

Broadening the operative field: the extent of surgery beyond the patient`s informed consent (the so-called therapeutic exception)

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INTRODUCTION. THE REQUIREMENT OF OBTAINING INFORMED CONSENT FOR TREATMENT

One of the conditions of the legality of a therapeutic procedure is that it is performed with legally effective informed consent given by the patient or the patient`s legally designated representative. This condition is independent of whether the medical intervention has been performed properly from a medical point of view, or otherwise. As stated by the Court of Appeals in Warsaw in the verdict of March 13, 2006¹, a medical procedure performed without patient`s informed consent is illegal even if performed in compliance with knowledge-based principles. Similar rulings were issued by the Court of Appeals in Lublin, which stated in its verdict of October 2, 2003² that the guilt of a physician performing “an invasive” procedure requiring the patient`s consent can consist of carrying this out inconsistently with the principles of medical practice, or without the patient`s informed consent after providing reliable information about the “technical” aspect of the procedure or its possible risk. The above verdicts show that the physician may be held liable even if the procedure has been performed correctly from the medical point of view yet without legally effective consent. The informed consent requirement results from the right of self-determination (which is currently treated affirmatively), including the right to decide about undergoing treatment. This right of the patient originates from the constitutionally guaranteed protection of private life and the right to decide about one`s private life³. There are numerous medico-legal

regulations normalising the patient`s right to give or withhold consent and the physician`s obligation to obtain such an approval and to respect the patient`s will. With regard to the above, Articles 31–35 of the Medical and Dental Practitioners Act of November 1996⁴ (further called the “MDPA”) are essential. From the patient`s point of view, this right results mainly from Articles 15–19 of the Act on Patient Rights and the Ombudsman for Patient Rights⁵ (November 6, 2008). The regulations included there are also enhanced by deontological-ethical norms. Internationally, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (the Biomedical Convention) is vital. In Art. 5, the Convention states that medical intervention cannot be carried out without the free and informed consent of the person undergoing it. Similar rulings are included in Art.15 of the Polish Code of Medical Ethics. Indeed, Part 1 states that diagnostic, therapeutic and preventive management requires the patient`s consent. Any case in which these requirements are not met may be associated with the multifaceted liability of healthcare practitioners. In the civil law setting, this may lead to the necessity of paying compensatory damages. Performing a therapeutic procedure without the patient`s consent is also an illegal criminal offence penalised in Art. 192 § 1 of the Criminal Code (CC) with a fine (up to 1,080,000 PLN), deprivation of one`s liberty (1 month to 2 years) or imprisonment (1 month to 2 years). Moreover, the court can order the prohibition of exercising the profession (Art. 43b of CC) if considered professional misconduct (Art. 41 § 1 of CC) for 1–15 years and the publication of the sentence (Art. 43b CC). Furthermore, a therapeutic intervention carried out

¹ Ref.: I ACa 973/05, Apel.-W-wa 2007/2/12.

² Ref.: I ACa 368/03 LEX no. 1681154.

³ Article 47 of the Constitution of the Republic of Poland states that everyone has the right to decide about his/her personal life. Personal freedom and bodily integrity are also upheld by Art. 41, paragraph 1 of the Constitution of the Republic of Poland.

⁴ Consolidation, Official Gazette of 2017, position 1318, as amended.

⁵ Consolidation, Official Gazette of 2017, position 1318, as amended.

not in accordance with the above-mentioned norms can be considered professional misconduct within the meaning of Article 53 of the Act of December 2, 2009 concerning the Chambers of Physicians⁶ that can be penalised by the medical board.

Consent, however, is not a formal act of signing an appropriate document. To be legally effective, i.e. valid, consent has to meet suitable conditions. It has to be given by an eligible person (most commonly the patient him/herself), be informed and voluntary. Moreover, consent ought to be sufficiently detailed. This means that the decision-maker approves a given therapeutic method,⁷ the way it is performed and its possible consequences, including the risk of the procedure itself. Considering the above, the essential function of consent to undergo treatment should be emphasised. Consent is not only a sign of patient autonomy but also results in shifting the responsibility for possible negative consequences of the medical intervention to the decision-maker. Once the patient approves the potential (or unavoidable) complications (obviously, having been provided with appropriate information) whenever they occur, the physician is not held responsible for them⁸. However, this concerns only those cases in which negative sequels have developed despite the observance of the required standards of medical management. In other words, the patient's consent cannot absolve the physician of responsibility for medical malpractice, as the patient approves only the risk of the procedure (even a very high one) which accompanies a medical intervention carried out *lege artis*⁹.

