Application of the fundamentals of health literacy to the informed consent

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Abstract

The informed consent is required for voluntary participation in research and health decisions. However, the information must be passed on to the patient or research participant so that it is effectively understood. Functional health literacy should be considered in the elaboration of these terms, in the design of graphic materials and interviews, and in verbal communication, so that the individual can evaluate the information transmitted and decide autonomously. Thus, this paper aims to identify obstacles to the application of these documents and their effectiveness, considering the real understanding of the interviewee, whether user of the health system or research participant. To this end, a bibliographic research about the way informed consent is presented was conducted. Based on this, a script is proposed for the preparation of these documents in view of the principles of functional health literacy.

Keywords: Informed consent. Information literacy. Communication. Health literacy.

Resumo

Aplicação dos fundamentos do letramento em saúde no consentimento informado

O consentimento informado é necessário para participação voluntária em pesquisas e decisões em saúde. No entanto, as informações devem ser passadas ao paciente ou participante de pesquisa de forma que sejam efetivamente compreendidas. O letramento funcional em saúde deve ser considerado na elaboração dos termos de consetimento, na concepção de materiais gráficos e entrevistas e na comunicação verbal, para que o indivíduo consiga avaliar as informações transmitidas e decidir com autonomia. Assim, este trabalho objetiva identificar entraves à aplicação desses documentos e à sua efetividade, considerando a real compreensão do entrevistado, seja usuário do sistema de saúde ou participante de pesquisa. Para tanto, foi realizada pesquisa bibliográfica sobre o modo como o consentimento informado é apresentado, com base na qual propõe-se roteiro para a elaboração desses documentos tendo em vista os princípios do letramento funcional em saúde.

Palavras-chave: Consentimento livre e esclarecido. Competência em informação. Comunicação. Alfabetização em saúde.

Resumen

Aplicación de los fundamentos del letramiento en salud en el consentimiento informado

El consentimiento informado es necesario para la participación voluntaria en investigaciones y en la toma de decisiones en salud. No obstante, la información debe transmitirse al paciente o al participante de la investigación de forma tal que sea efectivamente comprendida. El letramiento funcional en salud debe tomarse en consideración en la elaboración de estos documentos, en el diseño de materiales gráficos y de entrevistas, y en la comunicación verbal, para que el individuo pueda evaluar la información transmitida y decidir con autonomía. Así, este trabajo tiene como objetivo identificar las dificultades para la aplicación de estos documentos y para su efectividad, considerando la comprensión real del entrevistado, ya sea usuario del sistema de salud o participante de una investigación. Para ello, se realizó una búsqueda bibliográfica sobre la forma en que se presenta el consentimiento informado, en base a la cual se propone un guion para la elaboración de estos documentos, teniendo en cuenta los principios del letramiento funcional en salud.

Palabras clave: Consentimiento informado. Alfabetización informacional. Comunicación. Alfabetización en salud.

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According to the definition in Portuguese, the word "*alfabetização*" means "state or quality of literacy" [1], i.e., it refers to the acquisition of reading and writing. In turn, the term "letramento" is a neologism created from the transposition of the English term "literacy" [2], which highlights the socio-historical aspects of the phenomenon of this acquisition [3].

For Soares [4], the distinction between "alfabetização" and "letramento" is clear only in developed countries, like the United States; In Brazil, these concepts are still not well defined. The diffusion of the phrase "letramento funcional" (or "alfabetização funcional") occurred from the publication by the United Nations Educational, Scientific and Cultural Organization (Unesco): *A person is functionally literate when they can participate in all those activities in which literacy is necessary for the effective functioning of their group and also to enable them to continue to use reading, writing and calculating for their own development and that of their community* [5].

Letramento Funcional em Saúde – Functional literacy in health (LFS) had, as its initial definition, the individual's ability to use reading, writing, and computational ability properly to meet his or her needs [6]. However, the concept has undergone modifications, becoming broader and more multidimensional, although it is still not definitively and consensually stated.

The latest definition indicates the LFS as a set of knowledge, motivations, and skills to access, understand, evaluate, and apply information to judge and make everyday decisions in disease prevention and health care and promotion, maintaining or improving the quality of life [7]. This information can be conveyed by different means, which require skills such as reading, writing, numbering, communicating, and using electronic technologies [8].

Over time, in addition to the definition of the concept, instruments to measure the LFS were consolidated which demonstrated a limited level of the general population [9]. Then comes the perception that most patients have difficulty understanding health information, which, therefore, requires certain conducts to reverse this situation [10].

Low LFS is associated with poorer quality of life and leads to difficulties in reading, understanding and applying health guidelines, such as information on food labels and drug labels, and problems understanding medical instructions and informed consent documents. An association between low levels of LFS and lower probability of the individual completing interviews in prospective follow-up studies was also found [11-14].

