Who is the Patient? Disclosure of Information and Consent in Anesthesia and Intensive Care (Informed Consent)

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ABSTRACT

Physicians have always strived to uphold all the ethical postulates of the medical profession in all aspects of the practice, however with the vast advances in science and technology, numerous ethical dilemmas regarding all aspects of life and ultimately death have emerged. Medical decisions however, are no longer in the sole jurisdiction of traditional Hippocratic medicine but are now deliberated and delivered by the patient and they are comprised of a number of additional determining aspects such as psychological, social, legal, religious, esthetic, administrative etc., which all together represent the complete best interest of the patient. This is the basic goal of the »Informed Consent«. The widening of legal boundaries regarding professional liability may consequentially lead to a »defensive medicine« and a deterioration in the quality of healthcare. In the Republic of Croatia there a four types of liability and the hyperproduction of laws which regulate healthcare geometrically increase the hazards to which physicians are exposed to on a daily basis. When evaluating the Croatian informed consent for anesthesia, we can come to the conclusion that it is completely impractical and as such entirely unnecessary. Anesthesiologists should concentrate on an informed consent which would in brief, explain all the necessary information a »reasonable« anesthesiologist would disclose to a »reasonable« patient so that a patient could undertake a diagnostic or therapeutic procedure unburdened and with complete confidence in the physicians who are involved in the treatment of the respective patient.

Key words: Informed consent, Patient’s rights, Croatian healthcare, Medical liability, Medico-legal issues

Introduction

Throughout history, the foundation on which the treatment of an ill person was based on, was the relationship between the physician and the person who was ill and required treatment (the patient). The patient had a trust in the skills of a physician and the physician was committed to and bound by the notion of using his skills in an appropriate manner to the best interest of the patient. While the patient was dignified as a person, the physician at the same time had regard for the respect and autonomy of the medical profession.1

The Hippocratic Oath, a fundamental principle and code of conduct in the practice of medicine, gives no mention of the patient participating in the decision making aspect of his respective treatment. The oath, in-fact, specifically forbids disclosure of information to patients. «Informed consent» is a concept which has appeared relatively recently. It could be argued that it is more an expression of liberalism in modern society and politics rather than being a legacy of medical ethics and deontology.2 This new philosophy is more focused on the individual person and their rights, giving the individual a greater role in the decision making process in all issues concerning them, including the issue of their health.3

Informed consent, first appeared as a concept in trials and experiments of all investigative phases including clinical trials. In clinical medical practice however, in-
formed consent was in essence reserved only for more grave cases which demanded difficult treatment procedures or procedures that were potentially ethically ambiguous.6,7

Physicians have always strived to improve diagnostic and therapeutic procedures, to the benefit of their patients, respecting all ethical principles. However, technological advances in medicine have brought forth numerous ethical dilemmas concerning life and death in general.6 With time, it became evident that the formation of principles of conduct in the physician-patient relationship had outgrown the traditional setting posted by traditional medicine, which relied upon the Hippocratic Oath as a fundamental guideline. Consequently, today we have a situation where the terms of conduct are determined by numerous participants such as philosophers, theologians, psychologists, social workers, lawyers and of course physicians.7

In the Republic of Croatia, healthcare is defined and regulated by the Croatian Constitution and more than twenty legal Acts. «Informed consent» in Croatia was first mentioned and defined in the Mental Health Act and ultimately it became effective on all patients with the introduction of The Patient’s Rights Protection Act.8,9

The Patient’s Rights Protection Act does not contain the expression «informed consent» per se, but it mentions the right to co-decide or co-determine i.e. have a say in the decision of eventual treatment suggesting a right of the patient to be informed and the right to accept or refuse to undertake a certain diagnostic or therapeutic procedure.10 There is, essentially no difference between the two expressions. The expression «informed consent» was adopted from anglo-saxon nomenclature. The Croatian Legislator, intended to put an emphasis on the co-operation between the physician and the patient by inaugurating the expression of «co-deciding», however even though co-deciding is the general manner of conduct, ultimately it is the patient who makes the final decision and the physician is obliged to respect it.11 This right of the patient can be restrained in certain circumstances when the patient’s state justifies the restriction and such circumstance is specified in article 7. of the The Patient’s Rights Protection Act. Restricting the right to accept or refuse a certain diagnostic or therapeutic procedure in cases which necessitate an unadjournable medical intervention, the delay of which, could compromise the life and well-being of a patient or evoke permanent harm to the health of a patient, has greatly dispossessed the patient’s right to co-decide. In such circumstances, the physician determines the patient’s state of health, either individually or by a court order, which is based on expert medical opinion and only then is the ultimate decision on further course of action exclusively at the discretion of the physician, in the best interest of the patient. In all other circumstances, the decision making process is based on a mutual agreement between the patient or appointed guardian and the physician, brought forth in the best interest of the patient by the patient’s own conviction, taking into account psychological, social, legal, religious, esthetic, financial and other elements, which all together form the basis and goal of what constitutes an «informed consent».12,13

