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Evaluating the Opinions of the Supreme Court and the Council of State on “Informed Consent (Assent)” in Compensation Cases Filed with Medical Malpractice Claim

Tıbbi Malpraktis İddiası ile Açılan Tazminat Davalarında Yargıtay ve Danıştay’ın “Aydınlatılmış Onam (Rıza)” Hususundaki Görüşlerinin İncelenmesi

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ABSTRACT

Objective: Informed consent, which is one of the mandatory elements for the legality of medical interventions, is one of the most important elements of malpractice cases. Physicians are held directly and/or indirectly responsible for fulfilling the conditions of informed consent. Informed consent is stated in international medical ethics documents and has been put into practice with many legal regulations in our country. In our study; we aimed to contribute to the literature by raising the awareness of our physicians on the importance and necessity of the informed consent form by evaluating the reversing decisions of the high courts (Council of State and Supreme Court).

Methods: The decisions made by the relevant departments of the Council of State and the Supreme Court of Appeals between 2013 and 2022 regarding the cases of pecuniary and non-pecuniary damages brought against malpractice claims were examined. Hundred and 2 decisions were impaired due to the absence or lack of an informed consent form included in our study. Specialties of physicians, medical procedures, complications, average litigation times, informed consent forms, and relevant legal regulations were examined and recorded.

Results: A total of 72.5% of all the lawsuits filed in the civil and criminal jurisdictions together with administrative jurisdictions originate from the surgical branches, 100% of the symptoms occurring after the medical procedures were defined as complications, 20.6% of the cases were not prepared with an informed consent form, 24.5% were incompletely drawn up, 3.9% were filed by the relatives of the patients. It was determined that the decisions given by the first instance courts were overturned by the high courts due to incomplete examination, without investigating the informed consent form in 51% of the cases.

Conclusion: Informed consent form is evidence in legal disputes that may arise. Since the burden of proof is on physicians or hospitals, it should be fully regulated within the scope of the provisions of the legislation by the physician performing the procedure himself. Even if the deficits that occur after the medical intervention are accepted as complications, decisions are made against the physicians and hospital administrations by the high courts as a result of the fact that the informed consent forms are not prepared, are incompletely prepared, and signed by the relatives of the patients.

Keywords: Malpractice, informed consent, supreme court and state council

**In the Constitution of the Republic of Turkey and the Regulation on Patients' Rights, the word “assent” is not included and the word “consent” is used. However, since the word “consent” is used in current literature studies and in common usage, we also used the word “consent” in our study.*



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ÖZ

Amaç: Tıbbi müdahalelerin hukuka uygunluğu için zorunlu unsurlardan biri olan aydınlatılmış onam (rıza)* malpraktis davalarının en önemli unsurlarından biridir. Aydınlatılmış onam koşullarının yerine getirilmesinden doğrudan ve/veya dolaylı olarak hekimler sorumlu tutulmaktadır. Aydınlatılmış onam uluslararası tıp etiği belgelerinde belirtilip ülkemizde ise birçok yasal düzenleme ile uygulamaya konulmuştur. Çalışmamızda; yüksek mahkemelerin (Danıştay ve Yargıtay) bozma kararları incelenerek aydınlatılmış onam formunun önemi ve gerekliliği hususlarında hekimlerimizin farkındalığını artırarak litaretüre katkı sunmayı amaçladık.

Yöntem: 2013-2022 yılları arasında Danıştay ve Yargıtay ilgili daireleri tarafından malpraktis iddialarına yönelik açılan maddi manevi tazminat davaları hakkında verilen kararlar incelendi. Aydınlatılmış onam formu yokluğu veya eksikliği nedeniyle bozulan 102 karar çalışmamıza dahil edildi. Hekimlerin uzmanlık alanları, yapılan tıbbi işlemler, meydana gelen komplikasyonlar, ortalama dava süreleri, aydınlatılmış onam formu durumu ve ilgili yasal düzenlemeler incelenerek kayıt altına alındı.

Bulgular: Adli ve idari yargıda açılan davaların toplamda %72,5'inin cerrahi branşlardan kaynaklandığı, yapılan tıbbi işlemler sonrasında meydana gelen arazların %100'ü komplikasyon olarak tanımlandığı, olguların %20,6'sında aydınlatılmış onam formu düzenlenmediği, %24,5'inde eksik düzenlendiği, %3,9'ünde hasta yakınları tarafından imzalandığı, %51'inde aydınlatılmış onam formu durumu araştırılmadan ilk derece mahkemeleri tarafından verilen kararların eksik inceleme nedeniyle yüksek mahkemelerde bozulduğu tespit edilmiştir.

