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Title: Ethical Assessment of Blank Consent Forms for Medical Interventions in a Training and Research Hospital in Turkey

Running Head: Ethical Assessment of Consent Forms

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Özet

Amaç: Bir eğitim ve araştırma hastanesinde tıbbi girişimler için kullanılan matbu onam formlarının etik standartlara uygunluğunu değerlendirmek

Yöntemler: Bu araştırmada bir eğitim ve araştırma hastanesinde tıbbi müdahaleler için kullanılan matbu aydınlatılmış onam formlarının içeriği araştırmacılar tarafından sınıflandırıldı. Hasta Hakları Yönetmeliği ve Hekimlik Meslek Etiği Kuralları'na uyumu, Ateşman Okunabilirlik Formülü ile okunabilirliği ve tıbbi terminoloji kullanımı açısından değerlendirildi.

Bulgular: Araştırma süresinde hastanede kullanılan işleme özgü onam formu sayısı 336 idi. Araştırmacılar tarafından sınıflanan içeriğe göre müdahalenin amacı (>67), riskleri (>96) ve sorumlu hekimin adı-soyadı (>94) bölümleri en sık tekrarlanan bölümlerdi. Tüm bilgilendirme ve onam formlarının okunabilirlik seviyesi "zor" idi (>94) ve tıbbi terminoloji kullanımı özellikle cerrahi onam formlarında (>89) yüksekti. Formların içeriğinde hastanın bilmeme hakkını vurgulayan önemli bölümler olduğu gibi hasta dışında bir personelin imzası gibi hasta gizliliğini ihlal edebilecek bölümler de vardı.

Sonuç: Kullanılan matbu onam formlarının mevzuat çerçevesinde güncellenmesi ve anlaşılırlığının sağlanması aydınlatılmış onamın hayata geçirilmesinde yaşanan sorunları azaltabilir.

Anahtar sözcükler: tıp etiği, aydınlatılmış onam, onam formları, okunabilirlik

Abstract

Objectives: To assess ethical conformity of consent forms to the ethical standards which were using for medical interventions in a training and research hospital.

Methods: In this study, content of informed consent forms using for medical interventions in the hospital were categorized under standard topics by the researchers and were assessed according to updated Turkish Regulation on Patients' Rights, Ateşman's Readability Formula and medical terminology use.

Results: A total of 336 procedure-specific-consent-forms were using in the hospital. It was seen that the parts to which were given place at the highest rate were aim of the intervention (>67), possible risks (>96), name-surname and signature of the responsible physician (>94) and the patient (>94). All consent forms were displayed 'difficult' readability levels (>94) and medical terminology was highly used especially at surgical treatment forms (>89). There were some favourable topics such as right not to know of the patient as well as the titles that may lead to breach of autonomy of the patient such as signature of personnel other than the physician.

Conclusions: Updating the consent forms within the frame of titles recommended in this paper will ease arrangement of the content in accordance with ethical and legal standards.

Key words: medical ethics, informed consent, consent forms, readability

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Introduction

Informed consent is defined as the process whereby individuals with decision-making capacity give their permission for a given procedure after receiving information and confirming that they understand the diagnosis, treatment and alternative treatment options, as well as the possible positive or negative outcomes (1). The main objective is to protect an individual's autonomy, and so the process allows patients to exercise their right to decide (2). This is achieved by giving information to a competent and willing patient who can understand the information, which is demonstrated through concepts of competence, voluntariness, disclosure and recommendation, understanding, decision and authorisation.

While there remain no agreements for definitions of many issues in medical ethics, informed consent has had relatively standard ethical, legal and institutional definitions in national and international regulations for a long time (3). Moreover, the term 'informed consent' was entered as a keyword into Medical Subject Headings (MeSH) in 1973. However, as of February 2016, a Medline search revealed more than 35,000 articles that included informed consent as a keyword, indicating that it remains a topic of intense discussion.