The association between limited understanding of research participation documents and low health literacy has been pointed out by studies for some time, but there are few proposals for a solution to the question [15,16]. In both health service and research, the level of health literacy of individuals is often overestimated, making professionals and researchers consider in advance that the information passed on was understood [17].

An investigation of the level of LFS, with more than 10,000 people from 60 countries, including Japan, Pakistan, Spain, and the United States, included adult patients, doctors, and students. Results converged across countries, indicating that most of the sample lacked the skills needed to make qualified risk-based decisions [18].

As a requirement supported by ethical principles of respect for the person and their autonomy, the informed consent form has become the primary means of registration for participation in research and authorization of medical procedures. This instrument needs to adapt to the health literacy of the individual; however, professionals and researchers have not been elaborating it according to the LFS guidelines, overestimating the participants' ability to understand [19,20].

These forms seek to ensure that research volunteers understand the purpose, risks, and benefits of the research proposal before accepting participation. Thus, it is assumed that the signatory of the term understood the information provided [21]. However, studies have shown that many participants, even signing the consent form, do not understand all the benefits of the research and its risks [22], and many documents are characterized as extensive and complex [23,24].

In addition to the printed consent term, the ideal process for obtaining consent requires continuous and effective communication between volunteers and researchers who must be prepared to provide further clarification [25]. Some practitioners use more intelligible verbal language than printed documents, but such communication may leave out critical elements for fully informed consent. Thus, efforts have been focused on communicative skills training [26].

Several alternatives have been tested to encourage term assimilation, including form modifications, multimedia presentations, monetary incentives, communicative skills development,

and professional training programs. While some studies have had mixed results, evidence suggests that applying the principles of literacy improves understanding [27,28]. Strategies include broader dialogue and simpler, shorter forms [29].

The present study aimed to scale the barriers to elaborate and apply understandable and effective informed consent terms, considering the real understanding of the interviewee, patient or research participant. For this, a bibliographic survey was made, especially of North American publications of the last three decades, targeting the principles of health literacy to verify if they are taken into account in the development of documents and help to fulfill their purpose. The reflection was structured in topics and primarily addressing how the consent document is presented in research in Brazil and worldwide. Next, ways of designing the form based on LFS principles are proposed.

The free informed consent form

In all human research, the right to accept or refuse participation must be ensured. This principle has important ethical implications and must respect five essential components: the individual's ability to consent, the disclosure of all relevant information about scientific research, the understanding by participants, the freedom to consider participation without induction, and the explicit and formal consent, usually in writing, which constitutes, in Brazil, the free and informed consent form (FICF) [21,30,31].

This concern with research ethics began shortly after World War II, one of its hallmarks being the *Nuremberg Code* (1947), a pioneering document on the importance of consent by the participating individual. Thus, bylaws were established around the need for guidelines for the relationship between researcher and researcher, in order to avoid constraints and direct or indirect risks to the dignity of individuals [32].

In Brazil, the Conselho Nacional de Saúde – National Health Council (CNS) drafted Resolution 196/1996 [33], which regulated research involving human beings and was the first normative framework of ethics applied to research in the country. Revised after public consultation, the regulation was updated by CNS Resolution 466 of 12 December 2012 [34]. In addition to the *Nuremberg Code*, other international documents supported the preparation of this first Brazilian publication: the *Universal Declaration of Human Rights* (1948) [35], the *Helsinki Declaration* (1964) [36], the *International Covenant on Civil and Political Rights* (1966) [37], the *International Ethical Guidelines for Research Involving Humans* (1993) [38] and the *International Guidelines for the Ethical Review of Epidemiological Studies* (1991) [39].

With Resolution CNS 196/1996, the Brazilian Ethics Review System was created, composed of the Comitês de Ética em Pesquisa – Research Ethics Committees (CEP) and the Comissão Nacional de Ética em Pesquisa – Conep (National Research Ethics Commission), also known as the "CEP/Conep System". Longer and more detailed, the current resolution (466/2012) considers basic elements of bioethics, such as recognition and guarantee of dignity, freedom, autonomy, beneficence, non-maleficence, justice and equity, among others aimed at ensuring the rights and duties of the participants, the scientific community and the state. In this resolution, new international documents were incorporated, such as the *Universal Declaration of the Human Genome* (1997) [40], the *International Declaration on Human Genetic Data* (2004) [41] and the *Universal Declaration on Bioethics and Human Rights* (2005) [42,43].

In Resolution 466/2012, the item entitled "Free and Informed Consent" had its title changed to "Process of Free and Informed Consent", that is, all the steps were incorporated so that the people summoned to integrate a study can manifest with autonomy and conscience. In the early stage of the process, the researcher should provide the prospective participant, *at the most appropriate time, condition and location* (…)*, with clear and accessible language information* (…)*,* [providing] *adequate time for the guest to reflect* (…) [Next, one must present] *the free and informed consent form to be read and understood prior to signing* [34].