⁶ Consolidation, Official Gazette of 2018, position 168.

⁷ In the Court judicature, it is emphasised that the physician is to provide the patient with possible and suggested treatment options and their consequences (concerning both the provision and abandonment of treatment). However, the final decision is taken by the patient. The physician has to accept and respect the choice even if he/she believes that the choice is not optimal. Such an opinion was presented by the Court of Appeals in Łódź in the verdict of September 18, 2013 (Ref.: I ACa 355/13, OSAŁ 2014/1/2), stating that the autonomy of an individual and freedom of choice consists of the right to decide about himself/herself — including the choice of treatment method. To be considered informed, this choice has to be preceded by information concerning other alternative and available methods of treatment or diagnosis. The final decision belongs to the patient and the physician is obliged to respect this even if he/she thinks that the decision taken is not correct.

⁸ Such an opinion was expressed by the Court of Appeals in Katowice in the verdict of January 18, 2017 (Ref.: V ACa 146/16, LEX no. 2233014), which states that the patient's informed consent overrules the illegality of direct impingement on health, as well as assault and battery, yet also means the acceptance and taking on the procedure's risk (acting on the physician's own risk). Thus, the physician is not responsible for any incidental adverse consequences of the procedure.

⁹ The above issue was addressed by the Court of Appeals in Warsaw on January 21, 2016 (Ref.: VI ACa 322/15, LEX no. 2004480), which pronounced that even in cases where the management is consistent with the current knowledge and administered with due care, the risk of damage cannot be excluded. The notion of an admissible risk includes also medical failure. In

If the conditions of consent are not met, the procedure will be illegal, which can lead to legal consequences. In some cases, however, all of these conditions cannot be fulfilled. In particular, for the consent to be valid, the patient has to be in such a psychophysical condition to be capable of giving informed and conscious consent. Whenever the patient's condition does not allow them to give consent in such a way, substitutive consent or the agreement of a court has to be obtained. The issue becomes complicated, however, when there is no person to make the decision on behalf of the patient (the patient has a full capacity of legal activities, i.e. has no legally designated representative, but is unconscious). The urgency of the situation makes it impossible to apply to the guardianship court. This is particularly likely to happen when during the procedure some new circumstances are revealed, which have to be taken into consideration in order to avert a serious risk to the life or health of the patient. In such cases, the question is whether the physician alone can change the extent of therapeutic interventions and go beyond the informed consent obtained before the surgery. In particular, can the physician broaden the extent of surgery? Such a solution is provided for in Polish law and is called the therapeutic exception. The literature explains that this solution is used in three situations:

- 1) When the object of the surgery has been changed, e.g. an additional organ is involved.
- 2) When the procedure limits have been changed, e.g. amputation of an entire limb when the patient consented only to the amputation of a finger (toe).
- 3) When the surgical method has been changed, e.g. some more effective method is applied, which is, however, more invasive than the method approved by the patient¹⁰.

The causes of modifications of therapeutic interventions are diverse — for instance, a wrong diagnosis when after the onset of the procedure, especially surgery and the incision of abdominal integuments, a condition is found different from the one previously determined. Such cases can also be considered from the perspective of diagnostic malpractice (especially when the wrong diagnosis has resulted from the fault or negligence of the physician, e.g. due to the abandonment of a necessary examination). Another situation is observed when the diagnostic procedures were correct, the patient was informed and consented to the procedure based

general, consenting to a surgical procedure, a patient informed of the risk takes on the responsibility for any possible risk, which however, encompasses only common postoperative complications; therefore, it cannot be acknowledged that the patient's risk includes the complications resulting from the physician's errors, carelessness or clumsiness, in particular, injury to another organ, even if incidental and unintended.

¹⁰ Vide M. Sośniak, *Cywilna odpowiedzialność lekarza*, Warsaw 1977, p. 86.

on diagnostic findings, yet new, additional circumstances were revealed during the medical intervention, which were unpredictable before the procedure (e.g. the patient was found to be suffering from another serious disease)¹¹.

