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

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A B S T R A C T

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-

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formed consent was in essence reserved only for more grave cases which demanded difficult treatment procedures or procedures that were potentially ethically ambiguous.[4,5]

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. Consequentially, 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 iresponsible 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

or out of neglect and whether the physician was aware of, or if it was his duty to be aware of the unlawfulness of his action. This liability is always individual.

Civil liability is primarily pertained to liability for damages resulting from medical treatment. In general, patients are the plaintiffs while physicians, healthcare institutions and commercial associations are the defendants. The harmful actions from which damages arise are deviations and breaches of standards of good practice, the infringement of the right to physical integrity, unauthorized medical treatment, failure to render medical aid and failure to fulfill the obligations and duties of medical care guaranteed by law or contract. The damage itself may be material or immaterial and the interconnection between the incriminating action and the ensuing damage is determined by a court, on the basis of medical opinion by an expert witness, appointed by the court. Our Civil Law accepts a model of subjective liability, in which a responsibility of the defendant is sought as opposed to the model of objective liability where it is necessary only to establish a link between the implicated action and the resulting damage. Therefore, if the defendant wishes to be acquitted of liability, the defendant must give proof of his innocence or that the damage is a result of coincidence. Professional liability is regulated by healthcare and professional laws and regulations. Infringement of Common Law assumes that there is a breach of public order or other social values which are not protected by the Criminal or other laws.

Professional liability is established by the body of authority of the relevant professional association. Professional liability proceeds from the regulations specified in the Medical Profession Act, which states that the physician is professionaly liable should there occur a breach of the regulations in the Act, if there is a breach of the Medical Ethics and Deontology Code and if the duties of the physician are carried out unprofessionally. This type of liability is determined before the relevant professional authority which is commissioned for the pursuit and implementation of disciplinary proceedings.

The Medical Profession Act does not stipulate that a physician cannot be held accountable for not carrying out a medical procedure in the case when the employer did not secure the necessary logistics or the prescribed drugs and minimum of necessary equipment despite adequate knowledge and skills of the physician. Therefore, the Medical Chamber can offer only consultant-legal aid in the case of an imminent professional liability suit.

It is in the interest of individuals and society in general that professional liability for inadequate medical care expands. This does not necessarily imply that physicians are offering substandard care because the problems could also be due to an inefficient organization of the healthcare system which is not the responsibility of physicians and the medical service that they are offering. Such widely set legal boundaries may consequentially lead to a »defensive medicine«, a further deterioration in the quality of healthcare, a decline in interest for the medical profession and most tragically, a decline in the advancement of knowledge and investigation because every new idea will be burdened by numerous bioethical problems which new generations will neither want nor have the will to solve.[18]

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

court from 1975. which states: »It is unacceptable and contrary to the principle of physical integrity to perform a surgical procedure on a person against their will, even in the case when it is in the person's best interest, unless there are exceptional reasons which would justify such an action, such as a life threatening situation or if the patient is in such a condition that prevents him or her from giving his or her consent. At the time of this ruling there was no written form of informed consent for anesthesia.

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.[22,23]

Such a written consent form, would among complications such as postoperative pain, nausea, soreness of the throat, also have to include, tracheal stenosis or unrecognised 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.[24]

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 judgement and the answers are then sought in a court of law. The result of all this is that any patient, who experiences an unexpected side-effect or unwanted outcome of treatment, for which the patient believes that he or she was not warned of or informed of well enough or believes that they can convince a court of law in this, can file a law suit for liability on the grounds of negligence. Once the court has delivered a verdict, there is little more a physician can do. The entire public should be made aware of the possibility that every medical intervention carries with it certain risks, even when no mistakes are made on behalf of the medical profession..

A possible solution would definitely be in establishing a »no-fault« system of compensation for the patients who have suffered certain damages while undertaking a medical procedure.

The preoperative anesthesiological examination should be sufficient for the purpose of attaining the necessary information about the health condition of a particular patient and for the patient to be informed about the ensuing anesthesia, in the amount that the respective anesthesiologist deems sufficient. During this conversation, the patient may inquire about anything that was not mentioned in the »informed consent« paper.[25] There is no need to expand on this. There are a few reasons for this viewpoint.

The consent, be it written or oral, does not prevent the patient to abstain from a diagnostic or medical procedure at any time prior to its commencement.[26]

The consent does not prevent the anesthesiologist to refrain from the procedure if the respective anesthesiologist considers that the condition of the patient's health has changed during the period from the preliminary examination till surgery. It must also be said, that the anesthesiologist who caries out the anesthesia is not necessarily the anesthesiologist who obtained the consent and conducted the preoperative examination. For procedures conducted in the ICU almost anyone involved in the course of treatment could possibly be held liable.

We should consider the case where a patient has already signed the consent paper for a diagnostic or therapeutic intervention necessary to treat the illness of complaint, but the treatment can not be conducted without some form of anesthesia. The choice of anesthesia is based on expertise and it can not be delegated to the patient, Also, the patient can't refuse to be anesthetized because in that case, the patient is refusing the same medical procedure to which he or she have already consented.

All anesthesiological procedures, of which every one has its own risks, are exclusively directed at treating a patient's illness, as a part of a larger group of procedures, so it is very difficult to determine which particular tool or procedure could be presumed to be the precipitating one for an unwanted occurence.

The patient will file a law suit regardless of the fact that the conducted procedures were in accordance to all professional standards and despite the fact that the pa-

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 anesthesiology 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.

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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, smrti bolesnika. Međutim, medicinske odluke nisu uvijek isključivo u nadležnosti i području tradicionalne Hipokratove medicine, već su sve češće, većim dijelom uvjetovane bolesnikovim odlukama i uključuju čitavi niz čimbenika poput psiholoških, socijalnih, pravnih, vjerskih, estetskih i mnogih ostalih, koji zajedno predstavljaju sveukupni interes bolesnika. Obuhvaćanje navedenih čimbenika zapravo predstavlja osnovni cij »informiranog pristanka«. Sve šire poimanje pravnih okvira u pogledu profesionalne odgovornosti liječnika moglo bi u konačnici dovesti do nečega što se može nazvati »obrambenom medicinom« s posljedičnim opadanjem u kvaliteti zdravstvene skrbi. U Republici Hrvatskoj, postoje četiri vrste odgovornosti te bi hiperprodukcija zakona koji reguliraju zdravstvenu skrb, na svakodnevnoj

razini mogla uvelike predstavljati brojne probleme za liječničku struku. Kada razmatramo informirani pristanak za anesteziju, onakvim 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.