A possible reason for the continued debate is the difference between the theory and application of the informed consent process (4). As Beauchamp and Childress observed (5), informed consent is discussed and used with two different meanings. The first describes the process whereby the individual autonomously gives authorisation for a medical intervention (or participation in research) through the act of informed and voluntary consent, which occurs by doing more than expressing an agreement or complying with a proposal. The second

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meaning describes the process whereby professionals obtain legally and institutionally valid consent from patients to perform diagnostic and treatment procedures, but that does not require patient autonomy (5). Indeed, consent forms are only able to show that information has been given (and at best, that information has been given clearly), but does not provide any evidence that the patient is competent or consents voluntarily.

Within this framework, it is possible to separate the empirical research about informed consent into two broad subjects. The first concerns whether consent is an ethical symbol of autonomy and how this is relevant to the process of informed consent in terms of disclosing information, understanding information, competence, voluntariness and authorisation. The second concerns the physical written consent forms, which relate to the elements of disclosing information and authorisation and are the focus of this study.

In Turkey, there are no requirements concerning the form of informed consent needed for medical interventions, except for cases included in specific legislation, such as major surgical procedures, pregnancy termination, organ transplantation and genetic testing (3). Nevertheless, the informed consent process in Turkey typically entails obtaining a signed written consent form in which the focus is on explaining the risks of the procedure. However, article 26 was added to the Regulation of Patients' Rights (6) in 2014 (7) (hereinafter will be referred as the Regulation), and this specifically required a 'Consent Form' for procedures, stating '… For the medical interventions that are seen medically possible to give rise to unconformity with the cases foreseen in the legislation, the consent form, including the information stated in the 15th article, is prepared by the healthcare institutions …' and

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includes information about exceptions and how many copies of consent forms should be prepared and kept. It is foreseeable that this article will lead to expansion in the use of written consent forms that are currently used. The Regulation also outlines the requisite content of information in consent forms, thereby lending support to the ethical and legal standards of the Turkish Medical Association's Code of Medical Ethics) (hereinafter will be referred as the Code) (8). Over the last few decades in Turkey, although studies have been conducted on how healthcare professionals obtain or should obtain informed consent (2,9-15), there have been few studies on the content, readability or conformity of the consent forms to ethical guidelines (16-18).

To start resolving the problems associated with informed consent, it may be appropriate to start by assessing the conformity of consent forms and any reasons for unconformity to improve those areas that are inappropriate and need to be improved. Therefore, in this study, we aimed to assess the conformity to ethical standards of informed consent forms used for medical interventions in a hospital in Turkey.

Materials and methods

This study conducted between August 2015 and January 2016 in an affiliated 500-bed training and research hospital in the Aegean Region of Turkey. All informed consent forms used in the hospital for surgical treatments, nonsurgical treatments and diagnostic were assessed. The consent forms were typically prepared by the physician who conducted the procedure or by the department in which the procedure was conducted. Even if forms of national profession

associations were taken as reference for some forms, there was no a standard determined by the hospital. Any forms prepared and updated by physician(s) or department(s) were sent to the quality assessment department where the consent forms were archived online to be printed out when requested (this adds the corporate logo of the hospital and formalises them). Permission was obtained from the General Secretary of Public Hospitals Association to conduct this research, and consent forms were obtained from the quality management unit of the hospital with the consent of the Head Physician.

First, all forms were collected and grouped by two researchers (MO, DU) into three categories, as follows: (i) consent forms for surgical treatment (CFST), (ii) consent forms for nonsurgical treatment (CFNT) and (iii) consent forms for diagnostic procedures (CFDP). Then, forms were reviewed in each group and their content was further grouped based on the information available in the forms. When the two researchers in this stage could not reach agreement, the opinion of a third researcher (AA) was sought and consensus reached. Next, we prepared a schedule of the information in the three main groups to aid standardisation; to do so, information in the forms was assessed as either available or not available. The frequencies and percentage distributions of the obtained data were taken.

Second, all forms were assessed using the Microsoft Office Word, and the words were automatically counted. The readability level of each consent form was assessed using the Ateşman Readability Formula (16). If there were three and more terms in first 100 words that were consistent with medical terminology, we accepted this as indicating that medical terminology was present.

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Statistical analysis

Data were analyzed with descriptive statistics without a statistical software program.