The therapeutic exception will be discussed later in the text.

EVOLUTION OF OPINIONS [RULINGS?]

The issues regarding the admissibility of broadening the extent of surgery were considered already when the previous legislation was valid, i.e. when the Act of October 28, 1950 concerning the medical profession was in force¹². As the Act did not regulate this issue, guidelines had to be sought out in judicial decisions. An example is a case considered by the District Court in Dzierżoniów. The case concerned a patient who sustained some kind of severe injury to their thumb during an accident. The physician informed him that the thumb could be saved although skin graft was needed. The patient gave his informed consent to such a medical intervention. During the intervention the physician went beyond the patient's consent and amputated the thumb.¹³ However, the proceedings were discontinued as expert witnesses decided that the procedure was performed *lege artis*. The issue of infringement of patient's liberty and right of self-determination was completely neglected. The main judicial decision in this issue was the verdict of the Supreme Court of December 29, 1969¹⁴ issued on the basis of the case of a woman who had undergone gynaecological surgery. In this case, the preoperative diagnosis (a fist-sized tumour on the left uterine appendages) was wrong. The diagnosis was based exclusively on history-taking; the patient was informed that she had already been operated on and the right uterine appendages had been removed. Intraoperatively, it was found that the left uterine appendages were absent and the supposed tumour was just a blend knot of intestinal loops which had formed after the removal of the left uterine appendages performed earlier. Nevertheless, during the surgery, the patient's right appendages and the uterus were removed, which went substantially beyond the consent she had given and ultimately led to infertility. The Regional Court considering the case at the first instance dismissed the application as unfounded. The Supreme Court, however, questioned this verdict and applied for a retrial of the case, blaming the Regional Court for not examining the entire body of evidence (e.g. the reasons why physicians based their diagnosis exclusively on history-taking and not

medical records were not determined). The Supreme Court addressed also the fact of going beyond the patient's consent and accepted such a modification, distinguishing two situations:

- 1) In a special case when the abandonment of the procedure would put the patient's life at risk — in such a case any change that would eliminate the risk is permissible.
- 2) In the remaining situations, a slight, necessary correction of the procedure is permissible.

The above verdict was the basis of the management of physicians for about 30 years until the present law concerning the medical and dental professions was introduced, in which the issue in question is regulated in Article 35.

CONDITIONS FOR THE THERAPEUTIC EXCEPTION UNPREDICTABLE CIRCUMSTANCES REVEALED DURING SURGERY OR THERAPEUTIC/DIAGNOSTIC METHODS

The regulation in question states that the therapeutic exception concerns not only surgical procedures but applies to all medical interventions (diagnostic and therapeutic) during which new unpredictable circumstances are found, which could not have been anticipated before the surgery. From the practical point of view, however, the therapeutic exception is obviously most important in surgical procedures.

As far as the other circumstances or conditions are concerned, it is worth emphasising that they regard cases in which the patient is not be able to express his/her opinion during the procedure. It is essential that such circumstances were unknown prior to the procedure and were not objectively predictable. In other words, the circumstances happened suddenly during the surgical procedure. Otherwise, the physician is obliged to inform the patient about a potential need of carrying out certain interventions and about their health- and life-related consequences¹⁵, as well as obtain anticipatory consent, i.e. conditional approval which can be commonly used in surgical practice. According to the above-mentioned consent, the patient has to be warned about certain possible necessary actions during the procedure when the patient is not capable of making the decision (e.g. he/she is under anaesthesia). For anticipatory consent to be effective, it is essential to explain in detail the anticipated circumstances and describe the type of the medical intervention to be undertaken under such circumstances, its aim, direction and consequences. The patient anticipating such a need and its consequences can give his/her consent. If such requirements are not met, the physician may be held liable (unless the conditions of the therapeutic exception occur). The above ruling has been presented in

¹¹ Vide M. Świdorska, Zgoda pacjenta na zabieg medyczny, Toruń 2007, pp. 181–182, footnote 332.

¹² Official Gazette, No. 50, position. 458, as amended.

¹³ After: A. Zoll, Odpowiedzialność karna lekarza za niepowodzenie w leczeniu, Warsaw 1988, p. 21.

