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Editorial

Informed Consent in Surgery. Distance Between Theory and Practice☆

El consentimiento informado en cirugía. Distancia entre teoría y práctica

Information is an important aspect of the doctor–patient relationship and an important part of medical care. It would seem logical to expect that, together with the development of science and technology in medicine, patient information would also have improved. However, the current situation, as manifested by patients themselves, proves otherwise.

Nowadays, patients tend to demand more information from their doctors. It seems that the so-called principle of autonomy is gaining on the paternalistic attitude. Patient participation in decision-making that affects their health status has become critical and is the axis of the whole medical process.[1] As stated by Broggi,[2] "It's about discovering what the patient's expectations and preferences are and adapting to them as closely as possible, while putting our knowledge and possibilities at their disposal."

We might ask ourselves whether the so-called Informed Consent (IC) process has met this goal. IC should not be limited to merely signing a paper authorizing us to perform the proposed procedure. It requires certain conditions. Its prerequisites are patient competence and willingness, sharing information and recommending a treatment plan that the patient understands and, finally, is willing to sign.[3]

For proper implementation of IC, a calming approach is necessary. Bias should be avoided when explaining the information and appropriate documents should be designed. It is necessary to allot enough time for verbal communication as well as for the patient to read the document and make the decision without feeling pressured.

We often see factors suggesting that we still have much to improve in the process of implementing IC. These include the following:

Limited verbal information – Some physicians believe that since the information is provided in the document, it is not necessary to verbally inform patients about the details of the procedure.

Improper design or content–Deficiencies are frequently seen in some documents. They may not explain alternatives to the procedures, personal risks or highly likely consequences of the procedure. The frequency of risks and adverse effects may not be sufficiently defined, while only providing percentages from the literature and not the department itself. Likewise, there is usually no statement guaranteeing continued care even if the patient does not choose to consent to the procedure.

Sometimes, IC documents are written in such a way that they give the impression that their only objective is to establish legal safeguards. We may also find that certain documents intend for patients to accept everything that could happen, while assuming that any adverse effects would be due to mere chance.

Another situation that has been occurring is the use of documents requiring the patient to agree to the procedure and to sign that he/she has been completely informed, but with no information given in written form. In the same IC document, it is also common to request consent to film the procedure or to store tissue samples in biobanks, rather than using separate consent documents for these situations.

Legibility and comprehensibility–The use of excessive medical jargon, long sentences, etc. makes IC documents unclear and incomprehensible. There are tools that can help, such as the Flesch-Kincaid readability index and the Syntactic Complexity Index (SCI). The Flesch-Kincaid is based on the correlation between text difficulty and word/sentence length. A large number of syllables and words in sentences make them difficult to read. The SCI correlates the number of short sentences and the number of coordinating and subordinating clauses.[4,5] Diagrams, different font types, text boxes, shaded symbols, etc. may be used to improve legibility.

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Some studies have demonstrated that the comprehension of IC documents by surgical patients is not good.[6] In a study of patients undergoing interventions for colorectal cancer, 47% did not recall the information about risks for intestinal and sexual functions, and 57% did not remember the urinary function risks either. According to this study, the patients would like to know the functional results and immediate postoperative course. Only a minority wanted to know the cure rate, the need for a second operation or the ability of surgery to treat their symptoms.[7]

A systematic review of various techniques to improve the comprehension of IC forms[8] showed that multimedia techniques improved understanding by 31%; improvements to IC documents did so by 41%, extended discussions by 50% and feedback tests by 33%. Another review[9] demonstrated that interventions generally improve understanding and that the key points of the document should be clarified as much as possible.

A study in gynecological surgery[10] concluded that many patients do not understand the legal implications of signed consent, and they also do not recognize that it is done in their personal interest.

In the article about anesthesia IC included in this issue, only 40% of patients recalled a particular issue with anesthesia. This exposes the need for physicians to assume a more active role in checking whether patients understand the information and accept that IC is a process that facilitates a better doctor–patient relationship.[11]

Validation–IC documents are usually validated by Ethics Committees or other representative groups such as Medical Records Committees. Validation is a process that requires knowledge and time. Moreover, the collaboration of clinicians is frequently required to clarify terms and establish the rates of favorable results and adverse effects of the surgical procedure. Applying one of the readability and comprehensibility indexes can help. Likewise, ideally, the IC form should be previously applied in patients in order to verify its comprehensibility.

Application–Given that for many professionals IC documents serve mainly as a legal safeguard, they are given to patients with little time or in unsuitable places. Some physicians even ask nurses to give these documents to patients for signature.

Another aspect that should be changed is that, in general, only one document is signed, so the patient is unable to take a copy for later, calmer reading. Moreover, in emergency surgical situations IC documents are sometimes not used. Since many of these interventions are not extremely urgent, there could be enough time for their application.

Regarding the use of IC documents created by scientific societies (such as the Spanish Association of Surgeons), these initiatives are very useful and positively valued by medical professionals. Perhaps their main drawback is that they do not provide results from the surgical department itself. Whatever type of document is used, validation of the hospital center is always desirable.

In light of the arguments above, we can conclude that there is quite a gap between ideal theoretical legal practice and everyday practice in the application of IC. According to Leclercq et al.,[3] well-informed patients will have more realistic expectations about the surgical procedure and its risks. Likewise, they will be more satisfied and will probably be less apt to resort to litigation.

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