Acta Paulista de Enfermagem
ISSN: 0103-2100
ape@unifesp.br
Universidade Federal de São Paulo
Brasil

Pereira Melendo, Márcio; Viegas, Karin; Nogueira de Souza, Emiliane; Aquino Caregnato, Rita Catalina

Surgical patients' understanding of the free and informed consent form
Acta Paulista de Enfermagem, vol. 29, núm. 3, 2016, pp. 291-297
Universidade Federal de São Paulo
São Paulo, Brasil

Available in: http://www.redalyc.org/articulo.oa?id=307047624008

Surgical patients' understanding of the free and informed consent form

Termo de consentimento informado: entendimento do paciente cirúrgico

Márcio Pereira Melendo[1]
Karin Viegas[1,2]
Emiliane Nogueira de Souza[1]
Rita Catalina Aquino Caregnato[1]

Keywords
Informed consent; Surgical procedures, operative; Perioperative nursing

Descritores
Consentimento livre e esclarecido; Procedimentos cirúrgicos operatórios; Enfermagem perioperatória

Submitted
December 18, 2015

Accepted
June 6, 2016

Abstract

Objective: To know surgical patients' understanding of the free and informed consent form (FICF).

Methods: Cross-sectional study conducted with patients in the immediate postoperative period of different surgical procedures. Intentional sample. Data were collected by means of a questionnaire with Likert type responses, and analyzed through descriptive and analytical statistics.

Results: Of the 374 patients evaluated, 36.4% underwent surgical procedures on the musculoskeletal system, and 35.3% received the FICF from a non-medical professional (secretary). The patients agreed that they understood the information written on the FICF (44.7%), that the information was clear (59.6%), that doubts were clarified (57%), and that they knew the function of the FICF (59.6%). Only 28.6% of patients confirmed that they had obtained a signed copy of the FICF.

Conclusion: Most participants understood the written information on the FICF, but it is necessary to expand this understanding to all patients, as well as provide a copy of the signed document.

Resumo

Objetivo: Verificar o entendimento dos pacientes cirúrgicos em relação ao Termo de Consentimento Informado (TCI).

Métodos: Estudo transversal, realizado com pacientes em pós-operatório mediato de diferentes procedimentos cirúrgicos. Amostra intencional. Dados coletados por meio de questionário com respostas do tipo *Likert*, e analisados através de estatística descritiva e analítica.

Resultados: Dos 374 pacientes avaliados, 36,4% foram submetidos a procedimentos do sistema musculoesquelético e 35,3% recebeu o TCI de profissional não médico (secretária). Os pacientes concordam que compreenderam as informações escritas do TCI (44,7%), que as informações foram claras (59,6%), que houve esclarecimento de dúvidas (57%) e que sabia qual era a função do TCI (59,6%). Somente 28,6% dos pacientes concordaram que obtiveram uma cópia do TCI.

Conclusão: A maioria dos participantes compreendeu as informações escritas no TCI, mas é preciso ampliar esse entendimento para todos os pacientes, bem como disponibilizar a cópia do TCI para todos.

Corresponding author
Rita Catalina Aquino Caregnato
Rua Sarmento Leite, 245,
90050-170, Porto Alegre,
Rio Grande do Sul, Brazil.
ritac@ufcspa.edu.br

DOI
http://dx.doi.org/10.1590/1982-0194201600040

[1]Universidade Federal de Ciências da Saúde de Porto Alegre, Porto Alegre, RS, Brasil.
[2]Universidade do Vale do Rio dos Sinos, São Leopoldo, RS, Brasil.

Conflicts of interest: there are no conflicts of interest to declare.

