The Limits of Autonomy of a Young Living Donor in Transplantation

Abstract: The problem of legal regulation of ex vivo graft from a young living donor raises a lot of controversy. According to the Polish Act on the Collection, Preservation and Transplantation of Cells, Tissues and Organs, a minor can be a donor only in exceptional cases – a cumulative number of prerequisites must be met. At the same time, this regulation provides solutions which respect the autonomy of minors. Firstly, the object of transplant from a young living donor involves only cells able to regenerate, that is bone marrow and peripheral blood. Another necessary condition for the legality of transplantation is to determine whether it is legitimate and purposeful. Furthermore, the protection of the interests of a young living donor is reflected in legislation restricting the circle (group) of recipients – minors can only be donors for their siblings. The most important legal safeguard of young donor’s interests seems to be the procedure of obtaining judicial authorization for transplant, which is preceded by the consent of his or her legal representatives. Moreover, in the case of bone marrow transplant, the consent of a minor under 13 years of age is required.

Keywords: autonomy, young living donor, ex vivo transplantation, consent for transplant

1. Introduction

With the origin of liberal democracy, its values have started to affect the relation between a doctor and patient. Paternalistic approach reinforced by the Hippocratic oath, where a doctor was a final medical and moral expert while a patient had to be obedient¹, has gradually been abandoned. The partnership model is based on equality between the parties to medical relation that are capable of deciding about themselves and establishing their own priorities by themselves². Nowadays, it is emphasized that

² P. Łuków, op. cit., p. 100.
everyone is entitled to the right to decide about one’s own health. Individuals must be guaranteed that their autonomy, which is inalienable, shall be respected. Patients may neither waive this right nor effectively transfer the entire responsibility for medical decisions upon a doctor. The principle of autonomy of patient’s will also applies to transplantations involving minors.

The issue of legal regulation of ex vivo transplantation from a young (minor) donor continues to evoke a lot of controversy. Since minors cannot shape their own legal situation themselves, it seems necessary to assure them sufficient protection. It ensues from young men’s sensitivity, their yet undeveloped character, a lack of ability to evaluate a situation properly due to insufficient life experience as well as unawareness of the gravity of being a donor.

A purpose of the article is to establish the limits of autonomy of will of a young living donor within the field of medical transplantations. Taking into account a unique nature of the treatment, we should examine whether, and if yes, to what extent, minors’ autonomy is increasing. At the same time, it seems necessary to consider legal solutions increasing the protection of the rights and interests of young donors.

2. An attempt at defining a minor for the needs of the provisions on transplantation

Pursuant to the solutions contained in the Act of 1 July 2005 on the Collection, Preservation and Transfer of Cells, Tissues and Organs (hereinafter Transplantation Act), a donor of ex vivo transplantation can be an adult holding full capacity to perform legal acts. Under Art. 12 par. 2 of the Act, a minor can be a donor in exceptional cases. Transplantation Act does not define the term of a minor. However, based on a contrario reasoning, under Art. 10 § 1 of the Civil Code, it is assumed that a minor is a person who has not attained 18 years of age. A basic element of the term

3 J. Hartman, op. cit., p. 106.
7 The Act of 1 July 2005 on the Collection, Preservation and Transfer of Cells, Tissues and Organs (consolidated text Journal of Laws of 2015, item 793 as amended) [Ustawa z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszkpecianiu komórek, tkanek i narządów (tekst jedn. Dz.U. z 2015 r. poz. 793 ze zm.).]
8 Tak m.in. K. Mularski, Problematyka..., op. cit., p. 54; R. Kubik, Prawo medyczne, rozdział XIV Warunki prawne przeszczepiania komórek, tkanek i narządów, Warszawa 2014, pow. za wersją
of a minor is his or her lack of full capacity to perform legal acts, which results in the inability to shape their legal situation. This generates serious consequences within the scope of consent for the provision of a medical service. Doctrine representatives point out to doubts emerging under Transplantation Act in relation to individuals who became adults according to the principles specified in Art. 10 § 2 of the Civil Code, that is in effect of marriage. Following literal interpretation, such individuals should be treated as minors. It is assumed, however, that systemic interpretation should be applied here including the provisions of the Civil Code and Family and Guardianship Code. In consequence, such individuals are recognized as adults for the needs of Transplantation Act.