Some mandatory information should be included in the term: justification, objectives, and procedures of the research; possible discomforts and risks arising from their development; ways of accompanying and assisting participants; guarantee of freedom to the volunteer to stop participating at any time; and maintaining confidentiality. Each form is reproduced in two ways so that one of them stays with the participant [34].

The resolution also points out that the CEP should make FICF models available to researchers to avoid problems that make project approval

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unfeasible [44]. The form of writing of the term is free for each institution, in continuous writing or in topics, as long as it follows the resolution. Therefore, there is no standardization of document format.

The consent term focused on functional literacy

Application of LFS fundamentals to the informed consent process can lead to more informed decisions. In this perspective, it is necessary to think about verbal and written communication. Concerning the first, patients with limited levels of health literacy tend to retain only half of what is discussed and are not ready to ask questions [45]. Therefore, simple language is recommended, without medical jargon or scientific terms, with patient-mirrored vocabulary and clear, slow speech, with information divided into small parts [46-48].

One way to ensure that patients clearly understand the information is to use the teach-back method [49], which eliminates the traditional questions "Do you understand?" or "Do you have any doubts?", avoiding answers like" yes "or" no ". The method seeks the response of the patient to the following request: "I want to make sure that I can explain correctly what we are going to do. Could you repeat what you understood from what I said?" Thus, the individual explains the new information in their own words and allows the researcher to assess their understanding.

If necessary, the researcher can explain everything again and repeat the process until they consider that the information has been understood. Teach-back would, therefore, be a resource for evaluating the effectiveness of researcher communication and improving the effectiveness of information in informed consent [50].

In turn, the written material should reinforce the patient's knowledge in conjunction with verbal information [51]. Regardless of the recipient's level of education, printed communication should correspond to the reading level of the fifth to sixth grade at the most, and be limited to key points, avoiding excessive and unnecessary information [52]. These recommendations apply to different populations, since there is the equivalence of years of study between Brazil and the United States and interference of education in literacy level, even though people with reading habits make up for a few years of study [53].

Researchers report that long and complex documents can discourage the reading of volunteers, leading them to sign them without the proper absorption of information [54]. Also, a Brazilian scientific article showed that participants with more limited LFS were those who left the most unanswered questionnaire items, usually those with the highest degree of complexity [55].

Some studies have also evaluated new ways to obtain informed consent in research and services. In a clinical trial with low-income adults, some literacy assumptions were tested. Two forms were applied: one short and one traditional. The simplified form had the same information as the traditional but presented more succinctly, with less medical jargon, in the active voice and simpler formatting and organization of procedures and information, and is, therefore, better understood [56].

Another study looked at the effectiveness of two types of consent. Participants in the first group received a newsletter summarizing key study information, and the second group, in addition to receiving the newsletter, participated in a Q&A session. In the end, from the answers of both closed and open questions, the study concluded that the second had a better understanding [57].

A systematic review of interventions to improve patient understanding identified that multimedia features did not yield consistent results. Discussions between researchers and volunteers seem to be more efficient [58]. Another review, which looked at 54 forms of informed consent, also suggested that expanded discussions enhance participants' perceptions [59].

Also based on health literacy, a specific study evaluated the understanding of the assimilation of consent to donate to a biobank. In this case, the teach-back technique and information leaflets written in simple language were used, with short sentences, active voice, technical word definitions, headings before each section, contextualization, highlights for the main content and large font (size greater than 12) whenever possible. No sentences were used entirely in capital letters, and color schemes that distracted the reader were avoided. At the end of the analysis, participants preferred text with bold highlighted parts, explanatory captions for graphics, and color contrast between text and page [60].

Such features are emphasized by the National Institutes of Health [61], which advise researchers to produce reading-appropriate documents for the eighth grade (according to the US education system). Other guidelines also highlight the use of simple language, graphics and images that complement the text, clearly and descriptively arranged topics, and whitespace throughout the document [62,63].

Depending on the situation, numerical data may be essential for decisions, especially for consent about health care. These data include statistics on the benefits and risks of preventive behaviors, as well as disease and prognosis, and are assumed to improve understanding. But many people have difficulty with numbers – an important component of health literacy [64].

Visual aids such as schematics and images can improve the assimilation of patient information, particularly when risks and probabilities are reported [52,65]. In such cases, various tools may be used, such as icons, graphical examples of affected individuals within a given risk population [11].

Research or treatment flowcharts may also be included from previous assessments of what individuals know, as done by an American emergency department to clarify appendectomy in children. In this case, an instrument was used to assess the knowledge of the parents, to then present the steps of surgery and postoperative images, which facilitated the assimilation of the procedure by the guardians [66].

Other researchers have noted that consent is best understood when presented in plain language, shorter messages, graphics, whitespace, and appropriate font size [67]. This format, which makes materials accessible also to people with low literacy, should be developed with the help of communication specialists to facilitate dialogue between researcher and participant. In addition, developers should have a cultural repertoire and research experience [68].

