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Ethical evaluation of informed consent forms used in cardiology clinics and the importance of institutional standardized approach

Kardiyoloji kliniklerinde kullanılan bilgilendirilmiş olur formlarının etik değerlendirmesi ve kurumsal standart yaklaşımın önemi

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ABSTRACT

Objective: This study aimed to evaluate the content of informed consent forms (ICFs) used during cardiology interventions by the university, research and training (R&T), and private hospitals with regard to ethical standards and compare them with the Turkish Society of Cardiology (TSC) templates and among various institutions.

Methods: A total of 185 forms from the university, R&T, and private hospitals and 19 TSC templates were selected and analyzed for 26 criteria. Compliance with TSC templates was also evaluated. Data were presented as the percentage of ICFs satisfying the criteria and compared using the Fisher exact test, and 95% confidence intervals were calculated.

Results: TSC templates were more compatible and included more information to comply with ethical standards than ICFs of all 3 types of healthcare institutions. The areas of improvement for these templates were prospects of treatment and alternative treatments, quality of life, explanation for third-party consent, duration of hospitalization, and time to return to normal life. Among the 3 types of hospitals, R&T-ICFs were more compatible with templates. Private hospital ICFs had the poorest compliance with TSC templates. Separate anesthesia ICFs and detailed information about exposure to radioactivity were lacking.

Conclusion: The current ICFs for cardiology interventions have major ethical deficiencies and need urgent improvement. Professional societies such as TSC are essential institutions to develop and provide guidance and templates for ICFs to meet the ethical standards during the informed consent process and standardization of the process among various institutions.

ÖZET

Amaç: Bu çalışmanın amacı, üniversite, araştırma ve eğitim ve özel hastanelerin kardiyoloji girişimleri sırasında kullanılan bilgilendirilmiş olur formlarının (BOF) içeriğini etik standartlar açısından değerlendirmek ve Türk Kardiyoloji Derneği (TKD) taslak formları ile karşılaştırmak ve kurumlar arasındaki farkları belirlemektir.

Yöntemler: Üniversite, araştırma ve eğitim ve özel hastanelerde kullanılan 185 form ve 19 TKD şablon formu seçildi ve 26 kritere göre analiz edildi. Hastanelerde kullanılan formların TKD şablonlarına uyumları da değerlendirildi. Veriler, kriterleri karşılayan BOF'ların yüzdesi olarak sunuldu ve Fisher'in kesin testi kullanılarak karşılaştırıldı, %95 güven aralıkları hesaplandı.

Bulgular: TKD şablonları etik standartlarla daha uyumluydu ve her üç tür sağlık hizmeti kurumuna kıyasla etik standartlara uygun daha fazla bilgi içeriyordu. Bu şablonlarda tedavi ve alternatif tedavilere ilişkin beklentiler, yaşam kalitesi, üçüncü taraf onayının açıklaması, hastanede kalış süresi ve normal hayata dönme süresi kriterlerinde bazı eksikler saptandı. Üç hastane türü arasında araştırma ve eğitim hastanelerinde kullanılan BOF'lar TKD şablonlarına daha uyumluydu. Özel hastane BOF'ları TKD şablonlarıyla en zayıf uyuma sahipti. Ayrıca anestezi BOF'u ve radyoaktiviteye maruz kalma hakkında ayrıntılı bilgi sunumu genel olarak eksikti.

Sonuç: Kardiyoloji müdahalelerinde kullanılan mevcut BOF'ların büyük etik eksiklikleri vardır ve iyileştirilmesi gerekir. TKD gibi uzmanlık örgütleri, bilgilendirilmiş olur süreci ve çeşitli kurumlar arasında sürecin standardizasyonu ve etik standartlara uyumları için rehberlik sunmak ve BOF şablonları geliştirmek ve sağlamak için önemli ve temel kurumlardır.

The informed consent (IC) process is a fundamental ethical step in healthcare, especially for invasive procedures. The ethical basis for IC depends on the respect for autonomy principle. According to this principle, all competent individuals have the right to know and understand their disease, diagnostic and therapeutic means, alternatives, and risks and advantages of both the intended intervention and alternatives.[1] Moreover, they should come to a decision without undue influence. Beauchamp and Childress[2]

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emphasized that the patients should be free from limitations such as inadequate understanding of the facts about their health condition, paternalistic attitudes from physicians, or controlling interference of other parties. In legal terms, respect for autonomy and the right to IC was first recognized through a decision issued by the New York Court of Appeals in 1914. In this court opinion, Justice Benjamin Cardozo stated that "It is the right of any adult with the capability of making decisions concerning his own body, and that any surgical operation without the patient's consent should be considered as an assault."[3] Since then, the IC procedure and the duty of physicians to disclose information to their patients and give them the opportunity to enjoy their autonomy have been a part of both health legislation and good medical practice in most countries. However, the ethical and legal recognition of IC procedures did not solve all issues in practice, and new problems continued to emerge. These problems appeared in a wide spectrum, including the amount of information to be disclosed and the readability and language of informed consent forms (ICFs).[4-14]

