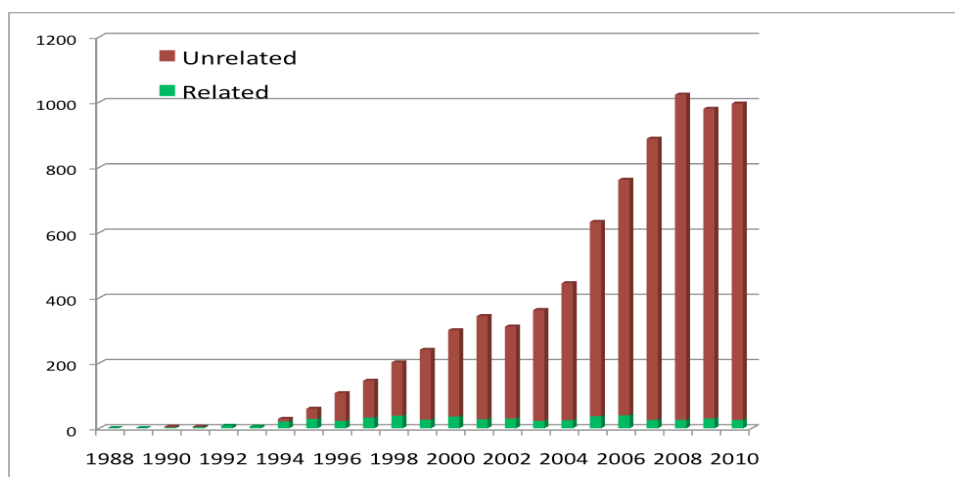


Eurocord-Ed Policy Document on Cord Blood Banking in Europe

Since the first cord blood transplantation was performed in Europe in 1988, a large number of cord blood banks have been established in order to facilitate unrelated cord blood transplantation. Over the years the number of units collected in Europe has increased to approximately 190 000 in 2011. Cord blood transplantation is a rapidly growing field with an increasing number of indications worldwide. The results reported by Eurocord reflect a strikingly rapid increase in activity (Fig. 1). For example, the Asian Pacific Blood and Marrow Transplantation Group reported 937 cord blood transplants in 2008 alone. In the USA, more than 40% of pediatric unrelated transplants are provided by cord blood.

Fig. 1: Eurocord data on Related and Unrelated Cord Blood Transplantation from 1988-2010



Initially, cord blood transplantation was implemented in children when it was not possible to find an unrelated stem cell donor. But it is also a therapeutic option for adult patients without an unrelated donor, and in particular for patients from ethnic minorities who may benefit from cord blood transplantation and for whom the probability of finding a suitable unrelated stem cell donor is low.

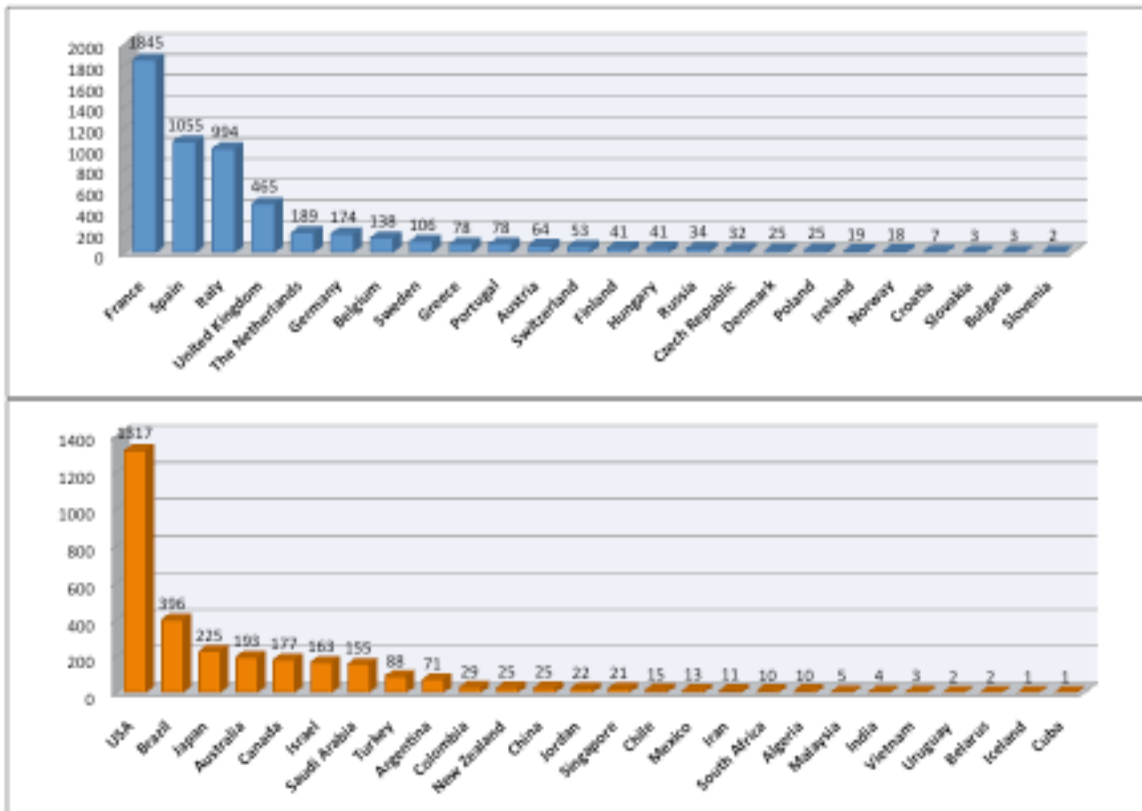
The use of cord blood as a source of stem cells for unrelated transplantation has several advantages over other sources of stem cells. These include a low incidence of graft-versus-host disease and a low transmission rate of viral infections. However, the number of stem cells in a cord blood graft is relatively low for adult patients and in principle there is no possibility to use donor lymphocytes for patients relapsing after transplantation. In addition, graft failure and delayed engraftment have been observed after cord blood transplantation, perhaps due to the low number of stem cells. Therefore, in recent years, double cord blood transplantation has been introduced for adult patients, in order to overcome the limited number of stem cells in a single graft. Initial results are encouraging and suggest that outcome is improved after double cord blood transplantation and reduced toxicity conditioning.

