N A T I O N A L B I O E T H I C S C O M M I S S I O N

O P I N I O N

on umbilical cord blood banking

The National Bioethics Commission considered upon invitation of the President thereof the issue of umbilical cord blood banking on 2.2.2007. This question has acquired relevance for "young" parents in our country as they become aware that biological material obtained in labour, which was useless so far, can be of potential use thanks to modern technology. The Commission has received a number of questions on the overall procedure and the matter has also been taken up by the media. The Commission points out the following.

A. General commentary

Umbilical cord blood "banks" provide services of collection, conservation and manipulation of blood obtained from the umbilical cord and the placenta of newborns with the aim to isolate progenitor haemopoietic stem cells to be used in future treatments.

The objective is to ensure reinstatement of normal haemopoiesis in patients suffering from severe blood conditions by transplanting such cells. So far the treatment of these conditions has been based on the transplantation of progenitor haemopoietic stem cells harvested from the bone marrow or the peripheral blood of adult individuals.

The first successful transplants of progenitor haemopoietic stem cells from umbilical cord blood were already reported in the late '80s. Currently, there are two modalities of storage of umbilical cord blood: a) non-profit (usually public) collections which represent 75% of the international reserves, and, b) collections of commercial nature that store umbilical cord blood for the exclusive use of the donor or his/her family representing 25% of reserves.

The former collect umbilical cord blood from donors for public use. Their operation is similar to blood or tissue graft banks. Anyone may obtain this biological material on condition of histocompatibility. In order to ensure the widest possible utilisation of cells, these collections are usually part of international networks.

As pointed out, in commercial banks umbilical blood is stored for the exclusive private use of donors or their families for a fee (usually a lump sum and an annual subscription for as long as the material is preserved). In this sense, they are more like a "safe-deposit box" since they keep the biological material in custody rather than marketing it.

The practice of private use avoids the problem of HLA matching - at least for the donors - since the haemopoietic stem cells originate in their own bodies. There

are two caveats, however. The quantity of cells is often not enough to cover the needs of transplantation in adults (and supplementation with haemopoietic stem cells from another donor again raises the problem of histocompatibility). On the other hand, it has been argued that the use of an autologous graft may have no curative effects in blood disorders due to mutation for the cause of the disease may also occur in the graft. In addition, in the case of leukemia, an allogeneic HLA-compatible graft may be more effective than an autologous graft because residual variations in the HL-antigens between donor and recipient may trigger a limited immune reaction, which contributes to eliminating leukaemic cells.

In view of the above, caution against the practical utility of commercial banks has been expressed by such authorities and bodies as the European Group on Ethics (EGE - see Opinion No 19) and the American Academy of Pediatrics (news release 6.7.1999) among others. (See also, L C. Edozien, NHS maternity units should not encourage commercial banking of umbilical cord blood, BMJ 2006 333: 801-804).

B. Ethical and legal approach

1. The main ethical issue

The private use of progenitor haemopoietic stem cells obtained from the umbilical cord and the placenta raises a prominently ethical-social issue, greatly emphasized upon by the Commission, in view of the extremely limited utility of this material for the donors or their family members. *Is the conservation of cells exclusively for private use justified or should they be made available to public use to avoid them being useless in the end?*

For the Commission, a firm guide to answer this dilemma is how to ensure the widest possible utilisation of these cells. As things stand today, this purpose is better served by heterologous transplantation which is ensured by networks of collections (for- or non-profit) and not by autologous transplantation. Since the potential use of the material exclusively by the donor or his/her family members is negligible[1] (and, conversely, the probability of final destruction of cells very high) the choice of private use cannot be justified on ethical grounds. All the more so considering that this choice would discourage making cells available to common use and would drastically reduce the availability of grafts to those who need them.

2. Other issues

a) The development of collection and storage facilities for umbilical cord blood must meet certain quality standards as it involves serious matters of health protection. In particular, the following must be ensured: i) accurate and valid information to the public on the particular application either by the State or by collecting organizations, ii) certification of these organizations under state

[1] The estimated probability is 1: 20000 for the first 20 years of life of the donor (see EGE, Opinion n. 19).

responsibility, iii) guarantee of viability and preservation of material in case of cease of operation.

b) The operation of commercial collections, in particular, must provide comprehensive information to prospective clients and refrain from misleading advertise enough time prior to any blood storage agreement. Freedom of will is crucial here - and must be adequately safeguarded - because prospective applicants are usually emotionally charged and in earnest desire to "secure the future" of the child they are going to have. In terms of relevant law, the legislation of consumer protection applies (Act 2251 / 1994). It is worth noting that according to the opinion of the EGE (Op. 19, 1.22) there may be an issue of breach of trust for the obstetrician who recommends the commercial collection and preservation of umbilical cord blood although aware of the scarce chances of practical use to interested parents.

C. Suggestions

Based on the above the Commission suggests:

a) The adoption of an explicit provision of law entrusting a public authority with the licensing and supervising of the operation of companies that collect and store umbilical cord blood. In view of relevance with transplants this authority could be the National Organization of Transplantation.
b) The immediate transposition of Directive 2004/23/EC on setting standards of quality and safety for biological material (which covers progenitor haemopoietic stem cells of the umbilical cord).
c) The development of appropriate public information tools (brochures, registration in websites) by the Ministry for Health (or the above mentioned authority once it is established).
d) The development and publication of consent forms and information documents for prospective users of already operating companies. Once a public licensing system for these banks is put in place, the content of these documents should be reviewed as a prerequisite for the license. Companies should also register forthwith with the Data Protection Authority, to protect the confidentiality of the sensitive data of blood donors.

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