Original paper

Awaiting consent to cure

Czekając na zgodę, by leczyć

Kamila Kocańda[1,2]

[1]*Collegium Medicum*, Jan Kochanowski University, Kielce, Poland
Head of the *Collegium*: Prof. Marianna Janion MD, PHD
[2]Regional Polyclinic Hospital, Kielce, Poland
Head of the Hospital: Bartosz Stemplewski

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Słowa kluczowe: zgoda pacjenta, zabieg o podwyższonym ryzyku, zastępcza zgoda sądu opiekuńczego.

Abstract

Introduction: The patient's consent must meet certain legally prescribed requirements in order to have legal force. Namely, it has to be informed, i.e. preceded by adequate therapeutic information, and it has to be consciously given. Medical practice, however, often involves patients who, due to their condition, are in no position to give legally efficacious consent.
Aim of the research: The analysis of cases in which medical proceedings were interrupted due to the impossibility of obtaining the patient's informed consent.
Material and methods: The study material comprised a group of 100 patients whose medical documentation was analyzed in the light of the reason for seeking substitutive consent from the court, the time the court took to decide, or, alternatively, a different outcome in the case of the patient's death or completion of the procedure for life-saving reasons without obtaining consent.
Results and conclusions: Legal provisions do not apply to situations where there is no premise that the delay caused by the consent procedure would pose a threat to the patient's life, cause serious injury or serious health impairment, but at the same time the necessity to perform a given procedure is so urgent that proceedings before a court in normal operation are not advisable. The physician is then in Antigone's situation – either of the two solutions is undesirable; hence, the doctor is forced to choose the lesser evil. The delay occasioned by waiting for the court's substitutive consent in the legally prescribed procedure may be excessive, as well as engaging the physician's legal and ethical responsibility. Hence, a legislative intervention appears necessary.

Streszczenie

Wprowadzenie: Zgoda pacjenta, by posiadać walor prawnej doniosłości, musi spełniać wymagane prawem warunki. Zgoda powinna być poinformowana, to jest poprzedzona należytym pouczeniem terapeutycznym, a także uświadomiona. W praktyce funkcjonowania podmiotów leczniczych częste są jednak przypadki pacjentów, którzy ze względu na stan zdrowia nie mogą wyrazić zgody w sposób prawnie skuteczny.
Cel pracy: Analiza przypadków, w których postępowanie medyczne zostało wstrzymane z uwagi na brak możliwości odebrania od pacjenta świadomej zgody.
Materiał i metody: Zgromadzony materiał badawczy objął grupę 100 pacjentów, których dokumentację medyczną poddano analizie w zakresie przyczyny, która uzasadniała wniosek o wydanie zastępczej zgody sądu, czasu oczekiwania na wydanie przez sąd tej zgody lub zakończenia postępowania w inny sposób, w razie śmierci pacjenta lub wykonania zabiegu ze wskazań życiowych bez jej uzyskania.
Wyniki i wnioski: Przepisy prawne nie odnoszą się do sytuacji, gdy nie występuje przesłanka, iż zwłoka spowodowana postępowaniem w sprawie uzyskania zgody groziłaby pacjentowi niebezpieczeństwem utraty życia, ciężkiego uszkodzenia ciała lub ciężkiego rozstroju zdrowia, ale jednocześnie konieczność wykonania danego zabiegu jest pilna na tyle, że procedowanie przed sądem w normalnym trybie nie jest wskazane. Lekarz jest wówczas w sytuacji Antygony – każde z dwóch rozwiązań jest złe, przez co zmuszony jest dokonywać wyboru mniejszego zła. Wystąpienie do sądu w przepisanym prawem trybie może wiązać się ze zbyt długim oczekiwaniem na zastępczą zgodę, co może również obciążać lekarza pod względem prawnym oraz etycznym. Konieczna w tym zakresie wydaje się ingerencja ustawodawcy.

Introduction

The patient's consent is a precondition of the legality of any medical intervention [1–3]. The form of this consent depends on the type of medical procedure. For surgical operations or any methods of diagnosis or treatment involving elevated risk for the patient, the law requires the patient's consent to be given in writing [4–6]. No regulation defines terms such as 'operation', 'surgery', or 'high-risk treatment'. Hence, in

practice, the distinction between procedures that can be legalised by the patient's implied or oral consent and those requiring a written statement of will is dictated by current medical knowledge and to some extent by those concerned – the doctor and the patient – who can decide to confirm the legality of a procedure in writing, if only for evidentiary purposes.

