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Forensic Evaluation of Informed Consent Deficiencies in Medical Practices

Tıbbi Uygulamalardaki Aydınlatılmış Onam Eksikliklerinin Adli Tıbbi Açıdan Değerlendirilmesi

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ABSTRACT

Background: Informed consent is a fundamental element of medical ethics and legal accountability. However, in many healthcare institutions, consent forms are still treated as a formality rather than a meaningful communication process between physicians and patients. In Türkiye, malpractice allegations and compensation claims related to incomplete or missing consent have increased in recent years, highlighting the need for standardized documentation and physician-led consent practices. This study aimed to evaluate the quality, completeness, and common deficiencies of informed consent documents referred to the *Adli Tıp Kurumu* (Council of Forensic Medicine) for forensic assessment.

Materials and Methods: A total of 441 medico-legal case files sent by judicial authorities to the Council of Forensic Medicine for expert evaluation of informed consent were retrospectively analyzed over a five-year period from January 2020 to December 2024. The Data included demographics, medical specialty, intervention type, hospital type, presence of written consent, risk and complication information, person obtaining consent, and identified deficiencies.

Results: Written informed consent was present in 201 cases (45.6%) and absent in 240 cases (54.4%). The most frequent deficiencies were missing physician's signature (10%), missing diagnosis (7.5%), and missing date (6%). Risk information was present in 98.5% of forms. Deficiencies were significantly higher when consent was obtained by nurses or other personnel ($p < 0.01$) and in private hospitals, where rates of deficiencies were about twice those in public institutions ($p < 0.01$).

Conclusion: Deficiencies in informed consent documentation remain common in Türkiye. Lack of physician involvement and incomplete forms undermine both patient autonomy and legal validity. Standardized, physician-led, and procedure-specific consent processes, supported by institutional oversight, are essential to ensure ethical and legal protection.

Keywords: Informed consent, verbal consent, forensic medicine, medical law, patient rights

ÖZ

Amaç: Aydınlatılmış onam, tıbbi etiğin ve hukuki sorumluluğun temel bir unsurudur. Ancak birçok sağlık kuruluşunda onam formları, hekim ile hasta arasındaki anlamlı bir iletişim süreci olmaktan ziyade, hâlen biçimsel bir gereklilik olarak ele alınmaktadır. Türkiye'de son yıllarda eksik veya hiç alınmamış onama bağlı malpraktis iddiaları ve tazminat taleplerinin artması, standartlaştırılmış dokümantasyonun ve hekim tarafından yürütülen onam uygulamalarının gerekliliğini ortaya koymaktadır. Bu çalışmanın amacı, Adli Tıp Kurumu'na adli değerlendirme amacıyla gönderilen aydınlatılmış onam belgelerinin kalite, bütünlük ve sık görülen eksiklikler açısından değerlendirilmesidir.

Gereç ve Yöntemler: Ocak 2020–Aralık 2024 tarihleri arasındaki beş yıllık dönemde, aydınlatılmış onamın adli bilirkişi incelemesi amacıyla yargı mercileri tarafından Adli Tıp Kurumu'na gönderilen toplam 441 adli tıbbi dosya retrospektif olarak analiz edildi. Veriler; demografik özellikler, tıbbi uzmanlık alanı, girişim türü, hastane türü, yazılı onamın varlığı, risk ve komplikasyonlara ilişkin bilgilendirme, onamı alan kişi ve saptanan eksiklikleri içermektedir.

Bulgular: Yazılı aydınlatılmış onam 201 olguda (%45,6) mevcutken, 240 olguda (%54,4) bulunmamaktaydı. En sık saptanan eksiklikler; hekimin imzasının bulunmaması (%10), tanının yer almaması (%7,5) ve tarihin bulunmaması (%6) idi. Risk bilgilendirmesi formların %98,5'inde mevcuttu. Onamın hemşireler veya diğer personel tarafından alındığı durumlarda eksikliklerin anlamlı derecede daha

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ÖZ

fazla olduğu ($p < 0,01$) ve özel hastanelerde eksiklik oranlarının kamu kurumlarına kıyasla yaklaşık iki kat daha yüksek olduğu ($p < 0,01$) saptandı.

