

Legal grounds for 'extending the scope or type of procedure'

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Abstract

Introduction. The development of patient rights and increasing number of lawsuits based on medical malpractice make medical doctors constantly improve knowledge regarding the acceptability of changing the scope of operation. This is particularly important when patients have expressed their refusal to changing the scope and type of procedure (ESTP) or no informed consent (IC) has been obtained from the patient prior to the procedure.

Method. The method of study comprised content analysis of existing legislation. The current jurisprudence and doctrine were confronted with existing regulations. An algorithm of correct formal procedures was elaborated.

Results. The doctor has right to realize ESTP when the patient has not given the consent to it or the refusal expressed by him was not fully conscious. Healthcare providers are absolutely prohibited from realizing ESTP when patient objected to any changes being thoroughly informed by the physician prior to the operation. When patient refuses possible ESTP, the doctor has the right to withdraw from performing surgery but should inform the patient about other places, where a similar procedure can be provided.

Key words

extending the scope of operative field, informed consent, informed refusal, legality of operation, withdrawal from health service provision

INTRODUCTION

The presented study is the first to deal with both the theoretical background of 'extending the scope or type of procedure' (ESTP) and elaborating a practical algorithm of realizing this extension.

The concept of 'the informed consent' (IC) should be regarded as a specific mental shortcut, since the patient has the right to express 'informed refusal' (IR) to accept the recommended medical service, as well as to choose among the available methods of treatment, which means the patient has right to express an 'informed decision' (ID).

The above consideration is particularly associated with the aspect of a patient's consent or lack of IC to effect the ESTP [1, 2]. In terms of the process of making ID, the situation looks different as the patient, due to anesthesia or analgesia, is not fully conscious, and therefore unable to properly understand information or express own decisions [2, 3]. From the legal perspective, executing the ESTP while procedure is being performed, means performing the particular type of procedure. In literature, ESTP is defined as exceeding the primary patient's consent regarding the subject of surgery, its limits, or the method of performing the surgery [4].

As a rule, the doctor cannot perform surgery different from that originally intended, or change its scope and mode of performance, either partially or totally [5,]; however, surgical practice shows that applying that rule seems to be not always possible due to occurrence of circumstances independent

from the doctor [6]. Changing the scope of a primarily planned surgical procedure or any other high-risk actions [7], could then be necessary.

In Polish law, performing the ESTP when the patient's consent was explicitly stated, and given prior to the procedure, is unequivocal [6]. Controversy arises when informed consent has not been obtained prior to the procedure, or the patient expressed explicit and unequivocal refusal to ESTP. Lack of clear regulations in this area results in a great deal of doubts associated with undertaking actions which are frequently necessary for the patient, and expose the doctor to the risk of taking responsibility for breaking the patient's right to make autonomous decisions in the process of treatment, and conducting the operation without patient's consent.

OBJECTIVE

The aim of the study is to address concern about the acceptability of ESTP depending on a patient's consent or refusal. The authors addresses performing the ESTP without any prior patient's decision concerning such a situation, and elucidate whether a doctor can refuse to conduct a medical procedure in patients objecting to any potential ESTP.

METHODS

The methods applied included content analysis of legal regulations concerning performing medical procedures with and without patient consent.

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Legislative Acts were confronted with the jurisprudence of the Polish courts that significantly affect formulation of the doctrine of law on this subject. The methods applied allowed exclusion of contradictory elements and systematize obtaining coherent conclusions.

RESULTS

The Medical Profession Act (MPA) [8] and the Act on Patient Rights (APR) [9], as well as administrative Acts, are the Polish main regulations applying to the performance of any action in patients. According to the main principle of the Medical Law specified in Article 32 §1 of the MPA, 'a physician can perform examination or any other medical service (...) with patient's consent' [2, 4, 8]. The 'valid' consent must be preceded by providing comprehensive information concerning the intended procedure, its possible complications and alternatives [1, 10]. It is obvious that a patient's consent to hospitalization must not be treated as consent to perform any medical procedure [11]. Performing the ESTP is an exception from the above general principle, due to the fact that the patient cannot be informed about all possible consequences nor complications of the undertaken action, prior to its commencement. Thus, the action cannot be claimed to be performed under regulations of the Article 35 §1 of the MPA [1, 8, 12–24]. Doubts concerning the legality of the ESTP do not arise when a patient consented to possible ESTP before health intervention. In such cases, the physician operates within the boundaries accepted by the patient. Patient consent, including agreement for the possible necessity of ESTP and information about the consequences and complications which may occur, eliminates the physician's liability even for severe complications. This principle was confirmed by the Supreme Court, which stated that:

if severe health disturbance or other complications lie within the boundaries of risk connected with a given procedure, occurrence of a given complication abrogates the physician's liability (...), provided the patient has been informed about the risk and consented to the procedure [15].