Moreover, medical developments introduced new areas of expertise. Interventional cardiology is one area that has flourished in the past decades. The IC procedure in cardiology involves specific features that justify scrutinizing the process from an ethical point of view. The interdisciplinary nature of cardiology, extensive use of diagnostic and therapeutic interventions, additional risks (and benefits) of these, and epidemic nature of cardiovascular diseases constitute these features. The course of cardiology may require anesthesiology, which obliges amending the IC procedure and ICFs in classical cardiology medical interventions. Risks of interventions and implementation techniques are other particularities that should be discussed with the patient and written down in ICFs in a plain language during the IC procedure. Moreover, invasive cardiology interventions are complex procedures that are usually difficult for patients to comprehend. The patient's stress in fatal conditions that require risky invasive cardiology interventions may reduce the competency and capacity to comprehend the disclosed information.[7] Nevertheless, more information about the intervention may change the patient's choice, making them less likely to accept angiography.[8]

Abbreviations:

CIs	*Confidence intervals*
ECG	*Electrocardiography*
IC	*informed consent*
ICFs	*Informed consent forms*
NA	*Not applicable*
NCEP	*National Core Education Program*
P	*Private hospital*
R&T	*Research and training hospital*
TSC	*Turkish Society of Cardiology*
U	*University hospital*

Oral disclosure of information and answering patient questions in person is a crucially important step for the IC procedure. However, patients' anxiety, stress, and discomfort may prevent them from comprehending the provided information. Literature shows that patients have failed to recall information orally disclosed to them.[9,15] This lack of understanding and recall may cause legal problems for physicians being allegedly accused of not disclosing sufficient information before the procedure.[10] The low efficiency of oral communication and its accompanying legal risks bring prominence to ICFs. Patients may read over ICFs when they feel more relaxed and may find time to comprehend what they could not during their meeting with the physician. Moreover, a properly signed ICF may provide legal evidence to prove that the physicians have fulfilled their duty to respect patient autonomy by disclosing sufficient information. Therefore, ICF content and readability have a particularly significant role in the IC procedure for patients undergoing invasive cardiology procedures.

Despite these challenges, the existing literature is considerably blind to the ethical challenges of the IC procedure in cardiology. In this study, we aimed to shed light on these challenges by assessing the content of the current ICFs used in research and training (R&T), private, and university hospitals and the templates of the Turkish Society of Cardiology (TSC). We also discuss the measures to improve them so that ethical and legal requirements are met.

METHODS

Cardiologists from 3 different institutions, namely, university, state R&T, and private hospitals, were randomly contacted to kindly provide ICFs used in their clinics. The cardiologists who responded to this request were from 9 university hospitals, 6 state R&T hospitals, and 6 private hospitals, and they provided a total of 185 ICFS. The forms were designated for 17 elective cardiologic interventions. TSC developed 19 template ICFs for 10 of these indications (Table 1).

Table 1. Procedures/indications of ICFs Included in the study

Indication	Number of ICFs
Enhanced external counterpulsation	1
Tilt table test	1
Application of drug-eluting stents	2
Treatments and interventions that may be performed in coronary care unit	4
Stress ECG	7
Temporary pacemaker implantation	10
Fibrinolytic treatment	12
Pericardiosynthesis	6
Interventions for congenital heart diseases	10
Medical/electrical cardioversion	12
Peripheral vascular interventions and imaging	14
Transesophageal echocardiography or stress echocardiography	16
Percutaneous coronary interventions	19
Percutaneous valve interventions*	19
Coronary angiography	21
Interventions and diagnostic tests for rhythm problems	24
Implantable devices†	26

ECG: electrocardiography; ICFs: informed consent forms.
*Mitral valve balloon dilatation, aortic valve balloon dilatation, transcatheter aortic valve implantation, and carillon mitral contour system.
†Implantable cardioverter-defibrillator, cardiac resynchronization therapy with or without defibrillator, and permanent pace maker.

The 185 ICFs and 19 templates were allocated numbers, and the origin of the form (i.e., which hospital it was from) was blinded, and they were then evaluated for their content regarding the principal ethical criteria that should be involved in ICFs. We also evaluated whether the institutional ICFs were based on the TSC templates.

