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Consent forms in Brazil: analysis of quality and legibility

Bernardo Corrêa Dias Pereira Leite*
Dauro Arantes Aragão*
Ian Victor Lacerda da Silva*
Julio Cesar Goulart Fonseca*
Gabriel de Queiroz Soares*
Júlio César Soares Aragão*

Abstract

The emergence of the informed consent form is a paradigmatic transition mark that leads doctors and patients to a more balanced and less paternalistic relationship. The objective of the study was to evaluate the quality and adequacy of the consent form to the ethical precepts inherent to the relationship established between doctors and patients. In this sense, the information provided to the patient becomes undeniably relevant, and registration is a necessity. The present study evaluated the quality and adequacy of the consent form regarding the information process necessary to make decisions. Consent Forms were collected from Brazilian medical societies and hospitals and submitted to the Flesch-Kincaid test to measure the legibility of texts and other essential items. 110 consent forms were analyzed, evaluating parameters that influence the patient's complete understanding. In the analyzed criteria, most of the forms identified the type of procedure to be performed (n=88), described the complications (n=93), required the joint signature of the doctor and the patient (n=61), and displayed adequate fonts and sizes (n=84). Meanwhile the minority presented information about the place where the procedure was performed (n=19), the description of the procedure (n=29), and the patient's right to refuse (n=10). From the analysis by the Flesch-Kincaid readability index, it was demonstrated that most of the terms analyzed presented a moderately difficult reading level (n=71), followed by a difficult reading level (n=27). Data analysis reveals texts that are difficult to understand and have serious flaws in their elaboration, not only in their readability, but also in their structure.

Keywords: Informed consent, Patient Safety, Doctor-Patient Relationship, Medical Ethics, Reading

INTRODUCTION

Historically, the relationship between doctors and patients has been marked by the preponderance of the physician's authority over the patient's autonomy. The Hippocratic model (named in honor of Hippocrates of Kos, considered the founder of medical science) makes use of attributes such as beneficence (or benevolence) and non-maleficence of the doctor, a situation in which the patient will have little say in relation to the treatment that they will be submitted to[1].

Beneficence, when analyzed in the context of medical practice, overcomes the subjective burden and is conceptualized as "promoting the well-being of others"; that is, it is up to the doctor, when respecting this principle, to remain able to provide the care expected by someone who seeks him, using his knowledge and technique to provide the user with the best possible treatment[2].

In contrast, the principle of non-maleficence is a manifestation in the opposite direction, as it rules that the doctor, in addition to always being able to act in a way to provide the well-

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*Centro Universitário de Volta Redonda- UNIFOA. Volta Redonda/ RJ. Brasil
E-mail: bernardocdpl@gmail.com

being of users, must also refrain from doing them harm (first, do no harm)[2].

Autonomy derives from the Greek expression, which means "to be governed by the law itself", having been defined, already by Kant, as "a will that does not suffer heteronomous influences"[3]. In the medical field, this principle manifests itself in the respect for the user's decision making, which, when deciding the direction of their own treatment, will be doing nothing more than exercising their right to making independent choices[4].

Although there is some controversy regarding patient consent in medicine, the use of the informed consent form emerges and takes shape in an effective way from legal disputes in the United States in the second half of the 20th century, consolidating itself as a good practice and an alternative to the Hippocratic paradigm starting from the last quarter of the century[5]. This change exemplifies the transformation of the relationship between doctors and patients, breaking with the idea of an omniscient professional, and starting to recognize a new reality in which patients play a more active role in relation to the elements that underpin the relationship, such as the need to receive adequate and pertinent information to their case[6], removing, albeit in a timid way, the unrestricted authority of the doctor over the decision-making processes related to patient care in the Hippocratic model[1].

The paternalistic model, until then hegemonic, gradually loses space for a system more guided by the dialogue between the poles of the relationship. This transformation certainly occurs, also, due to the technological advance of medical science itself[7]. Medicine, until then, dealt with personal information in a restricted way, since there were few interventions (therapeutic or diagnostic) and little was calculated concerning the consequences inherent to such procedures[8].

