The extent and manner of passing the information concerning the surgical implantation of cells, tissues or organs to the recipient of the transplant under the Polish law

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ABSTRACT

The purpose of article is to present, analyse and evaluate the effective legal regulations concerning the extent and manner of passing information about surgical implantation of cells, tissues or an organ to the recipient of the graft. The prospective recipient of the graft should possess extensive knowledge concerning the suggested medical intervention by way of implantation of cells, tissues or an organ as well as data regarding the subsequent medical procedures that follow. Therefore, information obtained by the patient ought to be as exhaustive as

possible. That is to say, it must contain any data that would enable the prospective recipient to make a reasonable decision whether to agree to the intervention or not while being fully aware of what they give their consent to and what might be expected. Information should be presented in a manner that is intelligible and comprehensive for the prospective recipient of transplant, which shall be assessed individually, on the basis of current intellectual abilities of the patient.

Key words: transplantation, legal regulations, recipient, patient, medical law

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INTRODUCTION

Transplantation surgeries constitute a common medical practice in Poland. They are thought to be an effective method of treatment in case of extreme failure of organs. Organs which can be transplanted include kidneys, liver, heart, pancreas, lungs or intestines. Multi-organ transplantations are also possible. For many patients transplantation is a chance to save life or restore health. One should bear in mind, however, that such surgeries are extremely complicated and involve risk, as it often happens. There is considerable danger of the occurrence of adverse complications in the recipient's condition, including death. The application of medical treatment by way of implantation of cells, tissues or an organ involves a risk not only during the surgical intervention itself but also afterwards, during further procedures which are aimed at reducing the possibility that the graft is rejected. This is connected with the necessity of taking medication by the recipient until the end of their life. Thus, the patient's decision regarding the application of this method of treatment must be deliberate and made on the basis of exhaustive information so as it could be fully aware. Due to the fact that transplantation intervention is a specific kind of surgery, the extent and manner of passing information to the prospective recipient of the graft is vitally important.

The focus of this paper is the presentation of legal regulations concerning the extent and way of passing information about the implantation procedure of cells, tissues or an organ to the recipient of the graft which are effective in Poland.

The purpose of article is to analyse and evaluate the aforementioned legal regulations.

MATERIALS AND METHODS

The following sources have been used herein: the Act of 1 July 2005 on Recovery, Storage and Transplantation of Cells, Tissues and Organs [1]; the Act of 5 December 1996 concerning the Professions of General Practitioner and Dental Practitioner [2]; the Act of 6 November 2008 on Patient's Rights and on Patients' Ombudsman [3].

The research method applied herein is a dogmatic-legal one, which consists in analyzing effective legal regulations. The discussion of the content of legal norms is accompanied by the review of the jurisprudence and judicial decisions.

RESULTS AND DISCUSSION

1. General remarks

Surgical transplantation of cells, tissues and an organ is a specific medical treatment. Owing to its nature the legislator passed a separate legal act

that contains legal provisions concerning this kind of surgery. The circumstances and preconditions allowing for the transplantation to be performed have been set out in detail in the Act of 1 July 2005 on Recovery, Storage and Transplantation of Cells, Tissues and Organs, hereinafter referred as Transplantation Act [1]. The aforesaid regulations refer to both the recipient and the donor of the graft. The Act determines, among other things, the extent of information which should be passed to the prospective recipient of the graft. It seems important to point out that, whereas the extent and manner of passing information to the prospective donor of the transplant is strictly defined in the Act, the provisions regarding the recipient are very concise and contained exclusively in Art. 12 section 1 paragraph 9 of the Transplantation Act [1], pursuant to which the prospective recipient should be informed about "the risk involved in the procedure of removing cells, tissues or an organ as well as about the possible consequences of the removal for the condition of the donor". In connection with the above, a number of questions arise, e.g. should information for the prospective recipient be restricted to this extent? Are these two items of information sufficient for the prospective recipient to make an informed decision regarding his or her undergoing a surgical implantation of cells, tissues or an organ? Moreover, in the Transplantation Act there is no provision regulating the way of passing information to the prospective recipient of the graft. Thus, a fundamental question emerges: what kind of information about surgical implantation of cells, tissues or an organ ought to be given to the recipient of the transplant? And in what manner must information be passed under the Polish law?