Ethics committee approval

Since the subjects of the research were not humans or animals only “blank consent forms” ethics committee approval and informed consent are irrelevant for this research.

Results

The hospital provides health services via 14 surgical clinics and 13 internal medicine clinics, each of which provides procedure-specific forms. The total number of forms used in the hospital in August 2015, as assessed in this paper, was 336; this comprised 267 for surgical treatments, 37 for nonsurgical treatments and 32 for diagnostic procedures. The orthopaedic department produced largest number of forms (63 different treatments), while the department of cardiovascular surgery produced the fewest number of forms (7 different treatments). The results for the content in the information and consent parts of the forms are given in Table 1 and 2. The results for the readability levels and use of medical terminology in the forms are given at Table 3.

Discussion and Conclusion

In this paper, we assessed the ethical conformity of consent forms used for medical interventions in a training and research hospital, which revealed both positive and negative

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aspects of current consent forms. Based on these findings, we offer recommendations that allow future forms to be made in line with ethical requirements, with greater convenience. When the consent forms in the study were reviewed in terms of each article from Regulation and Code (Table 4), disease diagnosis was only specified in one third of consent forms for surgical treatments. A possible reason for this is that the forms were prepared specific to the intervention rather than the disease. But it is important that the first stage of the informing be devoted to the disease or suspected disease of the patient. Therefore, it will be appropriate to add a section title 'diagnosis and specifications of the disease' and 'suspected disease' for diagnostic tests to be manually completed during the process of completing the consent forms.

The second stage of obtaining informed consent then concerns information about the intervention itself. None of the consent forms provided information concerning 'where the intervention will be done', as foreseen by the Regulation. However, neither the legislation nor the forms seemed sufficient for giving appropriate information about the intervention. Future forms would be improved by including the section titles similar to 'recommended treatment method type', 'aim', 'by whom, as well as where and how, it will be conducted', 'how long it will take', 'the chance of success' and 'possible complications'. Such an approach would combine the requirements of the Code, the Regulations and the useful information within current forms. Receiving input from professional associations about the 'success rates of the intervention' and the 'complication rates' will make the forms medically valid.

The most frequently reported (>90%) part in the forms for interventions was the section on possible risks/complications. This gives rise to the consideration that such high emphasis may

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have resulted from the fallacy that patients may not claim for compensation when they have had the risks mentioned. The presence of statements such as

"The patient accepts, declares and undertakes that s/he will not make any financial and emotional … complaint in the event that the negative outcomes of the procedures come true"

supports this assertion. Placing greater emphasis on the chance of success and the benefits of any intervention during preparation may allow perceptions to change from being to protect the doctor from later accusations (2).

Information about alternative treatments, benefits and risks of the treatment and problems that may occur if the intervention was rejected were given limited space on the consent forms in this study. But, in both the Code and the Regulations, emphasis is put on giving information about the possible outcomes with and without treatment, as well as the possibility of alternative diagnosis and treatment methods. Indeed, such information forms part of any proper informed consent process. In addition, although the specifications of drugs to be used have clearly been emphasised on both documents, and although the Supreme Court has made a decision on this subject (19), none of the forms in this study provided information about this subject. It will certainly be appropriate to add a title to cover this content in future forms. Concerning the need to make critical lifestyle recommendations, different considerations are necessary before and after the interventions. Therefore, it will be appropriate to standardise this for all forms when they are updated. Also, information concerning how to access medical assistance was not available at any of the forms. Even when contact information was given in good faith, only a few forms provided such information.

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When all the informed consent forms were assessed together, the part given most attention was that concerning the possible risks of the intervention. However, despite this, there were many ambiguous statements that were nonspecific, including

"I know there are risks of bleeding and infection relevant to anaesthesia (narcosis) that may be seen with all surgical operations".

Overall, most forms seemed to be prepared to ensure that patients knew the risks of a procedure, rather than being designed to obtain true informed consent, as per the definitions and standards of national and international ethics regulations. This may lead to clinicians ignoring the health status and disease of their patient, including information specific to the patient, as was seen in our study, even when using standard printed consent forms specific to the medical procedure, which may be beneficial (20). Therefore, it will be appropriate to update the content of forms with the detail in Regulation and Code as the standard printed content, leaving space for clinicians to add details about diagnosis and drugs manually. Additional information about the success rates, complication rates, alternative treatments and benefits and risks needs to be obtained from professional associations.