Creative technologies, such as videos that exemplify the risks and benefits of a particular method or study, can also improve understanding of the FICF. This strategy was shown to be effective in a study with preoperative women of hysterectomy who well understood the steps of surgery and the postoperative period, to the point of reducing the length of stay [69].

There are instruments to evaluate materials according to health literacy, among them the Suitability Assessment of Materials (SAM) [70], which identifies factors detrimental to the readability and comprehension of the document. Content, demand for literacy, graphics, layout, typography, learning and motivation, as well as cultural adequacy are considered. Thus, the instrument also sets standards for elaboration. In the shortage of materials for this purpose in Brazil, SAM was translated and adapted to Portuguese [71]. Frame 1 presents a proposal for a script to produce FICF based on the fundamentals of health literacy. Of course, each research center can use these guidelines according to its reality; what matters is that the quality of the terms is ensured for understanding by the target group.

Frame 1. Proposal for consent document based on health functional literacy

Category	Recommendations
Verb voice	Active
Reading level	Sixth year of basic education, avoiding medical jargon
	In case medical jargon is used, explain the meaning between parenthesis
Extension	Short text, limited to key points
	Sentences up to 15 words, with minimal use of polysyllabic words
Font type	Minimum 12 points and, in case of elderly or people with reading difficulties, 14 points
	Spacing: 1.2 to 1.5
	For the title, use a sans serif font and, for text body, use a serif font
Text organization	Using charts, where applicable, to communicate numerical data with explanatory captions
	Interleaving uppercase and lowercase letters
	Color contrast between text and page
	Blank spaces between topics
	Bold highlights for the main topics

Source: Adapted from Sudore et al. [46]; Schillinger et al. [47]; Parnell et al. [48]; Garcia-Retamero et al. [52]; Drake et al. [60]; Ridpath et al. [62]; Schnitzer et al. [63]; Tait et al. [67]

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Final considerations

The LFS should be considered from the interpersonal relationship to the transmission of information, from individual care at the community level to better adherence to treatment and empowerment of citizens. Therefore, it is essential to properly assimilate the information disclosed, especially regarding decision-making [72].

Informed consent depends on the individual's ability to accurately understand and assess risks and benefits of treatments or research. Thus, it is up to professionals and researchers to interpret and communicate content, using graphic means and accessible language, so that volunteers understand the information transmitted and use it to make their decision [73,74]. However, many professionals may not have communicative skills, even though they are explicit in Resolution CNS 466/2012 [75]. In addition, lower levels of health literacy tend to favor the paternalistic model, in which practitioners and researchers dominate decisions [76,77].

Writing an informed consent document in plain language can be challenging considering institutional and financial standards and requirements. In general, there is resistance to change, especially when it entails additional workload, either real or apparent. It was thus in the obligation of the FICF established by the CNS Resolution 196/1996 [33], when there were difficulties in elaborating terms that met the requirements. Often, as noted by CEP participants at that time, the return of research projects to authors for reformulation was solely due to the wording of the FICF.

Over time, there have been many strategies for broadening the understanding of research or medical service participants, but even today there are many inadequacies and irregularities in obtaining this consent. Researchers and practitioners need to consider health literacy when planning this process.

The document for obtaining informed consent cannot simply be a printed and signed text that does not truly expose what is being proposed to the participant. As highlighted in this article, some cautions can contribute to the quality of the written document. And in the case of verbal communication, teach-back is one of the key strategies for identifying topics that are most difficult to understand and enabling better-targeted approaches.

Ideally, it is important to know the LFS level of the target population; However, as this is not always feasible, documents accessible to all, including people with low LFS, can be designed to guarantee autonomy in consent [10]. As teams internalize the principles of health literacy as they design the FICF, more operational ideas and strategies will emerge, improving and facilitating the process.