Sonuç: Türkiye'de aydınlatılmış onam dokümantasyonundaki eksiklikler yaygınlığını sürdürmektedir. Hekim katılımının yetersizliği ve eksik doldurulmuş formlar, hem hasta özerkliğini hem de hukuki geçerliliği zedelemektedir. Etik ve hukuki korumanın sağlanabilmesi için, kurumsal denetimle desteklenen, standartlaştırılmış, hekim tarafından yürütülen ve işleme özgü aydınlatılmış onam süreçleri gereklidir.

Anahtar Kelimeler: Aydınlatılmış onam, sözlü onam, adli tıp, tıp hukuku, hasta hakları

Introduction

Informed consent is one of the cornerstones of modern medicine, both ethically and legally. While it is a basic principle in clinical practice, it has also gained increasing importance in the field of forensic medicine. This process, which protects patient autonomy, ensures that the nature, benefits, risks, and alternatives to a medical intervention are clearly explained to the patient and that the patient makes a conscious and voluntary decision based on this information (1).

Consent can be classified as written, verbal, or implied, depending on how it is obtained. Written consent ensures complete information flow and traceability; documents that explicitly include risks and complications offer clarity for both physicians and forensic evaluators, regardless of whether malpractice has occurred. By contrast, verbal consent often lacks supporting evidence, making it difficult to prove in court and more vulnerable to legal challenge. Implied consent is accepted in simple and routine procedures, such as when a patient attends for a physical examination (2,3).

Although informed consent is a medical obligation, it also has a legal basis. In Türkiye, the Law on the Practice of Medicine and Its Branches (Tababet ve Şuabatı Sanatlarının Tarzı İcrasına Dair Kanun, Law No. 1219, enacted on 11 April 1928) stipulates in Article 70 that "written consent must be obtained before any surgical intervention." This legal obligation is further reinforced by the ethical rules of the Türk Tabipleri Birliği (Turkish Medical Association) and by the Hasta Hakları Yönetmeliği (Patient Rights Regulation, 1998/2014) (4).

Prior work in Türkiye indicates that perceived service quality and patient satisfaction are often higher in private hospitals and clinics than in public institutions; this difference may shape expectations regarding documentation and consent processes (5).

As frequently noted in decisions of the Yargıtay (Court of Cassation), "lack of consent" or "insufficient consent" is often regarded a deficiency in expert reports and has given rise to legal liability. Recently, deficiencies in consent have increasingly been used as grounds for malpractice lawsuits (6).

In forensic medicine, unlike in some medical contexts, the issue of consent is often evaluated in terms of its legal validity. While obtaining consent before intervention is ethically mandatory, the evaluation of cases where no malpractice is alleged but the consent form is incomplete remains controversial among experts. Therefore, in such cases, the content of the file is of significant importance (7).

The aim of this study is to assess the presence, content, and adequacy of informed consent forms that were referred to the *Adli Tıp Kurumu* (Council of Forensic Medicine) for expert evaluation.

In Türkiye, the number of malpractice allegations and compensation claims related to insufficient or missing consent has markedly increased in recent years, yet there is still no nationwide standard for consent documentation or audit.

Therefore, this study was designed to highlight the current deficiencies in informed consent practices, to raise awareness among physicians and healthcare institutions, to provide an evidence base for developing national consent standards, and to strengthen the role of forensic medicine in the legal assessment of medical practice.

Materials and Methods

Study Design

A total of 47,500 case files referred by judicial authorities to the Adli Tıp Kurumu (Council of Forensic Medicine) between December 2024 and January 2025 for expert opinion on alleged medical malpractice were reviewed. Among these, 441 files specifically requested expert evaluation of the presence or adequacy of informed consent and were included in the study. Due to conflicts between the parties, cases involving claims of verbal consent could not be assessed. A detailed analysis of the content and deficiencies of the consent documents was conducted for only the 201 cases with written informed consent. All data were anonymized before analysis, and only variables directly related to informed consent were included to ensure consistency and confidentiality.