Based on the assessment of the consent section of the consent forms Article 20 of the Regulation and article 27 of the Code were relevant to patients who refuse to receive information. However, there was little acknowledgement of this requirement in the consent forms studies in this report, even though such a title would remind the physician of the patient's right to information, to withdraw informed consent and reject treatment. Rates differed in each of the three groups. In updated forms, it will be appropriate to include the topic of refusing or withdrawing informed consent as standard. Along with that, it is important

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to word the topic of consent by a proxy with care, because careless phrasing may lead to a risk that forms will be automatically signed by a relative of a patient (2). This risk could be prevented by including a statement such as "in cases when the patient is not of age, is unconscious, or may not be able to make a decision, such as in emergency situations …" at the beginning of the proxy consent.

The name-surname-signature part for the witness was available in 62% of the treatment consent forms, and personnel other than the physician and signature part that are seen at very three group form although at a less amount are the titles required to be removed. These sections were possibly added by the health-care institution/professionals with the aim of proving that the consent was taken, but are not requirements of any ethical or legal regulation and have the potential to breach patient privacy when applied. Therefore, it may be appropriate to remove their inclusion in forms.

The most problematic content of the consent forms was where it was stated that

"the physician will make decisions when additional interventions are necessary because of complications during the intervention".

Because in the 31th article of the Regulation clearly define the necessary additional interventions as "… If the intervention is not expanded when a need rises during a medical intervention, and a required medical procedure will lead to loss of an organ or loss of function, the medical intervention may be expanded without requesting further consent." (7).

However, in consent forms there was a wide variety of statements authorising physicians to perform additional interventions in 65% of surgical treatment forms. These includes:

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"Except for previously planned diagnostic and treatment applications, I know, understand, give consent and request that various procedures be done, even at different clinics or by different disciplines"

"I authorize my doctors all the different and additional operations that they thought necessary"

'*I authorise the doctors and their assistants to make necessary assessments and apply these procedures based on their occupational knowledge. The authorisation given in this paragraph includes situations that my doctor may not reasonably anticipate at the beginning of the operation, but that subsequently require treatment'*.

Notwithstanding that such indefinite authorisation is neither ethically nor legally valid, it is inappropriate to request such authorisation in the forms because patients may assume that it abolishes their future right to complain.

Concerning the assessment of the readability of the consent forms, how the information is given is as important as the information itself. Both the Regulation and the Code emphasise the need to give information in a way that is clearly understandable by patients. This 'understandability' corresponds to the readability of consent form. Readability refers to the following characteristics: (i) the ease of reading the printed manuscript; (ii) the ease of reading the content and (iii) the ease of comprehension and understanding, based on the writing format (21). We showed that (Table 3) medical terminology use was often too high in the forms used for surgical treatment and diagnostic procedures (75%). Therefore, it is necessary to use plain language and reduce the use of medical terminology.

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Ateşman's readability test is relevant to the third meaning of readability. Assuming no direct correlation with education level, readability was ordered in five steps from very easy to very hard, and most of the forms (49%) were categorised as hard to read. Thus, consent forms were not legible, even from the perspective of this limited assessment. However, other variables are important, including the competence of the patient, where he/she read the form, when the form was given [e.g. it the latest time should be 24 h before a procedure (22)] and how eager the patient was to take information (e.g. women have been shown to be more curious than men (23)). Research is needed to determine what additional factors affect the readability and understandability of consent forms.

Consequently in this paper, we identified both positive features and some easily improved problems in our consent forms. Together, these allowed us to make the following recommendations for the preparation of consent forms in the future.

First, adding subheadings to consent forms will ease the arrangement of content within a logical framework. The standard information about the procedure should be printed and titles should be given to allow handwritten content about factors such as the drugs to be used. All medical topics, such as the success and complication rates, should be written in plain language, have any ambiguous statements removed and be informed by professional associations (20).