Development of Ethical Criteria for ICF Assessment

A similar methodology that was constructed by Ekmekci et al.[10] to develop ethical criteria for ICF assessment was followed. The content and scope of a proper ICF, which was provided by Beauchamp and Childress[2] were used as a generic frame for assessment criteria. We called this frame the "primary list of ethical criteria for ICFs." The main ethical principles guiding this frame were respect for autonomy, non-maleficence, beneficence, justice, and the professional patient-physician relationship. The second step was to go through 3 current guidelines: Code of Medical Ethics of American Medical Association,[16] Consent Guide by General Medical Council of UK,[17] and Turkish Patient Rights Directive.[18] We listed the criteria requested in ICFs for each of these documents. These lists were cross-matched in a matrix. We selected the criteria that appeared in more than 1 guideline and placed them in the preliminary pool of practical criteria. The third step was to check this preliminary pool of practical criteria against the primary list of ethical criteria to construct the 26 final evaluation criteria, which are listed in Table 2. We then evaluated the presence of the criteria in a form. All blinded forms, including TSC templates, were read by each author, and if a criterion was present, it was signed as 1, and if a criterion was not present, it was signed as 0. For the 27th criterion, we checked the forms obtained from hospitals to verify whether they were based on TSC templates.

Statistical Analysis

The data were presented as the percentage of ICFs satisfying the criteria. The results of the university, R&T, and private hospitals were compared using the Fisher exact test, and the 95% confidence intervals (CIs) were calculated. Statistical significance was indicated by $p<0.05$. The data were analyzed using the Statistical Package for the Social Sciences version 25 software (IBM SPSS Corp., Armonk, NY, USA).

RESULTS

A total of 204 cardiovascular intervention ICFs were analyzed. The indications of these interventions and the number of ICFs for each indication are presented in Table 1. TSC has templates for indications 8 through 17.

Of the 204 forms, 185 were obtained from 21 different healthcare institutions. A total of 106 (57.30%) ICFs were from 9 university hospitals (U-ICFs), 52 (28.11%) were from 6 state R&T hospitals (R&T-ICFs), and 27 (14.60%) were from 6 different private hospitals (P-ICFs). The characteristics of these and the 19 templates of TSC were analyzed and compared for the content and compatibility with the ethical principles (Table 2).

We evaluated the forms for indications that necessitate the use of x-rays. None of these forms mentioned the use of radioactivity and its possible haz-

Table 2. Presence of preselected parameters in ICFs and the difference among the TSC templates and ICFs from the university, state, and private hospitals

Parameter	All hospital ICFs (n=185), n (%)	TSC-ICFs (n=19), n (%)	U-ICFs (n=106), n (%)	R&T-ICFs (n=52), n (%)	P-ICFs (n=27), n (%)
Emphasis on voluntariness/willingness	168 (90.81)	19 (100)	90 (84.91)*†	51 (98.08)	27 (100)
Diagnosis/prediagnosis of the patient	137 (74.05)	19 (100)	71 (66.98)*‡	48 (92.31)	18 (66.67)‡§
Sufficient information about diagnosed disease	146 (78.92)	19 (100)	84 (79.25)‡	46 (88.46)	16 (59.26)†‡§
Severity/grade of the patient's disease	96 (51.89)	19 (100)	54 (50.94)‡	35 (67.31)‡	7 (25.93)†‡§
Description of the proposed treatment	178 (96.22)	19 (100)	101 (95.28)	51 (98.08)	26 (96.30)
Duration of the proposed treatment	150 (86.49)	19 (100)	85 (80.19)*‡	50 (96.15)	19 (70.37)‡§
Expected benefits of the treatment	150 (81.08)	18 (94.74)	82 (77.36)*	48 (92.31)	20 (74.07)§
Prospects about quality of life after treatment	70 (37.84) NA: 1 (0.54)	16 (84.21)	33 (31.13)*‡ NA: 1 (0.94)	29 (55.77)‡	8 (29.63)‡§
Time needed to return to normal life course (if applicable)	32 (17.30) NA: 1 (0.54)	2 (10.53)	15 (14.15)† NA: 5 (4.72)	7 (13.46)§ NA: 4 (7.69)	10 (37.04)‡
Duration of hospitalization	74 (40.0) 7 (3.78 NA: 14 (7.57)	10 (52.63)	51 (48.11) NA: 12 (11.32)	20 (38.46) NA: 7 (13.46)	10 (37.04) NA: 3 (11.11)
Risks of the proposed treatment	182 (98.38)	19 (100)	105 (99.06)	51 (98.08)	26 (96.30)
Prospects of the treatment	79 (42.70) 5 (2.70) NA: 7 (3.78)	8 (42.11)	46 (43.40) NA: 3 (2.83)	21 (40.38) NA: 4 (7.69)	17 (62.96)
Alternative treatments	142 (76.76) NA: 4 (2.16)	19 (100)	77 (72.64)*‡ NA: 2 (1.89)	50 (96.15) NA: 1 (1.92)	15 (55.56)‡§ NA: 1 (3.70)
Risks and expected benefits of alternative treatments (if applicable)	28 (15.14) 42 (22.70) NA: 67 (36.22)	1 (5.26)	27 (25.47) NA: 39 (36.79)	16 (30.77)‡ NA: 18 (34.62)	6 (22.22) NA: 10 (37.04)
Prospects of alternative treatments	1 (0.54) NA: 44 (23.78)	0	0 NA: 45 (42.45)	0 NA: 21 (40.38)	1 (3.70) NA: 13 (48.15)
A statement about a separate informed consent will be taken for anesthesia (if applicable)	0 NA: 25 (13.51)	0 (NA)	0 NA: 13 (12.26)	0 NA: 9 (17.31)	0 NA: 3 (11.11)
A designated space for signatures of the physician	183 (98.92)	19 (100)	105 (99.06)	51 (98.08)	27 (100)
A designated space for signatures of the patient	184 (99.46)	19 (100)	106 (100)	52 (100)	26 (96.30)
Addressing the legal guardian if the patient is incompetent	183 (98.92)	19 (100)	106 (100)	52 (100)	25 (92.59)
If consent is given by a third person, a space designated for explaining the reason for that	119 (64.32)	14 (73.68)	80 (75.47)	23 (44.23)*‡	17 (62.96)
Special arrangement for patients with reading difficulties/who cannot read	154 (83.24)	19 (100)	83 (78.30)‡†	45 (86.54)§	27 (100)
Discrepancy between the diagnosis and explanations	14 (7.57)	1 (5.26)	9 (8.49)	2 (3.85)	3 (11.11)
Blanket consent	5 (2.7)	0	5 (4.72)	0	0
Explanation about who is going to perform the procedure	136 (73.51)	19 (100)	82 (77.36)‡*	48 (92.31)	6 (22.22)†‡§
Explanation about whether the procedure can be used for training purposes	111 (60.0)	19 (100)	66 (62.26)‡*	45 (86.54)	0†‡§
Providing a copy of consent form	123 (66.49)	19 (100)	83 (78.30)‡	25 (48.08)*‡	15 (55.56)‡†
Based on the TSC, if available	96 (89.72) NA: 78 (42.16)	NA	61 (92.42) NA: 40 (37.74)	27 (90.0) NA: 22 (42.31)	8 (72.73)†§ NA: 16 (59.26)

