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INFORMED CONSENT IN ALL SURGICAL SPECIALTIES: FROM LEGAL OBLIGATION TO PATIENT SATISFACTION

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Abstract: Daily practice is surgical specialties is characterized by an increased number and complexity of invasive procedures, while time pressure on the outpatient staff continues to grow. Proper informed consent is a legal and ethical imperative that is meant to protect patients who elect to undergo invasive medical procedures. The paper aims to review published articles on best practices in obtaining informed consent in surgical specialties and challenges encountered in current practice.

The current perspective moves away from the traditional medical paternalism to a reasonable patient (material risk) standard for disclosure. Although a full disclosure is not recommended, the patient has to be informed about the most frequent and most severe associated risks and the possible alternatives.

There are challenges regarding the IC process. Time pressure and insufficient understanding of the importance of an active dialogue between doctor and patient face ca often the informed consent is just the signing of a multi-page document, from which the patient does not understand much. Studies revealed that most legal cases are not due to failures in treatment, but due to failure in communication and are related to discrepancies between expected and achieved results and faulty information. Presently, there is an increased preoccupation to train doctors in adopting better practices during the inform consent process.

Conclusions. Informed consent process must be the base of a partnership between doctor and patient, in sharing the inherent risks associated with surgical procedures. Better-informed patients are more satisfied, have a higher commitment to their treatment, and demonstrate less tendency toward filing legal claims.

Keywords: informed consent, surgery, disclosure, self-determination, patient satisfaction.

INTRODUCTION

Daily practice is surgical specialties is characterized by an increased number and complexity of invasive procedures, while time pressure on the outpatient staff continues to grow. Moreover, high access to information by internet and mass-media made the patients to be more demanding and concerned about the possible risks and alternatives to the proposed treatment.

Informed consent (IC) has become a critical issue in surgical practice, due to the increased number of litigations related to insufficient information of patients and the change of concepts in medical law, which favors self-determination to traditional medical paternalism [1]. The paper aims to review published articles on best practices in obtaining informed consent in surgical specialties and challenges encountered in current practice.

Cornerstones in the evolution of the informed consent

The development of the notion of patient consent on the medical act, with legal value, began with the development of anesthesia and surgery techniques, at the beginning of the 20th century. The first court

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ruling in this regard was in the Schloendorff vs. Society of New York Hospital, was filed in 1914 when a surgeon resected a tumor from a patient who had only consented to anesthesia and diagnostic laparotomy [1]. The physician was found liable for violating the individual's fundamental right to autonomy regarding what is to be done to her body.

Another important moment was the Bolem case, in 1957, in UK, when a patient voluntarily accepted the electroconvulsive therapy, but suffered some serious injuries, including fracture of acetabula. He suited his doctor for he was not warned about the risk, nor he was given relaxants or was restrained. The Court decision was that the doctor cannot be accused of negligence if he acted accordingly to the common practice, adopted by the responsible medical body. This doctor-centered view resulted in a reasonable practice standard: Any surgeon should tell what other surgeons also tell their patients; a premise known as the Bolam principle [2,3]. In other terms, risks and possible unfavorable outcomes were often omitted in order not to bring sufferings and anxiety to the patients.

The first use of the term Informed consent (IC) was in 1972, in the US, in Canterbury v. Spence, in which a patient who underwent surgery for ruptured disk accuses his doctor for the postoperative pararesis [1]. The court decision led to a major shift in perspective from "professional practice standard" to a "reasonable person standard" in malpractice cases, creating the premises for more detailed patient information on possible risks and therapeutic alternatives, and largely opened the floodgates to the far more litigious medico-legal culture we have today.

In Europe, Montgomery *v.* Lanarkshire case in 2015 was a turning point in medical practice, leading to the abandonment of the Bolem principle in the trial of medical cases [2-4]. The case was of diabetic low stature women who underwent shoulder dystocia during her vaginal delivery, due to the baby big size, which resulted in her child cerebral palsy. She stated she would have asked for a C-section if she would have been informed about this risk. The process was considered the most important UK judgment over informed consent for the last 30 years and had a profound impact on the medical personnel view upon IC. They found they could suit not only for malpractice but also for negligence in case of omitting to present a risk which could be relevant from the patient's point of view.

Legal and ethical implications of IC

Proper informed consent is a legal and an ethical imperative that is meant to protect patients who elect to undergo invasive medical procedures. Doctors have the duty to ensure that each patient is aware of any material risk of any recommended treatment and of any reasonable alternative. As stated by The World Medical Association in the Declaration of the Right of Patients (2005), every patient has the right to self-determination and the right to get the necessary information to make his decision [5].