Introduction

Autonomy is a human characteristic that enables decision making and actions based on ethical principles and the valuation of one's will as an independent person.[1] The autonomy of the patient respects his will, thereby enabling his active participation in his therapeutic process.[2] To this end, in order to perform a surgery, it is necessary to obtain the patient's consent, which can be revoked at any time.[3]

Studies that scientifically evaluate the autonomy of human beings are important for researching how individuals manifest their will and desires, and thereby helping to avoid situations of people being subjected to scientific experiments without their informed consent, and associated physical and psychological damages. The struggle of ethics in research and the documentary record of the informed consent form for people undergoing medical treatment or research started during World War II,[4] with statement of the risks and benefits to which the individual would be submitted. The benefits of this document was reaffirmed by the Nuremberg Code in 1947, drawn up after judgment of Nazi officials and physicians, by the Declaration of Helsinki in 1964 and by the World Medical Assembly in Hong Kong in 1989.[5]

In Brazil, use of the informed consent form was standardized in the early 1980s, based on the documents of the Ministry of Health and the Federal Council of Medicine.[6] These documents have various nomenclatures to designate this form, the best known being the free and informed consent form (FICF).

Free and informed consent forms are signed in different situations such as conducting diagnostic imaging tests, scientific studies and therapeutic procedures. It is established by the Code of Medical Ethics that patients be properly informed by their physicians when obtaining consent to perform medical acts. Although nurses do not have a legal responsibility to provide the information necessary for the patient to evaluate the risks and benefits involved in surgical procedures, they have contributed in facilitating the process of obtaining the FICF. Through empirical observation of professional practice in a surgical center, it was found that some patients, after clarifications and signature of the FICF and without the presence of a physician, demonstrated that they had not understood the information provided, or had doubts regarding the function of the signed document, and sought clarification of their questions with other health professionals. In addition, little is discussed in nursing about the process of obtaining the FICF and its contributions. In this context, the objective of this study was to explore surgical patients' understanding of the free and informed consent form.

Methods

This was a cross-sectional study conducted in a large hospital, located in the city of Porto Alegre, in the southern state of Rio Grande do Sul, Brazil.

The study population was made up of patients who had undergone surgery of any specialty, performed in the main surgical center of the institution. Inclusion criteria were participants aged 18 years or older; undergoing elective surgeries of medium and large size; being admitted to the hospital and in clinical and psychological conditions to participate in the study. Patients with less than 24 hours of anesthetic recovery were excluded.

The sample consisted of 374 participants, considering the total number of surgeries (13,530) carried out in 2014, with a 5% margin of error, 50% heterogeneity and 95% confidence level.

Data were collected between May and August 2015, which entailed 1) daily query of records of patients in the postoperative period that passed through the anesthetic recovery room (from 24 hours to 10 days), identifying the patients from the surgical center being researched, and checking the hospitalization location; 2) the researcher went to the nursing station of the hospitalization unit of the selected patient, and introduced themselves to the nurse in charge, presented the opinion of the research ethics committee of the institution stating their purpose, and verifying

the availability of the patient to participate in the research; 3) after being authorized, the researcher went to the patient's bed, invited him or her to participate in the study, and clarified any doubts that may have arisen; 4) upon accepting to participate, the patient signed two copies of the FICF, one of which they kept; and 5) the researcher filled in the questionnaire, reading the response options, as each patient indicated the response that best expressed their opinion on each question investigated.

Data collection was carried out by means of a structured questionnaire, and the answers were given on a Likert type scale, varying from: strongly agree (SA); agree (A); disagree (D); strongly disagree (SD); and, I neither agree nor disagree or do not remember or do not know (ND). The questionnaire was validated by a team of judges composed of six nurses, three of which were professors in an undergraduate nursing course, and three worked in the surgical center under study. The data were collected by the researcher at the postoperative patient's bedside, then stored and analyzed in SPSS software by means of descriptive and analytical statistics. The variables were described with absolute and relative numbers, and for comparisons between proportions, the Pearson Chi-square test was used.

The study was registered in the Plataforma Brasil under Certificate of Presentation for Ethical Appreciation (CAAE, as per its acronym in Portuguese) number 40018314.8.0000.5335.

Results

Of the 374 participants, most were women (53.2%), and surgeries on the musculoskeletal apparatus were the most prevalent (36.4%) (Table 1).

When participants were asked about which professional informed them about the FICF, 35.2% responded that it was the secretary (Table 2). It is notable that 16.3% of the participants marked the response option "other", since they did not know how to identify which professional had presented the FICF.