Sonuç: Aydınlatılmış onam formu ortaya çıkabilecek hukuksal uyumsuzluklarda delil niteliği taşımaktadır. İspat yükü hekimlerde veya hastanelerde olduğundan dolayı bizzat işlemi yapan hekim tarafından özen gösterilerek mevzuat hükümleri kapsamında eksiksiz olarak düzenlenmelidir. Yapılan tıbbi müdahale sonrasında meydana gelen arazlar komplikasyon olarak kabul edilse bile, özellikle yüksek mahkemeler tarafından aydınlatılmış onam formlarının düzenlenmemesi, eksik düzenlenmesi, hasta yakınları tarafından imzalanması sonucunda hekimler veya idare aleyhinde kararlar verilmektedir.

Anahtar Kelimeler: Malpraktis, aydınlatılmış onam, yargıtay ve danıştay

**Türkiye Cumhuriyeti Anayasası ve Hasta Hakları Yönetmeliği'nde, "onam" kelimesine yer verilmeyip "rıza" kelimesi kullanılmaktadır. Ancak güncel literatür çalışmalarında ve yaygın kullanımda "onam" kelimesi kullanıldığından dolayı bizler de çalışmamızda "onam" kelimesini kullandık.*

INTRODUCTION

Harm to the patient due to the physician's lack of knowledge, inexperience or negligence is defined as malpractice (1). Although the prevalence and dimensions of malpractice lawsuits are not known clearly, it is seen that there has been an increase in lawsuits filed against all healthcare professionals, especially physicians, in recent years (2).

All procedures performed by legally authorized people in order to diagnose and treat physical or mental illnesses of individuals, to protect them from diseases or to make population planning within the framework of the rules and principles accepted by medical science are called medical intervention (3). Medical interventions should be carried out by authorized people, in accordance with the principles and rules generally accepted by medical science, with the condition of medical necessity (indication), with the informed consent of the patient (4,5). Informed consent, which is one of the mandatory elements for the legality of medical interventions, is very important in terms of respecting the autonomy of individuals and the right to determine their future. Informed consent is the acceptance or refusal of medical interventions to be made by individuals of their own free will without any external coercion (6,7). Physicians are held directly and/or indirectly responsible for fulfilling the conditions of informed consent. Informed consent is stated in international medical ethics documents and has

been put into practice with many legal regulations in our country (4,8).

In our study, we aimed to contribute to the literature by raising the awareness of our physicians on the importance and necessity of the informed consent form by examining the reversal decisions made by the high courts (the Supreme Court and the Council of State). The decisions in the filed malpractice claims and compensation cases were reversed due to the insufficient informed consent form or due to the absence of the informed consent form; which were not found guilty by the first instance courts (law, consumer, administrative courts) where the expert reports received in the appeal phase.

MATERIAL AND METHODS

File Review and Grouping

In our study; the decisions of the years 2013-2022, which we reached by using the keywords "informed consent" (by using the Turkish phrase "aydınlatılmış onam") on data banks (both from the official website of the Presidency of the Supreme Court of Turkey and from Legalbank) were combined and included. The decisions were belonging to the 15th Chamber of the Council of State and the 10th Chamber of the Council of State, to which it transferred its duties after this chamber was closed, the 13th Civil Chamber of the Supreme Court of

Appeals and the 3rd Civil Chamber of the Court of Cassation, to which it transferred its duties after this chamber was closed. The decisions were evaluated regarding the cases of pecuniary and nonpecuniary damages brought against malpractice claims. Among the decisions, 102 decisions were included in our study, which stated that there was no fault of the physicians or the administration in the expert opinion reports taken by the courts of first instance (law, consumer, administrative courts). However, they were rejected and were overturned due to the absence or insufficiency of an informed consent form. Data were examined according to the specialty of the physicians, medical interventions performed, the consequences of medical interventions performed, average litigation times, whether the informed consent form was prepared, the deficiencies in the informed consent forms by the appeal authorities and the opinions on how they should be arranged, the legal regulations on which the grounds for the annulment decisions by the appeal authorities were based.

Statistical Analysis

The results were recorded in the Excel 2016 for Microsoft program, and the findings were shown in tables and the characteristics of the cases were examined. Analysis of the data were done with SPSS 25.0 for Windows (SPSS Inc., Chicago, IL). Invariable groups were compared with chi-square tests (Pearson chi-square, Fisher's Exact test) and the statistical alpha significance level were accepted as $p < 0.05$.

RESULTS

There were 102 decisions of the 3rd and 13th Civil Chambers of the Supreme Court of Appeals and the 10th and 15th Chambers of the Council of State meeting the conditions for our study between 2013 and 2022. It was determined that 39.2% ($n=40$) of the decisions were cases originating from state/foundation/university hospitals and were given by the Departments of the Council of State, while 60.8% ($n=62$) were cases originating from private hospitals and were given by the Court of Cassation Law Offices (Table 1).