Second, we found that the patient's name and signature may be confused with other signatures that are needed from proxies, personnel other than the physician and witnesses. Therefore, forms should be printed with a section for the patient's signature, but also with information about the conditions when the proxy signature, physician signature and translator signature is to be added. Moreover, we recommend removing unnecessary parts, such as

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those authorizing the expansion of an intervention or where the signature of a witness or person other than the physician is required. However, sections concerning the declaration of the physician, summary of the information given and patient consent should be retained in future updates. These are important to proving that consent has been taken, and they can help with patient understanding.

Third, our assessment of the readability of consent forms indicates the importance of employing the services of a linguistic expert to assess and revise any updated forms before they are made available for use with patients (24). Fourth, the development of medically, ethically and legally valid content will require readability and understandability to be considered, using the guidance from studies concerning what information patients are able to understand (18, 25).

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Tables

Table 1. Content of information part of informed consent forms used for medical interventions

Subjects	CFST (n = 267)	CFNT (n = 37)	CFDP (n = 32)
Patient declaration regarding to his/her health status	76	12	9
Rejection of the information	11	7	2
Diagnosis	90	-	-
Aim of recommended procedure	188	25	24
Expectations-how to prepare	67	13	12
Expectations-recovery	98	11	11
Application type of the intervention	135	20	19
Period of the intervention	131	11	16
Benefits of the intervention	34	9	15
Risks of the intervention	259	36	31
Natural course and risks of no intervention	146	-	-
Additional interventions that may be required during the intervention	91	-	-
Authorizing physician if additional intervention necessary	185	13	-
Treatment options	89	8	4
Benefits and risks of treatment options	35	2	-

CFST: Consent Form for Surgical Treatment, CFNT: Consent Form for Nonsurgical Treatment, CFDP: Consent Form for Diagnostic Procedures

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Table 2. Content of consent part of informed consent forms used for medical interventions

Subjects	CFST (n = 267)	CFNT (n = 37)	CFDP (n = 32)
Name-surname, signature of the responsible physician	259	35	31
Contact information of responsible physician	2	4	2
Name, surname and signature of the personnel other than physician	12	4	4
Summarising content of the information	69	-	1
Forming subtitles and offering option for consent	232	31	21
Permission for recording operation for training purpose	201	8	3
Withdrawal right of informed consent	70	20	15
Name, surname and signature of the patient	264	35	32
Name, surname, signature of the proxy of the patient	239	33	30
Other (name, surname and signature of the witness)	167	23	2
Other (name, surname and signature of the translator)	114	4	16

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Table 3. Readability of informed consent forms used for medical interventions

Subjects	CFST (n = 267)	CFNT (n = 37)	CFDP (n = 32)
Readability of the form			
Very easy	-	-	-
Easy	-	-	-
Moderate hard	108	7	8
Hard	142	21	15
Very hard	17	9	9
Is medical terminology used?			
Yes	214	13	23
No	53	24	9

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Table 4 Assessment of the content of informed consent forms in terms of the current

regulations

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Subjects	CFST (n = 267)	CFNT (n = 37)	CFDP (n = 32)
a) Possible reasons of the disease and how it will progress			
Diagnosis and specifications of the disease	90/73	-	-
b) Where and how the medical intervention will be done and expected period			
Name and signature of the responsible physician	259	35	31
Where the intervention will be done	-	-	
Natural course and aim of recommended intervention	188	25	24
Recommended treatment method	135	20	19
How long it will take	131	11	16
Benefits of the intervention	34	9	15
c) Diagnosis and treatment options, benefits and risks of these options			
Treatment options	89	8	4
Benefits and risks of the treatment options	35	2	-
d) Possible complications			
Possible risks of the interventions	259	36	31
e) Possible benefits and risks that may occur in case of rejection			
Possible risks of no intervention	146	-	-
f) Significant properties of the drugs to be used.			
	-	-	-
g) Lifestyle recommendations critical for health.			
The aspects to be paid attention before the intervention	67	13	12
The aspects to be paid attention after the intervention	98	11	11
h) Information regarding medical assistance when needed.			
Contact information of responsible physician	2	4	2

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