Transplantation surgery of cells, tissues and an organ is a specific medical treatment that is carried out mostly subject to the provisions of Transplantation Act [1]. Other legal regulations set forth in separate legal acts are also applied, even if to a limited extent. Particularly, such provisions are contained in the Act of 5 December 1996 on the Professions of General Practitioner and Dental Practitioner, hereinafter referred as Medical Profession Act [2], and in the Act of 6 November 2008 on Patient's Rights and on Patients' Ombudsman, hereinafter as the Act on Patient's Rights [3]. One should not disregard the fact that implantation of cells, tissues and organs is a medical treatment characterized by increased risk. In many cases it involves surgical treatment during which doctors and other persons assisting them are obliged to follow all procedures specific for each medical intervention. Legal preconditions for carrying out medical interventions are set out in the Act of 5 December 1996 on the Professions of General Practitioner and Dental Practitioner. The said Act, among others, imposes an obligation to obtain the patient's consent for the medical intervention and defines the kind of information the patient should be provided with. Furthermore, it must be pointed out that the recipient of the graft is a patient who enjoys certain rights, including the right for information and the right to give informed consent for a medical intervention. The provisions set out in the aforesaid acts apply to transplantation surgery as regards the matters not regulated, or regulated in a limited scope, in the Transplantation Act, having regard to the nature and essence of carrying out transplantation surgery of cells, tissues and organs.

2. The extent of information concerning implantation surgery involving cells, tissues or an organ to be passed to the recipient of the graft

Informing the patient is a statutory obligation. Pursuant to Art.34 read with Art.31 section 1 of the Medical Profession Act [2] and corresponding as for the content with Art. 18 section 2 read with Art. 9 section 2 of the Act on Patient's Rights [3], medical intervention may only be performed after obtaining the patient's consent, prior to which the doctor is obliged to provide him or her with information regarding their state of health, diagnosis, suggested and possible diagnostic or medical methods, foreseeable consequences of their application or desistance, the effects of the treatment and prognosis. Moreover, subject to Art. 13 section 1 par. 9 of Transplantation Act [1], the doctor is obliged to inform the recipient of the graft about the risk involved in the procedure of removing cells, tissues or an organ as well as possible consequences of such removal for the donor's health.

Irrespective of the fact that the legal regulation seems quite explicit, it is a complex issue to define the necessary extent of information to be passed in order to allow for an assumption that the recipient's consent given on such basis is fully informed. While analyzing the issue a number of concerns may arise. Particularly, it should be noticed that "the extent of information passed to the sick person might vary depending on their intellectual abilities, frame of mind and sensitivity but also on the kind of medical intervention, its urgency and necessity [4].

The patient, among other persons also the prospective recipient of the graft, must be informed in particular about their state of health, diagnosis, suggested but also alternative methods of treatment that may be applied. Due to the fact that not every method of treatment is in common use in Poland, one may wonder whether the doctor is obliged to take into consideration also the methods of treatment which are not in domestic practice, but may be offered by foreign hospitals. Such methods, even if well-known to the doctor and far more

effective, are not used in Poland for various reasons, mostly due to the lack of specialized equipment or shortage of financial resources. The above may refer to medicaments, which are only available abroad and the patient might import them on their own account. Reflecting on this issue, with particular regard to the nature and consequences of transplantation surgery, one may conclude that the patient should enjoy the right to exhaustive information concerning all methods of treatment available worldwide so as they could consciously make a well-informed decision. One cannot exclude the possibility that the patient has the opportunity to obtain medical help abroad. The patient's right to free choice cannot be limited. It should be unconditionally up to the patient what decision will be made. So that the decision could be wellinformed, the patient must be exhaustively informed by the doctor, both in respect to any possible methods of treatment which can be applied in this case, but also about all the consequences that may result from each method, including the extent and scope of potential complications. The patient must be able to consciously participate in the choice of the optimal method in their case. As it is emphasized in judicial decisions, if the doctor mentioned here above fails to comply with the obligation to inform the patient, then Art. 31 of Medical Profession Act [2] is in breach. Such failure also deprives the patient of their right of choice and participation in decision-making process in respect to the way of treatment. Thus, "standard consent" for a medical intervention to be carried out by use of one of available methods cannot be considered as "informed consent" [5]. This approach deserves approval. After all, it is vitally important that the patient, being able to take advantage of a several alternative ways of treatment, should choose the one which is the most beneficial for him or her and involves the least possible inconvenience. It seems proper to emphasize that every human being is unique and the same method of treatment, even if in principle from medical point of view appears the most advantageous, for many reasons may not be the best choice in case of a particular patient. It is the patient that should decide whether to choose this method because this decision could affect the whole life of the patient. Obviously, the doctor must assist the patient in the decision-making process. The above refers also, or even mainly, to a patient whose life or health can be saved, among other methods, by transplantation of cells, tissues or an organ.