Data Collection and Variables

Files were obtained from the institutional archives, and only documents submitted by judicial authorities were examined. For each case, the following variables were recorded:

- Demographics: Age, sex
- Specialty and type of intervention: Cardiology, plastic surgery, general surgery, dentistry, orthopedics, ear, nose and throat (ENT), neurosurgery, ophthalmology, emergency medicine, oncology, urology, etc.; surgery, anesthesia, drug treatment, hospitalization, and other procedures
- Hospital type: Public or private healthcare institutions
- Consent information: Presence of written consent, person obtaining consent (physician, nurse, other healthcare staff), person providing consent (patient or relative), and whether complication/risk information was included in the form
- Deficiencies: Missing patient/relative signature, name, date, diagnosis, physician signature, and other documentation issues

Statistical Analysis

Data were analyzed using IBM SPSS Statistics 29.0. Descriptive statistics were presented as numbers (n) and percentages (%). Pearson's chi-square test was used for bivariate comparisons, and Fisher's exact test was applied when cell frequencies were low. Effect sizes were calculated with Cramer's V. In analyses of associations between multi-categorical variables, cell contributions were examined through standardized residuals. When necessary, deficiency types were combined and reanalyzed. A multivariable logistic regression model was planned; however, because of low frequencies in some cells, the model was restricted and the results focused primarily on significant bivariate findings. Statistical significance was set at $p < 0.05$.

Results

Among the 441 cases evaluated, females constituted 59.0% and males 41.0%. The ages of the cases ranged from 0 to 89 years. According to the World Health Organization (WHO) classification, 13.2% were adolescents (0–17 years), 72.3% were adults (18–64 years), and 14.5% were elderly (≥65 years). The majority of cases were working-age adults, corresponding to the period during which surgical and interventional procedures are most common.

The largest share of cases originated in surgical and interventional specialties, notably obstetrics and gynecology, plastic surgery, and general surgery (Figure 1). Surgical procedures accounted for 68.5% of interventions, followed by drug treatments, anesthesia procedures, and other interventions such as hospitalization or diagnostic tests (Table 1).

Private hospitals represented 61.5% of all cases, with deficiency rates nearly twice as high as those in public hospitals ($p < 0.01$).

Table 2 summarizes the presence of written consent and the inclusion of complication/risk information. Overall, 201 (45.6%) had written consent, while 240 (54.4%) lacked documentation. Complication or risk information was present in 98.5% of the written forms.

Consent was obtained primarily by physicians (94.5%), whereas deficiencies were significantly more frequent when consent was obtained by nurses or administrative staff ($p < 0.01$). Overall, 67 of the 201 written consent forms (33.3%) had at least one deficiency, and 21 forms (10.4%) contained two or more missing elements (Table 3).

No statistically significant associations were observed with patient age, sex, or the person providing consent.

Discussion

This study presents important findings regarding the practice of obtaining informed consent within healthcare delivery in Türkiye. Our results showed that cases without written consent (54.4%) were more common than those with written consent (45.6%). This finding suggests that informed consent is still not a fully standardized practice with respect to patient autonomy and the physician–patient relationship. Previous studies across different medical disciplines in Türkiye have similarly emphasized that obtaining formal consent is often neglected (8,9). International literature also indicates that in developing countries, written consent is often obtained only as a formality, and patients are not adequately aware of their right to refuse or withdraw consent. In contrast, in developed healthcare systems, these

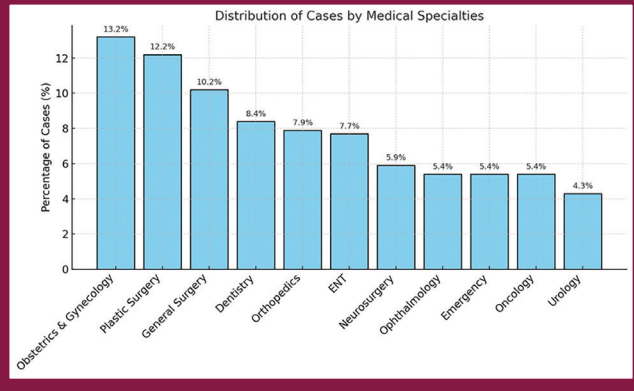

Figure 1. Distribution of cases by medical specialties. The most frequent specialties were obstetrics and gynecology (13.2%), plastic surgery (12.2%), and general surgery (10.2%).