On the other hand, in contemporary medicine, as there is a renewal of the techniques used and the emergence of new therapies, which propose to perform interventions that were impossible to be performed in past times, there is a relevant number of more recently developed procedures and therapies that can take to a range of outcomes and consequences that did not figure in the theoretical panorama of other times. The greater the knowledge of the risks involved, the greater the need is for discussion as to the possible results. Another relevant factor is the development of the biopsychosocial paradigm, in which patients leave the role of an object of medical conduct and assuming the role of subject, under equitable, cooperative, and even synergistic conditions to the person responsible for their medical care[6].

Knowing that society produces its norms according to the need for regulation to be presented, it is natural that such a paradigmatic change rests in a legislative gap. In the absence of specific legislation for doctor-patient relationship, the current law guiding consumer relationships, the Consumer Protection Code(9), is used in the analysis of such relations. Such legislation establishes safeguards for the hypo-sufficient (or vulnerable) pole of consumer relationships - the consumer - providing them with several legal guarantees that facilitate the defense of their rights, including the reversal of the burden of proof in the procedural scope[10,11].

In legal disputes, the burden of proof, or the task of presenting grounds that corroborate any thesis, automatically falls to the party who presents it[12]. This legal assumption serves as a guarantee and limit to the possibilities that can be exploited, judicially, by the parties, ruling out the possibility of false or falsifiable allegations being taken for granted by the magistrates to whom they will be presented.

In the field of health, the doctor has knowledge that goes beyond common sense,

which leaves the subject-patient in a situation of hypo-sufficiency regarding the technical-scientific aspect[13]. This hypo-sufficiency, in the light of current legislation and jurisprudence, is sufficient for to apply the dictates of the Consumer Protection Code, reversing the burden of proof.

Thus, it is vital that health professionals understand the relevance of formulating and maintaining records regarding the procedures and treatments they propose and carry out. It should be noted here that obtaining consent, one of the most important stages of patient care, is not limited to the mere note attached to the medical record, but is, in reality, the documentary expression of a medical act of informing and obtaining acquiescence of the patient[1]. It is noteworthy, therefore, that the present study will not be limited to the analysis of the effectiveness of the protection offered to the medical professional by the instrument of the consent form, but will also analyze aspects concerning patient information, a fundamental step in the process of obtaining consent[14].

The Informed Consent Form had its genesis in the 20th century in a historical context in which the physician ceased to be the strongest link in the doctor-patient relationship and a search began for greater patient autonomy and information about the procedures, informing and guaranteeing the patient their right to choose and be the protagonist in their own care[6,15].

The presentation and signature of the Informed Consent Form are often seen as a mere formality in the context of medical practice, failing to exercise its recommended role as a mechanism to assist the transmission of knowledge necessary to the inherent decision-making process for treatment, starting to appear as a bureaucratic step for the establishment of the doctor-patient relationship[16,17].

The analysis of the doctor-patient relationship indicates that both doctors and patients mistakenly understand the Informed Consent Form as a bureaucratic part of the medical care process, another stage of the contract to be established between the parties, and are unable to understand the real role that consent must play[15]. Such an idea may begin by the way the document is presented. As there is a disregard for the instrument in the medical field, such a notion of irrelevance on the part of the health professional ends up reflecting on the way the patient sees this tool, harming the positive impact that it should have on patient safety culture[18,19]. The health professional's view of the Informed Consent Form also differs from the true proposal brought by the instrument. Not infrequently, the Form is seen as the most effective way to protect the doctor from possible lawsuits, and their ability to assist in the process of transmitting patient information is ignored, a fundamental component for establishing a relationship of trust[20].

Thus, in spite of being recognized as an essential tool for the autonomous expression of consent in relation to the procedures to be performed during a medical care or research, the Informed Consent Form ends up remaining in a role similar to that played by the instruction manual for medication, which are that of a mere formality, as if it were only necessary to register the availability and delivery of technical information[14].

