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ORIGINAL ARTICLE

Does content of informed consent forms make surgeons vulnerable to lawsuits?

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Summary *Background:* Written informed consent forms (ICFs) are important for ensuring that physicians disclose core information to patients to help them autonomously decide about treatment and for providing substantial evidence for the surgeon in case of a legal dispute. This paper aims to assess the legal and ethical appropriateness and sufficiency of the contents of ICFs designed for several elective surgical procedures currently in use in Turkish hospitals.
Methods: One hundred and twenty-six forms were randomly selected and were analyzed for 22 criteria. The results were compared using the Fisher' exact test, and 95% confidence intervals were calculated.
Results: More than 80% of ICFs contained information about the risks of the proposed treatment, the diagnosis of the patient, and the patient's voluntariness/willingness, as well as a designated space for the signatures of the patient and the physician and a description of the proposed treatment. Some ICFs were designed for obtaining blanket consent for using patients' specimens.
Conclusions: The ICFs for general elective surgery contain many deficiencies regarding disclosure of information, and there is significant variation among primary healthcare providers. Unrealistic expectations regarding the surgery or the post-operative recovery period due to insufficient information disclosure may lead patients, who experience post-surgical inconveniences, to file lawsuits against their surgeons. Although all ICFs, regardless of their institution, are generally insufficient for defending hospital administrations or surgeons during a lawsuit, ICFs of private hospitals might be considered better equipped for the situation than those of state or university hospitals. However, further research is needed to show if private hospitals have lower lawsuit rates or better lawsuit outcomes than state or university hospitals in Turkey.

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1. Introduction

The main idea behind obtaining informed consent (IC) is that no person should be subjected to any medical intervention without understanding and agreeing to potential consequences of the medical diagnosis or treatment. The emphasis is on the individual's fundamental right to decide and act based on her values and according to her free will. The lack of a proper IC procedure prevents the patients from realizing their autonomy, which drives them to seek justice at courthouses. The first lawsuit, Schloendorff vs. Society of New York Hospital, was filed in 1914 when a surgeon resected a tumor from a patient who had only consented to a diagnostic procedure. The physician was found liable for violating the individual's fundamental right to autonomy regarding what is to be done to her body. In this case, Justice Benjamin Cardozo commented: "... and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages".[1]

Obtaining IC is more than receiving her signature on the IC form (ICF), but a procedure that requires excellent communication skills to transfer sufficient and customized information. However, clinical experiences and literature demonstrate that there are several parameters that adversely influence the IC process, such as long working hours, excessive number of patients, lack of awareness of physicians and/or hospital administrations, absence of quality assurance systems, inadequate training of medical professionals, and insufficient legal regulations.[2–4]

Considering the adverse impact of these factors on the IC procedure, written ICFs become more critical for ensuring that physicians disclose the core information to the patient and providing substantial evidence in case of a legal dispute. Surgeons and hospital administrations are subject to lawsuits due to lack of a proper IC procedure. New regulations on surgical IC procedures were implemented after the Montgomery vs. Lanarkshire Health Board case in the UK revealed that conducting proper IC procedure is a current and global problem.[5]

Physicians' associations, hospitals, and other organizations develop several ICFs. However, there is great heterogeneity among them regarding how much, how to, and when to disclose.[6,7] One of the reasons for the variations in written ICFs emerges from the question of how much information would be considered sufficient for accepting an IC as appropriate in legal terms. Some countries' jurisdictions use the reasonable person standard. Others might appeal to the reasonable physician standard, which has the spirit of a stronger paternalism by acknowledging the higher hierarchical and intellectual position of the physician to decide in the name of the patient.[8–11]

In Turkey, the law on the "practice of medicine and medical sciences"[12] requires written consent for surgical interventions to be performed and holds the surgeon and her institution responsible for proving the consent was obtained in case of a conflict or lawsuit. However, patients' rights legislation that describes the content of information finds verbal consent sufficient.[13] Moreover, according to this legislation, it is acceptable for the IC procedure to be conducted by a healthcare professional other than the physician who will conduct the medical intervention.[14] The imprecise legal definitions together with the oblivious manner of physicians and hospital administrations threaten the legal and ethical integrity of the IC procedure, which leads to serious consequences such as medical malpractice lawsuits. Recent studies have revealed that general surgeons are among the physicians who are most likely to be sued among for malpractice.[15,16] When a physician is involved in a medical malpractice dispute, she is responsible for proving that the patient was provided proper and sufficient information to ponder over the risks and benefits and to freely provide consent. The existence of a signed ICF might demonstrate that the patient consented. However, for it to be considered as substantial evidence of IC, the form should include written evidence of disclosing sufficient necessary information.[17,18] The patients' rights legislation defines the minimum information to be provided, however, according to our experiences, even the minimum requirement is not met by ICFs, and there is extensive variability of the ICFs among different healthcare institutions.