Table 1. Patients' characteristics

Variables	n(%)
Sex	
Male	175(46.8)
Female	199(53.2)
Age group	
> 18 to 30 years	52(13.9)
31 to 59 years	198(52.9)
60 to 79 years	111(29.7)
> 80 years	13(3.5)
Level of education	
Elementary school	167(44.6)
High school	126(33.7)
Complete higher education	81(21.7)
Surgery type	
Musculoskeletal apparatus	136(36.4)
Gastrointestinal tract	104(27.8)
Urinary system	68(18.2)
Reproductive system	38(10.2)
Ear, nose and throat	10(2.7)
Plastic/aesthetic surgery	7(1.9)
Circulatory system	5(1.3)
Breast/endocrine	6(1.6)

Table 2. Professional who presented the FICF, in the patient's view

Variables	n(%)
Professional who presented the FICF	
Secretary	132(35.3)
Surgeon	109(29.1)
Other members of the medical staff	42(11.2)
Nurse	27(7.2)
Clinical physician	3(0.8)
Other	61(16.3)

(FICF) - Free and Informed Consent Form

It was evidenced that 44.7% of participants agreed that they had fully understood the written information on the FICF; 59.6% agreed that the FICF contained clear information and plain language in the document; and 57% agreed that they had their doubts resolved and questions clarified. A total 63.1% did not get a signed copy of the FICF (Tabela 3).

Associations were identified between the professional who presented the FICF and the patients' understanding of information (p=0.008); clear and simple language (p=0.009); clarification of doubts (p=<0.001); importance of the FICF (p=0.002); signature without explanation of the FICF (p=<0.001); knowing the function of the FICF (p=<0.001); and being provided with a signed copy of the FICF (p=<0.001).

It was identified that female participants more strongly perceived that the information was in clear and simple language (p=0.046). There was also a significant association between level of education and clarification of doubts, knowing the purpose of the FICF and receiving a signed copy of the document (p=<0.001).

Tabela 3. Issues related to the free and informed consent form

Variables	Strongly disagree (n%)	Disagree n(%)	Do not agree not disagree or do not remember (n%)	Agree n(%)	Strongly agree n(%)	Did not answer n(%)	p-value*
I understood the information written on the FICF	82(21.9)	48(12.8)	3(0.8)	167(44.7)	73(19.5)	1(0.3)	0.008a
The information was in clear and simple language	11(2.9)	19(5.1)	-	223(59.6)	121 (32.4)	-	0.009a 0.046b
Questions were clarified	14(3.7)	24(6.4)	-	213(57)	123 (32.9)	-	<>a
I recognize the importance of the FICF	7(1.9)	11(2.9)	8(2.1)	184(49.2)	164 (43.9)	-	0.002a 0.074
I felt ashamed when asking questions	358(95.7)	2(0.5)	-	5(1.3)	9(2.4)	-	0.503
I felt afraid of the professional	361(96.5)	5(1.3)	-	5(1.3)	3(0.8)	-	0.135
There was enough time to clarify questions	17(4.5)	11(2.9)	1(0.3)	184(49.2)	161(43)	-	0.182
Only a signature was requested without explanation of the FICF	256(68.4)	8(2.1)	5(1.3)	34(9.1)	71(19)	-	<0.001a 0.641
I know the function of the FICF	86(23)	22(5.9)	2(0.5)	223(59.6)	41(11)	-	<0.001a <0.001c
I received a copy of the FICF	234(62.6)	2(0.5)	31(8.3)	14(3.7)	93(24.9)	-	<0.001a

*Chi-squared test. aIn relation to the professional informant; bIn relation to sex; cIn relation to level of education. FICF - Free and informed consent form

Discussion

It was identified that 35.3% of the patients obtained the FICF from administrative staff. Some patients (16.3%) reported that they received the FICF from the receptionist, along with other hospitalization documents, insurance guides and papers related to the hospital services fees. It is widely known that it is inappropriate to provide the FICF at the time of contracting a health care service, when payment and the rights and duties of the patient are discussed, because this situation is detrimental to understanding the procedure, and weakens the patient's autonomy, putting them in a position of emotional vulnerability without the option of choice.[7]