Decisions to act otherwise are considered to be those decisions, which are made in sound conscience and which do not necessarily represent the best interest of the patient, however, patients also have the right to these decisions as well and physicians again, are obliged to respect and act in accordance with them.14 Traditionally, when assessing the best general interest of the patient, physicians have a tendency to give too much significance to what they consider to be the best medical interest of the patient. This may become a problem when the physician has a legal obligation to give the patient a certain information, the content of which may require knowledge which the physician may not have, for e.g. knowledge from the domains of economics, law, religion, etc.. Another important issue which may present as a problem, is the extent of «information» which the physician must convey and the patient is willing to accept.15

The legal dispute, about the validity of an «informed consent» is generally led in two directions. The general dilemma is whether an informed consent, whose extent of information by depth and size of content is determined and disclosed by a «reasonable» physician (professional standard) is considered valid or, is the more valid consent the one whose extent of information would in a sense «satisfy» the expectations of a «reasonable» patient, on the grounds of which, a patient in a given situation could make a decision regarding the patient’s own health (material standard).16 In Croatia, as in the majority of European countries, the professional standard is predominantly in practice, however neither of the two standards of criteria are concise enough about what needs to be disclosed to the patient. Professional and material standards are legal terms, sometimes used in judicial proceedings where professional liability of physicians is the subject at matter.

In the Republic of Croatia, there are several types of liability applicable to medical practice i.e. physicians. Those are: criminal, civil, professional and moral liability.

Criminal law protects society and individual persons from irresponsible demeanor of medical professionals i.e. physicians. In the chapter «Criminal Offenses Against People’s Health» of the Croatian Criminal Code, there are several criminal acts stated which may be committed by physicians. Those are: medical malpractice, unauthorized medical treatment, illicit transplantation of parts of the human body, failure to render medical aid, negligence and failure to meet professional standards in preparing, prescribing and distributing medicinal drugs.17

A criminal action can be rendered as such only if there has been a flagrant breach of professional duty, with a substantial deviation from generally accepted standards of medical practice, resulting in a deterioration of health or worsening of illness. In order to proclaim a physician guilty of a criminal action, it must be determined whether the deed was committed with intent
advancement of knowledge and investigation because every new idea will be burdened by numerous biocultural problems which new generations will neither want nor have the will to solve.14

Physicians are often unaware of the dangers they encounter in their workplace and a hyperproduction of laws which are not directed at simplifying regulations certainly does not help the situation. The hyperproduction of laws and regulations is best portrayed in the Croatian Healthcare Protection Act, which in article 214. sets out 28 different statutes.19

There are numerous impracticalities with an informed consent for anesthesia and intensive care. Do we need a consent for anesthesia only? Do we need a consent for anesthesia and intensive care, or do we need two separate consent forms, one for each domain?

Let us take a look at what the problem is. Hypothetically, a physician could successfully treat a patient without his consent. In the case of a legal dispute, a physician could be held accountable for immaterial damages as a consequence of violating the right to physical integrity. In the hypothetical situation where the physician saved the life of a patient through a certain procedure of treatment, it would be assumed and concluded that the physician acted to the benefit of the patient’s health and it could, in principle, only diminish the indemnity that the physician would be indebted by on the basis of professional liability.

When a patient is treated for a certain illness without informed consent, despite the fact that the treatment is carried out at the highest professional standard, in the case of a poor or unwanted outcome, a physician is nevertheless considered liable for the resulting damages.

The basic questions are: Why and what kind of Consent do anesthesiologists need, should they be engaged in a law suit for any ground of liability? Does the standard informed consent embrace the undertaken procedures for the purposes of anesthesiological preoperative preparations, surgical (endoscopic, etc.) anesthesia and postoperative and intensive care?20 The anesthesiologist does not have a say in the plausibility of a medical intervention (the indication for a medical or surgical procedure is set by another respective specialist), or the patients are most often not in the position to give their consent as is the case in the emergency department or in the ICU. The only procedures in anesthesia which demand an informed consent are invasive procedures in pain medicine (instillation of catheters) because they are conducted independently of other diagnostic and therapeutic procedures.21

What the Legislator must have obviously had in mind when the obligatory aspects of informed consent were being formed, was responsibility for a delivered decision. Right to autonomy presumes that patients and their representatives must accept the possibility of unwanted events and expectations. In the Republic of Croatia, the court of law has been applying those principles for some time and this is best seen from a ruling of the Supreme
The consent must be valid. This means that the person must give the consent of their own free will and adequate understanding and it is not valid if it pertains to an unlawful deed or if the procedure is not medically justifiable. The Legislator has decided that the consent must be in written form and authorized by signature and by no means given orally as is the case in certain well-developed countries. However, even if the consent form has been signed it is not necessarily valid if the consent is given on the basis of general compliance or if the information is not adequately conveyed, i.e. if the language and terminology are such that they are not understandable to the general public and majority of patients.

