published by the Institute of Medicine in November 1999 that 44,000 to 98,000 patients die due to medical errors in the USA every year[7].

The result of these studies is that there is a high risk of patients' being harmed in the healthcare organizations. As mentioned in the beginning, considering the fact that the physicians cannot promise the patient of a recovery of 100%, two main elements are required for the negative medical practice to occur. First is the existence of "negligence", occurring as a result of doing something that was not to be done, and not doing something that was to be done, in a way that the patient will be harmed, failure to comply with the standard procedures, or failure to take the necessary measures beforehand against the risk of the patient's being harmed. In such a case, it is not important whether the informed consent was obtained. A compensation, penal sanction and disciplinary practices will be applied based on the ratio of the severity of harm the error caused for the patient. If the patient was harmed even if the physician paid the necessary attention, took all necessary measures, and he/she has no wrong in the harming of the patient, the issue in question will be complication, not negligence. The intervention is be legalized if the patient was told about all the risks of

complication and gave consent for medical intervention, and no compensation or penal sanction will be applied even if the patient was harmed[8].

Another important feature of health services, which contains in itself high levels of risks, is the great differences between the service providers and patients in terms of knowledge level. In order for the patients to make independent decisions for their own benefits, the physicians must tell them about their illnesses and related information in a way that is understandable for the patient, and plan the treatment process by taking into consideration the priorities of the patient. In a study comprised of Australia, Canada, New Zealand, the United Kingdom, and the United States of America, it was understood that every two to three patients were not given detailed information by the doctor, and were not asked about their opinion on the treatment options[9]. However, it is one of the basic rights of the patient to be informed about their own situation, and to be asked about their opinion regarding the treatment options. The conducted researches show that the health services provided by taking into consideration the needs and preferences of the patients ensure the increase in patient satisfaction, the obtainment of clinically successful results, and the health services to be rendered in a more effective and productive way[10]. When looked at from a legal perspective, a medical intervention is to meet the following conditions in order to be lawful[8]:

- Medical indication
- The physicians to be authorized for medical intervention in the concrete case (area of specialization)
- Patient's consent (informed consent must be obtained)
- The medical intervention to be conducted in compliance with the physician's attention requirement

The legal basis of informed consent is, primarily, Article 17 of the Turkish Constitution, which suggests that, "Everyone has the right to life and the right to protect and develop his material and spiritual entity./The physical integrity of the individual shall not be violated except under medical necessity and in cases prescribed by law; and shall not be subjected to scientific or medical experiments without his or her consent..." [11].

The concept of informed consent in Turkey is based on the other legal statute:

- It was decided in Article 70 of Law no. 1219 on the Mode of Execution of Medicine and Medical Sciences Arts, which came into force in 1928, that for all kinds of operations, physicians and dentists should obtain consent from the patient or, under specific conditions, from the patient's parents or guardian before the operation, and such consent should be written for large-scale operations[12].

- It was stated in Article 14 of the Code of Medical Deontology prepared in 1960 that the patient should be expressly informed on the diagnosis and measures to be taken, unless such information is likely to have an adverse effect on the patient and make the illness more serious[13].
- Law on Taking, Storing and Transfusing Organs and Tissue: It is stated that the donor should be expressly informed on possible risks, dangers as well as psychological, social and medical situations that may occur, and that written and signed consent should be obtained from the donor with two witnesses[14].
- Law on Population Planning: It is stated that informed consent should be obtained for procedures to be carried out[15].
- Patient Rights Regulations: It is stated that nobody should be given medical intervention without or against his/her consent, save for exceptional circumstances[16].

When the legal statute is examined as a whole, the concept of informed consent is possible to be described[17]. Accordingly, informed consent stands for a concept, which –although it was just a doctrine in the beginning– became mandatory to observe in through historical development, based on the opinion that an individual has the right to know and determine all kinds of medical applications on his/her own body, and guaranteed with laws on this issue, for the purposes of protecting the individual's personal rights at the time of illness. While the informed consent is received, the person is to be informed about his/her medical diagnosis, the possible negative situations that may be encountered during treatment, and the interventions to be applied in those negative situations. The patient is to be also explained the alternatives, advantages and disadvantages (if any) of the suggested treatment, the pessimistic scenarios that may occur in case an alternative treatment is applied, and the intervention methods. If the patient does not accept to be treated, the natural course of the illness is to be explained in detail. Finally, based on the information and cultural level of the patient, he/she is to be told nicely about what he/she should do before, during and after treatment. As a constitutional human right, "the right to determine your own future" is the most significant guarantee of the legality of the informed consent concerning the patient.