For these reasons, cord blood transplantation represents a realistic and equivalent alternative for unrelated hematopoietic stem cell transplantation.

Fig 2:



Number of CBT reported to Eurocord per country



Public cord blood banks aim to store cord blood for allogeneic transplantation purposes. These banks are typically not for profit entities where units are banked at no cost to the donor. A lack of appropriate financial structure has proven to be a major issue for these banks. In most countries, they are supported by charities and also, to a limited extent, by institutional support or public funding. However, a viable financial model has yet to be established. In order to provide a suitable unit for the majority of patients, including those belonging to an ethnic minority, the global inventory has been increased to approximately 600 000 units. As a result, the release percentage for units has been proportionally decreased even though the release of units is the only source of cost recovery for many banks. This explains why public banking activities are not cost-effective and require continuous financial support from either private or public sources. There is clearly a need to define and implement appropriate reimbursement mechanisms in order to recover the costs associated with cord blood banking.

In addition to public banks, a large number of private banks have also been established. In this setting, the cost of storage is covered by the cord blood donor and, therefore, private banks tend to have a solid structure that is generally for-profit. These banks aim to store cord blood for autologous use. But

in contrast to cord blood for allogeneic stem cell transplantation, the clinical benefit of units stored for autologous application remains to be proven.

In order to find a compromise, public-private hybrid bank models are currently the subject of intense discussions, notably driven by the wish to improve the financial viability of cord blood banks. A number of models for combined banking have been developed, including joint marketing of separate banking operations, opportunities to split units for private and public use, and the offer to initially bank units as either public or private but with the option to convert their status at a later date or event. To be useful to families, these approaches will need to be more rigorously adopted; accreditation standards need to be applied to them; the accuracy of their informed consent needs improvement; benefits to help research on cord blood cells need to be shared; and sibling banking needs to be regularly offered when there is a clear indication for haemopoietic stem cell transplantation.

Continuing academic research and help from industry for the development of new products and for the implementation of worldwide regulations will control and guarantee the quality, safety and potency of the cord blood market on the basis of new scientific data and clinical protocols, and rigorous clinical trials.

The umbilical cord blood community has recently set up Eurocord-Ed (www.eurocord-ed.org) as an online tool for vocational training in the field of umbilical cord blood. Eurocord-Ed is also a valuable instrument for healthcare decision makers, providing them with updated information, reviewed by experts, on the optimal use of umbilical cord blood for transplantation.

The decision to develop Eurocord-Ed was also based on the fact that public knowledge of cord blood as a therapeutic source remains limited. There is therefore a need to disseminate reliable, scientifically validated information provided and reviewed by experts in the field. The Eurocord-Ed project also aims to promote donation of cord blood to public banks and to stimulate the debate on public and private cord blood banking.

The Eurocord-Ed community makes the following specific recommendations:

1. Storage of cord blood for allogeneic transplantation should be reserved to units containing more than one billion nucleated cells (1×10^9 cells).
2. In order to further exploit the potential of cord blood for transplantation, a solid financial structure needs to be established. This will include a mechanism for reimbursement by insurance companies.
3. The lay public needs to be informed about the options of cord blood banking in order to promote public donation and to enable them to participate in the discussion on private versus public banking. All professional actors should be involved in this broad public discussion.
4. Cord blood is a valuable source of stem cells for regenerative medicine and research in this area should be stimulated.
5. Commercial activities in the field of cord blood banking must be supervised by governments at the national or the European level.
6. Parents' associations and pregnant women should be fully informed about the options of cord blood banking.

The field of cord blood transplantation has saved many lives throughout the world. And yet, in Europe access to cord blood technology is hindered by a low level of awareness of its therapeutic value and potential, and lack of appropriate infrastructure and organization.

The Eurocord-Ed Consortium declares that it is available for information and advice to all healthcare decision makers.

On behalf of the Eurocord-Ed Consortium,

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