ICF: informed consent form; NA: not applicable; P: private hospital; R&T: research and training hospital; TSC: Turkish Society of Cardiology; U: university hospital.
*p<0.05 when the U-ICFs were compared with R&T-ICFs.
‡p<0.05 when the hospital ICFs were compared with TSC-ICF templates.
†p<0.05 when the U-ICFs were compared with P-ICFs.
§p<0.05 when the R&T-ICFs were compared with P-ICFs.

ards, but some of the forms stated that "x-rays may be applied" without clearly mentioning the details of exposure, such as the dose, duration of exposure, why it is required, and its possible risks.

Characteristics of the ICF Templates of the TSC

No templates were available for nearly half of the cardiology interventions currently performed in the hospitals from where we obtained the ICFs.

All (100%) TSC-ICF templates covered the following ethical parameters: 1-6, 11, 13, 17-19, 21, 24-26 (Table 2). The number and percentage of TSC-ICF templates for other parameters are provided in Table 2.

General Characteristics of the University, R&T, and Private Hospital ICFs

The only parameter that none of the hospital forms included was the 16th parameter, informing the patient that a separate ICF will be requested if anesthesia was going to be administered, and this was not applicable for 25 (13.51%) of the forms (Table 2).

Comparison of ICFs From the University, R&T, and Private Hospitals With TSC-ICFs

Information on the severity/grade of the patient's disease (4th parameter) was included in all TSC-ICFs and was significantly more than all type of hospitals' ICFs (U-ICFs p=0.0001, 95% CI: 29.83-58.44; R&T-ICFs p=0.0045, 95% CI: 12.50-46.24; and P-ICFs p<0.0001, 95% CI: 48.88-86.83). Similarly, the prospects about quality of life after treatment (8th parameter) were included in 16 (84.21%) TSC-ICFs and were significantly more than the inclusion of similar information in all types of hospitals' ICFs (U-ICFs p<0.0001, 95% CI: 29.38-66.11; R&T-ICFs p=0.0288, 95% CI: 3.26-45.35; and P-ICFs p=0.0003, 95% CI: 25.78-71.76). Providing a consent form copy (26th parameter) was also included in all TSC-ICFs and was significantly more than U-ICFs (p=0.0252, 95% CI: 3.57-30.46), R&T-ICFs (p=0.0001, 95% CI: 30.52-64.89), and P-ICFs (p=0.0008, 95% CI: 20.63-62.68) (Table 2).