Ex vivo transplantation from a young (minor) donor is admissible only if numerous prerequisites are cumulatively satisfied. Medical, subjective and legal conditions contained in Art. 12 par. 2-5 of Transplantation Act underline an exceptional nature of this method of treatment.

3. Medical conditions of admissibility of transplantation from a young (minor) donor

Pursuant to Art. 12 par. 2 of Transplantation Act, the object of transplantation from a young living donor involves only cells able to regenerate, that is bone marrow and haematopoietic cells of peripheral blood. In the light of statutory provisions, there is an absolute ban on collecting material other than the one enlisted in the Act. Within the context, it should be depicted that Transplantation Act of 1995 allowed to retrieve (collect) solely bone marrow from a minor donor. Thus, the present Act extends the subject catalogue of biological material. Moreover, there are de lege ferenda postulates to extend the catalogue to cover other cells and tissue able to regenerate.

An indispensable prerequisite of the legality of transplantation is the establishment whether the treatment is justified and purposeful (Art. 12 par. 1 point 3 of Transplantation Act), as it should be remembered that from a donor’s perspective,
transplantation is a serious mutilation, which may even threaten his or her life. Hence, such treatment must be reasonably and seriously justified by medical conditions15.

3.1 Legitimacy of transplant surgery

Transplantation legitimacy is understood as a situation when transplantation will not cause inevitable and morally and legally unacceptable detriment (harm) to donor's health while concurrently contributing to saving the recipient's life or health. Transplantation will be solely justified if it does not cause any foreseeable impairment of the donor's organism while, at the same time, there is no other possibility of saving recipient's life since endeavours to save the recipient may not violate the protected interest of a donor. Therefore, the inclusion of proportionality of benefits for a recipient and risk for a donor becomes one of the most important tasks of a doctor deciding about the surgery16.

Doctrine representatives underline the necessity of occurrence of a direct threat of the recipient's loss of life which may only be saved through transplantation17. An immediate danger to human health is defined as the last stage between a threat of a specific interest and its violation. The Supreme Court's case law depicts that an immediate danger should be understood as "an immediate threat of a specific interest, i.e. to an extent that in case of any delay in launching a rescue operation, it may turn out to be irrelevant; or otherwise, when a violation of interest does not have to be effected immediately but its nature is inevitable while refraining from a rescue operation might increase the scope of imminent harm, or hamper its prevention"18. It should be noticed that the causes of a threat do not appear suddenly and rapidly but act inevitably, and without medical intervention they may lead to death19. In consequence, it seems that a doctor must assess whether the material must be collected in a given moment immediately and determine how a delayed surgery will affect changes in the recipient's health condition20.

3.2 Purposefulness of transplant surgery

The second medical condition of transplantation - a prerequisite of purposefulness - indicates that a purpose of transplantation must be saving an immediately (directly) threatened life of a recipient. The improvement of health condition or life comfort is not sufficient in this case21. Doctrine representatives emphasize a subsidiary nature of transplant surgeries performed with the

15 R. Kubiak, Prawo..., op. cit.
16 K.M. Znoń, Dopuszczalność..., op. cit.
17 Ibidem; also: J. Duda, op. cit., p. 136.
20 Also claims so: K.M. Znoń, Dopuszczalność..., op. cit.; R. Kubiak, Prawo..., op. cit.
21 K. Mularski, Problematyka..., op. cit.
participation of minors. Such interventions are admissible solely if there are no other equally efficient methods while transplantation is the only rescue (last resort) for a recipient\textsuperscript{22}. Such a surgery is not justified if the recipient's health or life is not immediately threatened and the surgery may be performed later as it happens that a delay may be sufficient for obtaining \textit{ex mortuo} material, which eliminates the necessity of collecting it from a living donor\textsuperscript{23}. In consequence thereof, transplantation will not be admissible if there are other methods of saving a recipient, or possibly improving his or her health condition without the necessity to carry out \textit{ex vivo} transplant\textsuperscript{24}. It should be noticed that such a solution has been introduced directly to the so-called European Oviedo Bioethical Convention, signed by Poland but still not ratified\textsuperscript{25}. Pursuant to Art. 19 par. 1 thereof, removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness\textsuperscript{26}.