It was found that in 100% ($n=102$) of the cases, reports were obtained from the Council of Forensic Medicine or the expert

committees of universities by the first instance courts of civil and administrative jurisdiction. It was determined that in 100% ($n=102$) of the reports received; the deficits occurring after the medical procedures were defined as complications. It was stated that there was no fault of the physician/health personnel or the service fault of the administration, and the cases were rejected by the first instance courts of civil and administrative jurisdiction. When the cases are examined in terms of trial periods; on average in the civil and criminal jurisdictions; it was seen that 1.2 years after the event date were passed and in administrative jurisdiction; it was seen that 2.2 years after the event date were passed for an application to the courts of first instance to file a lawsuit. In first instance courts; it has been determined that the trial takes approximately 3.5 years in the civil and criminal jurisdictions and 4 years in the administrative jurisdiction. In the appeal stages, it was determined that the cases were resolved in an average of 2.4 years in the administrative judiciary and 1.9 years in the civil and criminal judiciary. It was determined that the cases took an average of 3.7 years in the courts of first instance, and an average of 2.1 years in the Civil Chambers of the Council of State and the Supreme Court, without making any distinction between administrative jurisdictions and civil/criminal jurisdictions.

It was seen that 27.5% ($n=28$) of the cases were originating from branches belonging to internal sciences and 72.5% ($n=74$) were originating from surgical branches and this difference was statistically significant ($p < 0.05$) (Table 1).

The first three frequency order of the cases according to the specialties; it was determined that 22.5% ($n=23$) opened up against the emergency, 16.6% ($n=17$) obstetricians and 14.7% ($n=15$) general surgeons (Table 2). Of the most common medical interventions, 53.9% ($n=55$) were surgical interventions, 26.5% ($n=27$) intramuscular injections, 19.6% ($n=20$) were due to delivery, medical treatment and diagnostic procedures and statistically significant difference was found ($p < 0.05$) (Table 1). It was determined that death occurred in 4.9% ($n=5$) of the cases related to medical procedures, and that many other cases had symptoms at a level that would cause permanent weakening or loss of function in the senses/organs (Table 2).

Table 1. Health institutions, departments and medical interventions

Groups		% (n)	p-value
Health institutions	Private hospitals	60.8 (62)	$p > 0.05$
	State/university/foundation hospitals	39.2 (40)	
Departments	Surigical departments	72.5 (74)	$p < 0.05$
	Internal departments	27.5 (28)	
Medical interventions	Surgical interventions	53.9 (55)	$p < 0.05$
	Intramuscular injections	26.5 (27)	
	Delivery, medical treatment and diagnostic procedures	19.6 (20)	

Chi-square tests: $p < 0.05$

Table 2. Specialties (clinics), medical procedures and complications				
Clinics	Medical procedures	Complications	n	Total
Emergency Medicine	intramuscular injection	Injection neuropathy	22	23
	Chest pain, medical treatment	Death	1	
Anesthesia and Reanimation	General anesthesia	Malignant hyperthermia	1	3
	Epidural anesthesia	Paraplegia	1	
	Stabilization, lithotomy position	Peroneal nerve damage	1	
Neurosurgery	Lumbar disc surgery	Low back pain, anejaculation, iliac artery incision wound	2	7
	L2-3 extruded microdiscectomy surgery	Paraplegia	1	
	Post-operative injection in the service	Injection neuropathy	1	
	Vertebral fracture surgery	Infection at the surgical site	2	
	Cauda equina syndrome, laminectomy surgery	Urinary/anal incontinence, paraplegia	1	
Pediatric Surgery	Hirschsprung disease, transanal soave surgery, torso anastomosis	Intestinal, ureter injury	1	1
Gastroenterology	Colonoscopy	Perforation of the sigmoid colon	2	2
General Surgery	Bilateral total thyroidectomy	Voice restriction, vocal cord paralysis, shortness of breath	4	15
	Stomach reduction surgery	Leakage, death	1	
	Post-operative injection in the service	Injection neuropathy	1	
	Laparoscopic cholecystectomy	Intestinal perforation	1	
	Appendectomy	Sigmoid colon perforation, death	1	
	Anal abscess surgery	Infection, death	1	
	Laparotomy	Herniation	1	
	Hemorrhoid surgery	Bleeding, abscess, recurrence	2	
	Anorectal abscess surgery	Perianal fissure, sphincter defect, gas-fecal incontinence	1	
	Bilateral total thyroidectomy	Esophageal perforation	1	
Colectomy, colostomy	Wound infection, abscess	1		
Ophthalmology	Cataract surgery	Vision loss, dry eye	2	3
	Laser surgery	Increase in visual impairment	1	
Gynecology and Obstetrics	Hysterectomy, proximal 2/3 vaginectomy, vagina reconstruction	Urinary incontinence, coitus difficulty	1	17
	Tubal ligation	Pregnancy despite tubal ligation	1	
	Difficult birth	Brachial plexus injury	3	
		Uterine rupture, hypoxic ischemic encephalopathy	3	
	Myoma surgery	Urinary incontinence	1	
	Laparoscopic endometrioma	Intestinal perforation	2	
	Hysterectomy, bilateral salpingo oophorectomy	Bladder perforation, vesicovaginal fistula	2	
	Post-operative injection in the service	Injection neuropathy	1	
Insufficient diagnosis and guidance	Down syndrome	2		
Cardiology	Angiography	Infection, obstruction, below-knee amputation	1	2
		Nerve damage	1	

