VIA MEDICA

REVIEW ARTICLE

Anaesthesiology Intensive Therapy
2013, vol. 45, no 1, 44–48
ISSN 1642–5758
DOI: 10.5603/AIT.2013.0010
www.ait.viamedica.pl

Consent to eventual treatment in the intensive care unit expressed within the consent form for elective anaesthesia and surgery

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Abstract

In contemporary clinical practice, the issue of requesting patient consent to perform therapeutic treatment plays an important role. The conscious consent of a patient as an expression of one's will greatly strengthens the legality of medical procedures performed by a physician, regardless of the medical field. However, obtaining consent to treatment in the Intensive Care Unit (ICU) often poses enormous difficulties in daily clinical work, and has in recent decades been the cause of much dispute between doctors and lawyers. The correct interpretation of the provisions under the relevant laws determines the safety and comfort of the medical practice in the ICU.

This study compared the current rules of normative acts of Polish common law relating to medical practice in intensive care units and issued on the basis of the judgments of the common court of law over the past ten years. On the basis of those provisions, the authors conclude that the patient should be informed by the anaesthesiologist during the visit as to the possibility of postoperative therapy in the ICU. The extent of such information depends on the likelihood of having treatment in the ICU. The consent of the patient for hospitalisation in the ICU should be mandatory in the case of treatments which are very likely to necessitate such hospitalisation. This concerns especially cardiac surgery, neurosurgery and treatments for patients with a significant burden of disease.

The authors of this study propose that an information and consent form to undergo treatment in the intensive care unit should be included within the anaesthesia consent form.

Key words: anaesthetic questionnaire, consent form, consent to treatment, elective anaesthesia procedure

Anaesthesiology Intensive Therapy 2013, vol. 45, no 1, 44–48

In modern clinical practice, the patient's consent to therapeutic procedures is crucial. The informed consent, as the declaration of patient's will, forms the basis of legality of medical procedures carried out within any medical branch. On the other hand, the consent for treatment in the Intensive Care Unit (ICU) creates enormous difficulties in everyday clinical work, leading to many discussions between physicians and lawyers. The authors of the present study analysed the present legal status of the aforementioned issue and suggested practical solutions how to obtain the *pro futuro* consent for ICU hospitalisation, if required, from competent and adult patients scheduled for surgeries.

OBLIGATION TO OBTAIN CONSENT AND TYPES OF RESPONSIBILITY

Legality of any medical procedure, including ICU hospitalization, depends on the patient's informed consent obtained for a particular procedure [1]. For the purposes of clinical practice, the patient's consent for the therapeutic procedure should be considered as the declaration of will [2, 3] as defined by the Civil Code [4, 5]. Such a declaration of will fulfils the obligation of obtaining the consent for treatment, defined by Art, 34, section 1 of the Medical Doctor and Dentist Profession Act stating that "a written consent of the patient is necessary for the doctor to perform a surgical

procedure or apply a surgical or diagnostic method that increase the risk for the patient" [6]. Similar obligations are included in the Art. 18 of the Patient's Rights Act [7]. This means that the initiation of ICU treatment of any patient is conditioned by obtaining the appropriate consent and the only exceptions to the rule were defined in Art. 33 and 34, paragraph 3 and 4 of the Medical Doctor and Dentist Profession Act. The obligation to obtain the consent generates many organizational difficulties in the everyday functioning of ICUs admitting unconscious patients, those with life--threatening conditions, who cannot give their competent informed consent for medical procedures on admission. The situations, in which it is admissible to perform the therapeutic procedure without the patient's consent (or the substitutive consent of an authorized person), were enumerated. They include emergency interventions "when the delay resulting from obtaining the consent would be life--threatening, lead to severe body damage or severe health distress" and the situations in which it is necessary to file a petition in the Court of Protection due the lack of consent given by the patient or his/her legal representative. Except for the situations mentioned above, the consent for ICU interventions given by conscious and competent patients should be considered obligatory in all other cases.

CIVIL RESPONSIBILITY

The treatment administered properly from the medical point of view and with all the indications taken into account may have no legal grounds and give rise to legal responsibilities of a physician or a hospital if the informed consent has not been obtained.