¹⁴ Ref. II CR 551/69, OSPIKA, 1970, position. 224, pp. 480–481.

¹⁵ Compare: A. Zoll, 'Stan wyższej konieczności jako okoliczność wyłączająca przestępność czynu w praktyce lekarskiej', Prawo i Medycyna, 2/2005, p. 14.

the judicature. The Supreme Court, in its verdict of March 7, 1974, highlights that when the health consequences of the surgical procedure are predictable and the patient has not been informed about them, it would not be possible to absolve the defendant (State Treasury) of liability for the harm the patient sustained by referring to the informed consent previously given by the patient¹⁶. Similar rulings can be found in more recent verdicts, e.g. the case decided by the Court of Appeals in Warsaw (verdict of April 28, 2011)¹⁷. A female patient was admitted to hospital for surgery due to the presence of a right ovarian cyst. Already in the Emergency Department, she gave her informed consent to undergo hospital treatment and surgery. Immediately before the surgery, she was informed about possible changes in the extent of the surgery. During the procedure, after incising the abdominal integuments, the surgeon found the body of the uterus slightly enlarged by a myoma and bilateral ovarian endometrial cysts. This revealed on the right side, a cyst (7 cm in diameter) immobilised by adhesions and on the left side, a cyst (5 cm in diameter) adhering to the intestine and the Douglas sinus peritoneum. The fallopian tubes were unaltered; adhesions between the omentum and the parietal peritoneum and intestines were observed on the right side. Once the surgeon determined that the changes present were bilateral and larger, the decision was made to broaden the extent of surgery (the decision to do so was consulted with the senior registrar). The uterine appendages were liberated from the adhesions; the funnel pelvic ligament and the round ligament on both sides were underpinned, ligated and cut. The uterovesical fold was transversally incised and moved downwards together with the urinary bladder. The parametria and vascular follicles were shortened, underpinned and ligated on clamps. The body of the uterus, along with its appendages, was dissected from the neck. Preoperatively, the patient had been informed only about the right ovarian cyst and consented to its removal, biopsy of the left ovary and an intraoperative examination of biopsy specimens. Thus, she had not consented to an ovariectomy, which was actually performed during surgery. However, the expert witnesses in this case were of the opinion that from the medical point of view there were indications for this procedure. Therefore, the Court of the First Instance decided that the course of treatment was appropriate and the physicians were exonerated. This verdict, however, was annulled by the Court of Appeals, which reasoned that the evidence did not reveal what specific information the patient was provided with before the surgery, particularly whether the patient was aware of the possible removal of the organs mentioned. If

the information had been incomplete and inaccurate, the consent obtained was not sufficient for the procedure to be considered legal. As emphasised by the court, one's consent to a particular type of procedure is not automatically consent to all interventions (even if medically based). Being uncertain about the extent of surgery, the physician should have shared his/her doubts with the patient and obtained their consent for potential interventions. Thus, it is inadmissible to obtain blank consent. Consent to undergo medical procedures is consent given by fully informed patients. Thus, the approval obtained in the above case did not allow for broadening the extent of surgery. In addition, this was not considered anticipatory consent. Any modifications to the surgery were only possible based on Article 35 of the MDPA. In conclusion, the verdict of the Court of Appeals in Cracow of October 12, 2007 may be cited, in which the Court states that the patient's consent to a surgical procedure does not include the possibility of causing injury to another organ¹⁸.

According to the available literature, unpredicted circumstances can only consider new intraoperative findings (e.g. after opening of the abdominal cavity, the small intestine operated on was found to be perforated over a substantially longer distance than had been observed during earlier diagnostic examinations) or cases in which the patient's condition deteriorates suddenly during surgery. Commentators on this regulation state that this is used only in the first group of situations. Whenever the patient requires immediate additional interventions during the procedure (e.g. resuscitation), their consent is mainly based on Article 30 of the MDPA as this norm obliges medical staff to provide medical assistance in every urgent case¹⁹.

CONSEQUENCES OF NOT CONSIDERING NEWLY FOUND CIRCUMSTANCES

Failure to take appropriate medical actions in response to newly revealed circumstances is likely to lead to:

- 1) loss of life,
- 2) severe injury to the body or
- 3) severe body dysfunction.