The following items were included in all TSC-ICFs and were significantly more than both U-ICFs and P-ICFs: duration of the proposed treatment (6th parameter) (U-ICFs p=0.0341, 95% CI: 1.79-28.39 and P-ICFs p=0.0098, 95% CI: 7.89-48.48), explanation about the diagnosis/prediagnosis of the patient (2nd parameter) (U-ICFs p=0.0033, 95% CI: 14.30-42.43 and P-ICFs p=0.0055, 95% CI: 11.0-52.17), sufficient information about the diagnosed disease (3rd parameter) (U-ICFs p=0.0294, 95% CI: 2.67-29.43 and P-ICFs p=0.0016, 95% CI: 17.37-59.27), inclusion of information about alternative treatments (13th parameter) (U-ICFs p=0.0096, 95% CI: 8.91-36.53 and P-ICFs p=0.0008, 95% CI: 20.63-62.68), explanation about who is going to perform the procedure (24th parameter) (U-ICFs p=0.0216, 95% CI: 4.45-31.48 and P-ICFs p<0.0001, 95% CI: 52.75-89.39), and explanation whether the procedure can be used for training purposes (25th parameter) (U-ICFs p=0.0012, 95% CI: 18.83-47.24 and P-ICFs p<0.0001, 95% CI: 79.07-100.0) (Table 2).

P-ICFs were significantly more likely to mention the time needed to return to normal life course (9th parameter) (if applicable) (p=0.0462, 95% CI: 0.51-46.72) than TSC-ICFs (Table 2).

The content of the risks and expected benefits of alternative treatments in R&T-ICFs (14th parameter) (p=0.0268, 95% CI: 3.30-39.69) was significantly more than that in TSC-ICFs. Inclusion of a space designated for the explanation of the reason if consent is given by a third person (20th parameter) (p=0.0290, 95% CI: 3.27-48.69) was significantly lower than that in TSC-ICFs (Table 2).

The content about special arrangement for patients with reading difficulties/who could not read in U-ICFs (21st parameter) (p=0.0252, 95% CI: 3.57-30.46) was significantly lower than that in TSC-ICFs, which included this information in all forms (Table 2).

Comparison Among the 3 Institutions

Among the 3 institutions, the number of ICFs based on TSC-ICFs (27th parameter) was significantly low in P-ICFs than in both U-ICFs (p=0.0045, 95% CI: 4.96-38.85) and R&T-ICFs (p=0.0479, 95% CI: 0.08-36.88) (Table 2).

The content of the emphasis on voluntariness/willingness (1st parameter) was significantly lower in U-ICFs than in both R&T-ICFs (p=0.0123, 95% CI: 3.25-21.35) and P-ICFs (p=0.0320, 95% CI: 1.44-23.12). A space designated to explain the reason why consent is given by a third person (20th parameter) was included in U-ICFs significantly more often than in R&T-ICFs (p=0.0001, 95% CI: 15.08-45.79). Similarly, a statement that a copy of the consent form

will be provided to the patient (26th parameter) was significantly more common in U-ICFs than in both R&T-ICFs (p=0.0001, 95% CI: 14.35-44.86) and P-ICFs (p=0.0170, 95% CI: 3.74-42.20) (Table 2).

Information on diagnosis/prediagnosis of the patient (2nd parameter) is less often included in both U-ICFs (p=0.0005, 95% CI: 12.01-35.83) and P-ICFs (p=0.0038, 95% CI: 7.60-45.05) than in R&T-ICFs.. Similarly, the duration of the proposed treatment (6th parameter) was included more in R&T-ICFs than in both U-ICFs (p=0.0077, 95% CI: 4.76-24.99) and P-ICFs (p=0.0012, 95% CI: 9.25-44.84). Furthermore, the expected benefits of the treatment (7th parameter) were included more in R&T-ICFs than in both U-ICFs (p=0.0212, 95% CI: 2.39-24.94) and P-ICFs (p=0.0273, 95% CI: 1.73-37.56). Moreover, the prospects about quality of life after treatment (8th parameter) were mentioned more in R R&T-ICFs. than in both U-ICFs (p=0.0030, 95% CI: 8.28-39.61) and P-ICFs (p=0.0282, 95% CI: 2.99-44.83). Mention of the alternative treatments (13th parameter) was significantly more common in R&T-ICFs than in both U-ICFs (p=0.0005, 95% CI: 11.64-33.09) and P-ICFs (p<0.0001, 95% CI: 21.42-59.05) (Table 2).

Explanation about who is going to perform the procedure (24th parameter) was included significantly more often in R&T-ICFs than in both U-ICFs (p=0.0212, 95% CI: 2.39-24.94) and P-ICFs (p<0.0001, 95% CI: 48.80-82.60). U-ICFs included this information significantly more often than P-ICFs (p<0.0001, 95% CI: 34.61-68.66). Explanation of whether the procedure can be used for training purposes (25th parameter) was included in none of the P-ICFs and was significantly less than both U-ICFs (p<0.0001, 95% CI: 46.59-7.91) and P-ICFs (p<0.0001, 95% CI: 69.38-93.32). R&T-ICFs included this information significantly more often than U-ICFs (p=0.0018, 95% CI: 9.64-35.96) (Table 2).