Giving a patient information about predictable consequences of intended actions means that the patient 'takes over' the risk of their occurrence, thus eliminating the physician's liability for the complications about which the patient was informed. The development of a patient's rights and increase in the number of trials concerning physicians' liability for their violation resulted in a common use of consent forms which included clauses for a possible ESTP in the clinical practice [16, 17].

Lack of consent is not directly applicable in the case of great urgency. In Poland, providing urgent medical services does not require obtaining any consent from a patient [8]. Therefore, the physician extends the procedure beyond its typical frames on the basis of his assessment of the current state, especially if not considering the newly-occurred circumstances would directly pose danger to the patient [18]. Lack of consent is also identified with not obtaining any consent from a patient for ESTP, but not with refusal to it. The same applies to underage patients and adult patients, who are not capable of expressing their will, irrespective of the reason [8].

When no consent is obtained from the patient, justification for the actions taken stems from Article 35 of the MPA, according to which:

if circumstances, which if not considered, would result in the risk of a patient's death, severe body injury or heavy health disturbance occurring during the (...) procedure, and there is no possibility to immediately obtain consent from a patient or legal representative, the physician has the right to change the extent of the procedure (...) [8].

However, already in the 1970s, it was emphasized that the physician had not been absolutely free, even in patients who had not given any consent to ESTP. The Supreme Court claimed that:

if an operating physician (...), finds a state inconsistent with the one that has been concluded from clinical tests, he can in some cases, extend the scope of patient's consent. However, it can only take place in special circumstances, i.e. if the decision not to perform the necessary procedure would pose a threat of patient's death or when the required change in the procedure would be slight [19].

Undertaking the ESTP is also associated with the institution of a 'state of necessity', originating from the criminal law which defines it as sacrificing a welfare commonly considered to be of a smaller value, to save another one that is protected by the law [20]. In the context of ESTP, necessity should be interpreted as sacrificing a patient's right to make autonomous decisions in order to save their lives and health. However, jurisprudence emphasizes that the very occurrence of a state of necessity does not free a physician from the liability for ESTP without patient's knowledge if the conditions set out in Article 35 of the MPA are not met [21]. This means that, as a rule, the existence of necessity excludes the physician's liability [22, 23]; however, acceptability of ESTP without the patient's consent requires additional compliance with requirements specified in Article 35 of the MPA. When adjusting to the newly-occurred circumstances may be deferred in time, or would not be directly associated with protecting from death or avoiding severe health disturbances, the sheer existence of necessity (i.e. need for the protection of a person's health) is not considered to justify extension of the operative field.

In the authors' opinion, the clause 'failure to take that into account would put the patient in danger of loss of life' (MPA, Art. 35) should be understood not only as 'danger of death or direct severe grievous bodily harm' occurring shortly after the procedure, but also as a potential life-threatening situation or severe health deterioration, regardless of the time of occurrence. It must be stressed that the ESTP may not apply to actions not being strictly therapeutic, e.g. minimizing health risks. The Court decided that 'illegal extension of the Caesarean section by tubal ligation is a bodily harm'. It was pointed out that the fact that another pregnancy would threaten the woman's life did not decrease the doctor's responsibility [24]. In the case of an elective procedure, a physician's withdrawal from obtaining patient consent, including consent to ESTP, should be regarded as an act of recklessness or negligence.

Undertaking the ESTP when the patient made neither a positive nor negative decision concerning this subject is fully acceptable unless the requirements of the MPA, Article 35, are not fulfilled. However, when the patient agrees to the procedure itself but objects to ESTP, this causes problems.

In the opinion of the authors, the physician should respect the patient's decisions, which complies with reports from the literature emphasizing that the legal regulations in force do not oblige the patient to undergo any medical treatment proposed by the physician. [25]. The Supreme Court took a similar standpoint, emphasizing that:

the law does not oblige the patient to undergo any medical intervention and the physician to overcome patient's resistance either by performing actions to which no consent has been given or by taking the matter to the courts to contest the objection [26].

The Court noted that the principle of respecting patients' autonomy requires respecting their will, regardless of the motives. This means, therefore, that the patient's objection to a specific treatment is binding for the physician, and eliminates the risk of the doctor's liability for not fully performing a procedure or withdrawing from it. Similar reasoning appears in the USA. In the Barnett vs. Bachrach case, the Court stated that:

an adult, competent person has the right to decide what is going to happen with their body. A surgeon performing an operation or extending its scope without the patient's consent commits an unlawful act, for which they assume compensation liability [27].

