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# OPINION ON BLOOD AND TISSUE BANKS OF THE UMBILICAL CORD AND PLACENTA

**A joint report by the**
**Portuguese National Council of Ethics for the Life Sciences and the**
**Spanish Bioethics Committee**

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# Opinion on blood and tissue banks of the umbilical cord and placenta

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## I. GENERAL CONSIDERATIONS

The use of haematopoietic precursor cells in the treatment of malignant haematological (e.g., leukaemias and lymphomas) and non-malignant diseases (e.g., aplastic anaemia, Fanconi anaemia) has been a common practice for some decades.

The umbilical cord blood is a source of multipotent haematopoietic stem cells, which can be used for autologous (patient's own cells) or allogeneic (immunologically compatible donor) transplants in malignant and benign haematological diseases. Due to its easy availability, absence of risks for the donor, low risk of infection, low rate of rejection and less controversial ethical issues, those cells have proven clinical usefulness as an alternative to bone marrow cell transplants.

The limited amount of cells per cord can be overcome by using two or three cords per transplant, by *in vitro* expansion of the cells or obtaining induced pluripotent stem cells (iPSCs).

Autologous transplants are not useful in hereditary diseases, as they will carry the mutation causing the disease, or even in certain haematological neoplasias, because the cord blood sometimes already has clonal tumour changes.



Blood and mesenchymal cells from newborns' umbilical cord and placenta are very promising for application in other (degenerative, traumatic, ischemic) diseases, but their scientific validity and potential usefulness have not yet been established, and their use remains experimental.

Public banks of blood and tissue from the cord and placenta are therefore considered to be of great clinical usefulness and a real need.

The collection and conservation of these cells and tissues is carried out in biobanks, essentially according to two models: (1) by deposit for autologous use (or in close relatives, usually siblings), created by private and profit-seeking initiatives; or (2) through organ donation for allogeneic transplant in a compatible recipient, preserved in public banks, articulated in networks.

The conservation in public banks is based on the principles of altruism, gratuity, confidentiality and the highest quality; it follows very strict selection criteria, with reduced use of samples (offset by the exponential increase in availability) and has proven usefulness; it uses public funds and has a greater likelihood of continuity; the donation is altruistic, for allogeneic transplant in whoever might need it, anywhere in the world.

Conservation in private banks for own use is based on a business model, with less strict selection criteria and quality, claim of unreasonable applications (treatment of

common diseases of adulthood, when conservation is done for 20-25 years), aggressive marketing strategies and not very transparent practices, aimed at an audience at a particularly vulnerable phase of their lives.

Cells deposited in private biobanks have high costs for the costumers themselves and a negligible probability of ever being used in autologous transplant (1/20,000 to 1/250,000, according to the source). Private biobanks compete with public ones for the same samples. More than lying on different economic models, they offer health services which are not exactly the same and do have a very different ethical valuation. Because of this, private banks are banned in some countries (France, Italy) and earned strong ethical reservation from all national committees that have issued an opinion on them; the existence of at least one public bank should be ensured, in compliance with the principle of social justice.

Despite the huge growth in this sector at the public and private level, and the international networking of the public banks, some patients still cannot find a compatible donor, raising also the issue of access to health and human rights.

## II. RECOMMENDATIONS

Having regard to this reality, the CNECV and the CBE are of the opinion that one must:

1. Promote the free and altruistic donation of cord blood, the umbilical cord itself and placenta, for use in allogeneic transplants, through:

a) information campaign directed at the society at large about the existence of blood and tissue banks of the umbilical cord and placenta, their different nature and purpose (i.e., unequivocal differentiation between the public and private biobanks, regarding the conditions of conservation of the material of foetal origin and derived cells, as well as the accessibility to them), objective, rigorous and up-to-date indication on the current real capacities and future therapeutic potentialities of the material of foetal origin and derived cells;

b) obligation to inform the pregnant woman or couple about the possibility of donating those foetal products, by a health care professional with appropriate training and in an objective, rigorous and updated manner.

2. Disclose the importance of the solidary donation of such products at the time of delivery, for use in allogeneic transplants, and provide all the information necessary for the consent process, during the prenatal consultations, starting from the second trimester of pregnancy.



3. Establish a routine of collection of blood and tissue from the umbilical cord and placenta in all pregnant women, for a public biobank, which always considers the possibility of refusal on the part of the woman, ensuring the ethical process of obtaining informed consent.

4. Request accreditation for the licensing process of all banks, public or private, and demand the same quality criteria for all samples used in the country.

5. Require that all public or private banks comply with identical technical and scientific internationally established quality standards, as well as with the ethical and legal requirements that assure respect for the dignity of those involved and for social justice in the community.

6. Strongly discourage the commercial appeals for cryopreservation of these foetal products exclusively for autologous use, as they compete with samples available for allogeneic transplant, consequently harming the common good.

7. Provide public biobanks with the necessary means to test, process and store the derived cells, maintain a quality system and their connection to European and international networks, and safeguard their continued sustainability.

8. Allow the conservation in public banks of samples suitable for use in close relatives, in case there is a proven clinical indication.

9. Verify that advertised claims of therapeutic applications have proven validity and clinical usefulness.

10. Provide the public obstetrics services and maternity hospitals with the means needed for that collection, and include it in their functional duties.

11. Recommend special attention from the regulatory authorities to the advertisement by commercial services in maternity hospitals, obstetric services and health centres.

12. Prohibit any type of direct remuneration or compensation to health professionals from public entities who promote or make collections for private companies.

13. Regulate and supervise the activities of banks operating in each of both States and verify their compliance with international quality standards.

14. Ensure the representativeness of the samples preserved with respect to resident populations, with particular attention to population minorities and rare haplogroups.



15. Promote research into the methods of processing and preservation of cells derived from the umbilical cord and placenta, and new clinical applications.

16. Prevent the offer of other health-related genetic tests, without medical prescription, on the products collected at time of delivery or on blood samples from newborns.