The above condition is based on the earlier cited verdict of the Supreme Court of 1969. However, compared with this verdict, the regulation discussed gives one wider possibilities for going beyond the patient's consent; according to the Supreme Court, such interventions are permissible only in life-threatening cases and while the regulation also includes some other health-threatening conditions, they have to be sufficiently serious. The Polish legislature has not precisely determined whether the danger associated with

¹⁶ Ref.: I CR 43/74, LEX no. 7426.

¹⁷ Ref.: I ACa 751/10, LEX no. 1643032.

¹⁸ Ref.: I ACa 920/07, LEX no. 570272.

¹⁹ A. Dyszewska-Tarnawska [in:] L. Ogiegło (ed.), *Ustawa o zawodach lekarza i lekarza dentysty. Komentarz*, Warszawa 2010, pp. 317–318.

such conditions has to be direct. However, a new ruling may be found in the legal literature which states that in evaluating the admissibility of exceeding the scope of consent, the degree of proximity should be taken into account; especially when the procedure could supposedly involve important body organs²⁰. The danger has to be real and objective and should be referred to the moment of performing the medical intervention²¹. Therefore, the regulation discussed cannot be used in cases when another necessary surgical procedure is anticipated, e.g. the physician finds intraoperatively that the patient has cholelithiasis yet he/she cannot arbitrarily remove the gallbladder even when such a procedure is highly likely in the nearest future. In such cases, the physician should abandon any modifications of the procedure and take necessary actions once the patient's consent has been obtained. This kind of management is particularly ordered when an increase in the extent of surgery would concern important organs and was essential for the further functioning of the patient. Such rulings are found in various verdicts. The Court of Appeals in Katowice in its verdict of February 19, 2008²² decided that the "illegal broadening of a Caesarean section by ligating the ovarian tubes is an injury to the body. The ability to procreate is part of the physiology of man and depriving one of this ability is a specific kind of contraception which a particular individual may not accept. Thus, it is irrelevant whether the next pregnancy would be life-threatening for the women involved"²³.

NO POSSIBILITY OF OBTAINING PROMPTLY THE CONSENT OF THE PATIENT OR THE LEGALLY DESIGNATED REPRESENTATIVE

This condition indicates the uniqueness of the admissibility of increasing the extent of surgery, as the nature of this concept is the state of medical necessity; thus, it can be used only when the person competent to give their consent cannot express his/her opinion. This regulation most commonly refers to patients under general anaesthetics or other agents that limit one's perception, to patients who are severely debilitated, unconscious, etc. No possibility of obtaining the consent from the legally designated representative can happen in the situation when the whereabouts of the representative are unknown or he/she cannot be contacted or he/she is unconscious, etc. In such cases, the previously expressed opinion of the patient may be considered, e.g. when the patient clearly stated preoperatively that he/she does not approve of certain interventions or methods. In

studies on this condition, it was postulated that these issues should be explicitly normalised. It has been suggested that Article 35 of the MDPA should be supplemented with the phrase: 'The changes in the extent of surgery or methods of treatment and diagnosis cannot include such actions which the patient preoperatively, consciously and clearly disapproved of and did not consent to'²⁴. Ultimately, the Polish legislature did not decide to introduce such a solution. In the literature, however, it is commonly accepted that performing the procedure against the patient's will would be inconsistent with the protection of his/her autonomy, which, as mentioned in the introduction, is safeguarded by numerous legal regulations and deontological norms. Therefore, the physician should respect the patient's will and should not change the extent of surgery in a way which had been clearly rejected by the patient. Otherwise, the physician may be held legally liable, in particular, on the basis of Article 192 of the Criminal Code²⁵. Nevertheless, the physician should not act in a schematic manner and uncritically rely on the patient's objection. In such cases, the physician is obliged to provide additional information. Once the patient does not give their consent, the physician should explain in detail the consequences of such a decision and suggest an alternative method, whenever possible (e.g. instead of the surgical removal of a particular organ, pharmacological management can be suggested). However, if the patient maintains his/her opinion despite additional explanations, the physician is obliged to respect it.²⁶

CHANGES IN THE EXTENT OF SURGERY OR TREATMENT AND DIAGNOSTIC METHODS ESSENTIAL IN ORDER TO TAKE NEW CIRCUMSTANCES INTO ACCOUNT

This condition is a natural consequence of the nature of this concept as the state of medical necessity. The physician can go beyond the previously expressed consent yet only when objectively and actually deemed indispensable. Hence, the physician should refrain from any other interventions which are not so urgent and do not result in the danger of

²⁰ Compare: M. Filar, *Lekarskie prawo karne*, Kraków 2000, p. 271.