In order to evaluate this, we examined 126 ICFs designed for several surgical procedures that are currently in use in the state, private, or university hospitals in Ankara. The contents of the forms were analyzed regarding their adherence with the ethical and legal requirements. Significant deficiencies in the forms were described, and required amendments were discussed.

2. Methods

Among the available ICFs on the websites of the health institutions located in Ankara, 126 forms were randomly selected. The forms were designated for various elective surgeries. ICFs for emergency surgery were excluded from the study. Table 1 lists the surgical operations that the ICFs were designed for and the distribution of the number of forms included in the study.

In the Principles of Biomedical Ethics book Beauchamp and Childress provide a broad view for the content and scope of proper IC procedure in the context of respect for autonomy, non-maleficence, beneficence, justice and professional patient physician relationship. A primary *list of ethical criteria* which should be involved in ICFs were prepared with reference to the principles voiced by Beauchamp and Childress. Subsequently current guidelines such as Good Surgical Practice guide by The Royal College of

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Table 1 The surgical procedures of ICFs included in the study.

Surgical operation	Number of ICFs in the study
Total/partial colon/rectum resection	15
Hernia reconstruction	15
Breast resection (modified radical/partial resection and axillary lymph node resection/biopsy)	13
Laparotomy/explorative surgery	8
Ostomy operation	7
Anal fissure resection/lateral internal sphincterotomy	6
Cholecystectomy	6
Esophagus/gastrectomy operation	6
Intra-abdominal operation	6
Thyroidectomy	5
Hemorrhoidectomy	4
Splenectomy	4
Pilonidal sinus	4
Pancreaticoduodenectomy	4
Cervical lymph node excision	4
Liver resection/cyst resection	4
Leg/foot amputation	3
Parathyroidectomy	3
Thyroidectomy	2
Adrenalectomy	2
General surgery	1
Reconstruction of diaphragm rupture	1
Polypectomy	1
Liver biopsy	1
Soft tissue resection	1
Total	**126**

Surgeons of England, Code of Medical Ethics of American Medical Association and, Consent Guide by General Medical Council of UK, and Turkish Patient Rights Directive were assessed. The criteria requested to take place in ICFs by each document were listed in separate tables and were cross matched in a matrix. A criterion which appeared in more than one guideline was selected to be involved in the preliminary pool of *practical criteria*. This preliminary pool of *practical criteria* was checked against the *primary list of ethical criteria* to construct the final evaluation criteria. There were variations among the guidelines regarding the information about diagnosis and prognosis; options for treating or managing the condition — including the option not to treat —; the potential benefits, risks and burdens; the likelihood of success; and the duration of hospitalization or time needed to return to normal life (if possible) for each option. However, the people who will be primarily responsible for and involved in their care and addressing special conditions such as incompetency in decision-making or being illiterate were commonly considered essential by most of the reference documents. Since these criteria address the requirements of the primary list of ethical criteria, they were identified as essential elements and were selected as the evaluation criteria for the ICFs of the study. Since the wet signatures of the physician and the patient are required for legal validity, the presence of a designated space for signatures was added to the assessment criteria.

Other elements mentioned in some references, such as the benefits or risks related to which organization or doctor is chosen to provide their care, whether a proposed investigation or treatment is part of a research program, or is an innovative treatment designed specifically for the patients' benefit, the right to seek a second opinion, the cost of the treatment, and any personal or institutional conflicts of interest were excluded from the evaluation criteria.

The contents of the selected forms were analyzed for compliance with 22 criteria that had been developed by examining the literature on ICFs as well as the international institutions' websites and national guidelines.[12,13,18–21]

While reading through the ICFs, it was discovered that some forms were designed for obtaining "blanket consent", that is to say, the patient had to consent to provide the data or specimens for research purposes and to be photographed, taped, or video-recorded during the medical intervention. The forms were so arranged that the patient did not have the option to consent for the medical procedure but refuse to be a part of the research or be recorded. This situation was not included in the assessment criteria since it is not a component of a proper IC. However, it was considered an essential finding due to its legal and ethical implications. Hence, the presence of blanket consent was included in the results and reflected upon in the discussion.