The patient's consent must meet certain legally prescribed requirements in order to have legal force [7–10]. Namely, it has to be informed, i.e. preceded by adequate therapeutic information [11–13], and it has to be consciously given. Only a patient who is of age, not legally incapacitated, and in a competent mental and psychic state can consent consciously on their own [14–16]. Medical practice, however, often involves patients who due to their condition are in no position to give legally efficacious consent [17–19].

A mentally ill patient, if not incapacitated, should make a statement of will consenting to medical intervention, but such a patient's consent can still fail to have been consciously given. This is because such a patient often is unable to receive therapeutic instruction and to discern properly the consequences of a given medical procedure or the risks involved in foregoing it; hence, exclusion of competence to make an informed decision is possible [20–22]. A mentally sound patient can still temporarily, even for a short time, be in a condition preventing informed consent, either due to the principal condition or a trauma suffered, especially if the patient is unconscious [23–26].

In any case when the patient is not capable of legalising the physician's activities in the manner legally prescribed, there is a need for alternative legal avenues in order to enable the requisite medical procedures to be conducted in compliance with the law, so as to provide the patient with the necessary care and, at the same time, exclude the physician's risk of criminal liability for legally or ethically unjustified omission of treatment [27–30].

In situations when a patient who is of age and not legally incapacitated cannot give informed consent for a medical procedure, the law provides for the mandatory involvement of the custody court of competent venue for the location where treatment is provided. The idea of substitutive consent arises from the need to protect the interests of a patient who is currently unable to do so themselves for any reason [31–34]. The court's role is to decide on the merits of proceeding with a medical intervention in respect of a patient who is in no position to make that decision and make a statement of will in the matter [35–38].

Aim of the research

The study held by the Provincial Polyclinical Hospital in Kielce in 2012–2018 included analysis of medical documentation of 100 clinical cases in which the competent custody court granted substitutive consent to perform a medical procedure in a situation in which a patient was not in a position to express consent independently and had no statutory representative while at the submitting the petition the so-called life-saving indications for carrying out the procedure were not present.

The goal of this work is to analyse the reasons for seeking substitutive consent from the court, the actual time the court took to decide, or, alternatively, a different outcome (for example, in the event of patient's death or completion of the procedure for life-saving reasons without obtaining such consent) in individual years.

Material and methods

The study material was comprised of a group of 100 patients whose medical documentation was analysed in the light of the reasons for interrupting medical proceedings due to the impossibility of obtaining patient's informed consent, including types of medical procedures and diseases causing hospitalisation. The study inclusion criterion was for patients to have been unable to give informed consent.

The waiting time for a court's consent in the above-mentioned cases was also analysed in the form of a statistical analysis: the average over the period of and changes in the waiting time in individual years (trend analysis).

The analysis of the grounds for the requirement of a court decision has prompted the conclusion that this needed triggers in a variety of health scenarios and that the reasons why patients cannot consent in compliance with the law also vary. An important factor determining physicians' conduct is the coexistence of other diseases than the principal condition giving rise to the petition to the court. Such additional diseases were significant determinants in medical proceedings, resulting in the need to initiate proceedings before the custody court.

In the years 2012–2018 the Provincial Polyclinical Hospital in Kielce held a survey concerning the scale of applications from health-care establishments for substitutive consent from the family court to a high-risk medical procedure or surgery. Statutory provisions appear to regulate those situations which pose no significant interpretative difficulties in practice. If delay caused by consent proceedings involves the risk of death, grave bodily injury, or grave health impairment, the physician has the right to proceed with medical activities without requisite consent from the patient or the family court and only notify the patient's statutory representative or the competent custody court ex post.

If from the medical perspective the physician can wait, there is no obstacle to petitioning the court for substitutive consent, accepting the necessity for that court to adduce evidence of the merits of the relevant

Table 1. Categories of procedures involving substitutive consent

No.	Type of procedure	Number of petitions
1	PEG (percutaneous endoscopic gastrostomy)	34
2	Orthopaedic procedures (anastomosis, repositioning)	21
3	Caretaking-and-therapeutic institution, welfare home	14
4	Tracheotomy, gastroscopy, echocardiography	12
5	Resection of brain tumour	6
6	Pacemaker implantation	5
7	Pterygium or cataract removal	3
8	Blood transfusion	3
9	Caesarean section	2

medical procedure, call an expert, or appoint a guardian ad litem to represent the patient's interests. A problem arises, however, when the doctor cannot wait several weeks, but at the same time the contemplated medical procedure is not so urgent as for any delay to result in a danger of death or severe bodily injury or health disorder. This does not mean the patient is in no danger at all. It only means the danger is not so imminent and violent as to justify the physician legally in performing medical procedures without the patient's prior consent. Hence, it requires the court's substitutive consent.