Table 1. Demographic distribution of cases (n = 441).

Variables	Category	n	%
Gender	Female	260	59.0
	Male	181	41.0
Age	0–17	58	13.2
	18–64	319	72.3
	64–74	41	9.3
	75–84	18	4.1
	≥85	5	1.1
Hospital	Private	271	61.5
	Public	170	38.5
Type of procedure	Surgery	302	68.5
	Drug administration	51	11.6
	Anesthesia	35	7.9
	Other	53	12.0

Other includes hospitalization, diagnostic tests, reproductive health, and organ donation.

Table 2. Distribution of consent presence and risk/complication information.

Variables	Category	n	%
Consent	Present	201	45.6
	Absent	240	54.4
Risk/complication information	Present	198	98.5
	Absent	3	1.5

Table 3. Distribution of personnel obtaining consent, person providing consent, and deficiencies (n = 201).

Variables	Category	n	%
Obtained by	Physician	190	94.5
	Nurse	10	5.0
	Other (hospital staff)	1	0.5
Provided by	Patient	173	86.1
	Relative	27	13.4
	Not recorded	1	0.5
Deficiencies in written consent	Physician's signature missing	20	10
	Diagnosis missing	15	7.5
	Date missing	12	6.0
	Patient/relative signature missing	10	5.0
	Patient name missing	5	2.5

rights are more strictly protected, and informed consent is regarded as an integral part of patient autonomy (10,11).

In our study, women represented 59% of cases and men 41%. This distribution may be explained by the greater representation of specialties that are frequently accessed by female patients, such as gynecology, obstetrics, plastic surgery, and cosmetic procedures. The Literature also reports that women seek healthcare services more frequently than men and therefore participate more often in the consent process (12). However, no statistically significant difference was found between genders in the presence of deficiencies.

When age groups were reclassified according to the WHO standard, the majority of cases (72.3%) were adults aged 18–64 years, reflecting that most malpractice-related evaluations involve the active working-age population, who are the primary users of healthcare services. International studies also report that consent is most frequently obtained from young and middle-aged adults, especially in obstetric and general surgical procedures (13). In our series, however, age was not significantly associated with the presence of consent deficiencies. Overall, demographic data suggest that deficiencies are not specific to any age or gender group, but rather related to institutional, professional, and specialty-based factors.

This highlights the importance of focusing on process-related shortcomings in forensic evaluation rather than individual patient characteristics.

The specialties most commonly evaluated with respect to consent were obstetrics and gynecology (13.2%), plastic surgery (12.2%), and general surgery (10.2%), followed by dentistry, orthopedics, ENT, neurosurgery, ophthalmology, emergency medicine, oncology, and urology. This distribution reflects a predominance of malpractice claims among surgical and interventional specialties in Türkiye. These areas inherently carry a higher risk of complications, making the consent process particularly critical. Similarly, the literature underscores the importance of informed consent in surgical specialties, where complications are often unavoidable and patients' expectations are high (14,15). In plastic surgery, particularly cosmetic procedures, patient satisfaction is highly subjective, which further emphasizes the need for complete documentation of risks and complications. In our study, deficiencies were more common in surgical specialties (χ^2 test, $p < 0.05$), highlighting the need to strengthen consent practices in these fields.

Regarding types of procedures, surgical procedures were the most frequent, followed by drug treatments, anesthesia, and other interventions (hospitalization, diagnostic tests, reproductive health, organ donation). This was expected, as surgery carries the highest risk of complications and legal liability. The Literature also states that surgical procedures are the most frequent context in which informed consent is obtained, and that such documents serve as the most critical evidence in legal disputes (2). In our study, non-surgical procedures were associated with fewer written

consents. In particular, chemotherapy, anesthesia, and high-risk drug therapies were often obtained by verbal rather than written consent, which constitutes a serious deficiency. The Literature has emphasized that written consent is mandatory for these high-risk interventions (16).

