

Ethical and legal issues in haematopoietic stem cells (HSC) donation: the controversial and problematic aspects in minors

Paola Delbon¹, Federica Attico², Matteo De Nadai², Camillo Almicci³, Emilio Ferrari³, Michele Malagola⁴, Adelaide Conti¹

¹Department of Medical and Surgical Specialties, Radiological Sciences and Public Health, Forensic Medicine Unit, Centre of Bioethics Research, University of Brescia, Brescia, Italy; ²Department of Medical and Surgical Specialties, Radiological Sciences and Public Health, Forensic Medicine Unit, University of Brescia, Brescia, Italy; ³Department of Transfusion Medicine, ASST Spedali Civili di Brescia, Brescia, Italy; ⁴BMT Unit, Department of Clinical & Experimental Sciences, University of Brescia, ASST Spedali Civili di Brescia, Brescia, Italy

Abstract. Starting from the case of a male adult patient suffering from Acute Myeloid Leukaemia for whom no HLA-compatible non-family donors were found, and for whom his adolescent daughter was then proposed as a donor, this article deals with the delicate issue of the minor's consent, especially when the minor's legal representative is in conflict of interest. In the case presented above as an example, this conflict arose when the parent was simultaneously the legal representative of the donor and the transplant recipient. The Authors report ethical and legal issues in the collection of haematopoietic stem cells from minors for the purpose of family donation and analyse the guidelines from some overseas scientific societies, the conventions drawn up within international organisations and the Italian legal system. Such a donation raises complex questions, with regard to the admissibility of the procedure, the ownership of the decision-making power and the criteria of the decision-making process: this process must take place in a context that guarantees the protection of the potential donor and his or her autonomy.

Key words: adolescents, informed consent, parental consent, conflict of interest, haematopoietic stem cells donation

Introduction

Haematopoietic stem cell transplantation (HSCT) is used to treat various conditions; this procedure raises complex ethical questions.

Italy, the collection of haematopoietic stem cells from minors for the purpose of family donation is allowed, subject to the acquisition of the consent of those exercising parental responsibility (or of a guardian or a judge supervising guardianship), as well as of a donation suitability assessment with an evaluation of the risks specifically related to the procedure (1-3).

Such a donation raises complex ethical questions, with regard to the admissibility of the procedure, the

ownership of the decision-making power and the criteria for the decision-making process, in a peculiar context in which careful reflection and consideration cannot fail to deal with the specific nature of the case.

The possible incompatibility between the provisions for the admissibility of the collection of haematopoietic stem cells from minors contained in the laws regulating transfusion activities (1-2) and the provision on the age of majority requirement for bone marrow donations contained in the laws relating to the Italian National Registry of Bone Marrow Donors (4) has been superseded by a possible harmonisation of the provisions in question in view of the purpose of Law 52/2001, "which, with the establishment of

the national registry of bone marrow donors, intends to stimulate the search for non-consanguineous donors” (5) or “to encourage the willingness to donate in incertam personam, not linked, therefore, to the concrete need for a blood relative or, in any case, a person known to the donor, but identified on the basis of health criteria of suitability or compatibility” (6), thus providing that in cases of consanguinity the collection of stem cells remains admissible even in the case of minors. In fact, Decree No. 69 of 2 November 2015, containing provisions relating to quality and safety requirements for blood and blood components, specifies that “the donor of haematopoietic stem cells must sign an informed consent to donation before each donation. In the case of a consanguineous donor under the age of 18, consent must be obtained in accordance with the regulations in force concerning the consent of a minor”. (Annex XI).

Starting from the case of a male adult patient suffering from acute myeloid leukaemia for whom no HLA-compatible non-family donors were found, and for whom his adolescent daughter was then proposed as a donor, this article deals with the delicate issue of the minor’s consent, especially when the minor’s legal representative is in conflict of interest.