The study held by the Provincial Polyclinical Hospital in Kielce in 2012–2108 included analysis of 100 medical cases in which the competent custody court granted substitutive consent in a situation in which the patient was not in a position to consent independently and had no statutory representative while as at the filing of the petition the so-called life-saving indications for carrying out the procedure were not present.

Results

The study showed that PEG was responsible for 34% of all physician petitions to courts for substitutive consent (Table 1). The petitioning physicians argued that from a medical point of view they were unable to classify the relevant procedure as demanding immediate performance, while it constituted a high-risk procedure and the patients concerned were themselves not in a position to consent. On the other hand, waiting for the court's consent as prescribed by law was, due to the legal procedures in such cases, difficult to accept from the perspective of the patient's health, as the wait could take anywhere from several days to several weeks, the latter being inadvisable in the therapeutic process.

In such a case the petition for substitutive consent was a justified necessity, but at the same time insufficiently regulated, because in those types of cases, frequent in practice, neither of the two disjunct grounds materialised – neither was the procedure a typical life-saving situation, nor was it possible to comply with the substitutive-consent procedure, for medical reasons. The court petition served to comply with a legally prescribed procedure, often with a predictable result, making it merely a necessary formality, because the procedure needed to be performed at a time dictated by the patient's health needs and not the wheels of justice. That does not seem to have been the goal of the statutory regulation of substantive consent, the purpose of which ought to be judicial review of medical procedures carrying a significant risk to health with the patient being unable for objective reasons to offer consent.

A group of 14% of all cases requiring the court's acceptance involved placing the patient in a caretaking-and-therapeutic institution or welfare home. In both cases the court's consent was necessary due to the objective impossibility of the patient's own independent decision and statement of will due to the patient's condition. It must be clarified, however, that the patient's stay in a caretaking-and-therapeutic institution constitutes continuation of treatment outside of hospital structures, while the role of a welfare home is social, although it also requires consent for placement.

In the case of a caretaking-and-therapeutic institution, the therapy was often palliative, concerning patients with no improvement prognostics, residing for long periods in intensive-care units, requiring sustained medical procedures that cannot be provided at the patient's home. A welfare home, on the other hand, being a welfare institution, provides social assistance to helpless or lonely people who do not require around-the-clock care, while being unable to give independent consent to receive such economic and living assistance from such structures providing care following the completion of treatment.

A significant proportion (20%) of all petitions filed by medical personnel for substitutive consent from a court of law were orthopaedic procedures involving high-risk operations threatening permanent disability if not performed on the patient. Immediate performance was not required in every case, but the delay caused by waiting for the substitutive consent threatened significant harm to the patient's health. Frequently, it was possible to defer the procedure for a certain time, sufficient to initiate the substitutive-consent procedure, though not unlimited – rather, a definite time window such as several days. At the same time, the physicians were not approaching such types of cases as sufficiently urgent to justify, in their

view, the total omission of the court procedure, noting differences from such cases as amputations of limbs necessitated by an accident, where the patient is brought into an emergency unit by a rescue team.

Procedures such as tracheotomy, gastroscopy, or transoesophageal echocardiography (TTE) were responsible for 12 of the petitions. In non-emergencies, tracheotomy was performed as anaesthesiological preparation for a procedure requiring regulated breathing for a long time, e.g. during neurosurgical procedures involving the cranium, neck, or thorax. Petitions, therefore, noted both the auxiliary nature of the procedure relative to the principal contemplated procedure and the separate status of it as a high-risk procedure in its own right. The purpose of endoscopic diagnostics, on the other hand, was to verify the existing diagnosis or seek a new one in the therapeutic process, bearing on the efficiency of the diagnostic process, but not presenting an emergency.