What is more, pursuant to Art.31 section 1 of the Medical Profession Act [2], a doctor should inform the patient about foreseeable consequences of applying a specific method of treatment. This information is of great importance for the person who is about to make a decision whether to undergo transplantation surgery. Having regard to the

specific nature of transplantation, the prospective recipient of the graft ought to be aware of the consequences of the implantation surgery itself as well as be informed about further treatment which is one of the inevitable consequences of implantation surgery. The treatment is not over at the moment of performing the transplantation surgery, but requires further procedures, i.e. taking certain medicaments. Hence, there may appear a query what can be understood by the term "foreseeable consequences". What kind of consequences of surgical transplantation must be revealed to the prospective recipient of the graft by the doctor? It is not clear whether it concerns all consequences that may be imagined, including the unusual and uncommon ones whose occurrence is not likely, or rather only the typical consequences within the average risk that is inherent to performing the aforesaid medical intervention. This issue is quite controversial and it used to be analyzed in many judicial decisions.

In its decision of 28 September 1999, the Supreme Court awarded that the doctor should inform the patient about all the consequences of the medical intervention, both those which "are normally the result of the intervention, i.e. desirable and compliant with the purpose of treatment, and others which are considered side-effects". In the opinion of the court, information ought to include in particular these consequences which are predictable, especially if such consequences consist in a significant and material detriment to health and which - as side-effects - occur rarely or sporadically but cannot be excluded, and ought to estimate the degree of probability of their occurrence. In such event it can hardly be required that information enumerates all the possible symptoms of the consequences caused by the medical intervention and contains their description. It is sufficient that the patient receives general information about the kind of possible consequences of the surgery, whether they pose a threat to the patient's life and how they may affect correct functioning of the patient's body [6].

In another decision the Supreme Court adjudicated that it cannot be expected that the doctor notify the patient about all complications that may occur, particularly about those which occur exceptionally. The Court clarified that such a warning could result in unnecessary deterioration of the patient's condition and it might lead to unjustified refusal to give consent for the surgery [7]. In the decision of 20 November 1979, likewise, the Supreme Court decided that the doctor should explain the typical consequences of the surgery to the patient, but he or she need not, or even should not for the sake of the patient's well-being and acquaint the patient with atypical consequences, not connected with the standard risk involved in the surgery, which may happen in case

of rare undesirable complications [8]. The said line of judicature has been maintained up to now. The Supreme Court in its decision of 8 July 2010 stressed the fact that one cannot expect from the doctor to warn the patient against all potential complications, especially those which happen extremely rarely and are of incidental nature. A similar position was expressed in other court decisions [9,10,11]. Thus, in judicature there has been consolidated a concept according to which it is admissible, or even advisable, to limit information passed to the patient so as not to exceed the scope of typical and usual consequences of the surgery.

