Umbilical cord blood collection, storage and use: ethical issues

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Umbilical cord blood and the notion of gift

Cord blood has powerful symbolic connotations. To offer just one striking example, some Indonesian natives preserve it because they consider it the home of the soul, and the place where the soul finds refuge after death.

In addition to this symbolic meaning of cord blood in itself, the topic inextricably involves the symbolic meaning of gift giving. In 1924, Marcel Mauss, a sociologist who provided one of the most significant contributions to the analysis of the meaning of the notion of a "gift", published the book *Essai sur le Don: Forme et Raison de l'Échange dans les Sociétés Archaiques*, in which he analysed in depth the concepts of donating, receiving and returning[1]. His follower Alain Caillé, in *Critique de la Raison Utilitariste*[2] and in *L'Esprit du Don*[3] stated that these free gestures are decisive for the development of societies. Another sociologist, Marcel Hénaff, described three kinds of gifts: ceremonial (which oblige us to give in turn), free (which derive from spontaneous generosity) and of mutual aid (which denotes a social dimension of communities)[4]. In his book *Donner le Temps: la Fausse Monnaie*[5], the philosopher Jacques Derrida presented four points regarding gifts: in order for there to be a gift, reciprocity is necessary; in order for there to be a gift, the recipient cannot give it back, partially accept it, or reimburse the donor; the disappearance of the gift recipient implies the disappearance of the giver; and the gift cannot remain such if its status as freely "given" either vanishes or never appears. A final remark about the significance of the "gift" can be taken from Jean-Luc Marion, who described a gift as omnipotent and disinterested, insofar as it is impossible to prevent: although circumstances may prevent a person from giving, the intention of giving cannot be eliminated[6].

Gift giving is one of the gestures which most distinctly identifies—and ennobles—human beings. An example is meaningful. In some tribes of Papua New Guinea, there was a widespread belief that certain people, once deceased, could be transformed into pallid ghosts and cannibals. Consequently, white-skinned people naturally instilled fear in these tribes because they appeared to be such ghosts. Andrew Strathern, an anthropologist who studied these populations, had a telling experience: in order to determine whether he was a ghost or a man, the natives offered him pig meat. Familiar with the local beliefs and customs, the anthropologist offered them shells in return. Thanks to this exchange of gifts, the natives recognised him as a man and not a ghost.

While taking into account these profound sociological and philosophical thoughts, it is crucial to note that the meanings of giving are not merely symbolic. They also have important practical consequences: the debate regarding donation *versus* self-preservation of cord blood is also a problem of social relations. *The Gift Relationship: From Human Blood to Social Policy*, a provocative book published in 1970 by British social scientist Richard M. Titmuss, is a well-known source for this topic[7]. The all encompassing question of the book is: to what extent can we rely on altruism to provide for the needy? The author argues for the superiority of the voluntary system on two grounds.

First, the voluntary system encourages—while the market system discourages—a sense of social solidarity, altruism, responsibility towards others, and responsiveness to the needs of the others, in and between members of the society who are personally unknown to one another. Second, the voluntary system provides more blood of higher quality: when blood becomes a commodity, the author argues, its quality is corrupted.

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Ethical issues

Taking into account various documents from scientific societies, ethical commissions and similar institutions, several ethical problems related to umbilical cord blood collection and storage can be identified. A non-exhaustive list includes the following: informed consent; ownership; medical indications; claims related to medical benefits; allogeneic use *versus* autologous use; legal frameworks; public banks versus commercial banks; financing systems; access and organisation; quality assurance; traceability; costs; advertising; commercialisation and patenting; personal data protection; relationships between patients, doctors and umbilical cord blood banks; and relationships between recipients and umbilical cord blood banks.

The appendix contains a list of national and international documents addressing the ethical aspects of cord blood banking, which were drafted by national governments, parliaments and authorities; national bioethics committees; national *ad hoc* commissions; national and international agencies, organisations, and societies. Some relevant reviews are listed as well.

Since the 1990s, many countries have established national bioethics committees or commissions. Not many of these national committees or commissions have considered the problem of cord blood storage and utilisation until recently. Those that have are the Committees from: Austria[8], Belgium[9], Cyprus[10], France[11], Greece[12], Ireland[13], and Italy[14]. The opinions from the different Committees are fundamentally unanimous in their evaluations. A significant example is the opinion from the French *Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé*, which was chronologically the first (France was also the first country to establish a National Consultative Ethics Committee on February 23rd, 1983):

"Ethical difficulties arise because the concept of cord blood banks for exclusively autologous use carries with it a number of perils:

1) The gravest danger is for society in so far as setting up such banks is likely to contradict the principle of solidarity, without which no society can survive.
2) Such banks raise hopes of utopia and disguise a mercantile project using assistance to children as a screen.
3) They jeopardize justice and equity. If any reasonable indications existed, then the offer should be systematic, organised, managed, and supervised by public authorities; cost and broadness of scale then enter the picture. The disproportionate, and for the time being useless, cost of generalised autologous storage is in total contradiction with the obligation to provide public health based on solidarity and awareness of priorities.
4) Management by the private sector may be seen as discrimination based on wealth. However, this would hardly be exceptional in the healthcare sector, and those who use these programmes cannot be blamed for their ingenuousness.
5) The futility of autologous banks and their cost would be provocation in the eyes of the very poor, in particular in the Southern hemisphere"[11].