Case report

A 62-year-old man was diagnosed with high-risk Acute Myeloid Leukaemia due to the presence of a t-translocation (11;19). With no potential family donors available, the search for a Matched Unrelated Donor (MUD) was activated. The patient underwent induction with ICE (idarubicin, Ara-C and etoposide), following which a complete cytogenetic remission was achieved. In addition, various post-induction complications occurred, notably grade IV mucositis, gouty arthritis, fever of unknown origin (FUO) and enterorrhagia. Subsequently, the patient underwent three runs of consolidation therapy with high-dose Ara-C. After the third run, *E. coli* extended-spectrum beta-lactamase (ESBL)+ sepsis and biliary colic with an obstructing microcalculus occurred as complications. After about three months of searching for a non-family donor, no HLA-compatible donors were found,

so relatives were considered. The patient had no siblings, but he did have three daughters. One daughter, who was 32 years old had a positive history of epilepsy. His other daughter was 27 years old and weighed just 40 kg whilst his third daughter, 17.11 years old, with the methylenetetrahydrofolate reductase (MTHFR) mutation, was considered a potential donor after adulthood (18 years, according to the Italian legislation).

Discussion

The American Academy of Pediatrics’ Committee on Bioethics (7) has identified five specific conditions that must be met in order for the donation of haematopoietic stem cells from minors to be considered permissible: “1) there is no medically equivalent histocompatible adult relative who is willing and able to donate; 2) there is a strong personally and emotionally positive relationship between the donor and recipient; 3) there is some likelihood that the recipient will benefit from transplantation; 4) the clinical, emotional and psychosocial risks to the donor are minimized and are reasonable in relation to the benefits expected to accrue to the donor and to the recipient; and 5) parental permission and, where appropriate, child assent have been obtained”.

For the purposes of admissibility of haematopoietic stem cell donation from minors in a family environment, it would be of essential importance to consider the implications of such a gesture from the perspective of the potential donor. That is to say, a complex assessment of the risks and benefits for the potential donor, from a clinical and psycho-social point of view, must be made, whilst, at the same time the peculiarities of the context of the donation must be considered, as the ethical principles of beneficence and non-maleficence are applied. Some authors have pointed out that “It is tempting but erroneous to balance the benefits for the sick sibling rather than those for the donor against the medical risks of transplantation for the donor” and that “the benefits must be so substantial for the donor that it relates to the survival of the sick sibling with a view to justifying the risk of transplantation” (8).

When assessing the admissibility of the stem cell donation from a minor child family member, clearly it

would be essential to take into overall account to what extent the survival of the recipient could be ensured or how great the risk of serious complications due to his or her health condition would be, not to mention whether or not an adult donor could be found, i.e., the absence of alternatives. From a clinical point of view, though the donation of haematopoietic stem cells does not normally bring any direct benefit for the donor, it can bring positive effects on a psycho-social level. Nevertheless, the procedure would entail significant risks and negative effects from a clinical and psychological point of view.

The American Academy of Pediatrics' Committee on Bioethics (7) has emphasised the importance of making a comparative assessment of the situation of a donor sibling versus a non-donor sibling from the point of view of the possible psycho-social risks and benefits of the stem cell donation. In this regard, some (9) have pointed out that, whilst on the one hand, no donation is without risks (e.g., "Psychological sequelae for the donor - such as fear and post-traumatic stress - are possible and, therefore, pose an additional risk of harm"), on the other hand there may very well be benefits for the donor (e.g., in the case of a donation between sisters, which would also be "giving the sibling an opportunity to grow with her sister and deepen their sibling bond" and by bringing the donor a sense of personal satisfaction). In contrast, non-donation may in turn present certain risks ("for example, a sibling in need of an organ might be unlikely to receive a transplant otherwise. A child's refusal to donate might, therefore, reasonably mean imminent death of the sibling in need. Besides being a source of guilt and remorse, refusing to be a living donor for a sibling in need could undermine stability and support provided by parents").