It is essential that any doubts about the treatment or research to which it will be submitted are fully resolved during the patient's information and consent process. In order for this objective to be achieved, it is necessary that the doctor acts magnanimously and allows the patient to feel comfortable with impartial clarifications about the procedure to be performed, guaranteeing autonomy in the decision-making process[13].

In this context, it is necessary to refer to the concepts of Carl Rogers[21] when creating

the humanistic school. Unconditional positive consideration and empathy must be widely used in the medical field and ensure that the health professional does not dispel the fears and opinions of his patients, even if they differ from his own. This is because when you have empathy for someone, there is the emotional bond between the parties in the sense that they both walk concurrently in pursuit of the same objective, and are, in this situation, the patient's well-being[21].

Thus, the Informed Consent Form ends up being used as a true form of contract between the parties, as if it were only important for the doctor to make the facts available and the patient's unrestricted consent[15].

Therefore, a contradiction is created as to what is established about the importance of such a document and the role that the doctor should play, namely: the role of satisfactorily guiding the technical choice that must be made by their patient, through the information process necessary to obtain effective free and informed consent[22].

Thus, the Informed Consent Form ends up not fulfilling its primary objectives, as it is not able to assist in the patient's information process or legally protect the agents of the relationship established between patients and health professionals, who use it poorly[14].

What is expected from this moment is the overcoming of the authoritarian model of the doctor-patient relationship, in which the doctor had all the power of decision, and autonomy starts to appear as the nucleus of the decision-making process and the analysis of alternatives in the space of the medical treatment[19,23].

It is necessary to analyze this paradigm shift to determine what are the new foundations that will govern these relationships, with a concern for maintaining and promoting the good relationship between health professionals and their patients, whether in the clinical or research field[14]. Thus, decision-making in medical treatment is no longer an act solely based on the patient's submission to the dictates of the health professional, but becomes a real example of the individual's exercise of autonomy and freedom[24].

Once the new relationship established between the parties is based on the promotion of patient autonomy, and the holder of technical knowledge is the health professional, the most important aspect of the new relationship established between doctor and patient is the passage of information in a sufficiently satisfactory way. This is a process whose success will be called "clarification", which is limited to the understanding and absorption of information by the patient (or the subject participating in medical research)[19].

Logically, all this care in transmitting and obtaining accurate information must be properly documented. In this sense, creating a clear, concise, and technically accurate document, which can serve as a roadmap for clarifying and recording the consent obtained, is essential. Doctors need to surround themselves with good communication and information presentation tools in order to correctly achieve their goals. However, such tools are not widely available, and therefore it is essential that the tool used in the patient information process is, at least, readable for the greatest possible part of the population. In this sense, aspects such as age, educational, social, and cultural multiplicities of the patients to whom the information process is intended should be considered[25].

This study aimed to assess the quality and adequacy of the consent form to the ethical precepts inherent to the relationship established between doctors and patients, notably regarding the information process, necessary for decision-making.

It was also important to assess the effectiveness of the informative nature of the Informed Consent Form, studying the adequacy of the content for the lay public and understanding the differences in content of the Informed Consent Forms used in different hospitals in the public and private networks.

METHODS

The present work was a quantitative, descriptive study. In this type of research, there is no intention to establish causal relationships; like a photograph of the reality of a given moment[26].

The collection, which was carried out in the form of a convenience sample, was performed through searches, on electronic sites, for documents freely available by public and private hospitals, as well as associations of medical specialties.

Protected documents with restricted access to associated and/or paying participants were excluded from the collection.

The Informed Consent Forms from different areas of medical care were collected between January and May 2018. After collection, the documents were submitted to the Flesch-Kincaid readability test - a tool that measures the difficulty of understanding texts by analyzing the number of words per sentence and syllables per word[10]. This tool was validated for the Brazilian Portuguese language[27].

Based on the assumption that the biomedical model is established from a basis founded on epidemiology, qualitative analysis methods[28,29], such as discourse analysis, were passed over in relation to the Flesch-Kincaid test precisely because of its ability to generate quantitative responses, in the form of degrees, which make it possible to compare and index the results obtained in the analysis of different documents.