Informed consent

Contemporary bioethics gives particular importance to the principle of autonomy, and informed consent is closely linked to it. Autonomy has been defined as "the quality or state of self-governing". Beauchamp and Childress identified the following as the elements of the process leading to informed consent: (i) threshold elements (preconditions), including *competence* to understand and decide, *voluntariness* in deciding; (ii) information elements, including *disclosure* (of material information), the *recommendation* of a plan and *understanding* of the previous elements; and (iii) consent, including a *decision* in favour of a plan and *authorisation* of the chosen plan[15].

The implementation of the abovementioned three steps of the consent process in the context of umbilical cord blood collection, storage and use is problematic.

A first and fundamental question in dealing with the problem of informed consent for the storage of cord blood is ownership. The issue of who owns cord blood is debated. Some suggest that the cord blood sample is the property of the child on the basis that it is developmentally, biologically and genetically part of the child. Others suggest that it is the mother's property once the cord is cut.

The former position seems more sound: the umbilical cord derives from the allantois and it is, therefore, difficult to deny that it belongs to the baby. In this perspective, most of the controversies about ownership lack consistency. Even if accepting this position regarding ownership helps with the evaluation of several ethical aspects, several problems nonetheless remain.

Despite differences between the various regulations in force, and serious debates among philosophers, jurists, ethicists and scientists about the ontological status of the foetus, a child who is fully outside of the mother's body is recognised as a legal person by all national laws. Nevertheless, such a person is not able to understand and provide consent. The already mentioned principle of autonomy, therefore, becomes problematic: cord blood storage in public biobanks seems to contradict the principle of autonomy, since it could be considered a manipulation of human body parts without the individual's knowledge.

According to the Council on Ethical and Judicial Affairs of the American Medical Association, "a number of ethical considerations surrounding the collection and storage of umbilical cord blood deserve careful attention. The first, and most basic, is the issue of informed consent"[16].

In another document (the current version of the Opinion 2.165), the American Medical Association states: "Informed consent for the collection of umbilical cord blood stem cells should be obtained, when feasible, before the onset of labor. Physicians' ties to public and private cord blood banks must be disclosed during the informed consent process. Physicians shall not accept financial or other inducements for providing samples to cord blood banks"[17].

In an effort to transpose the ethical debate from the speculative level into practice, the main points of the discussion regarding informed consent for cord blood storage and use might be summarised as follows.

First of all, answers to some basic questions are needed in order to outline an ethical framework for consent: (i) Who has the right to give consent? Usually the mother is required to give consent, but, if we accept that the cord blood belongs to the baby, it is necessary to consider that the mother does not consent for herself, but on behalf the baby. Moreover, she shares parental authority with the father. The involvement of the father in the consent process is highly recommendable. (ii) What is the object of the consent? It is necessary to clarify the content of the consent. It is important that it includes not only the collection and storage of the blood, but also its possible uses. (iii) How should consent be obtained? Information is a constitutive part of informed consent. Again, it is not possible to inform the baby (the party directly concerned). The mother should be adequately informed and the consent should be obtained in a convenient form (written, not hurried, etc.). (iv) Who is qualified to accept consent? Various responses might be possible: the nurse, the medical doctor or the hospital administration. (v) When should consent be given? Different answers are again possible: on the occasion of a medical examination during the pregnancy, at the moment of hospitalisation, at the moment of childbirth. Since informed consent requires adequate reflection, a request of consent just before childbirth should be avoided.

Secondly, it is important to be careful of bureaucratisation, which is always a risk in every medical practice and intervention. This risk is augmented by the fact that "the informed consent procedure causes a not insignificant additional administrative workload for the medical and paramedical team". Moreover, consent should be given without shifty pressures.

Finally, informed consent is also connected to the problem of personal data protection. This problem has been taken into account, for example, by the Belgian Advisory Committee on Bioethics[9].