As the right to determine one's own future is a personal right, the informed consent cannot be legalized by making every patient signed the same printed documents. Even if a printed form is used, the patient-specific condition must be placed in black and white on the informed consent document. It is the responsible physician's duty to inform the patient[11].

There is no distinctive article in Turkish Law regarding the risks to be explained on the informed consent. This situation creates confusion among Turkish physicians with respect to explaining even the distant possibilities or not. In German Law, which is to a large extent

similar to Turkish penal and commercial laws, it is accepted that even a danger with a 3% risk of occurring must be explained to the patient[18]. In compliance with the comparative law principles, a risk of 3% can be defended in Turkish courts as well.

In some cases, the obligation to inform is completely eliminated. The cases in which a medical intervention can be conducted without the patient's consent: The person's being legally incompetent or unconscious during an emergency and a first degree relative's being unreachable, contagious diseases and intoxications determined by the Ministry of Health as a threat to public health, and illegal drug and stimulant addictions[11].

On the other hand, the concept of informed consent is a subject emphasized by both the Joint Commission International Hospital Accreditation Standards and Republic of Turkey Ministry of Health quality and accreditation standards.

Our objective is to put forth whether the legal requirements of the informed consent process in the investigations regarding the cases with the claim of negative medical practice are met, by analyzing the database of Istanbul Medical Chamber.

MATERIALS AND METHOD

In the study, a total of 1528 patient files, whose numbers were detected from the computer database of Istanbul Medical Chamber, which were reached from the archive, including the complaints of victims, and their relatives who applied to Istanbul Medical Chamber between 2009 and 2014 were investigated. 1508 patient files with the indicated areas of specialization were investigated.

During the evaluation of the findings obtained from the study, SPSS (Statistical Package for Social Sciences) for Windows 20.0 program was used for the statistical analyses. In addition to the descriptive statistical methods (Frequency, Percent) used in evaluating the study data, chi-squared distribution was used in comparing the qualitative data.

Table 1: Harm/disability distribution in the cases with erroneous medical intervention notice

Harm/disability	n	(%)
Harm except for permanent disability and death	775	50.7
Permanent disability	196	12.8
Death	233	15.3
No causality	103	6.7
Unharmed	221	14.5
Total	1528	100.0

In the examination, it was detected that 50.7% of the cases experienced harm other than permanent disability and death, 12.8% of them were permanently disabled, 15.3% of them

died, 6.7% of them did not experience any causality, while 14.5% of them were unharmed (Table 1).

Table 2: Informed consent usage distribution in the cases with erroneous medical intervention notice

Informed Consent	n	(%)
Yes	425	27.8
No	1103	72.2
Total	1528	100.0

72.2% of the cases did not have informed consent, whereas 27.8% of them had (Table 2).

Table 3: Informed consent adequacy distribution in the cases with erroneous medical intervention notice

Informed Consent adequacy	**n**	**(%)**
Printed inadequate	191	44.9
Printed adequate	230	54.1
Written inadequate	3	0.7
Written adequate	1	0.3
Total	425	100.0

191 (44.9%) of the informed consents are printed inadequate, 230 (54.1%) of them are printed adequate, 3 (0.7%) of them are written inadequate, and 1 (0.3%) of them is written adequate (Table 3).

Table 4: Comparison of the relationship between the existence of Informed Consent Form and harm in the cases

Harm/disability		**Informed Consent**		p
		No	Yes	
Harm except for permanent disability and death	n	552	223	0,000*
	%	71.2	28.8	
Permanent disability	n	125	71	
	%	63.8	36.2	
Death	n	152	81	
	%	65.2	34.8	
No causality	n	82	21	
	%	79.6	20.4	
Unharmed	n	192	29	
	%	86.9	13.1	

Chi-square distribution was used in analyzing the relationship between harm/disability and informed consent. There was a statistically significant relationship between harm/disability and informed consent ($p<0.05$). In the absence of informed consent, 71.2% was harmed, 63.8% was permanently disabled, and 65.2% died (Table 4).