Moreover, resources recommended by the Federal Council of Medicine that are considered essential for the proper development of the patient information process using the document, were also evaluated as queries for the analysis of the forms[30]. The following queries were listed: identification of the procedure to be performed; the establishment of the place where the procedure would be carried out; the technical details of the procedure; mention of possible complications resulting from the procedure; informing the patient of their right to refuse to proceed with the chosen treatment; the fields intended for the manifestation of awareness and agreement with the text, both of the patient and of the responsible physician/health professional; the font used to make the material - the fonts Arial and Times New Roman[31] are considered more pleasant to read; the score on the Flesch-Kincaid test, both for the entire text and the section for complications, if any.

The score values in the Flesch-Kincaid readability index are classified in order of difficulty as follows[27]: Above 90 - Very Easy; between 90 and 80 - Easy; between 70 and 80 - Reasonable Easy; between 60 and 70 - Standard Difficulty; between 50 and 60 - Reasonably Difficult; between 30 and 50 – Difficult; and less than 30 - Very Difficult.

The data of all documents were inserted in a database and analyzed according to their univariate and bivariate frequencies using the Stata software version 13.

RESULTS

The present study accounted for data from a total of 110 consent forms available on the sites of hospitals and/or medical associations and unions, which serve as a basis for the elaboration of the consent forms used by their associated professionals, union members, or employees within the scope of medical practice.

Most of the compiled forms came from medical societies or associations (54.55%), with the remainder coming from hospitals (45.45%). Regarding the creation date of the analyzed documents, it was noticed that 26 documents (23.64%) did not contain, in their metadata, indications referring to the date of their construction, while the chronological distribution of documents duly provided with metadata regarding the their creation dates listed the following result: 2004 – 07 (6.36%); 2005 – 31 (28.18%); 2010 – 07 (6.36%); 2011 – 01 (0.91%); 2012 – 01 (0.91%); 2013 – 05 (4.55%); 2014 – 09 (8.18%); 2015 – 02 (1.82%); 2016 – 09 (8.18%); 2017 – 10 (9.09%); and 2018 – 02 (1.82%).

Regarding the identification, in the body of the consent forms, of the medical procedures to which the patient is submitted, a total of 88 (80.0%) forms were found in which the procedure was mentioned, while in 22 (20.0%) of the samples analyzed no identification of the procedure was observed. Regarding the indication of the environment in which the procedure was performed, 19 (17.27%) of the analyzed forms met this requirement, while 91 (82.73%) omitted the place where the procedure would be performed. Finally, still in relation to the queries that deal with the procedure to be performed, it was observed that 29 (26.36%) models proposed to technically describe the procedure to be performed, while 81 (73.64%) were not dedicated to patient information about the body part being targeted during the procedure.

Regarding the description of complications, the result showed 93 (84.55%) cases in which the possible complications of the procedure to be performed were described, while 17 (15.45%) of the forms do not address the explanations necessary for the information process of the patient.

As for the information on the right to refuse or revoke consent, that is, the presentation of an informative text about the patient's right to refuse treatment, 10 (9.09%) of the models provided, in their elaboration, space intended for the manifestation of their desire to revoke the consent for which the form was used, while 100 (90.01%) models did not provide space for this theme.

Regarding the signature collection of the parties involved in the information process, it was found that 61 (55.45%) of the models had spaces dedicated to the signature of both doctors and patients, while 49 (44.55%) provided space only for the patient's consent, not recommending the joint manifestation of the responsible health professional.

The font chosen for making 41 (37.27%) of the models was Arial, while 43 (39.09%) used Times New Roman, and the remaining 26 (23.64%) were made using other fonts.

As for their legibility, using the Flesch-Kincaid Index as standard, 02 of the models (1.82%) were considered to be difficult, 27 (25.55%) were considered moderately difficult, 71 (64.55%) were considered at a standard level, while 09 (8.18%) were considered moderately easy, and 01 (0.91%) was considered easy.