Sufficient information about the diagnosed disease (3rd parameter) was significantly less common in P-ICFs than in both U-ICFs (p=0.0324, 95% CI: 1.59-39.67) and R&T-ICFs (p=0.0029, 95% CI: 9.35-48.72). Similarly, the severity/grade of a patient's disease (4th parameter) was significantly less common in P-ICFs than in both U-ICFs (p=0.0204, 95% CI: 4.04-4.81) and R&T-ICFs (p=0.0005, 95% CI: 18.24-58.34). However, the time needed to return to normal life course (9th parameter) was included significantly more in P-ICFs than in both U-ICFs (p=0.0068, 95% CI: 5.49-42.38) and R&T-ICFs (p=0.0162, 95% CI: 4.09-43.50). Similarly, special arrangements for patients with reading difficulties or who cannot read (21st parameter) were significantly more common in P-ICFs than in both U-ICFs (p=0.0080, 95% CI: 7.52-30.46) and R&T-ICFs (p=0.0472, 95% CI: –0.72 to 25.27) (Table 2).

DISCUSSION

The results indicate that TSC, a professional organization, is essential to provide guidance for ethical IC procedures. ICF templates provided by the organization were more comprehensive than most of the forms currently used by various healthcare institutions, if available. However, there are still essential areas in these templates that should be improved both in quality and quantity. Private hospital ICFs were less likely to comply with the ethical standards in many areas compared with both university and R&T hospitals. The latter 2 institutions complied with the TSC-ICF templates significantly more than private hospitals, which may explain the deficiency of this institution.

One other reason for the scarcity of ethical criteria in private hospitals compared with the other 2 "educational" institutions may be the institutions' aim of providing education itself. Obtaining proper IC from patients and developing ethically and legally appropriate ICFs are included in National Core Education Program (NCEP) for medical schools.[19] According to NCEP, medical schools should incorporate IC into their undergraduate curricula. It is suggested to teach the ethical grounds for taking IC within the discourse of patient rights and main principles of medical ethics. However, it is a fact that medical ethics education in undergraduate and residency trainings is a very problematic area of medical education. The main reason for this is the limited human resources. The number of academicians in the field of medical ethics is very scarce. Most of the medical schools do not have any lecturers with a Ph.D. in medical ethics. In these schools, ethics courses are taught by academicians from other fields such as public health, which raises serious concerns about the quality and content of these courses.[20] In addition, there are no structured medical ethics courses in cardiology residency training. Although the current cardiology residency

curriculum of the European Society of Cardiology has it as one of the learning targets,[21] IC training is not a learning objective in the current cardiology curriculum of the Turkish Ministry of Health.[22] Hence, it is plausible to say that training on IC and its ethical and legal implications is very limited in undergraduate and postgraduate medical education. Considering the ethical, legal, and professional consequences of a sloppy IC procedure, it is suggested strongly to embody a formal and well-structured training program on IC in undergraduate and residency curricula, which can be initiated by TSC as well.

We observed some discrepancies, which mainly included inconsistency about the indication in the title and in the body of the document. We believe this is mainly caused by the use of "copy-paste" during preparation of the forms. For instance, a peripheral angiography ICF contained and provided information about coronary stents, although coronary stents were not a part of the intervention, and the ICF regarding with coronary intervention with stent from this institution included a statement with exactly the same words.

Another problematic area we observed was the absence of satisfactory information regarding radioactivity exposure, risks, and long-term effects. The current practice clashes against the guidelines and the law explaining the importance and necessity of providing information about the use of radioactivity.[13,23,24] The information must be shared using plain language, explaining the type and duration of exposure and the dose and the short and long-term risks.

Efforts on improving the IC procedure and ICFs, in particular, are advancing along 2 different pathways. The first is IC for clinical research, and the second is IC for clinical procedures to diagnose or treat patients. These 2 IC procedures have several common and also some different features. For a considerable amount of time, the emphasis has been on IC for clinical research. However, the emergence of improvements in health services-like alternatives for treatment and diagnosis has increased by providing physicians advanced technical tools to intervene with more severe cases. This shed light on the clinical IC procedure together with ICFs. Physician associations, such as the American Medical Association[25] and the American College of Surgeons,[26] and international organizations, such as the World Health Organization,[27] have focused on IC and provided guidelines to advise the content and scope of information to be disclosed. However, this information is usually ambiguous in terms of what to disclose in a legally and ethically sound ICF.[11] Currently, there is no concrete content list for an ICF to meet the ethical and legal requirements. Therefore, health institutions must make inferences from general principles of medical ethics after obtaining general guidance from these guidelines to develop an ethically sound ICF.