²¹ M. Malczewska [in:] E. Zielińska (ed.), *Ustawa o zawodach lekarza i lekarza dentystry. Komentarz*, Warsaw 2014, p. 658.

²² M. Malczewska [in:] E. Zielińska (ed.), *Ustawa o zawodach lekarza i lekarza dentystry. Komentarz*, Warsaw 2014, p. 658.

²³ M. Malczewska [in:] E. Zielińska (ed.), *Ustawa o zawodach lekarza i lekarza dentystry. Komentarz*, Warsaw 2014, p. 658.

²⁴ M. Malczewska [in:] E. Zielińska (ed.), *Ustawa o zawodach lekarza i lekarza dentystry. Komentarz*, Warsaw 2014, p. 658.

²⁵ M. Malczewska [in:] E. Zielińska (ed.), *Act...*, pp. 660–661. These views are consistent with the opinion of the Supreme Court, which in the verdict of October 27, 2005 (Ref.: III CK 155/05, Biul. SN 2006, No. 2, position. 9) instructed that the statement expressed in cases of loss of consciousness, determining the will concerning the management of the physician in therapeutic situations, which may occur, is binding for the physician if expressed clearly and unequivocally. The above verdict was pronounced in the case of a 43-year-old woman involved in a road traffic accident. She was a Jehovah's Witness and carried a note prohibiting blood transfusions, and necessary treatments with their use, irrespective of the circumstances.

²⁶ M. Malczewska [in:] E. Zielińska (ed.), *Ustawa o zawodach lekarza i lekarza dentystry. Komentarz*, Warsaw 2014, p. 658.

loss of life, severe injury or serious health disorder. As mentioned earlier, such interventions may be undertaken after obtaining the separate consent of the patient (or a competent individual).

THE DUTY TO CONSULT

The physician is obliged, whenever feasible, to ask for a second opinion of another physician, preferably of the same speciality. The concept of this condition is identical to the solution accepted in Article 34, paragraph 7 of the MDPA. Moreover, its justification is similar, i.e. elimination of potential abuse and protection of the patient's rights. However, the duty to consult is not absolute as the Polish legislature is aware that in some cases this may be difficult due to the dynamics of the situation. Nevertheless, the physician should exercise all the diligence required. Firstly, he/she should ask the opinion of another specialist in this field; if this is impossible, the physician should consult any physician, no matter of what speciality (or one without a specialisation degree); if still impossible, the physician is exempted from the duty-to-consult requirement.

DESCRIBING CIRCUMSTANCES IN MEDICAL RECORDS

Formally, the description of circumstances of using the therapeutic exception in medical records is essential. This requirement is obviously of major importance from the practical point of view as such notes can be used as important evidence in any potential controversy, especially in litigation cases. Therefore, special care ought to be taken to meet this condition. In Article 35, paragraph 2 of the MDPA, the legislator only generally ordered the physician to include the appropriate information in the medical records and that this information should regard the circumstances addressed to in Article 35, paragraph 1 of the MDPA. This means that the physician should not only record standard medical information, e.g. surgical interventions, but also justify the use of the therapeutic exception. Thus, the circumstances have to be described in detail, along with the motives behind actions taken, as well as describing the way that everything took place. Moreover, it should be stated whether the case was consulted with another physician; if so, what the results of this consultation were; otherwise, the reasons should be given. The regulation does not determine the time when the physician should fulfil this requirement. However, for practical reasons, the requirement should be met as quickly as possible (i.e. immediately after the procedure). The above is also conformed in § 4 (1) of the regulation of the Minister of Health of November 9, 2015 on the types, extent and model of medical documents, as well as their processing²⁷. The above-mentioned regulation states that the data should be

recorded in documentation immediately after administering healthcare services, i.e. without undue delay.