The models were also analyzed for readability of the portion of the text dedicated to complications. In this regard, still according to the Flesch-Kincaid Index, it was found

that 01 (1.10%) of the texts was considered very difficult, 14 (15.38%) were considered difficult, 33 (36.26%) were considered to be moderately difficult, 39 (36.26%) were considered to be at a standard level, and 04 (4.40%) were considered moderately easy to read. It was found, therefore, that in 25 (26.88%) of the models the text dedicated to complications obtained a higher score in the adopted legibility index, in comparison with its entire text, while 68 (73.12%) presented a score lower than the entire text.

Table 1 – Characteristics related to the Consent forms analyzed. Brazil, 2018.

Source:		Medical societies or associations						Hospitals				
		n			%			n			%	
		60			54.55			50			45.45	
Creation date:	NC	2004	2005	2010	2011	2012	2013	2014	2015	2016	2017	2018
n	26	07	31	07	01	01	05	09	02	09	10	02
%	23.64	6.36	28.18	6.36	0.91	0.91	4.55	8.18	1.82	8.18	9.09	1.82

Table 2 – Adequacy of the Terms of Consent in each query surveyed. Brazil, 2018.

			Present	Absent
Quesito	**n**	**%**	**N**	**%**
Identification of the type of procedure	88	80.00%	22	20.00%
Place of the procedure	19	17.27%	91	82.73%
Description of the procedure	29	26.36%	81	73.64%
Description of complications	93	84.55%	17	15.45%
Right of refusal	10	9.09%	100	90.91%
Joint doctor and patient signature	61	55.45%	49	44.55%
Suitable font and size	84	76.36%	26	23.64%

Tabela 3 – Readability Categories (Flesch-Kincaid) of the complete texts and description of complications. Brazil, 2020.

	General text		Complications text	
Categoria	**n**	**%**	**n**	**%**
Very difficult	2	1.82%	1	0.91%
Difficult	27	24.55%	14	12.73%
Moderately difficult	71	64.55%	33	30.00%
Standard	9	8.18%	39	35.45%
Moderately easy	1	0.91%	4	3.64%
Very easy	0	0.00%	0	0.00%

DISCUSSION

The Arial and Times New Roman fonts have their abundant use justified by the ease of reading they promote[31] since they were developed precisely to better accommodate the arrangement of words in printouts. The result of the analysis, from which 41 (37.27%) of the models were written using the Arial font and 43 (39.09%) of the texts were written in Times New Roman, proved to be satisfactory, since in only 26 (23.64%) of the texts, which total less than a quarter of the total of models, opted for the use of a different font which prevents the improvement of the text's legibility.

It is important to make it clear that, as much as there is interest in improving the care provided to users, and an academic concern about the topic at hand, in Brazil, there is no initiative similar to the proposal brought by this work in this article.

Of the other items listed for the evaluation of the quality of the text contained in the analyzed models, only three displayed mostly satisfactory results. These results are: Procedure identification - 88 (80%) of the models identified the procedure in the body of their text; Description of complications - 93 (84.55%) of the models were provided information about the complications resulting from the procedure to be performed; and Signature - 61 (55.45%) of the models advocated the signature of both parts of the information process - patient and physician/ responsible health professional.

Conversely, three other items yielded mostly negative results. They were: Indication of the place where the procedure was performed - 91 (17.27%) of the models omitted the physical location intended for the exercise of the proposed activity; Description of the procedure - 81 (73.64%) of the models analyzed did not dedicate themselves to exposing and detailing the procedure throughout its writing; and mention of the right to revoke consent or refusal of the proposed medical treatment - 100 (90.91%) of the models did not deal with the subject at any time in their text.

It is important to note that there is no way to stipulate an adequacy rate that can be considered satisfactory, since what is recommended is that the rule should be that consent forms should be capable of assisting the health professional in the patient's information process. Therefore, it is expected that the number of documents to be found will approximate or be the equivalent to the totality of the analyzed texts. This panorama is very distant from the reality found, whose rate of inadequacy varies between 17 and 90%, depending on the item being examined.

The ease of reading the text is important because the user's lack of understanding prevents them from providing consent, since understanding the topic is a requirement for whether or not consent can be provided for medical care[32].