As stated by European and national law, in obtaining the patient's written consent, physicians are required to provide the patient with information at a scientifically reasonable level for his or her understanding of: diagnosis, nature and purpose of treatment, risks and consequences of proposed treatment, viable alternatives, their risks and consequences, the prognosis of the disease without the application of treatment [6]. IC refers to the autonomous authorization of medical intervention by individual patient, being aware of the possible benefit, risks and alternative choices. There are 3 components of a proper IC: capacity (the patient's ability to understand and to appreciate the consequences of his decision), voluntariness (the decision is freely expressed, without coercion or manipulation) and disclosure (understanding the possible risks) [7-9].

Disclosure in the IC

Given the numerous and diverse types of possible risks associated to all kinds of surgical procedures, the invasiveness and complexity of most of them, surgeons might ask themselves how much information is considered sufficient for the patient? Both medical and legal professionals agree that a total disclosure (telling the patient everything that might go wrong) cannot be given and might not be beneficial for the patient, increasing his anxiety and confusion.

Up to recent years, the professional standard disclosure was generally used that requires the physician to disclose what any reasonable health care provider would communicate in the same or a similar circumstance [9]. There are some drawbacks in using this standard, for instance there might not be an established standard for a certain procedure, or the risk standard may be to low This standard reflects the assumptions, values, and goals of a medical mindset. The actual opinions in medical law, which reject traditional paternalism and give more autonomy to the patient, agree that a patient's unique set of subjective beliefs, fears, and hopes cannot be measured through a professional standard.

A more patient oriented attitude is recommended

presently, the so-called material risk standard. The test of materiality defined in the Montgomery ruling was whether "a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it [4, 9]. The disclosure in the IC is not intended to protect the surgeon from medical malpractice, but it has to be patient-centered, with emphasis on options and self-determination rather than risk itself.

How to approach?

Prior to the surgery, the currant doctor must provide the patient all the information needed to take a decision whether to accept or not the proposed treatment. Written materials or short video presentations may be helpful especially if they can be accessed later by the patient, but the most important is the active dialogue between the doctor and the patient. IC should be patient-centered, explaining risks and benefits and treatment alternatives. This is the starting point in building a good communication, based on mutual respect and trust. The patient has the possibility to address questions and to receive individualized answer, considering his particular health condition and life-style. Signed IC form should be a result of a dialogue, and does not replace the consent process [10-12] (Table 1).

Adjacent aspects that should be discussed during IC are who should have access to their health information, if they want to be a part of the medical educational program, if they want to be photographed/filmed for research or learning purpose.

Challenges in current surgical practice

A proper informed consent is time consuming, and put a pressure on the already busy scheduled of doctors. The possibility that the surgeon to be accused of negligence if he omits to mention a certain possible risk related to treatment procedure to his patient, might encourage doctors practicing defensive medicine. On the other hand, a full disclosure, in which all possible risks are mentioned is not considered a good clinical practice [12].

It may be difficult sometimes for the doctor to estimate what are the relevant complications to be discussed for a certain person, as every person is different and might have different beliefs and expectations. Professional medical organizations and hospital management can help by implementing protocols, but every information should be given in a personalized manner. In general surgery, a recent online application was developed to help the doctor assess the patient's most relevant risks in individualized manner the Surgical Risk Preoperative Assessment System (SURPAS) is an open source risk assessment tool using parsimonious data input and requiring automatic entry of 3 and manual entry of 5 readily available preoperative predictor variables to accurately predict 11 probabilistic common adverse outcomes; it is incorporated into the local electronic health record (EHR) and is accessed in the active patient encounter. These patient-specific estimated risks are then compared with national averages for patients undergoing the same operation, with the intent of helping aid in the discussion of the risks of surgery [14].

Hearing their surgeon iterate a long list of things that can go wrong is frightening. Some patients may wish to know little or nothing about the risks, but this should not be assumed. One must presume that all patients wish to be well informed about benefits and risks, and paternalistic assumptions are not acceptable [12, 13, 15]. Although patient autonomy includes the right to refuse necessary surgery and the "therapeutic privilege" of withholding information is outdated, we want to minimize patients' fear and avoid anxiety-induced excess catecholamine release causing problems at administration of anesthesia. The surgeon's calm, reassuring demeanor goes a long way in relieving this stress.