If \textit{ex vivo} transplantation is the only therapeutic method, it is necessary to carry out an appropriate evaluation of the balance of gains and losses, positive results for the recipient in relation to negative consequences for the donor and probability of their occurrence\textsuperscript{27}. The subject literature underlines that in the situation when "profit is insignificant (e.g. slight alleviation of pain, or short-term prolongation of life) while a donor is seriously mutilated and thus his or her life is potentially shortened, the surgery may appear inadmissible. Hence a doctor should consider the potential chances of transplant acceptance and whether, due to the recipient's condition, forecast for the entire undertaking is positive"\textsuperscript{28}. Additionally, it should be emphasized that transplantation will not be admissible with regard to single organs that do not regenerate and possibly pairs of organs that do not regenerate (e.g. both kidneys) since such a surgery finishes with either donor's death or serious detriment to his her health\textsuperscript{29}.

In the light of the above opinions, it should be acknowledged that transplantation will be justified and purposeful when the surgery is "the only way of achieving highly

\textsuperscript{22} K.M. Zoń, Dopuszczalność..., \textit{op. cit.}; M. Guzik-Makruk, Transplantacja organów, tkanki i komórek w ujęciu prawnym i kryminologicznym, Białystok 2008, p. 301.


\textsuperscript{24} R. Kubiak, Prawo..., \textit{op. cit.; Also claims so: M. Sośniasz, \textit{op. cit.}, p. 221. In contrast, according to some representatives of the doctrine, ex mortuo and ex vivo transplantation is of equal nature – see: M. Guzik-Makruk, \textit{op. cit.}, p. 302.}

\textsuperscript{25} The convention for the Protection of Human Rights and Dignity adopted on the 4 of April 1997 in Oviedo (CETS No. 164).

\textsuperscript{26} R. Kubiak, Prawo..., \textit{op. cit.; J. Duda, Cywilnoprawna..., \textit{op. cit.}, p. 137.}

\textsuperscript{27} \textit{Ibidem.}

\textsuperscript{28} J. Duda, Cywilnoprawna..., \textit{op. cit.}, p. 155.

\textsuperscript{29} R. Kubiak, Prawo..., \textit{op. cit.}
probable beneficial results for the recipient’s health, on the one hand, while providing a low risk of negative consequences for the donor’s health, on the other hand”30.

4. Subject restriction of the circle of recipients

Enhanced protection of young living donors’ interests is also manifested in the regulation restricting a circle (group) of recipients. Pursuant to Art. 12 par. 2 of Transplantation Act, “(...) a donor for their siblings may also be minor”. It should be emphasized that from a medical perspective, transplantations are the most effective if a recipient and donor are closely related31. A circle (group) of recipients has been restricted in order to assure compliance of the Polish Transplantation Act with the so called European Oviedo Bioethical Convention. It is worth noticing that Art. 9 of the previously binding Transplantation Act of 199532 admitted transplantations for a much wider circle of entities, including ascendants and descendants33. Moreover, other legislations (e.g. Swiss) envisage that also parents and children may be potential recipients of a minor donor34.

Furthermore, the literature presents opinions admitting transplantation for the benefit of adopted siblings as well35. What is more, it is depicted that not related persons (family members), e.g. spouses, friends, or even strangers who want to help others, should not be refused donation of their material36. At the same time, Transplantation Act does not specify a minimum age of a transplant recipient37.

Exclusion of minor’s ascendants from the circle of recipients seems right due to a risk of potential abuses. Such a catalogue of recipients does not allow parents to use the child’s health in order to improve or save their health or life. Thus, legal protection of a minor donor has been emphasized38. On the other hand, current regulation seems to be too restrictive in relation to the minor’s descendants because the minor’s parents may not be donors for their own child. In specific and infrequent situations, waiting for transplantation until a minor mother turns 18 years of age may lead to serious and life-threatening consequences for the child’s life39.