Such a stand was presented in the judgement of the Court of Appeal of 29.09.2005 in Poznań. The reasons for the judgement state that "a doctor is liable not only for the fault in the process of treatment but for any fault not connected with the medical technique, hence as well for failure to fully inform the patient about the risks and consequences of the medical procedure. The mere formal consent of the patient obtained without informing him of the procedure-related risks and consequences makes the consent "uninformed" and as such defective, and as a consequence the doctor acts without the patient's consent and exposes himself to civil responsibility for the harm done to the patient even if he follows the standards of medical practice"[8].

CRIMINAL RESPONSIBILITY

The basis of criminal responsibility of the physician for conducting a particular method of treatment without the suitable consent is the Art. 192 of the Criminal Code, which states that "anyone who performs a therapeutic procedure without the patient's consent is liable to a fine, the restriction of liberty or imprisonment up to two years" [1]. Noteworthy, the offence mentioned in this Article is prosecuted when the victim files the petition. When the right for treatment consent has been violated, the patient treated in ICU can exercise the victim rights. If the patient died, the closest relatives or the prosecutor [9] can execute the rights. This clearly shows that the negligence of the obligation to obtain the consent can be the grounds for criminal responsibility even after the patient's death.

In the majority of cases of patients hospitalised in ICUs, the oral consent when the treatment is indicated is impossible due to lack of consciousness of the patient involved. In such cases, according to the Medical Doctor and Dentist Profession Act, life-saving procedures should be undertaken immediately, if the delay associated with the lack of consent, could threaten the patient's life or health. However, if the delay does not directly threaten the patient's life, the physician should take actions to obtain the suitable consent from the statutory representative or the appropriate court.

PROFESSIONAL RESPONSIBILITY

Besides the criminal and civil responsibility, the physician is also responsible professionally according to the Code of Medical Ethics (CME) and the Medical Doctor and Dentist Profession Act. The regulations regarding the consent for a medical procedure given by an adult patient are included in the Art. 15, point 1 and 3 of CME [10]. The regulations in question, defined by the National Congress of Physicians, provide the physician with markedly wider freedom in obtaining the consent for treatment from patients with life-threatening conditions, i.e. the majority of ICU patients. The Art 15, section 3 of CME states: "Initiation of diagnostic, therapeutic and preventive procedures without the consent of the patient is admissible only exceptionally, in special life- or health-threatening cases…", which implies that the admissibility of treatment without the patient's consent rests with the physician. Although the use of CME regulations in practice would facilitate the work of ICU physicians, the regulations are not the basis of legality of medical procedures as in the hierarchy of law sources the legal act is superior. When the ethical and legal norms are conflicting, the binding law regulation is decisive" [11].

Based on the legal norms mentioned, the consent for treatment (including ICU interventions) given by the patient should be considered indispensible. The legislator decides about the legality of each medical procedure based on such consents. The consent should meet several formal requirements:

1. objective: the consent should be informed, voluntary and obtained before the procedure,
2. subjective: the consent should be given by an authorised person,
3. the consent form should meet the suitable regulations for a given procedure.

PROVISION OF INFORMATION AND OBTAINING INFORMED CONSENT

During the anaesthetic visit, the standard management is to familiarise the patient with the procedure-related circumstances, particularly the method of anaesthesia burdened with the lowest risk of complications. The information regarding the course of anaesthesia, its duration, effects on the patient's health and possible anaesthesia-related complaints after the procedure should also be included. Thanks to that, the patient is provided with complete information necessary to give the informed consent. In most cases, the routine course of anaesthesia is described during such conversations.

Moreover, the physician should discuss possible anaesthesia method-related complications and possible options of their treatment, including hospitalisation in ICU. Once these conditions are fulfilled, the patient's consent is informed, hence binding for the physician.

The extremely comprehensive characteristics regarding the scope of necessary information are included in the decision of the Supreme Court of 1992 stating that "The information provided by the doctor before the procedure should include the data, which will enable the patient to give the consent being fully aware of what he consents for and what he might expect (…). In particular, the information should include the anticipatable procedure-related consequences, especially when the consequences are associated with substantial or significant detriment to health, and which as side effects occur rarely or very rarely yet cannot be excluded; additionally, the probability of their occurrence should be defined (…). It is sufficient to present a general description of possible procedure-related consequences and to define whether they are life threatening, or what their effects on proper functioning might be" [12]. In the light of the above decision, the authors believe that during the anaesthetic visit the patient should be informed about possible ICU hospitalisation in a life-threatening situation as the surgery-related complication.