Regarding legibility, only 10 (9.10%) models were considered easy to read (01 easy and 09 moderately easy), and in addition to 71 (64.55%) who obtained a score referring to the "standard" level of legibility, 02 of the models (1.82%) were considered difficult, and 27 (25.55%) were considered moderately difficult.

In this situation, it appears that most models were not able to provide a sufficiently understandable text and, therefore, capable of promoting the information process to which the patient who is submitted to the care of a doctor is entitled.

Much more than the full text of the document analyzed, it is of paramount importance that, when preparing the part

of the text dedicated to the explanation of complications, there is an even greater effort to make it understandable, as it is in this section that the most important information regarding the possible treatment results must be listed.

The models were therefore analyzed for readability of the portion of the text dedicated to treatment complications. In this regard, still according to the Flesch-Kincaid Index, it was found that 02 (2.17%) of the texts were considered very difficult, 13 (14.13%) were considered difficult, 36 (39.13%) were considered moderately difficult, 38 (41.30%) were considered at the standard level of difficulty, and 03 (3.26%) were considered easy to read.

At this point in the analysis, it is necessary to reflect on the PNAD 2016 National Household Sample Survey, which indicates that around 66 million people over 25 years of age (41.8% of the adult population) have not completed elementary school[27]. This portion of the population, at the time of the information process necessary for their proper medical care, requires a tool that can be made completely and undoubtedly understandable, with no chance of failure in this communication.

In total, 91.92% of the compiled models had a legibility index lower than the score considered satisfactory to make it understandable by a relevant part of the population. In addition, the statistics regarding the portion of the text that is dedicated to complications is also not satisfactory, since 69.23% of the texts would not be sufficiently comprehensible for the same portion of the population.

Furthermore, it was found that in 24 (26.09%) of the models, the text dedicated to complications obtained a higher score in the adopted legibility index compared to the form's entire content - which translates into a greater ease of reading, as it should be expected, in the elaboration of an instrument for the patients' information process. Meanwhile, 68 (73.91%) had a score lower than the full text, contrary to the ideal situation proposed by good medical practice.

The data presented are relevant, as it is expected that the instrument used in the information process at the moment that most requires attention to reading from the patient is dedicated to eliminating any obstacles or difficulties in the transmission of the content that it proposes to pass on to its reader, either in its entirety or as to the space dedicated to the possible complications arising from the option for the proposed treatment, a key factor in the patient's consent.

It is noted, therefore, that the same document may present inadequacies in several aspects, each of which are not exclusive hypotheses, and there is the possibility that, in a single document, there are problems in more than one aspect analyzed.

One of the limitations of the study is the fact that there is not much production about the readability of the consent forms. What is expected to be corrected, specifically through dedication to the study of the theme, is that the results of this study can be substantiated in a sufficient substrate to resolve the difficulties faced by future studies, translating it into a dynamic force capable of overcoming inertia of the displayed insipience.

CONCLUSION

Data analysis reveals texts that are difficult to understand and have serious flaws in their elaboration. The texts in large part do not detail the procedure to which the patient is submitted, nor the place where it will be performed. Although there is no predominance, a portion close to half does not allocate space for the signature of the physician responsible for the procedure; and, with regards to the portion of the text referring to complications, most of the analyzed terms proved to be deficient, either due to the total absence of the description or by increased difficulty of reading.

It was found that, although there is significant academic dedication to the study and discussion regarding the information process in the scope of medical care and the role that the Informed Consent Form should play in this process(32), the attempts at standardization capable of producing models sufficiently satisfactory for the daily use of health professionals are still incipient.

From knowing that the conception of a prescriptive model is not feasible, as it is an instrument that aims to solve communication difficulties inherent in the procedures performed in the daily routine of each health professional, lies the merit of good medical conduct in establishing quality parameters and criteria that guide the formulation of informed consent forms that assist medical practice by effectively assisting users in the information process.

Considering the reality described in the present study, it is clear that the efforts made to provide patients with complete and detailed information about their clinical situations (the primary objective of using the ICF in the information process) present a performance far below that which is desired, requiring new interventions and approaches by the institutions involved.

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