Statistical Analysis: Data were presented as the percentage of ICFs satisfying the criteria. The results of the university, state, and private hospitals were compared using the Fisher's exact test, and the 95% confidence intervals (CI) were calculated. Statistical significance was indicated by $p < 0.05$. SPSS statistics software was used for the data analysis.

3. Results

Of the 126 ICFs, 31.7% (n = 40) were from state hospitals, 38.8% (n = 49) were from university hospitals, and 29.3% (n = 37) were from private hospitals. More than 80% of the 126 ICFs included "the risks of the proposed treatment", "diagnosis of the patient", "the emphasis on voluntariness/willingness", "a designated space for the signatures of the patient and the physician", and "the description of the proposed treatment" (Table 2). Fewer than 20% of the ICFs included "the duration of hospitalization", "the severity/grade of the patient's disease", "the risks and expected benefits of alternative treatments", and "the prospects of alternative treatments". Unfortunately, the criterion "the people who will be mainly responsible for and involved in their care" was not included in any of the forms (Table 2).

Private hospitals' ICFs (PICFs) contained some information significantly more than both state hospitals' ICFs (SICFs) and university hospitals' ICFs (UICFs), which were

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Table 2 The presence of preselected parameters in ICFs and the difference between the university, state, and private hospitals.

	Parameter	All ICFs n = 126 (%; n)	UICFs n = 49 (%; n)	SICFs n = 40 (%; n)	PICFs n = 37 (%, n)
1	The risks of the proposed treatment	99.2 (125)	100 (49)	97.5 (39)	100.0 (37)
2	Diagnosis of the patient	92.9 (117)	20.4 (10)	52.5 (21)[b]	83.8 (31)[a,c]
3	The emphasis on voluntariness/willingness	89.7 (113)	87.8 (43)	85.5 (33)	100.0 (37)[a,c]
4	A designated space for signatures of the patient and the physician	81.7 (103)	57.1 (28)	95.0 (38)[b]	100.0 (37)[a]
5	The description of the proposed treatment	80.2 (101)	65.3 (32)	85.0 (34)[b]	94.6 (35)[a]
6	Addressing the legal guardian if the patient is incompetent	62.7 (79)	42.9 (21)	52.5 (21)	100.0 (37)[a,c]
7	The alternative treatments	52.4 (66)	44.9 (22)	42.5 (17)	73.0 (27)[a,c]
8	Duration of the proposed treatment	50.0 (63)	4.1 (2)	62.5 (25)[b]	97.3 (36)[a,c]
9	The prospects about quality of life after treatment	49.2 (62)	24.5 (12)	60.0 (24)[b]	70.3 (26)[a]
10	Sufficient information about diagnosed disease	46.8 (59)	20.4 (10)	47.5 (19)[b]	81.1 (30)[a,c]
11	The expected benefits of the treatment	40.5 (51)	18.4 (9)	37.5 (15)[b]	73.0 (27)[a,c]
12	Special arrangement for different age groups	40.5 (51)	10.2 (5)	22.5 (9)	100.0 (37)[a,c]
13	The prospects of treatment	35.7 (45)	6.1 (3)	30.0 (12)[b]	81.1 (30)[a,c]
14	If consent is given by a third person a space designated for explaining the reason for that	34.9 (44)	10.2 (5)	5.0 (2)	100.0 (37)[a,c]
15	A statement about a separate informed consent will be taken for anesthesia	34.1 (43)	24.5 (12)[a]	77.5 (31)[b,c]	0.0 (0)
16	Special arrangement for patients with reading difficulties/can't read	29.4 (37)	2.0 (1)	12.5 (5)[b]	83.8 (31)[a,c]
17	The time needed to return to normal life course (if possible)	24.6 (31)	0.0 (0)	45.0 (18)[b]	35.1 (13)[a]
18	The duration of hospitalization	15.9 (20)	8.2 (4)	37.5 (15)[b,c]	2.7 (1)
19	The severity/grade of patient's disease	13.5 (17)	10.2 (5)	25.0 (10)[c]	5.4 (2)
20	The risks and expected benefits of alternative treatments	11.9 (15)	12.2 (6)	12.5 (5)	10.8 (4)
21	The prospects of alternative treatments	2.4 (3)	0.0 (0)	2.5 (1)	5.4 (2)
22	The people who will be mainly responsible for and involved in their care	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)

ICF: informed consent form; PICF: private-hospital ICF; UICF: university-hospital ICF; SICF: state-hospital-ICF.
$p < 0.05$.
[a] When the PICFs were compared with the UICFs.
[b] When the SICFs were compared with the UICFs.
[c] When the PICFs were compared with the SICFs.