Hence, another central aspect that should also be taken into account when pondering the subject relates to the principles and criteria to be used in the decision-making process. This clearly concerns application of the benchmark of the donor's "best interest" as a guiding criterion in the decision-making process ("The procedures need not be risk free but parents should only consent to tissue harvest if the possible benefits for the donor outweigh the potential harm") (8), which is particularly complex, precisely in relation

to the peculiar context of tissue donation - "donor children are part of a family in which members have intersecting and interdependent needs and interests" (10). This is especially applicable to the case of donation between siblings, and to the peculiar position of the parents with decision-making authority. Precisely, "as donors are children, and because donation is non-therapeutic and occurring within a family, serious questions arise regarding the degree to which donors can consent, or assent, to donation, and parents' capacity to make decisions in the interests of both their sick and donor children. The ethical problem is that while parents are expected to make decisions that are in their child's best interests and not determined (solely) by others' interests (whether siblings, parents or the family unit), this simply may not be possible in the context of sibling donation" (10).

Some authors (11), questioning the principles and criteria that can guide the discussion on the admissibility of donation from minors, have pointed out the limits and critical issues that have arisen in the application of the best-interest principle, claiming that in order to "to justify organ donation it must be demonstrated that the organ donation is in the best interest of the donor", (i.e., the complexity of the substantial evaluation of the minor's best interest, also from a psychological standpoint, the too often neglected relevance of the value of the intimate relationship between donor and recipient, the attention given only to the benefits related to the donor's self-regarding interests) and the "intrafamilial principle", according to which "organ donation is ethically permissible if it satisfies two necessary conditions: 1) that the parents of the child donor have considered all the relevant benefits and risks of the donation and have consented to it, and 2) that the recipient of the donated organ is a family member of the donor" (for example, disagreement between the parents, the purely biological dimension of the relationship, the absence of an affective component, and the morally problematic conception of the family). The same authors (11) have proposed a further criterion, to be understood as an extension of the best-interest principle, to support parents, healthcare personnel and third parties in assessing the admissibility of donation in complex cases, which is the "intimate attachment principle", according to which it would be

fundamental that there is “an intimate attachment between the child donor and the recipient”. This is to say that the child’s welfare would be connected with the welfare of another person. Within this criterion, which is also not without critical aspects (12), the donation from a minor child to a parent would also find a place: “Children obviously have a strong interest in the continued survival of their parents. Their emotional development, as well as their physical support, clearly are at stake. For this reason [...] child organ donations to their parents could, where medically appropriate, be justified” (11).

On the other hand, when assessing the complexity of the donation to a parent, and in particular in the case of a minor who is unable to give informed consent to the donation, one cannot fail to consider that “for children over the age of assent, the legal right to refuse to meet their moral obligation can be safeguarded by allowing them to dissent. But for children below the age of assent [...], we are in effect setting a moral standard that we do not require of others” (13).

It is, therefore, very clear that the complexity of the decision-making process in situations wherein the exercise of parental decision-making authority and the involvement of the child is undoubtedly peculiar compared to that found in situations in which the treatment subject to the decision-making process entails a direct clinical benefit for the minor child who will undergo it.

Whereas the involvement of the minor and the consideration of his or her opinion are fundamental, even this aspect of the decision-making process is not free from problematic implications in such cases where: “the donor might appear to be willing, but the scenario remains fraught with ethical issues, not the least of which is whether a child can truly assent to an invasive procedure from which he or she might derive no medical benefit” (9).

Moreover, the peculiar position in which the minor child potential donor might find him or herself cannot be overlooked: “minors often find themselves in a position of vulnerability that can easily be exploited”, they “may find it almost impossible to refuse donation to a sibling if they are solicited by their parents” (14).

In Italy, the “Guidelines on the collection, handling and clinical use of haematopoietic stem cells”

(15), after indicating the information that must be offered to the patient or donor, or to the parents or guardian in the case of a minor subject, state that “the minor must be provided, directly and according to the most appropriate means of communication, with all the relevant information on the meaning, purposes, methods and any side effects relating to the procedure to which he or she will be subjected”. Annex XI to Decree No. 69 of 2 November 2015 states that “the donor of haematopoietic stem cells must sign an informed consent to donation before each donation” and that “in the case of a consanguineous donor under the age of 18, consent must be obtained in accordance with the regulations in force concerning the consent of a minor”, whilst nothing is specified in relation to the minor expressing his or her dissent.