Analysis of available literature and case law reveals that a physician has no right to perform ESTP if an adult patient, who is capable of making IDs, expresses unambiguous refusal. The refusal is valid only if it was preceded by exhaustive and comprehensible information given by the physician on the negative effects of the decision. Information concerning the negative effects of resignation from a procedure should be given in written form as an element of the patient's refusal. Obtaining a written objection to ESTP from a patient protects the physician from taking legal liability for violating the patient's right to information warranted by the MPA, Article 31 §1 [8] and the APR, Article 16 [9], as well as for unfounded withdrawal from a procedure meeting the current medical knowledge and, in consequence, for exposing the patient to a direct risk of life and loss of health.

It is crucial to answer the question whether a physician has the right to withdraw from the treatment when the objection to a possible ESTP makes it impossible for it to be performed. According to the MPA, Article 4, 'a physician is obliged to practice his profession in accordance with the recommendations of the current medical knowledge (...) [8]. However, the MPA, Article 30, states that 'a physician is obliged to provide help in every situation where a delay would cause a danger of loss of life, severe bodily injury or severe health disturbance (...) [8]. The first quotation eliminates the possibility of performing procedures which disregard all necessary actions for conducting the surgical, diagnostic or therapeutic process. Simultaneously, withdrawal from any treatment is considered a violation of the principles defined in the MPA, Article 30.

The obvious conflict between the above regulations can be easily seen. In order to solve the problem, one should recall the list of personal rights included in Article 23 of the Civil Code, which comprises life, health and autonomy of making decisions (free will) [28]. It is essential to decide which of the above rights would be of greater priority and what circumstances should occur, so that respecting only

few of them would not be a danger for a physician while providing healthcare services.

In the authors' opinion, the right of patients to autonomous decisions is of the utmost importance. Such a thesis has its grounds in the precedence of patient in the non-paternalistic patient-physician relationship and principles of providing medical services, which can be initiated only under a patient's consent. Informed refusal renders providing healthcare services impossible, which also includes situations in which withdrawal from medical actions may result in death, severe bodily injury, or severe health disturbance.

A physician's decision to withdraw from a medical procedure due to patient's objection to ESTP should be made based on the general principles of withdrawing from the treatment, i.e. in all cases that are not urgent. According to the MPA, Article 38 §2, 'a physician may withdraw from initiating or cease the treatment as long as a case as described in Article 30 does not occur (...) [8]. Such cases include *only* urgent danger of loss of life, severe bodily injury or severe health disturbance, as well as other urgent cases. No legal document defines 'a matter of great urgency' explicitly, and therefore the assessment always depends on physician's objective opinion. However, the definition can be implicitly deduced from MPA, Article 30.

It should be remembered that failure to initiate or withdrawal from providing services requires fulfilling additional requirements stated in the MPA, Article 38 §2, according to which:

in the case of withdrawal from the treatment the physician is obliged to inform the patient about that sufficiently early (...) and to specify real possibilities of obtaining the treatment from another physician or medical institution [8].

In the authors' opinion in a situation where a patient declares objection to ESTP, the physician is not obliged to begin or continue the treatment, unless the case is urgent. The same applies to the situation where a patient objects to the ESTP of special kind (e.g. blood transfusion), which could be necessary to perform when unexpected circumstances appear during the procedure.

DISCUSSION AND CONCLUSIONS

In the case that the consent with ESTP permission has not been obtained from a patient, the physician has the right and duty to perform the ESTP if it is necessary to save the patient's life, or protect him from the occurrence of significant harmful consequences, regardless the time of appearance. The existence of necessity, which does not meet the criteria specified in Article 35 of the MPA does not entitle the physician to perform ESTP.

1. Patient's consent to a surgery should contain a clause concerning 'changing the scope or type of the procedure'.
2. Failure to obtain consent including a clause concerning ESTP does not exclude the possibility of performing it, provided that the conditions specified in Article 35 of the MPA occurred.
3. Patient's IR to ESTP excludes the possibility of a physician's arbitrary actions in this respect.
4. Patient's objection to ESTP must be preceded by an exhaustive, comprehensive information, whose content

should be included in the consent form for the main procedure.

5. In a situation other than 'a matter of great urgency', a physician can withdraw from performing the surgery if the patient opposes the ESTP which would be necessary for the procedure to be performed correctly and the intended result achieved and, at the same time, should inform the patient about another possibility of receiving a similar health service.

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