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the diagnosis of the patient ($p < 0.004$, 95% CI = 10.45–48.57 and $p < 0.0001$, 95% CI = 43.46–75.77, respectively), the emphasis on voluntariness/willingness ($p < 0.01$, 95% CI = 2.29–28.48 and $p < 0.03$, 95% CI = 0.77–24.19, respectively), addressing the legal guardian if the patient is incompetent ($p < 0.0001$, 95% CI = 2.29–28.48 and $p < 0.0001$, 95% CI = 0.77–24.19, respectively), information about alternative treatments ($p < 0.003$, 95% CI = 8.40–48.69 and $p < 0.0001$, 95% CI = 7.02–45.57, respectively), the duration of the proposed treatment ($p < 0.0001$, 95% CI = 17.48–50.43 and $p < 0.0001$, 95% CI = 78.48–96.91, respectively), sufficient information about diagnosed disease ($p < 0.004$, 95% CI = 12.18–50.95 and $p < 0.0001$, 95% CI = 40.49–73.69, respectively), the expected benefits of the treatment ($p < 0.003$, 95% CI = 13.28–53.15 and $p < 0.0001$, 95% CI = 34.03–68.94, respectively), special arrangements for different age groups ($p < 0.0001$, 95% CI = 59.79–87.68 and $p < 0.0001$, 95% CI = 74.90–95.57, respectively), the prospects of the treatment ($p < 0.0001$, 95% CI = 29.38–66.31 and $p < 0.0001$, 95% CI = 56.52–85.25, respectively), a space designated for explaining the reasons for when a third party can provide consent ($p < 0.0001$, 95% CI = 80.13–98.61 and $p < 0.0001$, 95% CI = 74.90–95.57, respectively), and special arrangement for patients with reading difficulties/inability to read ($p < 0.0001$, 95% CI = 51.11–82.38 and $p < 0.0001$ 95% CI = 64.57–90.52, respectively) (Table 2).

Items that were included in both SICFs and PICFs significantly more than UICFs were "a designated space for signatures of patient and physician" ($p < 0.0001$, 95% CI = 26.99–56.77 and $p < 0.0001$, 95% CI = 20.66–52.23 respectively), the descriptions of the proposed treatment ($p = 0.05$, 95% CI = 12.54–50.43 and $p < 0.002$, 95% CI = 12.28–43.83, respectively), the information on prospects about the quality of life after treatment ($p < 0.001$, 95% CI = 15.06–52.44 and $p < 0.0001$, 95% CI = 24.76–61.53, respectively), and the average time needed to return to an ordinary course of life (if possible) ($p < 0.0001$, 95% CI = 28.96–60.17 and $p < 0.0001$, 95% CI = 19.94–51.21, respectively) (Table 2).

The items included in SICFs significantly more than both UICFs and PICFs were that a statement about a separate IC will be taken for anesthesia ($p < 0.0001$, 95% CI = 32.86–67.28 and $p < 0.0001$, 95% CI = 59.79–87.68, respectively) and the duration of hospitalization ($p < 0.002$, 95% CI = 12.15–45.63 and $p < 0.001$, 95% CI = 17.48–50.43, respectively) (Table 2).

The items included in SICFs significantly more than UICFs were the diagnosis of the patient ($p < 0.002$, 95% CI = 12.10–49.18), the duration of the proposed treatment ($p < 0.0001$, 95% CI = 40.30–72.09), sufficient information about diagnosed disease ($p < 0.02$, 95% CI = 7.42–44.56), and the prospects of the treatment ($p < 0.004$, 95% CI = 8.08–39.84) (Table 2).

A statement about the requirement of a separate IC for anesthesia was included in UICFs significantly more than PICFs ($p < 0.0001$, 95% CI = 10.85–38.10) (Table 2).

The severity of the patient's disease was one of the most neglected parameters in all ICFs. The SICFs included this information significantly more than in the PICFs ($p < 0.02$, 95% CI = 3.23–35.29) (Table 2).