Table 2. devamı				
Clinics	Medical procedures	Complications	n	Total
Otorhinolaryngology	Endoscopic sinus surgery, bilateral nasal polypectomy, turbinate surgery and septoplasty	Vision loss	2	7
	Nasal surgery	Loss of sense of smell, burn scars, nasal deviation	3	
	Tonsillectomy	Arterial incision, incision of tongue	1	
	Atticoanttratami tympanoplasty surgery	Right facial paralysis	1	
Orthopedics and Traumatology	Meniscus and cruciate ligament surgery	Contracture	2	7
	Post-operative injection in the service	Injection neuropathy	2	
	Knee synovitis surgery	Contracture	1	
	Finger fracture and tissue defect	Amputation	1	
	Total hip replacement	Sciatic nerve damage	1	
Plastic and reconstructive surgery	Face lift, eyebrow lift, filling	Numbness, disfigurement, spotting	3	11
	Prosthesis and revision surgeries on both zygoma and ear	Infection, bloody discharge, deformity	1	
	Nasal surgery	Deformity, difficulty in breathing	2	
	Ptosis surgery	Inability of eyelid closure and visual impairment	1	
	Liposuction surgery	Death	1	
	Breast reduction surgery	Nipple necrosis, deformity	3	
Urology	Ureterolithotomy, DJ insertion	Infection and nephrectomy, petrified stent	2	3
	Surgery with alleged nephrolithiasis	No nephrolithiasis	1	
Intensive care unit	Follow-up after traffic accident	Death	1	1
Total			102	

When the reversed decisions of the Court of Cassation and the Council of State regarding the informed consent are examined for the rejection decisions of the cases given by the first instance courts, at the appeal stage; it was seen that the informed consent form was not prepared in 20.6% (n=21) of the cases, incompletely prepared in 24.5% (n=25), signed by the relatives of the patients in 3.9% (n=4), and in 51% (n=52) cases. The decisions of the courts of first instance were given without investigating the informed consent form were overturned by the high courts due to incomplete enquiry, and a statistically significant difference was found between them ($p<0.05$) (Table 3).

In 24.5% (n=25) of our cases, the deficiencies stated in the informed consent form by the relevant departments of the Court of Cassation and the Council of State were determined and presented in a table (Table 4).

In the decisions given by the Supreme Court of Appeals and the relevant departments of the Council of State regarding informed consent, the Constitution of the Republic of Turkey, the Universal Declaration of Human Rights, the Law on the Practice of Medicine and Medical Arts, Turkish Code of Obligations, Human Rights and Biomedicine Convention, European Convention on Human Rights, Patient Rights. It was

Table 3. Informed consent (IC) form status		
Cases	% (n)	p-value
IC form was not prepared	20.6 (21)	$p>0.05$
IC consent form was prepared incompletely	24.5 (25)	$p>0.05$
IC form was not investigated before the decision	51 (52)	$p<0.05$
IC form was signed by the relatives of the patient	3.9 (4)	$p>0.05$
Total	100 (102)	
Chi-square tests: $p<0.05$		

determined that references were made to the relevant articles of the Regulation on Medical Professional Ethics (Table 5).

DISCUSSION

Harm to the patient due to the physician's lack of knowledge, inexperience or negligence is defined as malpractice of medicine (1). The concepts of malpractice is one of the most frequently spoken and discussed topics in the field of health in recent years. Although the prevalence and size of malpractice lawsuits are not known clearly, there has been an increase in lawsuits filed against all healthcare professionals,

especially physicians, in recent years (2). Among the reasons for the increase in malpractice cases we can see the increase in people's expectations from the field of health with scientific developments, the reflection of malpractice cases frequently in the media, increased awareness, the expectation of obtaining serious compensations and determination of malpractice as a special work area, the lack of communication between healthcare professionals and patients/patient relatives, legal regulations and working conditions (9,10). Medical documents must be kept accurately and completely in malpractice cases. Because medical documents are very important both for the diagnosis and treatment processes of patients and because they have the quality of evidence in legal disputes that may arise (11).