Medical language can be difficult to understand even for educated people. Verbal transmitted

Table 1. The elements of disclosure presented previous signing IC form

1. The purpose and nature of authorization as an act of consent.
2. The nature of the treatment.
3. The expected benefits of the proposed treatment.
4. The associated risks and consequences: most frequent, most severe or particular risks that may impact patient life style, work or beliefs*.
5. The alternative treatments and their outcomes.
6. The consequences of not treating.
7. Name(s) of person(s) responsible for treatment or procedure.

* E.g. halos post LASIK surgery may be a severe complication for a pilot, but a minor for general population).

information about procedure and alternatives could be easy forgotten or misunderstood. The doctor should ensure that the patient well understood his messages. Other studies found that video presentations could be helpful in this process [16-18]. Zhang and Karan showed that as the anatomy of the eye and ophthalmologic surgery are complex, using video presentation instead of verbal information or written materials improve the patients' capacity to understand the necessary information to signed the informed consent.

Informed consent and patient satisfaction

An increasing number of researches pay attention to the possible gap that appear between theory and current surgical practice and what is the doctors' and of the patients regarding the Informed Consent. Being a legal obligation, the signed informed consent is obtained regularly before invasive produces. Though, it is questionable if the consent is really "informed" in most of the cases. Time pressure and insufficient understanding of the importance of an active dialogue between doctor and patient face as often the informed consent is just the signing of a multi-page document, from which the patient does not understand much [19-24]. Signing of the IC apparently is not a popular part of the doctor–patient relationship, and presumably both parties are guilty. Most legal cases are not due to failures in treatment but due to failure in communication and are related to discrepancies between expected and achieved results and faulty information [1].

In a study of 233 cases of post-spine surgery malpractice, Grauberger shows that the most common allegations are related to insufficient risk documentation, followed by lack of information upon alternative treatments [20]. Clinical surveys revealed that in current practice, most often, the ones responsible to carry the informative talk with the patient and get the IC signed are residents. They performed well in explaining the procedure and the expected benefits, but are less capable to approach the patient's need in explaining risks and alternatives. Specific training programs were initiated to train junior doctors about the inform consent process [26, 27].

Akkad, in a survey on 733 patients who underwent obstetrical-gynecological surgery, found that only 40% of the patients think that the IC paper confirms their wishes, while 48% of patients feel that IC is more to protect the hospital and 68% to empower the doctor to further conduct the treatment [22]. Several studies confirmed the patients are not satisfied with the amount of information received prior to surgical procedure, this being one of the main reasons of low satisfaction during hospital stay [19, 26, 25, 28, 29].

By measuring patient understanding after informed consent discussions, clinicians may be able to better manage preoperative expectations, increase patient satisfaction, and improve the informed consent process [13, 30].

In conclusion, substantial weaknesses and omissions of IC process are evident. Important elements of disclosure and relevant information are largely neglected in daily practice. Presently, there is an increase preoccupation to train doctors in adopting better practice during inform consent process. The material risk standard is preferred for disclosure, and the surgeon must provide sufficient information regarding the individual and general risks if consent is given for a procedure, but also to present the possible therapeutic alternatives.

Informed consent process must be the base of a partnership between doctor and patient, in sharing the inherent risks associated to surgical procedures and understanding what the expectations should be. This will lead to better compliance to treatment in the postoperative period and increased trust and satisfaction. Better-informed patients are more satisfied, have a higher commitment to their treatment, and demonstrate less tendency toward filing legal claims.

Conflict of interest

The authors declare that they have no conflict of interest.

References

1. Leclercq WK, Keulers BJ, Scheltinga MR, Spauwen PH, van der Wilt GJ. A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. World Journal of Surgery. 2010;34(7):1406-1415.
2. Chan SW, Tulloch E, Cooper ES, Smith A, Wojcik W, Norman JE. Montgomery and informed consent: where are we now? BMJ. 2017;357:j2224.
3. Edozien Leroy C. UK law on consent finally embraces the prudent patient standard BMJ 2015; 350 :h2877.
4. Sokol Daniel K. Update on the UK law on consent. BMJ. 2015; 350: h1481.
5. https://www.wma.net/policies-post/wma-declaration-of-lisbon-on-the-rights-of-the-patient/
6. https://lege5.ro/Gratuit/g42tmnjsgi/legea-nr-95-2006-privind-reforma-in-domeniul-sanatatii?pid=82051596#p-82051596
7. Gupta UC. Informed consent in clinical research: Revisiting few concepts and areas. Perspect Clin Res. 2013;4(1):26-32.
8. Nelson RM, Beauchamp T, Miller VA, Reynolds W, Ittenbach RF, Luce MF. The concept of voluntary consent. Am J Bioeth. 2011;11(8):6-16.

