

Ethical aspects of umbilical

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Success in using cord blood stem cells to treat haematopoietic blood disorders has led to the exciting field of creating banks for cord blood in order to donate stem cells to potential patients to treat specific disorders.

This has led to private companies seeking to address the issue of giving potential parents the option, against a cost, of storing their children's cord blood, for their personal use in the case the child had to develop a blood disorder in the future. Storage also has the benefit that ongoing research in the area continues, and if new uses for these cells are found, then their storage would have been worthwhile in the long run. Different types of cord blood banks are now therefore distinguished: private and public, and, for-profit and not-for-profit ones.

In 2001, EU President Romano Prodi, requested the European Group on Ethics in Science and Technology to study the ethical aspects of these ventures. In 2004, chairman Goran Hermeren, with whom we are well acquainted in Malta in the ethical field, and his team issued an interesting report in this regard. The first of these articles summarizes this report; Part II will deal with what we actually mean by offering parents a choice and how we should view informed consent in vulnerable groups.

Cord blood can be an alternative to bone marrow transplantation in the treatment of patients with blood and immune disorders. It is currently being used for the treatment of leukaemia, lymphomas, aplastic anaemia and blood hereditary disorders.¹ It is also a source for stem cell research. It is useful to point out that the current use of cord blood stem cells has thus far been of an allogenic type – that is, the cells are obtained from donation. There is less likelihood of rejection of stem cells than there is in bone marrow transplant. In order to be useful the sample to be transplanted must contain sufficient quantities of cells which vary according to the patient's weight. Therefore this type of transplantation, for now, is only possible in people below 50kg, and therefore who are mainly children. Nevertheless, recent experience of combining samples have also shown success in adults. Until 2004 over 3000 transplantation from cord blood have occurred world wide. Therefore *'indications to store blood at birth in view of a future autologous graft are for the present time almost non-existent'*.² An exception would be those who have rare leukaemias.

The possibility of using one's own cord blood for autologous transplantation should the need arise is therefore purely hypothetical, and convincing parents to invest (about Lm900, locally) their future child's cord blood carries great ethical implications which, as we shall see, go beyond simply giving people a choice. The European group expressed concern that having people collect cord blood during the immediate post-partum can affect the team working during the delivery, and although the collection is technically simple, it needs to be done by experts and also on a regular basis so that these interventions become a natural procedure in hospital settings. This is why we should concentrate more on public banks.

There is indeed a need for a great diversity of cord blood in order to have as much HLA types as possible. Networks of banks and registries around the world have been created, the biggest



being the Bone Marrow Donors Worldwide (BMWD), which is a bone marrow and cord blood registry. Information technology help these networks to share and exchange samples. The European network is the NETCORD foundation³, which has even established an on-line search programme – Virtual Office – whereby transplant centres need only submit one search and avoid having to make multiple searches through many networks. The European Commission (EC) is also financing research projects through its Research and Development Framework Programmes (FP6 and FP7 frameworks). One such project has been EUROCORD, established in 1996, whose objectives include establishing a registry by working in close collaboration with NETCORD.

Legal Background

Article 21 of the Oviedo Convention of the Council of Europe provide that *'the human body and its parts shall not, as such, give rise to financial gain'*. An Additional Protocol to this convention, opened for signature in 2002, provides that what is applicable to tissues, is applicable also to cells, including haematopoietic stem cells. The European Health Committee of the Council of Europe adopted a recommendation on autologous banking stating that *'if cord blood banks are established, they shall be from altruistic and voluntary cord blood donation and used for allogeneic transplantation and related research'*, and that, *'the promotion of donation for autologous use and the establishment of cord blood banks for autologous use should not be supported by member states or their health services'*. It continues to proscribe accurate information to the population about the disadvantages and advantages of cord blood banking and where autologous banking is to be considered, proper informed consent procedures are to be adopted. This will be dealt with in part II of this article, but suffice it to say that in vulnerable people, such as expectant parents, it is not merely about providing a choice; information and understanding can easily be thwarted because of unnecessary fears or a sense of lack of duty towards their offspring being subtly instilled.

It is worth noting what some other European states have said on the issue of private banking. The French Bioethics Consultative

cord blood banking – Part I

Committee said that these banks contradict the principle of solidarity; raise hopes of utopia whilst covering a mercantile project using assistance to children as a screen; at the moment of birth, attention from the mother and child could be diverted, and even that the high cost for a currently useless technique would render even the management of an autologous bank by the state as unethical.⁴

The situation in Belgium is not so different and a draft Royal decree has been prepared which unequivocally states that the use of umbilical cord blood cells for preventive measures which aim at giving advantage to those who only can afford it should be condemned and prohibited. Any approval has to be given directly by the minister and can only be considered for non-profit-making organisations.

In Italy, private banking has been forbidden and any banking must be approved by the regional government and allowed only because therapies from umbilical cord blood are still under study. Cord blood banking is thus only authorized as a public conservation structure.

Ethically therefore there are three main areas of concern. The first is that the principle of solidarity is jeopardized if cord blood banking is done only for autologous use and not for altruistic reasons and donation; the principle of proportionality is breached when one balances the objectives against the means; finally, the

principle of doing no harm to vulnerable groups. The latter is most concerning. When one considers the value laden conflict between free enterprise against the principles of justice and solidarity, one must be careful not to allow the symbiotic relationship between industry and medicine, become a parasitic one. It is tempting for entrepreneurs to venture into health care, dragging with them professionals who risk damaging not only the reputation of their own profession but the very people they entered the profession to help. It goes without saying that being paid for such services ventures on the abuse of the patients to whom they were entrusted with. ☐

References

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2. Gunning, J., "A Worldwide study of umbilical cord cell banking", given with the EU report, June 2003.
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"When one considers how many times everyday, priceless umbilical stem cells are thrown away as hospital waste... it is absurd to contemplate that scientists would search for stem cells from the human embryo, where there are both legal and ethical issues involved."

JOSEPHINE QUINTAVALE, DIRECTOR OF COMMENT ON REPRODUCTIVE ETHICS

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