

**UPDATE**

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 consentimento, 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.

Declararam não haver conflito de interesse.

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 acquisition³.

For Soares⁴, 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 needs⁶. 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 life⁷. This information can be conveyed by different means, which require skills such as reading, writing, numbering, communicating, and using electronic technologies⁸.

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 population⁹. Then comes the perception that most patients have difficulty understanding health information, which, therefore, requires certain conducts to reverse this situation¹⁰.

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 found¹¹⁻¹⁴.

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 understood¹⁷.

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 decisions¹⁸.

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 provided²¹. However, studies have shown that many participants, even signing the consent form, do not understand all the benefits of the research and its risks²², 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 clarification²⁵. 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 training²⁶.

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 forms²⁹.

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 individuals³².

In Brazil, the Conselho Nacional de Saúde – National Health Council (CNS) drafted Resolution 196/1996³³, 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 2012³⁴. 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 participant³⁴.

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

unfeasible⁴⁴. 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 questions⁴⁵. Therefore, simple language is recommended, without medical jargon or scientific terms, with patient-mirrored vocabulary and clear, slow speech, with information divided into small parts⁴⁶⁻⁴⁸.

One way to ensure that patients clearly understand the information is to use the teach-back method⁴⁹, 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 consent⁵⁰.

In turn, the written material should reinforce the patient’s knowledge in conjunction with verbal information⁵¹. 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 information⁵². 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 study⁵³.

Researchers report that long and complex documents can discourage the reading of volunteers, leading them to sign them without the proper absorption of information⁵⁴. 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 complexity⁵⁵.

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 understood⁵⁶.

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 understanding⁵⁷.

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 efficient⁵⁸. Another review, which looked at 54 forms of informed consent, also suggested that expanded discussions enhance participants’ perceptions⁵⁹.

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 page⁶⁰.

Such features are emphasized by the National Institutes of Health⁶¹, 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 literacy⁶⁴.

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 population¹¹.

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 guardians⁶⁶.

Other researchers have noted that consent is best understood when presented in plain

language, shorter messages, graphics, whitespace, and appropriate font size⁶⁷. 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 experience⁶⁸.

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 stay⁶⁹.

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 Portuguese⁷¹. 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

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-making⁷².

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 466/2012⁷⁵. 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 196/1996³³,

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 consent¹⁰. 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.

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Participation of the authors

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


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