9. Singer AS, Viens AM. The Cambridge Textbook of Bioethics. Cambridge University Press. 2008.
10. Ventola CL. Social media and health care professionals: benefits, risks, and best practices. P T. 2014;39(7):491-520.
11. Hanson M, Pitt D. Informed consent for surgery: risk discussion and documentation. Can J Surg. 2017;60(1):69-70.
12. Anderson OA, Wearne IM. Informed consent for elective surgery-what is best practice? J R Soc Med. 2007;100(2):97-100.
13. Teuten B, Taylor D. "Don't worry my good man—you won't understand our medical talk": consent to treatment today. British Journal of Ophthalmology. 2001;85:894-896.
14. Angelos P. How SURPAS May Improve the Surgical Informed Consent Process Journal of the American College of Surgeons. 2020; 230 (6): 1033-1034.
15. Spatz ES, Krumholz HM, Moulton BW. The New Era of Informed Consent: Getting to a Reasonable-Patient Standard Through Shared Decision Making. JAMA. 2016;315(19):2063-2064.
16. Zhang Y, Ruan X, Tang H, Yang W, Xian Z, Lu M. Video-Assisted Informed Consent for Cataract Surgery: A Randomized Controlled Trial. J Ophthalmol. 2017;2017:9593631.
17. Karan A, Somasundaram P, Michael H, Shayegani A, Mayer H. The effect of multimedia interventions on the informed consent process for cataract surgery in rural South India. Indian J Ophthalmol. 2014;62(2):171-175.
18. Zhong R, Northrop JK, Sahota PK, Glick HB, Rostain AL. Informed about Informed Consent: A Qualitative Study of Ethics Education. Online Journal of Health Ethics. 2019; 15(2).
19. Gabay G, Bokek-Cohen Y. Infringement of the right to surgical informed consent: negligent disclosure and its impact on patient trust in surgeons at public general hospitals – the voice of the patient. BMC Med Ethics. 2019; 20: 77.
20. Grauberger J, Kerezoudis P, Choudhry AJ, Alvi MA, Nassr A, Currier B, Bydon M. Allegations of Failure to Obtain Informed Consent in Spinal Surgery Medical Malpractice Claims. JAMA Surg. 2017;152(6):e170544.
21. Wood F, Martin SM, Carson-Stevens A, Elwyn G, Precious E, Kinnersley P. Doctors' perspectives of informed consent for non-emergency surgical procedures: a qualitative interview study. Health Expect. 2016;19(3):751-761.
22. Akkad A, Jackson C, Kenyon S, Dixon-Woods M, Taub N, Habiba M. Patients' perceptions of written consent: questionnaire study. BMJ. 2006;333(7567):528.
23. Serban D, Smarandache AM, Cristian D, Tudor C, Duta L, Dascalu AM. Medical errors and patient safety culture - shifting the healthcare paradigm in Romanian hospitals. Rom J Leg Med, 2020; 28(2)195-201.
24. Ghulam AT, Kessler M, Bachmann LM, Haller U, Kessler TM. Patients' satisfaction with the preoperative informed consent procedure: a multicenter questionnaire survey in Switzerland. Mayo Clin Proc. 2006;81(3):307-312.
25. Pesudovs K, Luscombe CK, Coster DJ. Recall from informed consent counselling for cataract surgery. J Law Med. 2006;13(4):496–504.
26. Koller SE, Moore RF, Goldberg MB, Zhang J, Yu D, Conklin CB, Milner RE, Goldberg AJ. An Informed Consent Program Enhances Surgery Resident Education. J Surg Educ. 2017;74(5):906-913.
27. Meredyth NA, de Melo-Martin I. (Under)Valuing Surgical Informed Consent. J Am Coll Surg. 2020;230(2):257-262.
28. Shamsian N, Southern SJ, Wilkinson S, Scott DJ, Brodlie K. What is the medicolegal implication of a Web-based three-dimensional interactive virtual reality plastic surgery package? Plast Reconstr Surg. 2005;116(6):1839-1840.
29. Keulers BJ, Scheltinga MR, Houterman S, Van Der Wilt GJ, Spauwen PH. Surgeons underestimate their patients' desire for preoperative information. World J Surg. 2008;32(6):964-970.
30. Hallock JL, Rios R, Handa VL. Patient satisfaction and informed consent for surgery. Am J Obstet Gynecol. 2017;217(2):181.e1-181.e7.