By hospital type, 61.5% of consents were obtained from private hospitals and 38.5% from public hospitals. This may be related to differing patient expectations and institutional practices in the private sector, where service quality and satisfaction are generally perceived to be higher. Deficiencies were nearly twice as frequent in private hospitals (χ^2 test, $p < 0.01$; Cramer's $V \approx 0.20$). This suggests that consent in private institutions often remains a formality rather than a substantive process. The Literature has similarly noted that pressure to maintain patient satisfaction in private hospitals may result in superficial consent practices (17). Studies in Türkiye also report that private hospitals tend to use standardized forms that provide inadequate individualized information on risks and complications (8). In contrast, documents from public hospitals appear more formal and subject to oversight, with lower deficiency rates.

Deficiencies were strongly linked to institutional and professional factors and were higher in private hospitals and when recorded by non-physician staff, particularly in surgical specialties.

In discussions of malpractice and consent deficiencies, attention is primarily focused on the individual physician. However, from a forensic and legal perspective, the responsibility for obtaining and documenting informed consent lies not only with the practitioner but also with the institution where the medical procedure is performed. The consent process has three essential components: the patient, who must be adequately informed and make a voluntary decision; the physician, who has the professional duty to disclose and explain; and the institution, which must ensure the availability of standardized forms, proper record-keeping, and administrative oversight. Institutional deficiencies—such as the absence of updated consent templates, the lack of training for staff involved in documentation, or insufficient auditing mechanisms—may directly contribute to the legal vulnerability of both the physician and the healthcare facility. Therefore, strengthening institutional policies and ensuring active monitoring of consent procedures are as crucial as physician-level diligence in preventing malpractice disputes.

It should also be acknowledged that there are exceptional circumstances in which the process of obtaining informed consent may be limited or temporarily bypassed. These include emergency interventions where immediate action is required to save lives or prevent serious harm; unforeseen complications that arise during a standard course of treatment and must be controlled promptly; and legal obligations where examination or intervention is mandated by law—such as in forensic cases or infectious diseases that pose a public health risk. In such contexts, the physician's priority is to act in the patient's best interest and in accordance with legal mandates, while still providing information to the extent possible. These exceptional situations illustrate that responsibility for consent cannot rest solely on the individual physician but must be considered within the broader context of institutional and legal frameworks.

Content analysis of written consents revealed that 198 of 201 cases (98.5%) included information on complications or risks, while only three cases (1.5%) lacked such information. While this indicates that risk information is usually present, the key issue is whether it is sufficiently detailed and individualized. The literature suggests that information about complications is often provided in generic terms, and patients frequently fail to fully understand the real risks. In one study, only 34% of patients recalled the risks and only 26% recalled alternatives (2). Thus, the mere presence of risk information is not enough; it must also be clear, comprehensive, and tailored to the patient. Evaluations from Türkiye confirm that consent is often based on standard templates rather than individualized communication. Kurt (4) emphasized the need for forms adapted to patients' social and psychological conditions, while Yıldırım et al. (18) showed that, especially in surgical specialties, consent in practice is usually delivered in generalized terms. Forensic assessments must consider this distinction, since courts evaluate not only the existence of a consent form but also its adequacy.

Although most consents were obtained by physicians, deficiencies were significantly lower when physicians were directly involved and significantly higher when consents were obtained by nurses or other personnel (χ^2 test, $p < 0.01$; Cramer's $V \approx 0.30$). This underscores that informed consent is not merely a signature but a professional responsibility that requires explanation, disclosure of risks, and patient–physician communication. The literature also reports that non-physician staff often obtain consent beyond their scope of authority, thereby reducing the quality of consent documentation (19). Our findings reinforce that the consent process must remain the responsibility of physicians. In practice, certain emergency or high-workload situations may require assistance from nurses or other healthcare staff during the consent process. This support typically involves logistical help—such as form preparation or witness documentation—rather than assuming the physician's ethical and legal responsibility for disclosure. Recognizing

these circumstances is important for distinguishing between delegation of tasks and of responsibility, ensuring that physicians remain primarily accountable while acknowledging the practical realities of healthcare delivery.