INFORMING THE PATIENT AND OTHER INDIVIDUALS COMPETENT FOR GIVING THE CONSENT ABOUT THE COURSE OF SURGERY AND THE CIRCUMSTANCES ACCOMPANYING IT

As in the case of notes in the medical documentation, the information should include the need to go beyond one's consent, especially the range of interventions. This obligation should be carried out immediately after the completion of a particular medical intervention (e.g. immediately after awakening the patient from anaesthesia). In cases of hospitalisation, this kind of information should also be included in the case history, specifically, in the section regarding one's discharge from hospital²⁸; and the patient should be informed. Moreover, one's legally designated representative and the customary primary carer should also be informed. The regulation orders one to also inform the guardianship court, yet this court was mentioned at the end of the list, which can indicate that the court is informed as a last resort, whenever other persons are unavailable (e.g. the patient is still unconscious, there is not any designated representative or customary primary carer. The above interpretation leads *a contrario* to the conclusion that the provision of information to the patient (or other individuals mentioned above) excludes the necessity of informing the guardianship court (the conjunction "or" used before the guardianship court). This means that the fulfilment of the condition (i.e. informing the patient and other individuals mentioned) is sufficient and absolve one from the need to inform the court (the alternative's predecessor versus successor).

NO POSSIBILITY OF RELYING ON THE STATE OF NECESSITY

The above considerations demonstrate that the limits of informed consent can be exceeded exceptionally while the regulation being discussed should be interpreted restrictively. In each case, the physician should assess whether the conditions of the therapeutic exception have been met. Otherwise, the physician cannot defend himself that he obtained consent from a third party (e.g. spouse, adult relatives). Moreover, in judicial decisions, the possibility of referring to the state of necessity is excluded. This concept is present in civil law (Art. 424 of CC²⁹) and criminal law (Art.

²⁷ Official Gazette. position. 2069.

²⁸ Compare § 20 of the regulation of the Minister of Health on types, ranges and model medical documents and their processing.

²⁹ This regulation states that an individual who has destroyed or damaged an item belonging to someone else or killed or injured someone's animal to avert the danger associated with this item or animal is not responsible for the harm if the danger was not caused by this individual and the dan-

26 of CC.). Generally, it states that the individual is not to be held liable, despite the fact that he/she endangered or even violated a law if it was necessary in order to avert an imminent threat to another law. In such cases, the conduct of the perpetrator will be justified by social viability of sacrificing one right in order to save another, more valuable right. A special variant of the state of necessity is the collision of obligations regulated by Art. 26 § 5 CC. This rule states that the regulations regarding the state of necessity are used in cases when only one of the obligations of the perpetrator can be met. In such cases, one's obligation concerning a law of a higher value should be fulfilled while the law of a lower value should be abandoned. *Prima facie* this concept could be used in cases when the obligation to provide the patient with medical assistance and to respect his/her will collide. Thus, it may be assumed that such values as life and health are more valuable than the right to decide about one's treatment. However, the literature explains that such a conflict is apparent as the obligation to administer help is activated only when the patient (or the designated individual) has given the legally effective approval to a particular medical intervention³⁰. This issue may be also important in cases in which the extent of surgery has to be broadened. The dilemma associated with this is whether the physician referring to the conflict of obligations without fulfilling the conditions of Art. 35 of the MDPA may change the extent of surgery neglecting the patient's wishes (especially when the circumstance revealed is of decisive importance for saving the patient's life). This possibility, however, has to be rejected. From the theoretical-legal point of view, observing the rule "*lex specialis derogat legi generali*", it should be assumed that Art. 35 of the MDPA, as the detailed regulation, takes precedence over Art 26 of the Criminal Code, which is general. Such rulings are also presented in the judicial decisions. For instance, during surgery, a surgeon detected a right-sided inguinal hernia. Without the previously obtained consent of the patient, he repaired this hernia. At the same time the conditions of the therapeutic exceptions were not met, in particular, he did not consult any other physician and did not suitably annotate this in the medical documentation. Moreover, it was doubtful whether during the surgery the patient's life or health were endangered due to this new circumstance. Both the Court of the First Instance and the Court of Appeals acquitted the physician. The Regional Court dealing with the case at the second instance decided that the basis

ger could not have been prevented in any other way and if the interest protected is clearly more important than the interest violated.