Table 5: Distribution of the cases with indicated areas of specialization according to the areas of specialization

Specialization	n	%
Gynecology	403	26.7
General Surgery	106	7.0
Orthopedics	79	5.3
Otorhinolaryngology	50	3.3
Urology	35	2.3
Family Medicine	151	10.0
Pediatrics	239	15.9
Neurosurgery	42	2.8
Ophthalmology	84	5.6
Cardiology	120	7.9
Plastic Surgery	29	1.9
Anesthesia	86	5.7
Other	84	5.6
Total	1508	100.0

Table 6: Distribution of the usage of Informed Consent Form in the cases in various areas of specialization

Specialization		Informed Consent		p
		no	yes	
Gynecology	n	283	120	0,000*
	%	26.0	28.6	
General Surgery	n	73	33	
	%	6.7	7.9	
Orthopedics	n	58	21	
	%	5.3	5.0	
Otorhinolaryngology	n	28	22	
	%	2.6	5.3	
Urology	n	19	16	
	%	1.7	3.8	
Family Medicine	n	136	15	
	%	12.5	3.6	
Pediatrics	n	186	53	
	%	17.1	12.6	
Neurosurgery	n	33	9	
	%	3.0	2.1	
Ophthalmology	n	46	38	
	%	4.2	9.1	
Cardiology	n	72	48	
	%	6.6	11.5	
Plastic Surgery	n	16	13	
	%	1.5	3.1	
Anesthesia	n	67	19	
	%	6.2	4.5	
Other	n	72	12	
	%	6.6	2.9	

Chi-square distribution was used in analyzing the relationship between the area of specialization and Informed Consent. There was a statistically significant relationship between the area of specialization and informed consent ($p<0.05$). The presence rate of the informed consent forms was under 5% in Urology, Otorhinolaryngology, Orthopedics, Family Medicine, Plastic Surgery, and Neurosurgery, whereas Gynecology, Pediatrics and Cardiology had the highest number of consent forms. It is observed that the presence or absence of the informed consent forms varies according to the departments (Table 6).

Table 7: Distribution of the examination of the cases conducted by Istanbul Medical Chamber

Result	n	%
Fine	44	2.7
Warning penalty	51	3.1
No action needed	1220	81.4
Ostracizing from profession for 15 days	7	0.4
Ostracizing from profession for 1 month	4	0.2
Adjourned after the lawsuit	21	1.3
Inability to evaluate due to missing papers	9	0.5
Cancellation due to physician's death	3	0.2
Inability of the complainant to provide the required documents	124	7.5
Reconciliation	9	0.5
Lack of evidence	15	0.9
Not related with medical doctorate	3	0.2
Closure due to inability to reach the physician	6	0.4
No action due to nonconformity of the petition	4	0.2
Notified to Social Security	1	0.1
Sending of expert opinion	7	0.4
Total	1528	100.0

It was observed that 81.4% of the examined cases were not put into operation for various reasons, 2.7% of them were fined, and 3.1% of them were warned (Table 7).

RESULTS AND DISCUSSION

Our examination consists of the complaints victims and their relatives who claim that they were harmed as a result of negative medical practices. Istanbul Medical Chamber primarily evaluates the accuracy of the aforementioned claims. The first medical documents examined by the medical chamber is comprised solely of the ones the complainant sent and there is, naturally, no informed consent form among these. If the claim is found appropriate, the patient's medical file is demanded after the physician and the healthcare organization pleaded, and that is when the informed consent form (if any) is reached. Among the examined cases, it was understood that 14.5% of the patients were not harmed, and the claims of the 6.7% of them were not in any way related with medical intervention, therefore, there

was no situation to be deemed flawed. In these circumstances, 21.2% of the cases, the total of the above mentioned rates, were not asked to send the informed consent form.

50.7% of the patients were harmed in some way due to medical intervention, 12.8% of them were permanently disabled, and 15.3% of them died. As all of the medical papers related to these persons were to be demanded from the related physician and healthcare organizations, informed consent forms with a rate of 78.8% should have been sent. However, the rate of informed consent forms in the patient papers was 27.8%. This rate shows that the informed consent document, which ensure the legality of medical intervention, was either never prepared, or it was evaluated by the healthcare providers a simple bureaucratic detail, and the importance of its presence in the defense was not comprehended.