The impracticality of an anesthesiological written consent is dual. Firstly, it is impossible to either know or possess all the necessary knowledge to determine the intellectual reason a patient has and the will of the patient to hear all or some of the risks associated with the illness or intended medical procedures. It is also impossible to list all of the possible complications that might arise in the course of treatment, including 'complications of complications', which in most cases can not be attributed to anesthesiological procedures. Such a written consent form, would among complications such as postoperative pain, nausea, soreness of the throat, also have to include tracheal stenosis or unrecognized oesophageal intubation which can lead to brain damage or death, regardless of the rare incidence of such complications. Such a written consent paper would also have to include all the possible side effects of all the drugs that might be used in the course of treatment. There are more than 10 complications that could arise as a consequence of arterial and central venous cannulation which could lead to injury or even death. The discussion on possible risks of blood and blood-product transfusions in the case of need is expensive and long-lasting for the anesthesiologist and unsettling for the patient. Epidural or spinal anesthesia can lead to post-punctural headaches or even paralysis whereas treatment in the intensive care units necessitates an explanation of the possible infections which may arise or possible organ failure and ultimately, a fatal outcome.

There is an abundance of details and possibilities that the patient could be informed about, but all this exceeds the boundaries of common sense. It is precisely this lack of common sense in estimating the amount and depth of information that should be disclosed to the patient in a valid informed consent, that presents as a problem to most healthcare systems, because as a consequence, the right to co-decide has interfered with the medical judge-
tient was adequately informed and had consented to the procedure.

At present, in the Republic of Croatia, the consent forms that are currently implemented, are not up to date with the new Statute which was the result of a 30-year old tendency of anesthesiologists to distinguish their own consent paper from the one used by surgeons and to validate anesthesia as a separate medical specialty. One of the manifests of autonomy was a separate consent paper for anesthesia. At the time when the consent form was being created, there were not so many aspects present in the patient’s rights field so such a consent was at that time sufficient. Every anesthesiological association had and still has their own consent. The liability suits of anesthesiologists were exclusively professional.

If we are to, as a professional discipline, have an anesthesiological consent paper, regardless of the extent of the content for the purposes of informing the patient, we are exposing ourselves to the legal system which is bound to find any elements unlisted in the consent papers and preoperative conversations with the patients. This will most certainly make us vulnerable to some form of liability on the basis of the decisions made on a professional principle.

Anesthesiologists must concentrate on a written notice which will briefly and precisely portray and describe everything a “reasonable” anesthesiologist would make known to a “reasonable” patient so that a patient could undertake a diagnostic or therapeutic procedure unburdened and with confidence in all the physicians that will take part in the treatment of the patient.

REFERENCES


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TKO JE PACIJENT? INFORMIRANI PRISTANAK I OBJAVA INFORMACIJA PACIJENTIMA U ANESTEZIJI I INTENZIVNOJ MEDICINI (INFORMIRANI PRISTANAK)

SAŽETAK

Liječnici su oduvijek nastojali održavati sva etička načela medicinske struke, u svim aspektima medicinske prakse, no zbog velikog napretka u znanosti i tehnologiji, nastale su brojne etičke dvojbe koje se izravno dotiču života i u konačnici prava bolesnika. Međutim, medicinske odluke nisu uvijek isključivo u nadležnosti i području tradicionalne Hipokratove medicine, već su sve u vezi s etičkim aspektima medicinskog ponašanja prilikom preduzimanja medicinske intervencije. Anesthesiologi su se koncentrisali na zapisivanje liječničkog odredbe i pravila, a izravno je na sebi težao da u svim aspektima medicinske prakse ustanovi prethodne ili novi aspekti medicinske odgovornosti.

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razini mogla uvelike predstavljati brojne probleme za liječničku struku. Kada razmatramo informirani pristanak za anesteziju, onakvom kakav je u Hrvatskoj, možemo zaključiti da je većim dijelom teško primjenjiv i kao takav gotovo nepotreban. Anesteziolozi bi se trebali usredotočiti na informirani pristanak koji bi ukratko pružio sve potrebne podatke koje bi „razuman“ anesteziolog objasnio „razumnom“ bolesniku, tako da se u konačnici svaki bolesnik može podvrgnuti dijagnostičkim i terapijskim postupcima bez opterećenja i s potpunim povjerenjem u liječnike koji su uključeni u liječenje bolesnika.