Physicians are the recommended health professionals to provide information contained in the FICF, since this document is largely misunderstood by patients.[8] In addition, the Code of Medical Ethics advocates that physicians should obtain the patient's signature on the FICF,[9] and be responsible for providing clarification on the surgery and requesting the patient's signature, obtaining the correct and legal form of the FICF, and justifying and consolidating the medical act as something fair and right.[2] In addition, planning, intervention, evaluation of care and counseling of patients contribute to obtaining consent, as actions within the legal scope of nursing practice.[10]

In the opinion of the participants, the FICF fulfilled its purpose, and was written and presented in such a manner that was easy to read, even for those patients with basic education, because most of them understood the written information available on the form. One study that evaluated the understanding and readability of FICFs in patients participating in clinical research showed that 50% did not understand the information contained in the form.[11]

When the FICF is misunderstood, this undermines the act of providing information inherent to the document itself, the procedure and the willingness to undergo the process. Professionals should always consider the mental, emotional, cultural and educational condition of the patient at the time of providing the FICF, because if there is definite risk to the patient's health, they will not be able to understand the document, as they will be vulnerable and not display their full autonomy.[12] Many patients have limited understanding about the implications of the FICF, and are unable to understand that the document protects their interests and enables them to exercise autonomy.[13]

In this study, it was found that the vast majority of participants agreed that the FICF had plain language and clear information. This is in contrast to another study, in which the FICF presented a high degree of difficulty reading.[14] For patients to consent or refuse to sign the FICF, it is necessary that they are provide with clarifications on it that are adapted to social, cultural and psychological circumstances.[4] This question had a significant association when related to the professional who

informed the patient (p=0.009), and in relation to the patient's sex (p=0.046). Another study[15] that aimed to evaluate patients' understanding of the information in the FICF by 143 patients showed that there was no correlation between sex and level of knowledge of the information in the document; however, the language used was directly correlated to their understanding. The text should conform to the intellectual level of the population served; in the case of Brazil, it must not exceed the level of primary education.[16]

As for clarification of doubts and the opportunity to ask questions related to the FICF and the surgical procedure, in this study, there was an association in relation to the study time and professional informant (p<0.0001), showing that the higher the level of education of the patient, the lower the level of doubt. It is notable that the majority of respondents had an intermediate or higher level of education, which explains the high level of understanding of the FICF among the patients surveyed. Patients with higher education had a level of understanding and clarification of doubts about the FICF greater than patients who had only high school, and even greater when compared to patients who had only primary school.[11] "Literary skills" are pointed to as determinants for the process of understanding, and therefore so when these are inadequate, the information contained in the FICF will be undermined.[17]

In relation to the importance of the FICF, 93.1% agreed or strongly agreed that the it was an important document, with an association (p=0.002) with the professional informant being observed. During data collection, it was observed that the perception of the patient varied in relation to the importance of the FICF according to the professional informant. As reported by the participants themselves, the greater prevalence of those who considered the FICF to be important were patients who received the FICF out of the hands of the surgeon or another member of the medical staff. Data from one study show that the majority of participants in a clinical trial signed the FICF without sufficient knowledge of the study information, and were influenced in their decision to participate in the study.[15]

Most of the patients surveyed denied feeling ashamed of asking questions about the FICF and the proposed surgical procedure, and claimed that they were not afraid of the professional who presented the FICF, with a significant relationship with the professional who informed the patient being observed (<0.001). In another study[18] carried out with adolescents, none of the patients interviewed said that they were afraid of the professional, or even the proposed procedure, but only the possible damages inherent to the treatment, such as pain. In surgical patients, the presence of feelings such as worry and fear is related to the surgical procedure itself.[19] However, the relationship nurse-patient facilitates identification of anxiety, which can impact understanding of the FICF and be influenced by the content of the text. It is known that the format in which the informed consent is provided (oral, written or video) has no significant effect on the patient's anxiety.[20]