The main ethical principle of informed consent is patient autonomy with proper information, resulting in voluntary choice about their health and medical care. The information provided by ICFs should be enough for patients to comprehend how the suggested medical intervention suits their health needs, the benefits and risks, alternatives for treatment, and their pros and cons.[2] However, a deeper thinking process about how a patient makes a decision would reveal that they might need additional information before making a deliberative decision; this may include the time required to return normal course of life, the need for another person's care to sustain basic life routine, or hospitalization or immobilization durations.[12] It is plausible to say that the additional information may vary owing to medical specialty specifics. The content of cardiology ICFs should be developed using this perspective. We are faced with a fundamental question at this point: do ICF authors have enough competency to consider the ethical, legal, and scientific aspects of a proper ICF? The results of this study suggest a negative answer to this question. In fact, the inconsistencies between the title and body of some of the ICFs show that they were developed by copying and pasting previously existing ICFs. This may explain the lack of crucial information in invasive cardiology about the use of radiation and the risks it encounters.

Literature suggests that ICFs and the IC procedure in cardiology are problematic because of poor understanding of health status, future lifestyle, benefits of procedures, unrealistic expectations from the suggested intervention, and lack of awareness about alternative methods.[15,28,29] The results of this study suggest that deficiencies in the evaluated ICFs are similar to the existing problems in the literature.

Although the TSC-ICFs include more ethical principle parameters than all 3 types of hospital

ICFs and are more standardized for indications that are available, there is significant room for improvement in the TSC-ICFs. This is particularly true for providing information about the duration of the proposed treatment, the prospects about quality of life after treatment, a space designated for explaining the reason why consent was given by a third person, the duration of hospitalization, the time needed to return to normal life course, and the prospects of the suggested and alternative treatments. Knowing about those headlines is an important part of the patient being fully informed, and it is essential for the patient's autonomy. Hospital ICFs, especially from private hospitals, are poorer regarding selected parameters of evaluation. Moreover, TSC-ICFs do not utterly cover the indications that are thought to be principal interventions, such as fibrinolysis and stress tests. Regarding the aforementioned indications, guidance of TSC seems to be indispensable.

One of our important findings was that ICFs did not adequately mention radiation doses and long-term cancer risk. The radiation issue is particularly concerning, and it is clearly recommended to be a routine part of clinical reports.[30] Its importance is emphasized in using the shared decision-making process, and physicians are the main party who is responsible for providing patients with all the information for every step of the procedure that patients will undergo and for providing patients with all the information that will be useful in the patient's decision making.[29,31] However, one important issue blocking the improvement of the process is that both patients and physicians think the IC process is perfunctory.[30,32] With the increasing importance of providing a valid written document during malpractice cases, providing lectures regarding obtaining ICs in medical school curricula, providing training on these issues available to healthcare providers, implementing the IC process in all levels of healthcare, and improving health literacy surrounding the process may also increase the quality and success of the IC process.

Improving ICFs has resulted in better patient understanding of invasive cardiology procedures. According to a study performed among patients hospitalized for programmed coronary angiography, patient knowledge was assessed before and after they read the information sheet concerning indication, modalities, benefits, possible complications, or later possibilities. Patient knowledge improved significantly only for some of the risks (allergy, bruising, and cardiac risks).[33] This study highlights the importance of better and effective provision of information and evaluating patient understanding of the information. A more efficient IC procedure is crucial for obtaining better patient support for the treatment and to prevent forensic implications. In two studies conducted in 9 hospitals in Spain,[34,35] defining areas of improvement for forms[35] and implementing corrective measures were effective.[34] Similar improved results were obtained via several interventions, such as multimedia presentations (videos, interactive computer-based presentations, audiotape recordings of their consultations, telephone, e-mail, and text messages), designing ICFs in a health literacy-based form, and providing sufficient time for a 2-way discussion between the patient and physician.[36] None of the forms we evaluated included a descriptive figure, diagram, or other elements that could be used to improve patient understanding.

However, the length and sophistication of an ICF may negatively affect patients' intention to read and understand the ICF.[36] Therefore, the authors should derive a balance between providing enough information and avoiding repulsiveness toward reading the document, which is very hard to achieve.

According to several studies, ICFs are complex, incomplete, and have poor readability scores; these ICFs require improvement.[13] As we did not perform a readability test on the ICFs we evaluated, the utility of these forms will be improved by considering the findings of others during the preparation of improved forms.[13,14]

Institutions and professional societies may play an important role in developing proper ICFs.[17,24,26,27,30] They have access to enough professional experience provided by their senior members about which information would be crucial for patients when making up their minds. Although the members may not have enough ethical expertise to write down a sound ICF, they may get professional consultations from ethicists. In this context, the ethical assessment of TSC becomes more important, as we assume that its flaws would be duplicated in ICFs at several institutions. Similarly, the practice at main university hospitals that serve as key opinion leaders is also important because they set a process example. One university

hospital ICF was designed as a general form called "ICF for surgical/invasive procedures/high-risk procedures." It stated that verbal information was provided, there are spaces to write indications, and the form included general explanations about the benefits and risks of interventions. As this is one of the leading university hospitals, it may be used as a sample by other institutions, which brings the risk of an exponential increase in the deficiencies and ethical incompatibilities of this sample.