According to numerous comments, the most important information in surgical procedures performed under life-threatening conditions is the extent of danger, its probability and anticipated consequences rather than the description of the organ or body part, which might be affected [13]. Such criteria of the scope of information enable the anaesthesiologist qualifying for scheduled higher-risk procedures (e.g. cardiac, neurosurgical or other extensive procedures within vital organs) to obtain the effective informed consent for possible ICU hospitalisation as the treatment of the surgery-related complication. This stand shows proper provision of information, which does not have to include all the possible complications but should make the patient aware of the type of risk involved [14].

This kind of written informed consent of a fully competent patient is legally binding and allowing ICU interventions even if the patient is post-operatively unconscious and unable to consent on his/her own unaided. The Civil Code describes this consent as the declaration of will *pro futuro*, i.e. coming into force once the circumstances the patient has been informed about occur, when he is unable to effectively consent. In legal disputes, this consent for treatment and the medical procedure was the source of numerous doubts and diverse interpretations, particularly in cases confronting the opinions of lawyers and physicians. The proper meaning of the written consent *pro futuro* (or refusal) was defined by the Supreme Court in the statement of the Civil Chamber of 27.10.2005: "The declaration of the patient's will in case of loss of consciousness regarding medical management in therapeutic situations that may occur is binding for the doctor if expressed clearly and unambiguously" [15]. By obliging the physician to respect the patient's will, the Supreme Court indicates the obligation to respect the patient's will, even at the expense of his life. The obligation becomes even more important when the life-saving procedures were consented to (rather than refused).

From the point of view of the physician providing ICU medical services, the fact of giving binding consent is of great importance in everyday work. Once the informed consent for ICU treatment has been obtained, the inference for surrogate consent, i.e. the consent given by the court of protection, is not required. However, the binding consent for possible ICU hospitalisation has to be given consciously prior to the surgical procedure.

The anaesthetic visit is the best moment to obtain the consent, as it enables to meet all legal requirements. In most cases, the patient during the anaesthetic visit is fully competent and may decide about his actions. To guarantee the legal safety of the physician, the patient giving the consent should not be premedicated or under the influence of other agents that can impair the assessment of independent decision-making. Moreover, it is extremely important for the physician to explain his intension of obtaining the consent and its aim, as the consent is the formal requirement of treatment legality [16]. The consent for anaesthesia and possible ICU interventions obtained during the anaesthetic visit fully fulfils the condition of "the consent given before the procedure".

THE SCOPE OF INFORMED CONSENT

The obvious doubts of the physician/practitioner are associated with the fact that in each case before the procedure the patient has to be provided with information regarding the full range of complications that can develop during the course of anaesthesia, particularly if the anaesthetic procedure concerns routine surgeries of low probability of complications requiring ICU hospitalisation.

The anxiety that accompanies any surgical procedure is likely to be enhanced by excessive information regarding severe, life-threatening complications, which are extremely rare.

However, it should be emphasised that according to the published study findings, the development of anaesthetic complications has lesser effects on the patient's assessment of the services provided than the lack of information about potential complications [17, 18]. Therefore, it can be assumed that the provision of complete information about the procedure and its possible complications can markedly reduce the level of patient's anxiety without affecting the quality of the consent.

During the last two decades of the 20th century, the judicial decisions were based on the Supreme Court opinion that the consent is effective when the physician informed the patient about the type of procedure and its "direct and normal consequences" [19]. Nowadays, the subjective model is more commonly accepted, according to which "the scope of information provided does not depend on what the doctor believes the patient should know but on what the prudent person placed in the patient's situation objectively needs to hear from the doctor to make the informed decision". Even when such a strategy of informing the patient is accepted, the concealment of facts in exceptional cases is permissible [20, 21].