Of the UICFs, 40.8% (n = 20) were designed to obtain blanket consents. These forms initially resembled a standard ICF. However, toward the end of the forms, before the section for the signatures of the patient and the physician, a couple of paragraphs were inserted. One paragraph declared that by consenting to this procedure, the patient also provides consent for her data or tissues to be used for any medical research purposes. The second was for consenting to be taped or video recorded during the procedure for training and educational purposes. Some forms included a statement for consenting to the involvement of trainees during the procedure. None of the forms with the said paragraphs had sufficient assurance or information about how patient data would be protected. The patients were not provided with the choice to consent to the medical intervention but refuse to be included in research or recorded. None of these forms specified which data or specimens of the patients would be used. Moreover, no information was disclosed about the topics, methodology, or aims of the research projects. None of the PICFs requested blanket consent for research.

4. Discussion

The results demonstrate that the ICFs for general elective surgery contain many deficiencies and lack standardization across the leading healthcare providers. One of these deficiencies is that the forms are designed in a one-size-fits-all format. ICFs were written in a standard fashion to disclose information on the surgical procedure. However, the risks, expected benefits, and the average time of hospitalization might vary remarkably due to the stage of the diseases of each patient.

Moreover, patients might require customized ICFs due to social or personal factors, such as vulnerabilities, disabilities or language barriers.[5,22] The ICFs in use contain no space for surgeons to record the specifics of the patient. Although it would not be practical to write customized ICFs for each patient, appealing to alternative methods developed to customize information would improve the legal and ethical appropriateness of the forms and the entire IC process.[23]

In addition to being generic, the disclosed information is also insufficient. Some items that would affect the decision of the patient due to the impact on quality of life are excluded. Sufficient information about the diagnose, the severity of the disease, expected benefits of the treatment, the average time needed to return to normal life, duration of hospitalization, the risks and benefits of alternative treatments, the prospects of the proposed and alternative treatments are not adequately described in most of the ICFs.

Overall, ICFs from private hospitals were more comprehensive than those from state and university hospitals. There were significant differences in particular parameters such as comprehensive information about the diagnosis and the treatment and post-treatment process. Moreover, parameters with strong legal implications like addressing legal guardians, providing a space designated for third-party consent, or the emphasis on the patient's voluntariness/willingness were meticulously detailed in the PICFs. In addition, special arrangements for different age groups and patients with reading difficulties/inabilities were

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considered significantly more in the PICFs. The surgeons and hospital management should be aware that sufficient and proper documentation of the IC procedure with a written ICF has legal value.[24]

The literature demonstrates that disclosing inadequate information before the surgery may create unrealistic expectations from the surgery or post-operative recovery period[25] and, if the possible negative consequences regarding post-operative life quality are not adequately explained, patients might easily be driven to file a lawsuit due to any inconveniences after their surgery.[26] Although all ICFs, regardless of their institution, are vulnerable to defend hospital administrations of medical doctors in case of a lawsuit, PICFs may be considered better equipped for such a situation than that of SICFs or UICFs.

Lack of information on who will perform the surgery is another general problem in all ICFs. It is beyond doubt that for the consent to be informed, the expertise and experience of the surgeon should be disclosed to the patient. It could be argued that it is plausible to assume that the surgeon who obtains the IC and signs the ICF is the one who would perform the surgery. However, this assumption is overruled by surveys revealing that several professionals are assigned to obtain IC in the clinics. Junior doctors, nurses, or even administrative personnel might be responsible for obtaining IC.[27] Moreover, the possibility of the execution of surgery by junior surgeons should be disclosed to the patients.[28] The results of this study illustrate that there is a general inclination of informing the patient that junior doctors would be involved in the treatment procedure for training purposes. However, not specifying the extent of their involvement is problematic both in ethical and legal terms.

Requesting the consent of the patients for using their data or specimens in research as part of the IC procedure for clinical interventions is inappropriate both in legal and ethical terms. The Declaration of Helsinki and the Declaration of Lisbon on the Rights of the Patient clarify that IC for research purposes should be very different from the IC for medical/clinical purposes.[29–31] Driving the patients to provide consent for taking part in any research that they have no information about is a clear violation of the principle of respect for autonomy, privacy, and confidentiality. Considering the Law on Protection of Personal Data, this consent would be insufficient for using patients' personal information for unspecified research purposes.[32] Hence, these ICFs pose a high risk for surgeons and researchers who operate and conduct research on this basis.

This study illustrates that some ICFs that are currently in use significantly risk disrespecting the autonomy, privacy, and confidentiality of the patients. Moreover, they create substantial legal risks for surgeons and hospital administrations.

Declaration of Competing Interest

Authors declare no conflict of interest.

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