Here, we only evaluated ICFs, which are only a part of the process. The IC process can be affected by many factors and patients', healthcare providers', and healthcare systems' characteristics, including inadequate communication skills, inadequate understanding, insufficient information, and coercion.[36] All these factors decrease the quality of the gold standards and consequences of failure to implement in a single step, decreasing the chance to achieve an effective, high quality, and standard IC procedure. With agreement on the importance of each step and participant to the process, we at least shall begin with improving and standardizing our forms because ICFs are the cornerstone of this process. To achieve more standardized, feasible, achievable, proportionate, and justified IC procedures, the collaboration between healthcare authorities and specialist societies with the essential contribution of ethics specialists is the initial step.[36] Moreover, continuously updating ICFs is also essential in accordance with the continuous flow of clinical and scientific data.

This study shows that there are several discrepancies in the ICFs of several institutions. These discrepancies not only result in breaches in realizing respect for autonomy, one of the main principles of medical ethics, but also lead to legal problems for the physicians and hospitals in case of an administrative complaint or if is brought before the court. Therefore, it is of utmost importance to make sure that the ICFs meet the minimum criteria required to be ethically appropriate. At this point, the TSC is subject to play a significant role. Providing an appropriate example of ICFs designed for major invasive cardiology implementations would be helpful for invasive cardiology clinics to develop their own forms. However, it should be kept in mind that a one-size-fits-all approach is not workable for ICFs. Invasive cardiology clinics may have their unique circumstances, which need to be reflected in the ICFs. Copying and pasting a template ICF would fail the interlocutors by creating a false belief of fulfilling their legal and ethical obligations in this regard. Therefore, in addition to providing example ICFs, developing standards for writing down ICFs is a preferable suggestion for the TSC. It is the responsibility of each clinic to custom design their ICFs by checking boxes of these standards.

The practice of providing information and gathering consent may vary among healthcare institutions, as elaborately presented in our results. Handling the IC procedure without utmost care and attentiveness may not only result in harm to the patient but also to the healthcare professional and institution that are providing care. Clinics should be diligent for keeping proper records of ICFs in their files. In case of a lawsuit, it is the defendant's responsibility to provide the ICF to the court. Failing to submit the signed ICF may result in problems in terms of malpractice allegations.[37,38]

This study showed us the importance of developing standardized guidelines and forms for IC procedure by the scientific authority and proposing them to the healthcare community. The current TSC forms must be increased in number to cover all interventions performed by cardiology specialists and improved in accordance with the universal ethical standards to set a high-value healthcare system.

Limitations

The number of forms we evaluated were limited, and they were mostly obtained by contacting cardiologists in 9 university, 6 R&T, and 6 private hospitals. A more systematic approach, maybe via society, might increase the number of forms we obtained and thus increase the homogeneity and reliability of the results. However, we believe that an increased number of forms might provide similar results.

We only evaluated ICFs, which are only a part of the process. The process as a whole can be evaluated. The authors are planning to perform a follow-up study after improving the quality of ICFs and evaluating the impact of more ethically standardized forms on the IC process, which is a shortcoming of this study because we only evaluated the available forms rather than the impact of the different quality forms on the process.

We obtained limited data (number of words, number of medical terms, and font type and size) on the

readability of the forms, and we did not perform a structured readability test on these forms. Therefore, we did not share these data.

Conclusion

Our results highlight the importance of the specialty-specific professional society guidance. The higher ethical quality of the TSC template ICFs would improve the quality of the process if the institutions base their IC procedures on the guidelines and templates provided by the society. We believe that increasing awareness about the presence of the templates and the practical importance of applying the ethical considerations to daily practice is also a duty of the professional society, which may be achieved via collaboration between the specialty professionals with medical ethics and law specialists.

Based on our findings, we conclude by several recommendations to achieve the highest ethical standards:

1. Standardization of the forms.
2. Coverage of all indications, especially if they require invasive therapeutic and diagnostic procedures.
3. Formal training on the IC procedure and contents of an ethically sound ICF not only for undergraduates but also during residency training. Moreover, TSC as the main cardiology occupational and scientific society should organize education programs (online, in symposiums, in congresses, etc.) for currently active specialists as well.
4. Conducting a multicenter research on the practical application of IC procedure from a cardiologists' point of view.
5. Customizing the ICF to meet particular risk factors specific for that clinic. We suggest standardizing the coverage of all ICFs and the TSC to be the leader of this. However, if there are risk factors specific to a clinic, we suggest customizing the "standard" template ICF in accordance with their needs.
6. Updating the ICFs on a regular basis according to the laws and contemporary scientific data.

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