On the other hand, it seems important to point out that adopting the criteria of commonness regarding the results of the medical intervention still leaves a lot to desire and is not precise enough. There might be a number of concerns related to the extent of information to be obtained by the patient. Undoubtedly, it is vital to determine the meaning of 'usual' or 'typical' consequences of surgical implantation of cells, tissues or an organ. As it is stressed by jurisprudence, the criterion of 'being typical' first appeared in German research, according to which this term refers to risks known to medicine but of relatively low frequency. Practically, 'the range of commonness' used to be apprehended as 'rigid average', very often presented by measure of percentage, which does not reflect the facts due to the development of medicine and varied professional skills of the team responsible for the surgery. Therefore, incident rate for an outstanding specialist could equal to 1% but for other doctors – to 5% or more. It has also been noticed that development of technology in medicine results in some changes in risk assessment. The level of risk which may be considered typical becomes modified with time [12]. Having regard to the above, one should admit that the notion of 'being typical' must be assessed on an individual basis in each case. It seems necessary to take into consideration all circumstances, such as in particular the patient's state of health and coexisting diseases that may affect the risk involved in the medical intervention, medical qualifications and experience of the operation team as well as the medical equipment used in the hospital.

Yet one more fact needs to be emphasized, namely – that the patient should be informed about the possibility of adverse consequences of operation which, even though infrequent, are gravely hazardous for the patient's health or pose a threat to his or her life [11]. The above mentioned opinion of the Supreme Court, which can hardly be contested, becomes iustified especially in case transplantation surgeries, where possible complications may often result in serious adverse consequences for the recipient of the graft, including such consequences that put the patient's health or even life at risk. Undeniably, the recipient of cells, tissues or an organ should be aware of the possibility of such complications of the operation.

Moreover, in the judicial decisions another fact is pointed out - there is a difference in the doctor's obligation to inform the patient about possible complications of the planned operation. The situation is incomparable when it comes to an operation aiming at improving health and when the operation is necessary to save the person's life. In the latter case, the doctor must not inform the patient about facts which could adversely affect the patient's frame of mind and thus increase the risk involved in the operation [13]. In the court's assessment, the extent of information to be passed to the patient depends also on the nature of the surgery, i.e. whether in this particular case the indications for the transplantation are absolute - it is a life-saving operation – or the indications are relative [14,15].

According to the Supreme Court, in the event of operation which is absolutely necessary, the doctor should explain to the patient only the purpose and kind of surgery as well as its typical consequences [5,14]. In the court's opinion, for the sake of the patient's well-being and health, the doctor needn't, or even ought not, acquaint him or her with atypical consequences, beyond the normal risk involved in the surgery, which might occur in exceptionally complicated cases. If the operation is necessary to save the patient's life, the doctor ought not inform the patient about complications which sporadically because this could occur only adversely affect the patient's morale and lead to unjustified refusal to give consent for performing the operation or increase the risk involved in the operation [10,13]. In the Supreme Court's view, in case of life-saving medical intervention it does not follow from the obligation to provide the patient with information pursuant to Art. 34 section 2 read with Art. 31 section 1 of the Medical Profession Act [2] that all possible effects of the operation must be enumerated [16]. Such an approach, as it appears, allows for restricting information provided to the patient and, consequently, enabling the doctor to decide about the extent of information, in a way. Therefore, the patient's picture of the facts will not be sufficient and their decision will not be fully informed. It is vitally important in case of the recipient of transplant since quite transplantation is a life-saving intervention. As it was mentioned before, the method of treatment entails considerable risk of which the patient should be aware. While making such an important decision, it seems essential that the patient should be in possession of all information which may enable them to make a proper choice. For the above reasons, one may reasonably assume that the prospective recipient of the graft should have the extensive knowledge of the suggested surgical implantation of cells, tissues or an organ as well as

the subsequent medical procedures. Therefore, information obtained by the patient must be as exhaustive as possible and concerning foreseeable consequences of applying or failing to apply transplantation as a form of medical treatment. The doctor is not obliged to inform the patient about exceptional, unlikely or unexpected consequences of the intervention [17]. Additionally, it seems that the technical issues, complex medical procedures and irrelevant details having no impact on the patient's consent might be ignored. The abundance of useless information is likely to hinder the patient from selecting information that is essential for them. It would be advisable to inform the prospective recipient mainly about life-threatening complications or those of particularly hazardous nature. Importantly, information passed on a standard basis ought to be accompanied by the data which is material for the individual patient. The sick person must be informed about any circumstances that may affect their decision [18]. Obviously, information should be passed in a way that does not have adverse impact on the patient's morale leading to unjustified refusal of consent for the transplantation.