In 6 cases, thus once a year throughout the studied period, physicians petitioned the court to consent to the resection of a brain tumour other than in emergency cases such as cerebrovascular ruptures. Nonetheless, a long wait for the substitutive consent required in such cases posed a health risk for the patient, while making the duration of the patient's stay dependent on the completion of the court procedure had a significant bearing on the financial aspect of hospitalisation, generating costs in excess of the value that could be claimed from the payer.

Five times during the whole period the hospital petitioned for consent to implant a pacemaker. Three petitions involved blood transfusion and two a Caesarean section. For a small group, with triviality threshold 5 or less in a scale of several years, only a single petition for a cataract surgery appears to have fulfilled the procedural conditions enabling delay until completion of legally prescribed formalities and court procedure as provided by law, including the open hearing, the appointment of a guardian ad litem to represent the patient concerned and of an expert for the purpose of substantive evaluation of the health-care institution's petition especially in the context of risks entailed by both the proposed medical procedure and its omission. It appears, therefore, that only in 3% of the cases the court procedure for substantive consent could be completed without putting the awaiting patient's health at risk.

Table 2. Categories of procedures involving substitutive consent - International Statistical Classification of Diseases and Related Health Problems (ICD-10), Vol. I, 8th ed.

No.	Type of disease	Number of petitions
1	Multiple, no contact, multiple ICDs	20
2	I68 (cerebrovascular disorders in diseases classified elsewhere); I61 (intracerebral haemorrhage); I64 (stroke, not specified as haemorrhage or infarction); I63 (cerebral infarction); I60 (subarachnoid haemorrhage)	16
3	S09 (other and unspecified injuries of head); S06 (intracranial injury); S01(open wound of head)	10
4	G93 (other disorders of brain); G90 (disorders of autonomic nervous system); G82 (paraplegia and tetraplegia); G40 (epilepsy); G20 (Parkinson's disease); G12 (spinal muscular atrophy and related syndromes)	9
5	S82 (fracture of lower leg, including ankle); S79 (other and unspecified injuries of hip and thigh); S72 (fracture of femur); S70 (superficial injury of hip and thigh)	9
6	T09 (other injuries of spine and trunk, level unspecified); T07 (unspecified multiple injuries); T06 (other injuries involving multiple body regions, not elsewhere classified); T01 (open wounds involving multiple body regions); T02 (fractures involving multiple body regions)	7
7	R69 (unknown and unspecified causes of morbidity); R50 (fever of other and unknown origin); R41 (other symptoms and signs involving cognitive functions and awareness); R40 (somnolence, stupor, and coma); R27 (other lack of coordination); R06 (abnormalities of breathing)	7
8	J81 (pulmonary oedema); J69 (pneumonitis due to solids and liquids); J18 (pneumonia, organism unspecified); J06 (acute upper respiratory infections of multiple and unspecified sites)	6
9	F20 (schizophrenia); F09 (unspecified organic or symptomatic mental disorder); F07 (personality and behavioural disorders due to brain disease, damage, and dysfunction)	6
10	I49 (other cardiac arrhythmias); I46 (cardiac arrest); I45 (other conduction disorders)	4
11	C71 (malignant neoplasm of brain); C40 (malignant neoplasm of bone and articular cartilage of limbs)	3
12	H26 (other cataract); H25 (senile cataract); H11 (other disorders of conjunctiva)	3

Table 3. Analysis of the wait duration per year and type of procedure

No.	Duration	Types of surgeries	Which years
1	0 days	PEG (12), orthopaedic procedures (8), pacemaker implantation (4), tracheotomy, gastroscopy (4), blood transfusion (2), caretaking-and-therapeutic institution (1), pterygium removal (1)	2012–2015 = 32 in total
2	1 day	PEG (9), endoprosthesis, fracture fixation (osteosynthesis) (3), gastroscopy (1)	2014–2015 = 13 in total
3	More than 1 day	PEG (5), caretaking-and-therapeutic institution (4), cataract removal (3), removal of brain tumour (3), tracheotomy, gastroscopy, cardiac echo (4), fracture repositioning, fixation (4)	2012–2017 = 23 in total
4	Performed as a lifesaving measure	PEG (4), Caesarean (3), caretaking-and-therapeutic institution (1), blood transfusion (1), tracheotomy, gastroscopy (2)	2015–2018 = 11 in total
5	Discontinuation due to death, or death	Caretaking-and-therapeutic institution, welfare home (7), limb amputation, fracture fixation (6), PEG (5), gastroscopy, tracheotomy (1), anaesthesia (1), pacemaker (1)	2014–2018 = 21 in total