Among the patients surveyed, most agreed the time used to obtain the signature of the FICF was sufficient to clarify their doubts, and disagreed with the statement of having signed the FICF without receiving some type of information. Different from the results found for the present study, another study[6] found that often the professional who presents the FICF simply requests the patient's signature, without providing information on the document. Another study[10] found that 32.9% of patients signed the FICF without reading its contents. One of the reasons reported for not reading and only signing the FICF without requesting explanation of the information contained in it were: fear of reading it and finding out the risks that they would be subject to, hurry to complete the bureaucratic part of hospitalization to perform the procedure as soon as possible, and fear of not signing and not being cared for or operated on, among other factors listed as the reason to merely sign it (without reading).[13] On the basis of their higher level of knowledge, it is possible that the physician implicitly exercises on their patient an involuntary psychic duress, making the patient feel embarrassed to read the document and sign it anyway.[21]

When asked if they knew the function of the FICF, 28.9% disagreed. One integrative review study identified participants' difficulty reading and understanding the FICF, and that the main factor influencing these aspects were low level of education.[11] This variable showed an association with the professional who presented the form (<0.001) and level of education. Therefore, understanding the importance of the FICF is related to the professional who presents the form, since it depends on the degree of knowledge and professional preparation of who will explain and clarify the patients' doubts, and the patient's level of education, for which the higher the level, the greater the perception about the importance of the form.

During data collection, many patients claimed to know the purpose of the FICF, and reported that this served only to defend the physician and the institution in the event of a lawsuit, demonstrating that despite claiming to know its purpose, they had a distorted view of it. It is important to mention that many patients who responded to consider the FICF important, then responded that they did not know what it was for. Despite not knowing its purpose, they thought it was important, because if it was not, the physician or institution would not have spent time providing them with information on it, and requesting their signature.

It was observed that only 28.6% of the participants claimed to have received a copy of the FICF, even though, in some cases, the copy had been delivered to a family member with the patient's knowledge.

It is noted that defensive medicine has contributed to the distortion of the process of obtaining the FICF, and reduced it to a simple term that has, among other goals, exempted the professional from fault in the event of possible malpractice,[22] turning it into a mere formality usually performed and filed in the record for legal purposes, forgetting that the patient is also an active party in the process of providing information on the FICF, and that they have the right to receive a copy. As members of the health care team, nurses can contribute to transforming the process of obtaining the FICF, which is often characterized by simply obtaining a signature for the moment of shared decision making.

Among the limitations of this study is the impossibility of investigating all the factors that influence understanding of the FICF, since a questionnaire was applied to the participants with pre-defined responses, in which patients could choose only the answer that came closest to representing their opinion.

Conclusion

It was found that the majority of surgical patients received the FICF from non-physician professionals such as a secretary, nurse and other unidentified professionals. Most of the surgical patients who participated in this study claimed to have received information about the form and the proposed procedure before signing the FICF, that the information was presented in simple and clear language, and that their doubts were clarified during the process of providing information on the form, that they had sufficient time to provide such information, and that they considered the FICF to be important. Although most of the participants said they knew the purpose of the FICF, nearly one-third said the opposite. This study demonstrated that many patients who considered the FICF to be important did not know its function, and were not provided with one of the two signed copies of it. Despite the FICF not being the legal responsibility of nurses, these professionals' proximity to patients can assist in discerning the content of the FICF, mostly related to therapeutic complexity.

Collaborations

Melendo MP, Viegas K, Souza EM and Caregnato RCA declare that they contributed with the project design, data interpretation, relevant critical review of its intellectual content and final approval of the version to be published.

References

1. Carretta MB, Bettinelli LA, Erdmann AI. Reflexões sobre o cuidado de enfermagem e a autonomia do ser humano na condição de idoso hospitalizado. Rev Bras Enferm. 2011; 64(5):958-62.

2. Clotet J. O consentimento informado nos comitês de ética em pesquisa e na prática médica: conceituação, origens e atualidade. Rev Bioét. 2009; 3(1):51-9.