30 Ibidem.
31 Ibidem.
32 The Act of 26 October 1995 on the Collection and Transfer of Cells, Tissues and Organs (consolidated text Journal of Laws No. 138, item 682) [Ustawa z dnia 26 października 1995 r. o pobieraniu i przeszczepianiu komórek, tkanki i narządów (Dz.U.Nr 138 poz. 682)].
33 K. Mularski, Problematyka..., op. cit., p. 57.
34 K.M. Zoń, Dopuszczalność..., op. cit.
35 Tak m.in. J. Haberko, Ustawa..., op. cit., p. 132.
36 See: R. Kubiak, op. cit. and the literature given there.
37 J. Haberko, Ustawa..., op. cit., p. 132.
38 N. Kraszkiewicz, Małoletni..., op. cit.
39 K. Mularski, Problematyka..., op. cit. p. 59; compare also: J. Haberko, Ustawa..., op. cit., p. 133.
5. Legal criteria of transplant surgeries

The minor donor’s interest is secured by the entities taking part in the transplantation procedure, i.e. the court relying on the expert psychologist opinion, minor’s statutory representatives, and the minor himself or herself after they attained 13 years of age⁴⁰.

5.1 Court’s authorization to collect material from a minor donor

Art. 12 par. 4 and 5 of Transplantation Act regulates the procedure of obtaining a court permission to collect material from a minor donor. The proceedings are initiated upon the request of potential donor’s statutory representatives; both parents holding parental authority must submit the request amicably. On the other hand, if a donor is over 16 years old, his or her request (application) is additionally required⁴¹. Issuing a permission, the court should hear the opinion of the interested party himself or herself with due diligence. Prior to this, he or she should be provided with all and any necessary information conditioning informed consent⁴². Transplantation Act does not specify a minimum age at which a minor donor should be heard; therefore, the expert psychologist opinion is helpful therein. Its purpose is to determine whether a child could make a decision according to his or her will, and whether it will be reliable⁴³. At the same time, it should be noticed that such hearing is of an exclusively informative nature because the legislator has not regulated the effects resulting from a potential objection expressed by a minor⁴⁴. What is more, the Act has failed to include directives for the court too, pursuant to which a minor’s objection is an obstacle to grant permission⁴⁵. The literature postulates that the objection expressed by a minor should prevent the court from issuing permission. Such interpretation apparently secures the child’s interest. One should approve of the opinion according to which it is necessary to resign from the material collection if a minor capable of sufficient understanding of the situation has objected to it⁴⁶. This opinion is grounded in the provision of Art. 20 of the so-called European Oviedo Convention, in the light of which, one of the conditions of admissible explanation

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⁴⁰ K. Mularski, Problematyka..., op. cit., p. 59.
⁴¹ R. Kubiak, Cywilnoprawna..., op. cit.
⁴² Ibidem.
⁴³ K.M. Zoiń, Dopuszczalność..., op. cit.
⁴⁴ Ibidem.
is no objection raised by a potential donor\textsuperscript{47}. The application of such a solution guarantees full protection of the minor’s rights.

Furthermore, it should be emphasized that following the procedure of granting permission, the court must consider medical reasons; in particular verify whether a transplant surgery will not result in serious consequences for the donor’s health. In order to examine the case reliably and expel any doubts, the court should ask for additional information coming from, e.g., the minor’s medical records, opinions of medical entities he or she was treated in, or the opinion of a statutory representative. A request (application) for the initiation of the proceedings should contain a medical opinion acknowledging that the collection of bone marrow will not cause a foreseeable impairment of the minor’s organism\textsuperscript{48}. The doctrine representatives postulate that this requirement should not be limited to bone marrow but it should also include haematopoietic cells\textsuperscript{49}.

The above-mentioned legislative solution has been positively evaluated by the doctrine. Being an additional condition of admissibility of a transplant surgery, court permissions limit cases of potential abuses by parents willing to use the material coming from one child to save another one. The court issuing permission safeguards parents’ undue emotions\textsuperscript{50}.