Types of diseases involved in substitutive-consent petitions

The list of health reasons underlying petitions for substitutive consent to an operation or high-risk procedure is highly diverse (Table 2). The category involving multiple diseases and no contact, with a varied aetiology, claims 20% of the petitions. In both cases the effect of inability to give legally effective consent precluded the consent from being received from the patient themselves. A large number of circumstances prompting a petition to the court comprise neurological and neurosurgical diseases including without limitation traumas and primary diseases of the central nervous system. Approximately 15% of patient diseases involved accident injuries adversely impacting the patient's capacity for self-determination. Mental disorders accounted for only 6% of all cases cited in a petition for substitutive consent.

Waiting time for the court's substitutive-consent

The most significant risk factors triggered by proceedings before the custody court are the clinical consequences of awaiting the court's substitutive consent (Table 3). This delay can have a significant adverse impact on the patient's health and additionally unduly delay the patient's stay in the health-care establishment. Despite the institutional gravitas of consent as a precondition of the legality of a medical procedure, one has but to observe the futility of awaiting the court's consent when the wait can last several weeks, with the indications for a given medical procedure being urgent, though not strictly lifesaving.

While the decision to petition the custody court for substitutive consent can carry negative consequences for the patient, the law only waives this requirement in those cases when the delay would threaten the patient with loss of life or health. Where the negative health impact is not obvious, on the other hand, it appears necessary to comply with the court procedure, even though the delay itself is a negative consequence for the therapeutic process.

In the procedure involving substitutive consent for an operation or high-risk procedure, time is of the essence. In 32 of all analysed cases the court permitted the high-risk procedure on the same day. A total of 21 times the patient died before the court made the decision, which resulted in discontinuation of the case, hence no decision was made on the merits because that would have been futile due to the patient's death. Over the course of the several years covered by the study, in 11 cases the physicians opted not to wait for the court's consent before receiving it or before the patient's death, deciding that any further delay occasioned by waiting for the consent carried a risk of disability or death; hence, they decided to proceed without it. In 6 cases the duration exceeded 1 month but was not longer than 3 months. In 1 case the hospital was forced to wait 110 days for the court's decision.

In relation to the analysed cases, it was shown that the waiting time for court's substitutive consent was made longer thirteen times in 2015–2017 compared to 2012–2014, from less than one to almost 10 days. In over 1/3 of cases (32 out of 100), in which the hospital applied for substitutive consent, a medical procedure was performed without waiting for it, or a patient died before the court granted such consent (Table 4).

Discussion

The studies point toward the existence of a significant legislative lacuna. The law does not regulate the manner of proceeding in the cases under the study. It authorises physicians to decide about high-risk procedures when the delay occasioned by the substitutive-consent procedure poses a threat of serious health consequences for the patient. Alternatively, whenever waiting for the court's consent is medically viable, the procedure for substitutive consent applies.

The legislator seems to regulate those situations which do not pose major difficulties in terms of interpretation. If a delay caused by the proceedings for obtaining consent would pose a threat to patient's life, serious injury or serious health impairment, the doctor has the right to perform medical activities without the required patient's consent or substitutive consent, and then notify patient's statutory representative or the competent court after this fact.

The legislator seems to regulate those situations which do not pose major difficulties in terms of interpretation. If a delay caused by the proceedings for obtaining consent would pose a threat to patient's life, serious injury or serious health impairment, the doctor has the right to perform medical activities without the required patient's consent or substitutive consent, and then notify patient's statutory representative or the competent court after this fact.

Legal provisions do not in any way refer to the situation of urgent necessity to perform a procedure that, while not lifesaving, requires immediate medical intervention. The physician is then in Antigone's situation – either of the two solutions is undesirable, so the doctor is forced to choose the lesser evil. There is a debate in the literature about the forms and methods for consenting when the patient's articulation capacity is limited [39–41]. The topic of substitutive consent in cases admitting of no delay but not meeting the statutory requirements for proceeding without consent is largely not analysed. While any medical procedure may be lifesaving in the long term, its 'unauthorised' performance may have legal ramifications not only if complications arise [42–46]. On the other hand, waiting for the court's consent and watching the patient's health deteriorate can be difficult for a physician to accept, if only for ethical reasons, and ultimately it can lead to liability if harm ensues as a result of neglecting to perform the procedure.