In order to ensure the patient's comfort and his own highest legal safety, the physician/practitioner should use the possibilities included in the Art 34, section 4 of the Medical Doctor and Dentist Profession Act, stating that the physician can limit the range of information within the so-called "therapeutic privilege". If such actions are undertaken, the patient's good and the lowest level of anxiety should be the priority.

This form of providing information helps to avoid excessively complicated data and anxiety related to complications, which are rare in clinical practice. Since the sentence was passed more than 25 years ago, today's decisions better reflect the role of the patient as a partner in therapeutic decision-making and the range of information. Consequently, to meet the requirements of the binding consent for treatment, during the anaesthetic visit, the patient should be additionally informed about possible ICU hospitalisation as a method of treatment under life-threatening conditions being the complications of the scheduled procedure and about circumstances that would have to occur to undertake intensive therapy. Obvious doubts are raised by the necessity to inform patients about the way and circumstances of ICU treatment in cases of routine surgical procedures, in young patients without clinically significant medical history. In such cases, the range of information provided should be confined only to the consent for planned anaesthesia due to low probability of ICU treatment. The cases of cardiac and neurological scheduled procedures and those in patients with severe medical history, who are most likely to require ICU treatment, are completely different. In such cases, the information should be widened and include circumstances connected with ICU medical procedures. It seems grounded to include the information about planned anaesthesia together with the information regarding possible ICU treatment in the anaesthesiological questionnaire. The physician will be able to explain the additional information to the patient obtaining the suitable consent signed by the patient, as in cases of scheduled procedures.

Since the information in question does not increase the patient's anxiety (which was demonstrated in the above-mentioned studies), the role of ICU and its medical personnel in the treatment under life-threatening conditions is also worth describing. This increases the legal safety of the physician and affects the patient's awareness concerning the role of the specialist in anaesthesiology and intensive therapy during the treatment as a person responsible not only for anaesthesia and pain management but also as someone who guarantees the patient's safety in the perioperative period.

DOCUMENTATION OF CONSENT FOR ICU INTERVENTIONS

The procedure consent is mainly regulated by the Medical Doctor and Dentist Profession Act [6], which includes the division of medical procedures into:

— simple procedures,
— higher risk procedures.

In simple procedures, the consent can be oral or implied, i.e. by the patient's behaviour, in which he explicitly consents for a particular procedure and cooperates with the physician during the procedure. For instance, during blood sampling, the patient in the sitting position uncovers the forearm for the needle to be inserted. Considering that all actions undertaken in ICU regard the treatment of patients under direct life-threatening conditions and are associated with increased risks of failure and possible complications, the consent should be consistent with the Art. 34 of the Act for surgical procedures and methods of treatment of higher risks. In such cases, the written consent should be obtained. The division of procedures into simple and higher risk ones is not strict and in each case requires the physician's further clarification. Noteworthy, when doubts arise, the physician should obtain the best possible kind of consent, as during possible legal proceedings, the physician will have to prove that the appropriate consent was obtained. Assuming that the possible ICU interventions and related procedures are of increased risk, during the anaesthetic visit the patient should give the written consent for the type of anaesthesia

and treatment of life-threatening complications. According to the decision of the Supreme Court of 17.12.2004 "The burden of proof of the performance of a statutory duty of providing the patient and his statutory representative with information in an accessible way prior to the patient's consent for surgery [….], rests with the doctor" [22]. The safest form of documenting the patient's consent for ICU treatment is to include it in the anaesthesia consent form, most commonly in the separate part of the anaesthesiological questionnaire. The physician should make all efforts to provide understandable information. The contents of information should be possibly widest and consider the patient's perceptive abilities, so that the patient's consent could ensure the highest safety of the physician administering potential further treatment in ICU.

CONCLUSIONS

1. During the anaesthetic visit, the range of information about possible ICU hospitalisation due to surgery-related complications the patient is provided with by the physician depends on the probability of ICU interventions.
2. The patient's consent for ICU hospitalisation should be obligatory in procedures associated with planned postoperative treatment in ICU or its high probability, which mainly regards cardiac and neurosurgical procedures as well as surgeries in severely ill patients**.**
3. The information and consent form for possible treatment in ICU should be included in the anaesthesia consent form.

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Received: 24.09.2012
Accepted: 15.01.2013