Let us notice that the court's position according to which it is admissible to diversify the extent of information depending on the significance of a particular doctor's action for the patient's life and health (i.e. the kind of indications for performing this action) arouses some objections in According to M. Świderska, doctrine. circumstance that a certain intervention is a lifesaving surgery should not lead to the exclusion of reliable information. As it is argued by the Author, 'this is not sufficiently justified by so called patient's welfare interpreted exclusively from the point of the medical ethics' principle salus aegrotii suprema lex esto' [19]. The court's standpoint was also challenged by P. Daniluk, who claims that 'it is based on paternalist rationale and allows for limitation of information for the sake of peculiarly interpreted welfare of the patient' [20]. In the Author's view, one cannot approve of, as it is a farreaching interpretation, an approach that the practitioner not only is under no obligation but also is not expected to pass exhaustive information to the patient in the event such action could adversely affect the patient's morale and consequently result in their decision not to undergo a life-saving treatment. An approach like this entitles the doctor to unauthorizedly make the extent of information contingent upon the kind and significance of this particular surgery [20]. According to Nesterowicz it cannot be required that the the patient practitioner notify about complications which might occur, especially about the ones happening 'extremely seldom'. The way of instructing the patient upon obtaining their consent for the intervention must depend on the kind of

surgery [21]. Simultaneously, the Author declares that the patient ought to be informed about the consequences of the treatment and the degree of probability that they might occur, in particular if they cause major and substantial health deterioration, regardless of how infrequent or sporadic they might be [22]. In M. Nesterowicz's opinion, which can hardly be challenged, the practitioner must find balance between the patient's right to be informed and the obligation not to cause harm by "excessive information which may rarely become fact" [4]. As far as it concerns the recipient of the graft, M. Nesterowicz unambiguously concludes that such person should be informed by the doctor about the full hazard and all consequences of the surgery, including those more or less probable but nevertheless typical and fairly likely to occur [23].

To sum up the discussion regarding the extent of information about the transplantation treatment in relation to the prospective recipient of the graft, it seems proper to point out that the purpose of passing information to the patient prior to the intervention is to acquaint the sick person with their state of health and consequences of treatment. Therefore, information must contain any data that may enable the patient to make a decision whether or not give their informed consent for the treatment while being fully aware of what they agree to and what may be expected. It is necessary that the patient know what their consent entails and be aware of the risk involved in the medical intervention and its consequences, especially those which may result in grave complications, not excluding life-threatening ones. The principle of the patient's right for the truth is in force and the obligation to comprehensively inform the patient burdens the doctor [10]. The extent of the obligation to inform the patient depends on what a reasonable person in the prospective recipient's position should realize so as to be able to make an informed and prudent decision whether to undergo the suggested treatment [24].

Moreover, in *ex vivo* transplantation, it is the doctor's responsibility to inform the recipient about risk involved in the procedure of recovery of cells, tissues or an organ as well as about possible consequences of the recovery for the donor's state of health. Extending the scope of information with the details specifying the consequences of explantation on the part of the donor is supposed to make the recipient aware of the fact that their decision concerns not only themselves but also causes some implications for another person. The obligation to inform the patient in this regard follows from the nature of transplantation surgery in which both persons participate - the recipient and the donor.

3. The manner of passing information about surgical implantation of cells, tissues or an organ into the recipient's body

In the Transplantation Act [1] there are no legal regulations determining the way of passing information concerning surgical implantation of the graft in regard to the recipient. Therefore, the provisions of the Medical Profession Act [2] and the Act on Patient's Rights [3] shall apply.

Pursuant to Art. 34 section 7 read with Art. 31 section 1 of the Medical Profession Act [2] and Art. 9 section 2 of the Act on Patient's Rights [3], there exists an obligation to pass 'intelligible' information. However, it needs to be stressed that in no legal act does the legislator set out what should be understood by this term. Hence, it is the right thing to reflect on the way of passing information to the prospective recipient of the graft so that it can be described as 'intelligible'. This issue appears vitally important as the failure to provide 'intelligible' information is equivalent to the lack of the patient's informed consent for the treatment [24].