The framework of the patient-physician relationship has been determined legally and ethically by written texts such as laws, national and international conventions, declarations, and regulations (12). As a result of medical practice errors, physicians have professional responsibilities towards the professional chambers they are affiliated with and administrative responsibilities in terms of discipline against the institutions they work in, in addition to their criminal and legal responsibilities. However, in order to be able to talk about the responsibility of the physician, it is necessary to establish a causal link between the physician's action being unlawful, the occurrence of a damage, the link between the damage and the physician's faulty action (13). In our study, an examination was

made in terms of compensation cases filed within the scope of the legal responsibility of the physicians and the hospital administrations. A large part of the health services are carried out by the hospitals affiliated to the Ministry of Health and university (state/foundation) hospitals in our country (14).

It was determined that 60.8% (n=62) of our cases were frequently filed against physicians working in private health institutions such as private hospitals, private medical centers and private clinics. Similar studies in the literature report that cases are filed against physicians working in private health institutions at rates of up to 36.2-58.9% (15-17). The reasons for this may be explained as difficulties in reaching public hospitals, private health institutions being preferable in densely populated big cities, patients' paying the fee of private health institutions and the increased expectations of patients/patients' relatives about health services. We think that the population preferring private health institutions have a higher motivation to apply to judicial remedies due to their higher socio-economic and socio-cultural levels.

Courts seek the opinions of experts in cases where the solution requires special or technical knowledge (Law of Civil Procedure, Article 266, Law Number: 6100, Date of Acceptance: 12/1/2011) upon the request of one of the parties or on their own accord. With the increase in malpractice cases in our country in recent years, it has become inevitable to request reports from institutions that provide expert services such as the Council of Forensic Medicine, professional chambers

Table 4. Twenty-five cases with insufficient informed consent form

Defficiencies in the IC form	n	%
There was no explanation about the success rates and the duration of the treatment method, the risks to the health of the patient, medical consequences and possible complications.	7	28.0
Although some complications were mentioned, there was no information about the complication that occurred.	4	16.0
There were abstract statements not containing specific information/preprinted document	6	24.0
Declaration of acceptance with no date and signature/declaration with general sentences	3	12.0
Not indicated in the IC form that the operation may continue as an open operation/there will be a need for intensive care after the operation/consent was not obtained for the second operation / the consent form does not indicate which operation it belongs to	5	20.0
Total	25	100

Table 5. Legal regulations referred to in judicial decision justifications

Name	Article numbers (n.)
The Law on the Style of Execution of Medicine and Medical Arts	n.70
Convention on Human Rights and Biomedicine	n.1-n.4-n.5
Medical Professional Ethics Rules	n.13-n.26
Patient Rights Regulation	n.1-n.11-n.15-n.18-n.22-n.24-n.26-n.31
Constitution of the Republic of Türkiye	n.2-n.17-n.56-n.125
Turkish Code of Obligations	n.170-n.394-n.396-n.502-n.506
European Convention on Human Rights	n.2
Universal Declaration of Human Rights	n.25

and universities in order to distinguish medical intervention errors from complications (14,18,19). In our study, in 100% of the cases, reports were obtained from the Forensic Medicine Institute or the expert committees of universities by the first instance courts of judicial and administrative jurisdiction, and in 100% of the reports received, the defects occurring after the medical procedures were defined as complications and the cases were rejected by referring to these reports. In a similar study conducted by Şeker (5), it was stated that expert reports were obtained at a rate of up to 95%. We think that the judicial bodies should continue their practice of obtaining expert opinion from the relevant institutions for a correct and reliable trial process by eliminating the natural lack of knowledge on malpractice issues that require special or technical knowledge. In the statistical study conducted between 2012-2019 by the General Directorate of Criminal Records and Statistics; it has been stated that the duration of the proceedings varies between 0.5-1.2 years in the courts of first instance and between 1.2-1.4 years in the Civil Chambers of the Council of State and the Supreme Court (20). In our study, it was determined that the cases took an average of 3.7 years in the courts of first instance, and 2.1 years in the Civil Chambers of the Council of State and the Supreme Court and it was understood that these periods were much higher than the statistical studies. We can say that malpractice litigation times are too long due to reasons such as applying to many expert institutions and receiving a large number of reports, the absence of courts and judicial personnel specialized in malpractice, and the excessive workload of courts and public institutions, as special or technical knowledge is needed for the resolution of cases.