Referências

1. Ferreira ABH. Dicionário da língua portuguesa. 5ª ed. Curitiba: Positivo; 2014.
2. Soares M. Letramento: um tema em três gêneros. 4ª ed. Belo Horizonte: Autêntica; 2006.
3. Tfouni LV. Adultos não-alfabetizados em uma sociedade letrada. São Paulo: Cortez; 2006.
4. Soares M. Letramento e alfabetização: as muitas facetas. Rev Bras Educ [Internet]. 2004 [acesso 4 jun 2019];(25):5-17. DOI: 10.1590/S1413-24782004000100002
5. United Nations Educational, Scientific and Cultural Organization. Aspects of literacy assessment: topics and issues from the Unesco Expert Meeting [Internet]. Paris: Unesco; 2005 [acesso 4 jun 2019]. Disponível: https://bit.ly/31CnuQJ
6. Parker RM, Baker DW, Williams MV, Nurss JR. The test of functional health literacy in adults. J Gen Intern Med [Internet]. 1995 [acesso 2 maio 2018];10(10):537-41. DOI: 10.1007/bf02640361
7. Sørensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z *et al*. Health literacy and public health: a systematic review and integration of definitions and models. BMC Public Health [Internet]. 2012 [acesso 2 maio 2018];12(1):80. DOI: 10.1186/1471-2458-12-80
8. Kutner M, Greenberg E, Jin Y, Paulsen C. The health literacy of America's adults: results from the 2003 National Assessment of Adult Literacy [Internet]. Washington: National Center for Education Statistics; 2006 [acesso 2 maio 2018]. Disponível: https://bit.ly/2FjkPlH
9. Pleasant A. Appendix A: health literacy around the world: part 1 health literacy efforts outside of the United States. In: Roundtable on Health Literacy, Board on Population Health and Public Health Practice, Institute of Medicine. Health literacy: improving health, health systems, and health policy around the world: workshop summary [Internet]. Washington: National Academies Press; 2013 [acesso 2 maio 2018]. Disponível: https://bit.ly/2XXz1rx
10. U.S. Department of Health and Human Services. Healthy people 2010: understanding and improving health [Internet]. 2ª ed. Washington: U.S. Government Printing Office; 2010 [acesso 2 maio 2018]. Disponível: https://bit.ly/2MU2aTD

11. Garcia-Retamero R, Cokely ET, Ghazal S, Joeris A. Measuring graph literacy without a test: a brief subjective assessment. Med Decis Making [Internet]. 2016 [acesso 2 maio 2018];36(7):854-67. DOI: 10.1177/0272989X16655334
12. Hersh L, Salzman B, Snyderman D. Health literacy in primary care practice. Am Fam Physician [Internet]. 2015 [acesso 2 maio 2018];92(2):118-24. Disponível: https://bit.ly/2Rkiuvw
13. Sheridan SL, Halpern DJ, Viera AJ, Berkman ND, Donahue KE, Crotty K. Interventions for individuals with low health literacy: a systematic review. J Health Commun [Internet]. 2011 [acesso 2 maio 2018];16(Supl 3):30-54. DOI: 10.1080/10810730.2011.604391
14. Leak C, Goggins K, Schildcrout JS, Theobald C, Donato KM, Bell SP *et al*. Effect of health literacy on research follow-up. J Health Commun [Internet]. 2015 [acesso 2 maio 2018];20(Supl 2):83-91. DOI: 10.1080/10810730.2015.1058442
15. Donovan-Kicken E, Mackert M, Guinn TD, Tollison AC, Breckinridge B, Pont SJ. Health literacy, self-efficacy, and patients' assessment of medical disclosure and consent documentation. J Health Commun [Internet]. 2012 [acesso 2 maio 2018];27(6):581-90. DOI: 10.1080/10410236.2011.618434
16. Nielsen-Bohlman L, Panzer AM, Kindig DA, editores. Health literacy: a prescription to end confusion [Internet]. Washington: The National Academies Press; 2004 [acesso 2 maio 2018]. Disponível: https://bit.ly/2L0fFyo
17. Rogers ES, Wallace LS, Weiss BD. Misperceptions of medical understanding in low-literacy patients: implications for cancer prevention. Cancer Control [Internet]. 2006 [acesso 2 maio 2018];13(3):225-9. DOI: 10.1177/107327480601300311