It is stressed in the jurisprudence that information is such that is 'intelligible' comprehensible for the patient [28]. However, as it follows from the practice of the Patients' Rights Ombudsman Office, 'patients often have difficulties understanding the content of the consent which they sign, due to specialist or vague terminology that is used in such documents' [26]. So as to be passed in a comprehensive way, information should be adjusted to intellectual capacity of the specific patient, their ability to comprehend both the facts put forward and words used by the doctor [27]. Then, the extent of information provided to the patient can vary depending on this particular person's needs and abilities [27,29]. At the same time, it must not be overlooked that hermetic professional jargon is not appropriate in this situation since, basing on various terminus technicus might be incomprehensible for the general public' [29]. The practitioner should, as long as it is possible, use simple expressions and avoid so called professional jargon, i.e. medical terms or phrases known to the medical professionals only [30]. One ought to use such words, terms and phrases that the prospective recipient of the graft is able to fathom given their intellectual capacity, age, education as well as concentration level. As it is stressed by M. Świderska, not the professional value of the communication is substantial here but its comprehensibility [25].

One needs to bear in mind that the way of passing information must be adjusted to the specific situation. Information ought to be presented to the prospective recipient of the graft in a straightforward manner, which is to be assessed individually, on the basis of current intellectual

ability of this patient. It seems impossible to conceive a model or standard explanation pattern which, when followed, guarantees that information complies with the requirement of 'intelligibility'. The practitioner should take into account the fact that information that is clear for one person might be absolutely incomprehensible for someone else [30].

The doctor is obliged to inform the patient in a true and fair manner. Any attempt of manipulating the patient is unacceptable [29, 30]. The prospective recipient of the transplant should understand what he or she is giving consent to and what choice is being made.

Although such obligation does not directly follow from legal regulations, it appears proper to pass information about the surgery to the prospective patient in the course of individual conversation. The above does not exclude the possibility of handing over a brochure or leaflet concerning the transplantation as a treatment method, which provides a chance to broaden the patient's knowledge that subsequently might be useful while making the decision as for the treatment method. One needs to emphasize, however, that the said brochure is only an auxiliary means [25]. It may prepare the patient for the conversation with the doctor, but it may not replace such personal communication. In the course of conversation the prospective recipient of cells, tissues or an organ has the chance to ask questions and have their ambiguities clarified.

Information for the prospective recipient of transplant may be passed orally. There is no provision of law that requires written mode. However, one cannot exclude the possibility that there are no questions on the recipient's side. Here, it must be noticed that in the event that the prospective recipient of transplant does not ask the doctor any questions, one cannot treat it as equivalent to their resignation of being informed. The patient has the right to expect that they obtain information sufficient for making the decision whether or not undergo a surgical implementation of cells, tissues or an organ without requesting for it.

CONCLUSIONS

The extent and manner of passing information about the surgical implantation of cells, tissues or an organ into the recipient's body stems from the legal regulations set forth in the following acts: the Act of 1 July 2005 on Recovery, Storage and Transplantation of Cells, Tissues and Organs [1]; the Act of 5 December 1996 concerning the Professions of General Practitioner and Dental Practitioner [2]; the Act of 6 November 2008 on Patient's Rights and on Patients' Ombudsman [3].

The prospective recipient of transplant, in compliance with the law, should be informed about the state of health, diagnosis, suggested and possible diagnostic and treatment methods, foreseeable consequences of their application or failure to apply, treatment results, prognosis, risk involved in surgical removal of cells, tissues or an organ and its possible consequences for the donor's health.

The prospective recipient of the graft should possess extensive knowledge concerning the suggested medical intervention by way of implantation of cells, tissues or an organ as well as data regarding the subsequent medical procedures that follow. Therefore, information obtained by the patient ought to be as exhaustive as possible. That is to say, it must contain any data that would enable the prospective recipient to make a reasonable decision whether to agree to the intervention or not while being fully aware of what they give their consent to and what might be expected.

Information should be presented in a manner that is intelligible and comprehensive for the prospective recipient of transplant, which shall be assessed individually, on the basis of current intellectual abilities of the patient.

Conflicts of interest

None.

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