Although there is not an adequate and clear study in terms of the prevalence of malpractice cases, their epidemiology, their distribution according to the relevant clinics, and the complications that arise, in some studies in the literature, the first three clinics, which were sued, vary among the specialists of emergency, obstetrics, general surgery, plastic surgery, orthopedics. It was stated that lawsuits were filed against surgical branches with a rate of up to 77.6%, medical interventions were surgical procedures at a rate of 36.9-71.9% and death occurred at a rate of 17.9-35.4% (5,15,21-23). Our study is largely compatible with literature studies; in which 72.5% of the lawsuits were filed against the surgeons, the first three frequencies according to the branches; It was determined that 22.5% of them were opened against emergency, 16.6% obstetrics and 14.7% general surgery specialists, 53.9% of the most applied medical interventions occurred as a result of surgical interventions, and death occurred in 4.9% of the cases related to medical procedures has been done. The reasons why surgical branches are sued more frequently; we think that patients who apply to surgical branches have more serious diseases and their clinical conditions are more severe, surgical

procedures are risky and complex due to their nature, and patients and their relatives have higher expectations of benefit after surgical treatment.

In our study, it was determined that the most frequently applied medical intervention after surgical interventions was intramuscular injection with a rate of 26.5%. In general, published by the Ministry of Health; it has been stated that “verbal informing of patients is necessary and sufficient since injection applications are not for major surgery, and there is no obligation to obtain written consent if the current treatment prescribed by the physician is performed by authorized healthcare professionals after seeing the patient’s prescription” (24). However, in our study, contrary to this the Court of Cassation Civil Chambers and the Council of State considered the absence of an informed consent form during the intramuscular injection procedure or the decision without investigating whether it was present as a deficiency, and decisions were made to reverse it. Therefore, we think that an informed consent document should be issued before the injection procedure, as it is an evidence against malpractice claims that may arise and for ease of proof. All procedures performed by legally authorized people in order to diagnose and treat physical or mental illnesses of individuals, to protect them from diseases or to make population planning within the framework of the rules and principles accepted by medical science are called medical intervention (3). Due to the fact that medical interventions are procedures for the physical and spiritual integrity of the body; it should be done by authorized people, in accordance with the principles and rules generally accepted by medical science, with the condition of medical necessity (indication), by obtaining the informed consent of the patient (4,5). Informed consent, which is one of the mandatory elements for the legality of medical interventions, is very important in terms of respecting the autonomy of individuals and the right to determine their future. Informed consent is the acceptance or refusal of medical interventions to be made by individuals of their own free will without any external coercion. Free will, correct and sufficient information and consent/consent constitute the elements of informed consent (6,7). It is stated that malpractice claims are reduced when the patient is actively communicated with and given adequate information and taken part in the decision-making process regarding his/her treatment. Therefore, the physician’s informing and obtaining the patient’s consent before the medical intervention increases the relationship of trust between the patient and the physician, as well as the legal and ethical obligation, leading to a decrease in malpractice claims (5,25). Physicians are held directly and/or indirectly responsible for fulfilling the conditions of informed consent, which are very important both in terms of the patient’s exercise of his rights and the responsibility of the physician. Informed consent is stated in international medical ethics documents

and has been put into practice with many legal regulations in our country. In the literature studies, it is stated that the Law on the Execution of the Style of Medicine and Medicine, the Human Rights and Biomedicine Convention, the Patient Rights Regulation, the Medical Professional Ethics Rules constitute the basis of the legal basis of informed consent (4,7,8,26). In our study, in addition to the literature studies by the Supreme Court and the Council of State, references were made to the Constitution of the Republic of Turkey, the Turkish Code of Obligations, the European Convention on Human Rights, and the Universal Declaration of Human Rights. In Article 2 of the European Convention on Human Rights, everyone's right to life is protected by law, and in Article 25 of the Universal Declaration of Human Rights, everyone has the right to adequate living standards and medical care, TR. In its Constitution, everyone has the right to live, to protect and develop their material and spiritual existence, the state regulates health institutions to plan and provide services from a single source in order to maintain everyone's life, physical and mental health, and judicial remedy is open against all kinds of actions and transactions of the administration (Republic of Turkey). Constitution, Articles 17, 56. and 125, Law Number: 2709, Adoption Date: 18/10/1982), the Turkish Code of Obligations mentions the power of attorney agreement, where the attorney is obliged to personally fulfill his debt and carry out his debt with loyalty and diligence (Turkish Code of Obligations, Article 502, 506, Law No: 6098, Date of Adoption: 11/1/2011) (27,28). With the main mistakes about informed consent in the relevant legal regulations; that the intervention in the field of health can be carried out after the person concerned freely and informed consents to this intervention in accordance with professional obligations and standards, that each medical intervention should be individually consented, that the information should be given to the patient himself by the healthcare professional who will perform the intervention, that the information is based on the socio-cultural background of the patient. It should be explained clearly by the patient, taking into account the situation, the course and causes of the disease within the scope of information, by whom, where and how the medical intervention will be performed, how long it will take, possible complications, the benefits and risks of other diagnoses and treatments, the drugs to be used and the lifestyle. It is stated that the consent obtained by pressure, threat, insufficient illumination or deception is invalid, if the patient is a child or confined, permission should be obtained from the parent or guardian, the medical intervention should be within the limits of the consent given by the patient, and the patient can always withdraw their consent (1, Patient Rights Regulation, Article 1,11,15,18, 22, 24, 26, 31, Official Gazette dated 01.08.1998 and numbered 23420, Law on the Practice of Medicine and Medical Arts, Article 70, Law No. 1219, Date of Adoption: 11/4/1928). The necessity of obtaining informed consent before medical