Independently of the flaw, the relationship between the presence or absence of the informed consent document among the defense papers and the complaints of the patients exposed to death/disability/harm was examined, and it was observed that the healthcare providers did not provide the informed consent form in the defense even in the existence of an accusation which was reflected on the professional organizations and whose results may be very serious. We believe that this case constitutes evidence about the fact that the healthcare providers were unable to comprehend the significance of the subject.

When we examine the relationship between the areas of specialization and the presence or absence of informed consent documents among the defense papers, it is observed that the departments of Gynecology, Pediatrics, and Cardiology pay more attention that is statistically significant (Table 6). The fact that these areas of specialization are also among the ones that receive the highest number of complaints makes one think that the healthcare providers gained awareness when encountered with concrete incidents. Among the claims asserted to Istanbul Medical Chamber between 1999 and 2003 with regards to medical error and/or negligence, it is indicated that 27% of them occurred in Gynecology, and 19% of them occurred in General Surgery departments. It is stated that there were 63 and 171 cases in 1999 and 2004, respectively. Approximately 20% of the cases that were proven guilty as charge of the malpractice claim and punished resulted in death. It was detected that 41% of the surgical errors occurred in Orthopedics. 540 files submitted to the Supreme Council of Health between 1995 and 2000 were examined retrospectively, and it was observed in the study that the number of the complications arising from the treatment applied by the surgeons outside of their area of specialization increased, and that as a result of not obtaining or not completing the Informed Consent form, the complaint rates increased due to insufficient information [2]. As a result of the evaluation made by Istanbul Medical Chamber, any flaws

or negligence were not detected concerning the service provider in 81.4% of the applications, and no disciplinary action was needed.

The distribution of disciplinary actions are as follows: 3.1% was warned, 2.7% was fined, 0.4% was ostracized from profession for fifteen days, 0.2% was ostracized from profession for a month, 1.3% was adjourned due to the continuation of the litigation process, and in 0.5% no decision was made due to the inability to obtain the required papers. In 0.2% of the cases, the evaluation process was cancelled as the physician, against whom a complaint was made, died, in 7.5% no decision was made as the complainant did not send the required documents and did not follow his/her complaint, and 0.5% of the cases resulted in reconciliation between the complainant and the physician. 2.2% in total was not concluded due to various bureaucratic reasons (Table 7).

When the decisions of the Istanbul Medical Chamber was examined, it is observed that only in 6.4% of all the applications a decision suggesting that the service provider was flawed was made. Informed consent document was present in only 27.7% of all cases. It is understand from out data that Istanbul Medical Chamber does not consider the absence of informed consent document in defense unless there is a complaint specifically related to the information.

Informed consent is the document ensuring the legality of medical intervention. Even if there is no flaw in medical intervention, the absence of informed consent is considered in itself a flaw.

When a malpractice claim is brought to trial, the only way for the physician to defend himself/herself is to prove that he/she was not negligent in the harming of his/her patient, and that the cause of the harm was complication. The basis of the physician's claim that he/she is not guilty is formed by an adequate informed consent document (with added patient-specific conditions even if printed) to be present among the documents he/she is to submit to the court for defense, and which are prepared specially for the patient.

As the informed consent document includes all risks, even if their possibility of realization is 3%, and the measures to be taken, and is prepared specially for the patient, it determines the quality standard of the presentation of the health service.

It is concluded from the investigation of the claims made to Istanbul Medical Chamber that the significance of the informed consent form is still not comprehended by the service providers. We believe that the on-the-job training programs, in which the professional chambers and specialization associations talk about the significance of informed consent in collaboration with the healthcare-providing institutions, will contribute to the solution of the problem and help the quality standards to rise.

We reckon that the process of service provider awareness will be accelerated if the professional chambers demand the "informed consent" document among the physician defense documents while evaluation the complaints made to them by emphasizing its importance, and if they use sentences underlining the significance of the informed consent in the disciplinary practice resolution texts (even if the sentences are regarding the inessentiality of applying).

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