In our series, the majority of consents (86.1%) were signed directly by the patients, while 13.4% were signed by relatives. This generally reflects respect for patient autonomy. However, obtaining consent from relatives when patients are competent raises ethical concerns. The Literature states that consent should be obtained directly from adult patients with decision-making capacity and from legal representatives only in cases of unconsciousness, severe mental impairment, or when the patient is a minor (2,10).

The most frequent deficiency observed in written consents was the absence of physician signatures. This directly undermines the medical and legal validity of the form, since the physician's signature is proof that they personally conducted the informed consent process. The literature also emphasizes that consent forms lacking a physician's signature are often deemed invalid in court, thereby increasing physician liability (19). Missing diagnoses, dates, and patient signatures are also important. In particular, the absence of a diagnosis leaves unclear what the patient has agreed to, while missing dates undermine the legal validity of the document. The absence of a patient signature renders the form entirely null.

In forensic practice, consent forms are not only ethical tools but also critical documents defining legal accountability. The Court of Cassation frequently classifies lack of consent or incomplete consent as "fault," leading to liability (7). Especially in surgical cases, deficiencies in form and content are often considered to constitute insufficient disclosure. Our findings are consistent with this perspective: nearly one-third of forms had at least one deficiency and one-tenth had multiple deficiencies. These shortcomings may seriously disadvantage physicians and institutions in legal proceedings. Moreover, consent obtained by non-physician staff is particularly problematic with regard to legal validity.

Study Limitations

This study has certain limitations. The analysis was based solely on case files referred to the Adli Tıp Kurumu (Council of Forensic Medicine) for expert evaluation, which inherently limits access to comprehensive demographic or clinical information. In particular, variables such as education level, occupation, and marital status were not consistently documented in the judicial referral files and therefore could not be analyzed. This reflects a structural limitation of medico-legal data systems in Türkiye rather than a study-specific omission. Despite these constraints, the dataset represents a large and nationally relevant sample that accurately reflects the forensic perspective on informed consent practices.

The study was designed to evaluate the adequacy and completeness of informed consent forms from a forensic perspective, not to re-assess the medical indications or diagnostic decisions underlying the interventions. Information on clinical indications was not consistently available in the judicial referral files and was therefore excluded from the analysis to maintain a focused and standardized evaluation of consent quality.

It should be noted that the present study focused solely on written informed consent forms. In cases without written documentation, it was not possible to verify whether verbal consent had been provided, as the case files contained conflicting statements from the parties and lacked objective evidence. The assessment of verbal consent belongs primarily to the legal domain, and its verification requires a different methodological framework. Therefore, this study evaluated only the existence and adequacy of written consent documents.

Conclusion

This study provides evidence that deficiencies in informed consent documentation are still common among cases referred for forensic evaluation in Türkiye.

However, since the analysis was limited to the content and completeness of consent forms, the findings should not be generalized to all clinical settings. The results primarily reflect the documentation quality of cases under legal scrutiny, rather than the overall performance of the healthcare system.

This study demonstrated that significant deficiencies remain in the practice of obtaining written informed consent in Türkiye. The higher frequency of deficiencies in private hospitals, and of deficiencies in consents obtained by non-physician personnel, is particularly noteworthy. The most common deficiencies involved the absence of physicians' signatures, diagnoses, and dates, all of which weaken both the medical and legal validity of the documents. From a forensic medical perspective, not only the presence but also the content and completeness of consent forms are of critical importance. Considering that such deficiencies are often regarded as "fault" in court decisions, physicians and institutions must treat the consent process not as a formality, but as a process that directly affects patient rights and their own legal accountability.

Accordingly, several steps should be taken: the national standardization of consent forms; the adaptation of documents to the specific specialty and procedure; the restriction of the consent process to physicians; the provision

of complication and risk information in a clear, detailed, and patient-specific manner; and the establishment of regular institutional audit mechanisms.

Ethics

Ethics Committee Approval: This study was reviewed by the Scientific Research and Training Commission, Adli Tıp Kurumu (Council of Forensic Medicine) and approved (decision number: 21589509/2025/949, dated: 12.08.2025).

Informed Consent: Since this study was retrospective and based on archived judicial case files, individual informed consent was waived.

Footnotes

Conflict of Interest: No conflict of interest was declared by the author(s).

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