18. Ghazal S, Cokely ET, Garcia-Retamero R. Predicting biases in very highly educated samples: numeracy and metacognition. Judgm Decis Mak [Internet]. 2014 [acesso 2 maio 2018];9(1):15-34. Disponível: https://bit.ly/2IQkh7D
19. Raich PC, Plomer KD, Coyne CA. Literacy, comprehension, and informed consent in clinical research. Cancer Invest [Internet]. 2001 [acesso 2 maio 2018];19(4):437-45. DOI: 10.1081/CNV-100103137
20. Montalvo W, Larson E. Participant comprehension of research for which they volunteer: a systematic review. J Nurs Scholarsh [Internet]. 2014 [acesso 2 maio 2018];46(6):423-31. DOI: 10.1111/jnu.12097
21. World Medical Association. WMA declaration of Helsinki: ethical principles for medical research involving human subjects [Internet]. 2002 [acesso 2 maio 2018]. Disponível: https://bit.ly/2rJdF3M
22. Sanchini V, Reni M, Calori G, Riva E, Reichlin M. Informed consent as an ethical requirement in clinical trials: an old, but still unresolved issue: an observational study to evaluate patients informed consent comprehension. J Med Ethics [Internet]. 2014 [acesso 17 ago 2018];40(4):269-75. DOI: 10.1136/medethics-2012-101115
23. Kass NE, Chaisson L, Taylor HA, Lohse J. Length and complexity of US and international HIV consent forms from federal HIV network trials. J Gen Intern Med [Internet]. 2011 [acesso 2 maio 2018];26(11):1324-8. DOI: 10.1007/s11606-011-1778-6
24. Taylor HE, Bramley DEP. An analysis of the readability of patient information and consent forms used in research studies in anaesthesia in Australia and New Zealand. Anaesth Intensive Care [Internet]. 2012 [acesso 2 maio 2018];40(6):995-8. DOI: 10.1177/0310057X1204000610
25. Lentz J, Kennett M, Perlmutter J, Forrest A. Paving the way to a more effective informed consent process: recommendations from the Clinical Trials Transformation Initiative. Contemp Clin Trials [Internet]. 2016 [acesso 2 maio 2018];49:65-9. DOI: 10.1016/j.cct.2016.06.005
26. Koyfman SA, Reddy CA, Hizlan S, Leek AC, Kodish DE. Informed consent conversations and documents: a quantitative comparison. Cancer [Internet]. 2016 [acesso 2 maio 2018];122(3):464-9. DOI: 10.1002/cncr.29759
27. Campbell FA, Goldman BD, Boccia ML, Skinner M. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: a comparison of print, video, and computer-based presentations. Patient Educ Couns [Internet]. 2004 [acesso 17 jun 2018];53(2):205-16. DOI: 10.1016/S0738-3991(03)00162-9
28. Matsui K, Lie RK, Turin TC, Kita Y. A randomized controlled trial of short and standard-length consent forms for a genetic cohort study: is longer better? J Epidemiol [Internet]. 2012 [acesso 25 jul 2018];22(4):308-16. DOI: 10.2188/jea.JE20110104
29. Tamariz L, Palacio A, Robert M, Marcus EN. Improving the informed consent process for research subjects with low literacy: a systematic review. J Gen Intern Med [Internet]. 2013 [acesso 17 ago 2018];28(1):121-6. DOI: 10.1007/s11606-012-2133-2
30. Goldim JR, Pithan CF, Oliveira JG, Raymundo MM. O processo de consentimento livre e esclarecido em pesquisa: uma nova abordagem. Rev Assoc Med Bras [Internet]. 2003 [acesso 17 ago 2018];49(4):372-4. DOI: 10.1590/S0104-42302003000400026
31. Katz J. The Nuremberg code and the Nuremberg trial: a reappraisal. Jama [Internet]. 1996 [acesso 2 maio 2018];276(20):1662-6. DOI: 10.1001/jama.1996.03540200048030
32. Editorial: revisão ética na pesquisa em ciências humanas e sociais. Educ Soc [Internet]. 2015 [acesso 10 jul 2018];36(133):857-63. DOI: 10.1590/ES0101-73302015v36n133ED
33. Conselho Nacional de Saúde. Resolução CNS nº 196, de 10 de outubro de 1996. Aprova diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Diário Oficial da União. Brasília [Internet], nº 201, 16 out 1996 [acesso 10 jul 2018]. Seção 1. Disponível: https://bit.ly/2ekI03l