The analysis of indications to obtain court's decision led to the conclusion that the necessity to submit a petition for substitutive consent is updated in various health cases, as well as that there are numerous reasons for patient's inability to express consent which meets the requirements of the legislator. An important factor determining doctors' conduct was the coexistence of other diseases together with a core disease which was the reason for submitting a petition for substitutive consent to the court. Additional diseases significantly determined the medical procedure, resulting in the necessity to implement the procedure earlier than after obtaining the court's consent.

Table 4. Analysis of the waiting time for performing a medical procedure in individual years

No.	Year	Averagewaiting time for the procedure in days	Number of procedures performed without consent or a patient died before obtaining it
1	2012	1.5	–
2	2013	0	–
3	2014	0.7	3 out of 24
4	2015	8	12 out of 43
5	2016	13	5 out of 12
6	2017	11	8 out of 13
7	2018	–	4 out of 4

In situations where, from a medical point of view, medical procedures were not urgent enough to be performed under the so-called life saving indications, the doctors, without waiting for court's substitutive consent, were seeking support in a decision-making process in the manner provided by the legislator. However, the proceedings in cases submitted by the hospital for court examination updated the premise for the performance of the procedure without the competent custody court's consent, because a delay caused by the proceedings for obtaining consent became a real danger for the patient. In the light of the above, the initiation of the court procedure exposed the patient to health risk, but this circumstance only became manifest during the procedure.

The studies have shown that over the course of several years in the health-care establishment studied a hundred petitions for consent to an operation or high-risk procedure were filed in the custody court of competent venue. Out of all such petitions 32 were granted on the very same day, but this trend occurred only in years 2012–2015; thereafter, the delay prolonged significantly. The types of procedures involved in the doctors' petitions were varied, which proves that the problem affects multiple medical fields. Only in 11 cases physicians went ahead with the procedure for life-saving reasons despite having already filed for substitutive consent, while in 21 cases the patient did not live to see the court's consent. The above illustrates not only the scale but also the significant importance of the problem in the context of daily hospital practices along with the dilemmas facing the physicians therein [47–50].

Conclusions

In hospital realities the necessity for petitioning the court for substitutive consent to perform a non-emergency but necessary procedure is a relatively frequent occurrence with a negative impact on the therapeutic process. The physician may forego the petition and classify the procedure as admitting of no delay due to the threat of health impairment or disorder, but from the medical point of view such a classification constitutes an abuse and is untenable. The delay occasioned by waiting for the court's substitutive consent in the legally prescribed procedure may be excessive, involving a significant risk for the patient, as well as engaging the physician's legal and ethical responsibility. Hence, a legislative intervention appears necessary in order to resolve this dilemma. Until such time the burden and the consequences of the decision are solely for the doctor to bear.

If, from a medical point of view, the doctors can wait, there are no obstacles for them to file a petition for substitutive consent to the court, agreeing to the court to conduct evidence proceedings regarding the legitimacy of a given medical procedure, possible appointment of an expert, appointment of a probation officer who would represent patient's interests in the proceedings. The problem arises, however, when the doctor cannot wait a few weeks, but at the same time the medical procedure intended to be performed is not so urgent that delay in its implementation would soon result in the risk of loss of life, serious injury or serious health impairment. This does not mean, however, that a patient is not at risk of danger, but only that it is not so sudden and immediate to entitle the doctor, in the light of the applicable regulations, to perform medical procedures without prior consent, but basing on the institution of substitutive consent.

However, the analyses carried out proved that waiting for substitutive consent takes place in conditions in which the resignation from the proceedings before the custody court is a burden for the doctor who may either postpone the medically advisable procedure at a time when it is not yet very urgent or perform a procedure that is not life-saving at the moment without the required substitutive consent. In both cases, it is a burden which should not rest on the doctors' shoulders as such important decisions should be based on a clear statutory instruction, and not be the result of only a specific interpretation, as it negatively affects legal certainty, which could result in legal consequences when evaluating doctors' conduct.

Conflict of interest

The author declares that she has prepared the article within her employment relationship, as she works at the hospital discussed in the article as a legal advisor. The article has been approved by the CEO of the hospital.

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Address for correspondence

Dr **Kamila Kocańda**
Collegium Medicum
Jan Kochanowski University
Al. IX Wieków Kielc 19A
25-317 Kielce, Poland
Phone: +48 691399389
E-mail: kamila.kocanda@gmail.com