intervention has been stated in many legal regulations in our country, it has been emphasized that the burden of proof is on the physician or the hospital in the case of informed consent (Court of Appeals 13th Civil Chamber, 12.12.2019 dated 12.12.2019 and 2019/12469 decision number). Lack of consent continues to be an important problem in our country. In some studies in the literature, it is stated that only 46-47% of the files contain informed consent forms (5,22). In our study, it was found that informed consent forms were not prepared in 20.6% of our cases, in accordance with literature, incompletely prepared in 24.5%, signed by the relatives of the patients in 3.9%, and the informed consent form was decided by the courts of first instance without investigating the status of the informed consent form in 51% of our cases. Among the reasons for this are the high workload of physicians in our country, the accelerated delivery of health services, the lack of awareness among physicians about the importance of informed consent, and our general lack of medical record keeping.

CONCLUSION

Informed consent, which is one of the mandatory elements for the legal and ethical compliance of medical interventions, is very important in terms of respecting the autonomy of individuals and the right to determine their future, the relationship of trust between the physician and the patient and preventing malpractice claims. Informed consent form should be prepared in full within the scope of the provisions of the legislation, with due care, by the physician who performs the procedure, since it is an evidence in legal disputes that may arise and the burden of proof is on the physicians or hospitals. Even if the deficits that occur after the medical intervention are accepted as complications, it should not be forgotten that the decisions against the physicians were made as a result of the non-preparation/incomplete preparation of the informed consent forms, especially by the high courts (the Supreme Court and the Council of State).

ETHICS

Ethics Committee Approval: Our study complies with the Declaration of Helsinki.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: T.V., Concept: T.V., M.E., Design: T.V., Data Collection or Processing: T.V., Analysis or Interpretation: T.V., M.E., Literature Search: T.V., Writing: T.V., M.E.