The U.S. Committee on Establishing a National Cord Blood Stem Cell Bank Program, in the well known report "Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program", furnishes some practical criteria for the management of informed consent. Recommendation 5.1 calls for cord blood collection centres with "clear policies about who must provide consent for donation and a plan in place to address paternal objections to the donation of cord blood". Recommendation 5.2 states that "informed consent for the collection, storage, and use of cord blood should be obtained before labor and delivery and after the adequate disclosure of information". According to Recommendation 5.3, "information provided to a donor must include a balanced perspective on the different options for banking. The information disclosed for allogeneic donation should not include language that gives the donor an impression that the unit will be available to the family after donation". Recommendation 5.4 affirms that "secure links between the medical records of the donor and the banked cord blood unit must be established to ensure the safety of transplantable products and the patients receiving the transplants. These records must be kept confidential and afforded the full protection of the law. If an abnormality is discovered during testing, the results must be delivered to the donor in a manner that is appropriate in relation to the severity of the abnormality". Finally, Recommendation 5.5 declares that "those who collect cord blood for public banks should disclose to potential donors all possible clinical and research uses of the cord blood and, furthermore, that donation will terminate a prospective donor's ability to direct the use of the cells"[18].

Conclusions

According to the European Group on Ethics in Science and New Technologies, there are several fundamental ethical principles which can be considered relevant: "The principle of respect for human dignity and integrity, which asserts the principle of non commercialisation of the human body; the principle of autonomy or the right to self-determination on the basis of full and correct information; the principles of justice and solidarity, as regards to fair access to healthcare services; the principle of beneficence, or the obligation to do good, especially in the area of health care; the principle of non-maleficence, or the obligation not to harm, including the obligation to protect vulnerable groups and individuals, to respect privacy and confidentiality; the principle of proportionality which implies a balance between means and objectives". In addition, certain value conflicts have significant weight: "the values of freedom and free enterprise can conflict with the principles of solidarity and justice, according to which access to healthcare should be on an equitable basis and based on realistic needs, as well as with the principle of protection of vulnerable groups"[19].

Moreover, according to the same opinion by the European Group on Ethics in Science and New Technologies, "the legitimacy of commercial cord blood banks for autologous use should be questioned as they sell a service, which has presently, no real use regarding therapeutic options. Thus they promise more than they can deliver. The activities of such banks raise serious ethical criticisms. While some members of the Group consider that this activity should be banned, the majority of the Group considers that the activities of these banks should be discouraged but that a strict ban would represent an undue restriction on the freedom of enterprise and the freedom of choice of individuals/couples. These banks should operate under strict conditions. If commercial cord blood banks are allowed by a State, such activity must be subject to strict regulation. Such regulation should include previous licensing by the competent State Authority and close supervision of the procedures followed both in the public and the private domain. If commercial cord blood banks are allowed, appropriate information should be given to the consumers willing to use their services, including the fact that the likelihood that the sample may be used to treat one's child is currently negligible, that the future therapeutic possibilities are of a very hypothetical nature and that up until now there is no indication that the present research will lead to specific therapeutic application of one's own cord blood cells. Therefore, information has to be particularly explicit that the auto conservation has little value in the current state of scientific knowledge. This information should be made clear on all media, including internet, and in any contracts linking commercial banks to their customers. Any kind of advertising made by commercial cord blood banks in the media, including on the internet, must be adequately controlled by public authorities" [19].

The opinion by the European Group on Ethics in Science and New Technologies is consistent with Recommendation Rec(2004)8 from the Committee of Ministers of the European Council issued the same year[20].

Returning finally to the concept of the "gift", with which this discussion begun, it seems appropriate to highlight the profound implications of the issue in terms of solidarity and sustainability. If the decision to preserve cord blood for private use - awaiting a therapeutic need - were to prevail, a rich source of donated blood significantly increasing the possibility of treatment for many patients would no longer be available. Furthermore, from an economic perspective, private preservation could lead to social discrimination. The creation of a state-run system would obviously be possible, but without such a system, private preservation would remain the prerogative of families that can afford such a hefty economic undertaking.

On the annual World Blood Donor Day, Pope John Paul II always sought to recall the value of blood donation. Citing the words that the Pope pronounced on in June 2004, on the last World Blood Donor Day before his death, provides an appropriate conclusion which also carries a wish: "Giving one's blood voluntarily and as a free gift is an act of great moral and civic value. It is 'a gift for life'" [21].

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Keywords: Ethics, cord blood, biobank, informed consent

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APPENDIX - List of documents from National and International Institutions

Europe

Council of Europe

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European Union

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National bioethics committees

Austria

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Belgium

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Cyprus

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France

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Greece

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Ireland

- Irish Council for Bioethics. Stem cell research: hope or hype? Exploration of ethical questions. 2008, 6 p. www.bioethics.ie/uploads/docs/stemcell.pdf

Italy

- Comitato Nazionale per la Bioetica. Mozione del Comitato Nazionale per la Bioetica sulla raccolta e la conservazione di cellule staminali derivate da cordone ombelicale. Approvata nella seduta plenaria del 13 luglio 2007. 13 July 2007. www.governo.it/bioetica/mozioni/mozione cordonali.pdf

Sweden

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United Kingdom

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Scientific societies, professional societies

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