Law No. 219 of 22 December 2017, containing rules on informed consent and advance care directives, promotes the autonomy of the minor by stating that, although parental responsibility is vested in those who are entitled to give consent to health treatment in the best interests of the minor, the minor child “shall be entitled to making the most of his or her own understanding and decision-making capacities” and “must receive information on the choices relating to his or her own health in a manner appropriate to his or her capacities in order to be put in a position to express his or her will”. The Law states that “informed consent to the health treatment of a minor shall be given or refused by the persons exercising parental responsibility or by the guardian taking into account the will of the minor person, in relation to his or her age and degree of maturity, and with the aim of protecting the minor’s psychophysical health and life with full respect for his or her dignity”.

The valorisation of the minor’s autonomy, the right to be heard and to be involved are also recognised in the “Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine” (16) of the Council of Europe, which, in Article 6.2 (“Protection of persons not able to consent”), states that “The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity”.

Specifically, Article 14 (“Protection of persons not able to consent to organ or tissue removal”), which is part of the “Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin” (17), identifies specific conditions for the removal of regenerative tissues from a living person not having the capacity to give consent, which is permitted in exceptional cases and under the protective conditions prescribed by law, as an exception to the rule that “No organ or tissue removal may be carried out on a person who does not have the capacity to consent”: 1) “there is no compatible donor available who has the capacity to consent”; 2) “the recipient is a brother or sister of the donor”; 3) “the donation has the potential to be life-saving for the recipient”; 4) “the authorisation of his or her representative or an authority or a person or body provided for by law has been given specifically and in writing and with the approval of the competent body”; and 5) “the potential donor concerned does not object”. Article 15 (“Cell removal from a living donor”) specifies that the 2nd and 3rd conditions might not be applied to cells “insofar as it is established that their removal only implies minimal risk and minimal burden for the donor”.

The Explanatory Report to the Protocol (18) expressly addresses the issue of bone marrow donation between siblings specifying that the exception provided for in the rule is “justified by the fact that regenerative tissue, in particular bone marrow, can only be transplanted between genetically compatible persons, often brothers and sisters” and, in relation to the fifth condition states that “the removal may not be carried out if the potential donor objects in any way. This opposition, in whatever form, is decisive and must always be observed”. The donation process also requires “the agreement of the competent body”: “the intervention of such a body (which might be a court, a professionally qualified body, an ethics committee, etc.) aims to guarantee that the decision to be taken is impartial”. In relation to Article 15, the Explanatory Report specifies that “the purpose of those provisions is to protect the donor from physical risks and from instrumentalisation contrary to their dignity, but where the risks and burdens are minimal it may not be appropriate to prohibit, for example, a minor donating cells to a family member other than a sibling”.

The provision in the Protocol of the child’s power of veto and the authorising intervention of the competent authorities would thus be functional to ensure that “conflicts of interest are excluded and that there is a certain guarantee that the child’s will has been freely and consciously formed” (19).

On the other hand, the involvement of a third party has been advocated in order to provide support to parents in assessing the best interest of the potential donor and at the same time to intervene to assist in understanding the reasons for a possible refusal expressed by the donor. According to the American Academy of Pediatrics’ Committee on Bioethics, “Although the parents’ consent alone may be sufficient, unless state law or institutional policy requires the minor’s active assent, a donor advocate should explore the reasons for the refusal and determine if further education and discussion can modify the minor’s refusal. A child mental health professional and/or an ethics consultant/ ethics committee may also need to be involved to help clarify the child’s concerns” (7). Some have specified in this regard that “a third party like a donor advocate or some similar mechanism is needed to help understand why the child is refusing and whether the refusal is for morally valid reasons”: for example, “a refusal by a young child who fears needles can be overcome by appropriate counselling, play therapy, and, if necessary, the promise of some material reward” (20); on the other hand, in case of siblings with negative relationships, “such as in the case of sexual or repeated physical or emotional abuse, HLA typing should not be performed. Although parents may not be aware of such abuse, a donor advocate should screen for these rare issues” (21). Therefore, it would appear to be of fundamental importance that the underlying reasons for the child’s objection be taken into consideration, also in view of the level of maturity reached by the child: “obviously, the more understanding shown by the child, the more weight should be given to their objection. And, where such objection is consistently expressed, a child’s wishes not to participate ought to be respected” (22).