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REFERENCES

- Hekimlik Mesleği Etik Kuralları. Available from: https://www.ttb.org.tr/kutuphane/h_etikkural.pdf. Accessed: 04.01.2023.
- Erg H, Kiroğlu F. Tıbbi malpraktisde hekimlerin cezai sorumlulukları. *Atlas Journal*. 2021;7(44):2227-2242. <https://doi.org/10.31568/atlas.745>
- Kaya M. Hekimin hastayı aydınlatma yükümlülüğünden kaynaklanan tazminat sorumluluğu. *Türkiye Barolar Birliği Dergisi*. 2012;100:45-82.
- Özer O. Tıbbi müdahalenin hukuka uygunluğunun şartları. *İstanbul Barosu Dergisi*. 2016;90(5):117-134. <https://doi.org/10.21492/inuhfd.899101>
- Şeker Z. Malpraktis davalarında aydınlatılmış onam ile ilgili yargıtay kararlarının değerlendirilmesi (Uzmanlık Tezi). Çukurova Üniversitesi Tıp Fakültesi Adli Tıp Anabilim Dalı, Adana, 2020. https://acikbilim.yok.gov.tr/bitstream/handle/20.500.12812/119058/yokAcikBilim_10337483.pdf?sequence=-1
- Kurt MG. Tıbbi müdahalelerde aydınlatılmış onam. *Türkiye Barolar Birliği Dergisi*. 2020;146:187-218.
- Bacaksız P, Özkara E, Dokgöz H. Hekimlerin yasal sorumlulukları. Dokgöz H (Ed.). *Adli Tıp & Adli Bilimler*. Akademisyen Yayınevi. Ankara 2019. p. 51-70.
- Türk Tabipler Birliği Aydınlatılmış Onam Klavuzu. Available from: https://www.ttb.org.tr/mevzuat_goster.php?Guid=78a19f94-a285-11e7-9205300896da83fe. Accessed 20.01.2023.
- Tekinarslan M. Tıbbi malpraktisin hasta ve hasta yakınları üzerindeki psikolojik, sosyal ve ekonomik etkileri (Yüksek Lisans Tezi). Süleyman Demirel Üniversitesi Sosyal Bilimler Enstitüsü, Isparta, 2015.
- Ertem G, Oksel E, Akbıyık A. Hatalı tıbbi uygulamalar (malpraktis) ile ilgili retrospektif bir inceleme. *Dirim Tıp Gazetesi*. 2009;84(1):1-10.
- World Health Organization. Medical records manual: a guide for developing countries. 2006. Available from: https://apps.who.int/iris/bitstream/handle/10665/208125/9290610050_rev_eng.pdf?sequence=1%26isAllowed=y. Accessed 10.03.2023.
- Altun G, Yorulmaz AC. Yasal değişiklikler sonrası hekim sorumluluğu ve malpraktis. *Trakya Üniversitesi Tıp Fakültesi Dergisi*. 2010;27(1):7-12.
- Tuğcu H, Yorulmaz C, Koç S. Hekim sorumluluğu ve tıbbi malpraktis [Physician liability and medical malpractice]. *Klinik Gelişim* 2009;22:1-10.
- Kaplan G. Ölümle sonuçlanmamış tıbbi uygulama hatası iddialarından kaynaklanan tam yargı davalarında alınan adli tıp kurumu bilirkişi raporlarının danıştay içtihatlarına etkisi (Yüksek Lisans Tezi). Bakırçay Üniversitesi Lisansüstü Eğitim Enstitüsü, İzmir, 2022.
- Kahyaoglu KE. 2015-2020 Yılları arasında Yargıtay'a intikal etmiş malpraktis dosyalarının sağlık yönetimi açısından analizi (Yüksek Lisans Tezi). Sağlık Bilimleri Enstitüsü, Ordu, 2022.
- Çarıkçı F, Eslek S, Kirbaş Ç, Aktaşçı B, Baştımur F. Günlük gazetelere yansıyan tıbbi uygulama hataları üzerine retrospektif bir inceleme. *Journal of Medical Sciences*. 2021;2(4):59-66. <https://doi.org/10.46629/JMS.2021.56>
- Çakmak C, Balçık PY. Sezaryen yöntemi ile gerçekleştirilen doğumlarda ortaya çıkan malpraktis olgularının yargıtay kararları ile incelenmesi. *Jinekoloji-Obstetrik ve Neonatoloji Tıp Dergisi*. 2019;16(3):155-159.
- Işıksaçan VY. Tıbbi müdahale hatalarında bilirkişinin rolü (Yüksek Lisans Tezi). Sosyal Bilimler Enstitüsü, İstanbul, 2014.
- Yüksel C. Tıbbi uygulama hatalarında bilirkişilik (Yüksek Lisans Tezi). Sosyal Bilimler Enstitüsü, İstanbul, 2012.
- Adli Sicil ve İstatistik Genel Müdürlüğü. Adli İstatistikler 2019. Available from: <https://adlisicil.adalet.gov.tr/Resimler/SayfaDokuman/22420211427211062020170359HizmeteOzel-2019-bask%C4%B1-%C4%B0SA.pdf4>. Accessed 25.03.2023.
- Şanyüz Ö, Birgen N, İçmeli ÖS. Tıbbi uygulamalar ile ilgili tazminat davalarının uzmanlık alanlarına göre dağılımının zorunlu sağlık sigorta primlerinin kademelendirilmesi. 9. Adli Bilimler Kongresi, 14-17 Ekim 2010, İzmir.
- Kalkan EA. Analysis of the high court decisions on informed consent cases in Turkey from a forensic point of view. *Journal of Scientific Perspectives* 2018;3(3):125-34. <https://doi.org/10.26900/jsp.2018.8>
- Kara M. Tıbbi Uygulama hatası nedeniyle yapılan soruşturmalarda, 2009-2014 yılları arasında, İzmir Tabip Odası Onur Kurulu tarafından verilen kararların değerlendirilmesi (Yüksek Lisans Tezi). Sosyal Bilimler Enstitüsü, İzmir, 2015.
- T.C. Sağlık Bakanlığı. 2019/11 Sayılı Enjeksiyon Uygulamaları Hakkında Genelge. Available from :<https://shgmhastahakdb.saglik.gov.tr/TR-55483/201911-sayili-enjeksiyon-uygulamaları-hakkında-genelge.html>. 2019. Accessed 27.03.2023.
- Posner KL, Severson J, Domino KB. The role of informed consent in patient complaints: Reducing hidden health system costs and improving patient engagement through shared decision making. *J Healthc Risk Manag*. 2015;35(2):38-45. <https://doi.org/10.1002/jhrm.21200>
- Özkara E, Dokgöz H. Tıbbi uygulama hataları. Dokgöz H (Ed.). *Adli Tıp & Adli Bilimler*. Akademisyen Yayınevi. Ankara 2019. p. 71-90.
- Avrupa İnsan Hakları Sözleşmesi. Available from: <https://www.yargitay.gov.tr/documents/AIHM.pdf>. Accessed 28.03.2023.
- İnsan Hakları Evrensel Bildirgesi. Available from:<https://www.ihd.org.tr/insan-haklari-evrensel-beyannames>. Accessed 01.04.2023.