3. Simões LC. Consentimento informado: o desafio médico-jurídico de nossos dias. Rev Bras Ortop. 2010; 45(2): 91-5.

4. Marques-Filho J. Termo de consentimento livre e esclarecido na prática reumatológica. Rev Bras Reumatol. 2011; 51(2): 179-83.

5. Doncatto LF. Uso do termo de consentimento informado em cirurgia plástica estética. Rev Bras Cir Plást. 2012; 27(3):353-8.

6. Conselho Federal de Medicina. Resolução nº 1.081 de 12 de março de 1982. DOU 23/03/1982:4996.

7. Bazzaco AA, Valelongo PO, Miziara ID, Barbosa CP. Entendimento do consentimento livremente esclarecido na reprodução assistida. Rev Bioét. 2014; 22(1):134-44.

8. Hirschheimer MR, Constantino CF, Oselka GW. Consentimento informado no atendimento pediátrico. Rev Paul Pediatr. 2010: 28(2): 128-33.

9. Conselho Federal de Medicina. Código de ética médica: Resolução CFM nº 1931, de 17 de setembro de 2009 (versão de bolso) / Conselho Federal de Medicina. - Brasília: Conselho Federal de Medicina, 2010.

10. Menendez JB. Informed consent: essential legal and ethical principles for nurses. JONA'S Healthcare Law, Ethics and Regulation. 2013;15(4):140-5.

11. Rodrigues-Filho E, Prado MM, Prudente CO. Compreensão e legibilidade do termo de consentimento livre e esclarecido em pesquisas clínicas. Rev Bioét. 2014; 22(2):325-36.

12. Biondo-Simões ML, Martynetz J, Ueda FM, Márcia Olandoski M. Compreensão do termo de consentimento informado. Rev Col Bras Cir. 2007; 34(2):183-8.

13. Guinand J, Gapany C, Simon JP, Wasserfallen JB, Joseph JM. A survey on surgeon's perceived quality of the informed consente process in a Swiss paediatric surgery unit. Patient Saf Surg 2015; Aug 28;9:30. doi: 10.1186/s13037-015-0076-3. eCollection 2015.

14. Souza MK, Jacob CE, Rodrigues JG, Zilberstein B, Cecconello I, Habr-Gama A. Termo de consentimento livre e esclarecido (TCLE): fatores que interferem na adesão. Arq Bras Cir Dig. 2013; 26(3): 200-5.

15. Lobato L, Gazzinelli MF, Gazzinelli A, Soares AN. Conhecimento e voluntariedade para participação em pesquisas: um estudo descritivo com participantes de um ensaio clínico. Cad Saúde Pública. 2014; 30(6):1305-14.

16. Godinho AM, Lanziotti LH, Morais BS. Termo de consentimento informado: a visão dos advogados e tribunais. Rev Bras Anestesiol. 2010; 60(2): 207-11.

17. Meneguin S, Zoboli EL, Domingues RZ, Nobre MR, César LA. Entendimento do termo de consentimento por pacientes partícipes em pesquisas com fármaco na cardiologia. Arq Bras Cardiol. 2010; 94(1):4-9.

18. Schoen TH, Vitalle MS. Tenho medo de quê? Rev Paul Pediat. 2012; 30(1):72-8.

19. Sampaio CE, Costa TM, Araújo D, Santoro DC. Mecanismos de enfrentamento desencadeados por pacientes em situações estressoras: cirurgia ambulatória. Rev Enferm UERJ. 2014; 21(4):515-20.

20. Goldberger JJ, Kruse J, Kadish AH, Passman R, Bergner DW. Effect of informed consent format on patient anxiety, knowledge, and satisfaction. Am Heart J. 2011; 162(4):780-785.e1.

21. Oliveira VL, Pimentel D, Vieira MJ. O uso do termo de consentimento livre e esclarecido na prática médica. Rev Bioét. 2010; 18(3):705-24.

22. Fernandes CF, Pithan LH. O consentimento informado na assistência médica e o contrato de adesão: uma perspectiva jurídica e bioética. Rev HCPA. 2007; 27(2):78-82.