\section*{5.2 Authorization by the minor’s statutory representatives}

Another prerequisite of collecting material from an \textit{ex vivo} minor donor is obtaining consent of his or her statutory representatives. Since the legislator has not envisaged formal requirements within this scope, under Art. 60 of the Civil Code, consent of a statutory representative may be given by/through any conduct implying his or her will\textsuperscript{51}. The Supreme Court’s judgments acknowledge that a failure to make a written statement by a patient giving consent to the surgery does not invalidate the consent while the effects of a failure to follow the required form are specified in Art. 74 of the Civil Code\textsuperscript{52}. Taking the above into account, the doctrine representatives argue that the very submission of a request for the court permission for transplantation may be recognized as implied consent for the surgery\textsuperscript{53}.

\section*{5.3 Minor donor’s consent and prerequisites of its efficiency}

Apart from the requirement of obtaining consent of a minor’s statutory representative and the court, another prerequisite of collecting bone marrow from

\begin{footnotes}
\item[^47] Zwraca na to uwagę m.in. R Kubiak, Prawo..., \textit{op. cit.}.
\item[^48] R. Kubiak, Prawo..., \textit{op. cit.}; K. Mularski, Problematyka..., \textit{op. cit.}, p. 62.
\item[^51] K. Mularski, Problematyka..., \textit{op. cit.}, p. 63.
\item[^52] The judgment of the Supreme Court of 11 April 2006, I CSK 191/05, OSNC 2007, No. 1, item 18.
\item[^53] K. Mularski, Problematyka..., \textit{op. cit.}, p. 62.
\end{footnotes}
a minor is also consent of the minor donor himself or herself. This specific medical intervention is subject to distinct principles regulating the provision of consent to medical treatment\textsuperscript{54}, which differ from the requirements envisaged by the Act on the Profession of a Physician and Dentist\textsuperscript{55}. It results from the fact that transplantation from a young living donor does not satisfy a therapeutic purpose benefiting him or her while implying a detrimental effect for his or her organism. As far as \textit{ex vivo} transplantation from a minor donor is concerned, a special form of consent shall be required. In the light of Art. 12 par. 2 sentence 2 of Transplantation Act, attaining 13 years of age by a minor donor means that they themselves become subjects that are additionally entitled to give consent thereto. Compared to general principles resulting from the Act on the Profession of a Physician and Dentist, the above quoted provision lowers the age limit authorizing a minor to give parallel consent. One should approve of the opinion according to which this solution considerably increases the scope of autonomy of will of a young living donor compared to patients subject to common medical services\textsuperscript{56}. Yet, it should be emphasized that consent of a minor who attained 13 years of age concerns solely bone marrow collection. The Act does not introduce the need to obtain his or her consent when they donate peripheral haematopoietic blood. The doctrine representatives have criticized this solution\textsuperscript{57}.

Prerequisites of efficiency of a minor's consent have not been precisely specified in the Act. Nevertheless, they are determined for donors holding full capacity to perform legal acts (Art. 12 par. 1 point 5 and 7 of Transplantation Act).

Consent for the collection of material for transplantation will be efficient when, prior to it, a potential donor has been precisely informed in a written form by a doctor performing the surgery and a doctor not participating directly in transplantation about a type of the surgery, risk involved and foreseeable consequences for the donor's health in the future\textsuperscript{58}. Entities authorized to obtain such information are all individuals due to give consent including minors who attained 13 years of age. The provision of Art. 31 par. 1 of the Act on the Profession of a Physician and Dentist determines a minimum scope of such information and enlists other Acts referring to special surgeries supplementing it by subsequent elements\textsuperscript{59}. As depicted by the doctrine, "a characteristic feature of the consent for \textit{ex vivo} transplantation is


\textsuperscript{55} Act of 5 December 1996 on the Profession of a Physician and Dentist (Journal of Laws of 2005, No. 226, item 1943 as amended) [Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty (Dz.U. z 2005 r., Nr 226, poz. 1943 ze zm.)].

\textsuperscript{56} K.M. Ząb, Dopuszczalność..., 

\textsuperscript{57} J. Duda, Cywilnoprawna..., op. cit., p. 138.

\textsuperscript{58} K. Mularski, Problematyka..., \textit{op. cit.}; J. Duda, Cywilnoprawna... \textit{op. cit.}, p. 144.