³⁰ Vide P. Kardas, 'Zgoda pacjenta na zabieg leczniczy a problem odpowiedzialności karnej lekarza za niewypełnienie obowiązku zapobieżenia skutkowi', *Przegląd Sądowy*, 10/2005, p. 55 and further.

of the lack of responsibility is the state of necessity — Art. 26 CC, assuming that the defendant acted in an abnormal situation facing the necessity to choose between respecting the patient's autonomy and saving his life and health. However, this opinion was not shared by the Supreme Court, which in its verdict of November 28, 2007 ruled that it is not permissible to discharge the physician of liability regarding the change in the extent of surgery without the patient's consent based on Art. 26 § 1 or § 5 CC when the conditions defined in Art. 35, paragraph 1 and 2 of the regulation of December 5 1996 about the profession of doctors and dentists [...] are not met, as this would mean that the restrictions (of a guaranteed nature) resulting from the last regulation had been ignored³¹. Thus, the Supreme Court gave primacy to the regulation included in Art. 35 of the MDPA.

THE RIGHT OR OBLIGATION OF THE PHYSICIAN TO BROADEN THE EXTENT OF SURGERY

The doctrine discusses the issue whether, having fulfilled the conditions of the therapeutic exception, the physician can or should broaden the extent of surgery. In the regulation discussed the Polish legislature used the expression "the physician has the right", which would indicate that the physician is entitled to do so and discharged him/her of liability for the change in the extent of surgical interventions. According to some authors, in such cases the regulation grants the physician discretionary powers and enables him/her to take decisions following his/her conscience³². However, the opinion that this issue should be considered based on Art. 30 of the MDPA seems to prevail. Art. 30 orders one to administer assistance in each emergent case, particularly when delayed help can be life-threatening, cause severe dysfunction or damage to one's health. Thus, when a physician intraoperatively reveals the circumstances which are likely to lead to the dangers mentioned above, he should take appropriate actions to eliminate such circumstances, hence modify the extent of surgery. Otherwise, he may be responsible for negative health or life consequences associated with abandonment³³.

SUMMARY

Polish law treats the right of the patient to give the consent affirmatively, originating from constitutionally pro-

³¹ Ref. V CC 81/07, OSN IKiW, No. 2, 2008, position 14.

³² A. Zoll, 'Zaniechanie leczenia — aspekty prawne', *Prawo i Medycyna*, 5/2000, p. 36.

³³ Compare T. Dukiet-Nagórska, 'Autonomia pacjenta a polskie prawo karne', *Warsaw 2008*, p. 95; 'Niepodjęcie — zaprzestanie terapii a prawo karne', *Prawo i Medycyna*, 1/2010, p. 36; Ł. Caban, M. Urbańska [in:] M. Kopeć (ed.), *Ustawa o zawodach lekarza i lekarza dentysty. Komentarz*, Warsaw 2016, p. 689; J. Kulesza, 'Brak zgody pacjenta na zabieg leczniczy a lekarski obowiązek udzielenia pomocy', *Prawo i Medycyna*, 2/2005, pp. 82–83.

tected values, i.e. freedom and privacy. However, for consent to be legally effective, the decedent (patient) has to be capable of giving informed consent. During some interventions, especially surgical procedures, this possibility is excluded. Therefore, the physician should anticipate any possible need to carry out certain activities during surgery and inform the patient about them in detail, attempting to obtain anticipatory consent (conditional). If, however, new, unpredictable circumstances are revealed intraoperatively and they are vital enough to be considered in order to prevent the danger of death or severe damage to one's health, the physician has to make the decision on his own. In such cases, his actions will be legal if the conditions of the therapeutic exception are fulfilled. In particular, he/she is obliged to consult the case with colleagues and can change the extent of surgery only when new circumstances are taken into account; describe the situation post factum in the medical records and inform the patient. Only in such cases will he/she be not held liable for performing the procedure without the

patient's consent. In the situation discussed, the physician cannot refer to the approval of a third party (those without the competence to make therapeutic decisions), e.g. spouse or some relatives. In the case discussed, the concept of the state of necessity cannot be applied either. It should be emphasised, however, that when the patient has been informed about certain activities and the consequences associated with them or their abandonment prior to surgery and has objected to such activities, the physician should respect the patient's will following the principle "*voluntas aegroti suprema lex est*".

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