In some of the most controversial cases - “where legislative conditions cannot be satisfied; where no legislation is present or some uncertainty as to the legality of using a child as a donor in that specific instance

arises; or where disputes between parents or health practitioners regarding a child acting as a donor arise” (22) - it may become necessary to bring the donation question to the attention of the courts.

In Italy, the Court of Perugia ruled on a request by the parents of a 14-year-old boy for permission to withdraw tissue from their son for his mother, who was suffering from a severe cancer (23). In this specific case, in which the parents had already expressed their consent, the judge declared the Court’s lack of jurisdiction to issue the requested authorisation and, with the understandable intention of ensuring protection for the minor’s rights, the judge adopted a solution, which aroused perplexity with respect to established legal theories and practices (24,25), namely, the appointment to the minor of a guardian extraneous to the parties, who would have legitimate authority to express consent to the donation by the minor child donor. This was justified by the consideration that there was a conflict of interest between the position of the parent for whom the transplant was the only possible therapy and the child’s interest in the protection of his or her physical and psychological health. Commenting on the ruling in question, some pointed out the advisability of an intervention by the legislator “who might well expressly provide for the need for personal consent by the minor to a bone marrow donation, at least if over the age of 14” and that “there would be an obligation to respect the dissent to the collection of tissue for transplantation expressed by the possible donor at any age” (24). Moreover, “there should also be the provision for a form of judicial control, requiring the Court to hear the minor personally before allowing the collection of his bone marrow” (24).

On the other hand, the implications and problematic aspects of donation as a minor should be translated into a series of regulatory interventions aimed at improving the donation experience wherever it might take place. A recent study investigating the experience of donation to parents by adolescent and adult donors, identified five key themes, “perception of choice, act of giving back, burdens of donation, anticipated health benefit to parent, and impact of donation on parent/child relationship” (26). Also, some strategies to improve this experience were outlined, such as interventions focused on “increased education about potential

delays in screening”, “better descriptions of possible complications for recipients”, and “provision of emotional support following donation” (26).

Hence, the process of decision-making must take place in a context that guarantees the protection of the potential donor and his or her autonomy: in investigating the problematic issues related to this peculiar donation, some have concluded by stating that “If a minor can clearly enunciate his or her values, wishes for donation, and appears to comprehend the attendant risks and benefits, a rebuttable presumption of competence may be appropriate. Similarly, the satisfaction that a minor feels from donation may be just as valuable as a physical improvement following medical treatment. Finally, the presence of an independent party may occasionally be necessary to protect the interests of the donor child” (27).

In conclusion, our case report offers a brief description of some ethical and legal issues linked to HSC donation by minors. The social role of the minor, as indeed that of the physician, has changed markedly. According to international legislation, minors have the right to be heard and to have their opinion taken into consideration in accordance with their age and their capacity of discernment, even where the legislation does not expressly attribute an obstructive value to any dissent expressed by them.

In view of the scope and implications of such an act, as well as of the choice to not donate, it would be essential to verify the reasons underlying the minor’s reluctance or refusal. At the same time that the assessment of the admissibility of the donation is done, there should also be completed a risk-benefit assessment of the donation and of the non-donation, including the opinion and the wishes of the potential donor, according to a procedure that would guarantee the comprehensive protection of the same donor: “taking into account the particularities of living donation and the fact that minors have important vulnerabilities as compared to adult donor candidates, a high standard of legal protection is required where living donation by minors is considered” (14).

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Correspondence:

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Paola Delbon, PhD

Department of Medical and Surgical Specialties, Radiological Sciences and Public Health

Viale Europa, 11, Brescia, 25123 Italy

E-mail: paola.delbon@unibs.it

ORCID: <https://orcid.org/0000-0002-7697-3840>