\textsuperscript{59} K.M. Ząb, Dopuszczalność..., \textit{op. cit.}
increased obligation of information manifested in two levels\textsuperscript{60}. On the one hand, the scope of information being conveyed is increasing since a doctor must inform a patient about the essence, purpose, importance and technical elements of the surgery as well as the ensuing risk embracing data concerning medical intervention itself and the likelihood of possible complications and problems. Additionally, a donor should be aware of foreseeable temporary and potential consequences for his or her health in the future\textsuperscript{61}.

The above information must be conveyed by two entities: a doctor performing transplantation and a doctor not taking part in the surgery\textsuperscript{62}. The doctrine believes that “a double manner of satisfying the obligation of information is to objectivize and increase a number of sources of information”\textsuperscript{63}.

Consent for transplant surgery should be given freely and in writing before a doctor\textsuperscript{64}. This regulation results directly from Art. 12, par. 1, point 7 of Transplantation Act. The doctrine representatives claim that consent may not be replaced by a lack of objection. However, the form of consent is reserved solely for the purpose of keeping evidence; therefore, a failure to follow it does not invalidate the relevant statement\textsuperscript{65}. What is more, it is assumed de lege lata that the very submission of a request for the court permission to collect material by a minor who attained 16 years of age is not equivalent to his or her consent for the surgery\textsuperscript{66}. In principle, the consent should also specify a recipient\textsuperscript{67}. The requirement of specifying a recipient of transplantation does not regard the collection of bone marrow or other self-regenerating cells and tissues. The above requirements are to guarantee that a donor has been fully aware of his or her decision\textsuperscript{68}.

Furthermore, it is worth indicating that Transplantation Act has regulated uniquely a possibility of withdrawing consent. First of all, for obvious reasons, this right must be exercised before the surgery. What is more, Art. 12 par. 1 point 8 introduced the obligation to inform a donor about the consequences for the recipient’s life and health since a withdrawal of consent may evoke serious effects for the recipient being prepared for the surgery, both physical – \textit{inter alia} connected with taking medicine to lower immunity – and psychological\textsuperscript{69}.

\textsuperscript{60} \textit{Ibidem.}
\textsuperscript{61} J. Duda, Cywilnoprawna..., \textit{op. cit.}, p. 149.
\textsuperscript{62} K.M. Zoń, Dopuszczalność..., \textit{op. cit.: J. Duda, Cywilnoprawna..., op. cit.}, p. 149.
\textsuperscript{63} K.M. Zoń, Dopuszczalność..., \textit{op. cit.}
\textsuperscript{64} K. Mularski, Problematyka..., \textit{op. cit.}
\textsuperscript{65} K.M. Zoń, Dopuszczalność..., \textit{op. cit.}
\textsuperscript{66} J. Haberko, \textit{op. cit.}, p. 139.
\textsuperscript{67} K. Mularski, Problematyka..., \textit{op. cit.}
\textsuperscript{68} \textit{Ibidem.}
\textsuperscript{69} K.M. Zoń, Dopuszczalność..., \textit{op. cit.}
6. Conclusion

Conditions of performing a transplant surgery in relation to a young living donor are restrictively formulated and they admit the application of this medical intervention only to a narrow extent. Pursuant to Art. 12 par. 2 of Transplantation Act, a minor may be a donor of bone marrow or peripheral blood haematopoietic cells only if the recipient's life – minor donor's siblings – is directly threatened, and when such a threat could not be avoided in any other way but through transplantation. Material is collected from a minor as an exception, after cumulative satisfaction of numerous prerequisites70.

Minor's protection is further enhanced by the circle of entities whose parallel consent is required prior to this unique medical intervention. Material may be collected from a minor donor after obtaining consent of his or her statutory representative and permission of a guardian court competent with regard to the donor's residential address. If a minor attained 13 years of age, he or she is also entitled to give consent to the surgery. The introduction of such regulation manifests fuller respect for the autonomy of minor individuals71. It is also expressed in a possibility of raising effective objection regardless of the minors' statutory representative72.

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70 Ibidem.
71 See: K.M. Zois, Dopuszczalność, op. cit.
72 N. Kraszkiewicz, Małoletni..., op. cit.
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