34. Conselho Nacional de Saúde. Resolução CNS nº 466, de 12 de dezembro de 2012. Aprova diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Diário Oficial da União [Internet]. Brasília, nº 12, p. 59, 13 jun 2013 [acesso 10 jul 2018]. Seção 1. Disponível: https://bit.ly/2B2jJZK
35. Organização das Nações Unidas. Resolução ONU nº 217 A (III) da Assembleia Geral. Paris: ONU; 1948.
36. Associação Médica Mundial. Declaração de Helsinki. Helsinki: AMM; 1964.
37. Organização das Nações Unidas. Pacto internacional sobre os direitos civis e políticos. Paris: ONU; 1966.
38. Conselho das Organizações Internacionais de Ciências Médicas, Organização Mundial da Saúde. Diretrizes éticas internacionais para a pesquisa envolvendo seres humanos. Genebra: Cioms; 1993.
39. Conselho das Organizações Internacionais de Ciências Médicas, Organização Mundial da Saúde. Diretrizes internacionais para revisão ética de estudos epidemiológicos. Genebra: Cioms; 1991.
40. Organização das Nações Unidas para a Educação, a Ciência e a Cultura, Comitê Internacional de Bioética. Declaração universal do genoma humano e dos direitos humanos. Paris: Unesco; 1997.
41. Organização das Nações Unidas para a Educação, a Ciência e a Cultura, Comitê Internacional de Bioética. Declaração internacional sobre os dados genéticos humanos. Paris: Unesco; 2004.
42. Organização das Nações Unidas para a Educação, a Ciência e a Cultura. Declaração universal sobre bioética e direitos humanos. Paris: Unesco; 2005.
43. Rippel JA, Medeiros CA, Maluf F. Declaração universal sobre bioética e direitos humanos e Resolução CNS 466/2012: análise comparativa. Rev. bioét. (Impr.) [Internet]. 2016 [acesso 10 jan 2019];24(3):603-12. DOI: 10.1590/1983-80422016243160
44. Siquelli SA, Hayashi MCPI. Ética em pesquisa de educação: uma leitura a partir da Resolução 196/96 com expectativas da Resolução 466/12. Hist Perspect [Internet]. 2015 [acesso 17 ago 2018];(52):65-81. Disponível: https://bit.ly/2L0hiMv
45. McCarthy DM, Waite KR, Curtis LM, Engel KG, Baker DW, Wolf MS. What did the doctor say? Health literacy and recall of medical instructions. Med Care [Internet]. 2012 [acesso 2 maio 2018];50(4):277-82. DOI: 10.1097/MLR.0b013e318241e8e1
46. Sudore RL, Schillinger D. Interventions to improve care for patients with limited health literacy. J Clin Outcomes Manag [Internet]. 2009 [acesso 23 maio 2018];16(1):20-9. Disponível: https://bit.ly/2WOEDYK
47. Schillinger D, Bindman A, Wang F, Stewart A, Piette J. Functional health literacy and the quality of physician-patient communication among diabetes patients. Patient Educ Couns [Internet]. 2004 [acesso 23 maio 2018];52(3):315-23. DOI: 10.1016/S0738-3991(03)00107-1
48. Parnell TA, McCulloch EC, Mieres JH, Edwards F. Health literacy as an essential component to achieving excellent patient outcomes. Institute of Medicine of the National Academies [Internet]. 2014 [acesso 10 jul 2018]. Disponível: https://bit.ly/2IqrfkA
49. Tamura-Lis W. Teach-back for quality education and patient safety. Urol Nurs [Internet]. 2013 [acesso 17 ago 2018];33(6):267-71. DOI: 10.7257/1053-816X.2013.33.6.267
50. White M, Garbez R, Carroll M, Brinker E, Howie-Esquivel J. Is "teach-back" associated with knowledge retention and hospital readmission in hospitalized heart failure patients?. J Cardiovasc Nurs [Internet]. 2013 [acesso 2 maio 2018];28(2):137-46. DOI: 10.1097/JCN.0b013e31824987bd
51. Mexas F, Efron A, Luiz RR, Cailleaux-Cezar M, Chaisson RE, Conde MB. Understanding and retention of trial-related information among participants in a clinical trial after completing the informed consent process. Clin Trials [Internet]. 2014 [acesso 4 jun 2019];11(1):70-6. DOI: 10.1177/1740774513509316
52. Garcia-Retamero R, Galesic M. Who profits from visual aids: overcoming challenges in people's understanding of risks. Soc Sci Med [Internet]. 2010 [acesso 2 maio 2018];70(7):1019-25. DOI: 10.1016/j.socscimed.2009.11.031
53. Carthery-Goulart MT, Anghinah R, Areza-Fegyveres R, Bahia VS, Brucki SMD, Damin A *et al*. Performance of a Brazilian population on the test of functional health literacy in adults. Rev Saúde Pública [Internet]. 2009 [acesso 4 jun 2019];43(4):631-8. DOI: 10.1590/S0034-89102009005000031
54. Lorell BH, Mikita JS, Anderson A, Hallinan ZP, Forrest A. Informed consent in clinical research: consensus recommendations for reform identified by an expert interview panel. Clin Trials [Internet]. 2015 [acesso 2 maio 2018];12(6):692-5. DOI: 10.1177/1740774515594362
55. Firmino RT, Fraiz FC, Montes GR, Paiva SM, Granville-Garcia AF, Ferreira FM. Impact of oral health literacy on self-reported missing data in epidemiological research. Community Dent Oral Epidemiol [Internet]. 2018 [acesso 4 jun 2019];46(6):624-30. DOI: 10.1111/cdoe.12415
56. Ittenbach RF, Senft EC, Huang G, Corsmo JJ, Sieber JE. Readability and understanding of informed consent among participants with low incomes: a preliminary report. J Empir Res Hum Res Ethics [Internet]. 2015 [acesso 2 maio 2018];10(5):444-8. DOI: 10.1177/1556264615615006
57. Kass NE, Taylor HA, Ali J, Hallez K, Chaisson L. A pilot study of simple interventions to improve informed consent in clinical research: feasibility, approach, and results. Clin Trials [Internet]. 2015 [acesso 2 maio 2018];12(1):54-66. DOI: 10.1177/1740774514560831
58. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. Jama [Internet]. 2004 [acesso 25 maio 2018];292(13):1593-601. DOI: 10.1001/jama.292.13.1593

59. Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC Med Ethics [Internet]. 2013 [acesso 2 maio 2018];14(1):28. DOI: 10.1186/1472-6939-14-28
60. Drake BF, Brown KM, Gehlert S, Wolf LE, Seo J, Perkins H *et al*. Development of plain language supplemental materials for the biobank informed consent process. J Cancer Educ [Internet]. 2017 [acesso 2 maio 2018];32(4):836-44. DOI: 10.1007/s13187-016-1029-y
61. U.S. National Institutes of Health. Guidelines for the conduct of research involving human subjects at the National Institutes of Health [Internet]. Washington: U.S. Department of Health and Human Services; 2004 [acesso 25 maio 2018]. Disponível: https://bit.ly/2FjjBGS
62. Ridpath JR, Wiese CJ, Greene SM. Looking at research consent forms through a participant-centered lens: the PRISM readability toolkit. Am J Health Promot [Internet]. 2009 [acesso 25 maio 2018];23(6):371-5. DOI: 10.4278/ajhp.080613-CIT-94
63. Schnitzer AE, Rosenzweig M, Harris B. Health literacy: a survey of the issues and solutions. J Consum Health Internet [Internet]. 2011 [acesso 25 maio 2018];15(2):164-79. DOI: 10.1080/15398285.2011.573347
64. Lipkus IM, Peters E. Understanding the role of numeracy in health: proposed theoretical framework and practical insights. Health Educ Behav [Internet]. 2009 [acesso 25 maio 2018];36(6):1065-81. DOI: 10.1177/1090198109341533
65. Bento SF, Hardy E, Osis MJ. Process for obtaining informed consent: women's opinions. Dev World Bioeth [Internet]. 2008 [acesso 4 jun 2019];8(3):197-206. DOI: 10.1111/j.1471-8847.2006.00183.x
66. Rosenfeld EH, Lopez ME, Yu YR, Justus CA, Borges MM, Mathai RC *et al*. Use of standardized visual aids improves informed consent for appendectomy in children: a randomized control trial. Am J Surg [Internet]. 2018 [acesso 17 ago 2018];216(4):730-5. DOI: 10.1016/j.amjsurg.2018.07.032
67. Tait AR, Voepel-Lewis T, Nair VN, Narisetty NN, Fagerlin A. Informing the uninformed: optimizing the consent message using a fractional factorial design. Jama Pediatr [Internet]. 2013 [acesso 2 maio 2018];167(7):640-6. DOI: 10.1001/jamapediatrics.2013.1385
68. Kraft SA, Doerr M. Engaging populations underrepresented in research through novel approaches to consent. Am J Med Genet C Semin Med Genet [Internet]. 2018 [acesso 17 ago 2018];178(1):75-80. DOI: 10.1002/ajmg.c.31600
69. Pallett AC, Nguyen BT, Klein NM, Phippen N, Miller CR, Barnett JC. A randomized controlled trial to determine whether a video presentation improves informed consent for hysterectomy. Am J Obstet Gynecol [Internet]. 2018 [acesso 17 ago 2018];219(3):277. DOI: 10.1016/j.ajog.2018.06.016
70. Doak CC, Doak LG, Root JH. Teaching patients with low literacy skills. 2ª ed. Philadelphia: Lipincott; 1996.
71. Sousa CS, Turrini RNT, Poveda VB. Translation and adaptation of the instrument Suitability Assessment of Materials (SAM) into Portuguese. Rev Enferm UFPE [Internet]. 2015 [acesso 17 ago 2018];9(5):7854-61. DOI: 10.5205/reuol.6121-57155-1-ED.0905201515
72. Batterham RW, Hawkins M, Collins PA, Buchbinder R, Osborne RH. Health literacy: applying current concepts to improve health services and reduce health inequalities. Public Health [Internet]. 2016 [acesso 17 ago 2018];132:3-12. DOI: 10.1016/j.puhe.2016.01.001
73. Anderson BL, Schulkin J, editores. Numerical reasoning in judgments and decision making about health. Cambridge: Cambridge University Press; 2014.
74. Zikmund-Fisher BJ, Mayman G, Fagerlin A. Patient numeracy: what do patients need to recognize, think, or do with health numbers? In: Anderson BL, Schulkin J, editores. Numerical reasoning in judgments and decision making about health. Cambridge: Cambridge University Press; 2014. p. 80-104.
75. Lenzi JA, Sarlo R, Assis A, Ponte M, Paura P, Araújo C *et al*. Family informed consent to organ donation: who performs better: organ procurement organizations, in-hospital coordinators, or intensive care unit professionals? Transplant Proc [Internet]. 2014 [acesso 4 jun 2019];46(6):1672-3. DOI: 10.1016/j.transproceed.2014.05.036
76. Garcia-Retamero R, Wicki B, Cokely ET, Hanson B. Factors predicting surgeons' preferred and actual roles in interactions with their patients. Health Psychol [Internet]. 2014 [acesso 2 maio 2018];33(8):920-8. DOI: 10.1037/hea0000061
77. Galesic M, Garcia-Retamero R. Do low-numeracy people avoid shared decision making? Health Psychol [Internet]. 2011 [acesso 2 maio 2018];30(3):336-41. DOI: 10.1037/a0022723

Participation of the authors

Both authors planned the study, collected data, analyzed de results and write the manuscript.

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