

News Letter

January 2008

Total Inventory Surpasses 150,000 in NetCord Banks

The total inventory of cord blood units in NetCord-member banks has surpassed 150,000.

As of October 2007, the combined inventory was 153,830, an increase of nearly 30,000 units or 23% in the past 12 months.

Transplant centers can perform a preliminary search for the most suitable matched units at no cost through the foundation's online Virtual Office. Since December last year, search reports from the Virtual Office have also included the inventory of the National Marrow Donor Program (NMDP), which has an additional 60,000 units.

The year-old partnership between NetCord and NMDP offers expanded access and efficiency for transplant center teams treating more than 35,000 people diagnosed with life-threatening blood diseases each year.

NETCORD Inventory and Use – October 2007

CB Bank	Inventory	Transplanted	Children	Adults
Athens	498	5	4	1
AusCord	17712	321	181	116
Barcelona	7517	347	163	184
Düsseldorf	12538	437	229	197
France Cord	6014	606	384	222
Gauting	2085	28	14	14
ITCBN	6006	234	107	127
Helsinki	2750	15	9	6
Houston	3143	25	18	7
Leiden	3472	55	25	30
Leuven	7912	102	60	42
Liege	5032	190	78	112
London	8612	174	105	69
Málaga	7816	61	19	42
Mannheim	1627	27	16	11
Mexico - CNTS	973	63	39	24
Milan	6468	325	178	147
New York	35220	2453	1585	868
Prague	2725	18	10	8
Santiago de Compostela	4834	37	21	15
Seoul	4599	8	0	8
Tel Hashomer	1320	4	4	1
Tokyo	4957	692	194	498
TOTAL	153830	6227	3443	2749

President's Message

International NetCord Foundation Begins its Tenth Year: a Moment for Reflection and Setting New Goals

By Joan Garcia, President
and E. J. Shpall, Vice President

As 2008 begins, the International NetCord Foundation is entering the 10th year since its founding. At such a time, an organization's leaders can look back and critically summarize the achievements and the mistakes made in their inaugural decade. Our organization is no exception.

NetCord's birth was the inspiration of three colleagues: Peter Wernet, Girolamo Sirchia and Paolo Rebulla, who rapidly convinced Pablo Rubinstein and a growing list of cord blood (CB) banking leaders and programs to join the project, at a time when CB banking and transplantation were considered risky propositions. At the time there were only several hundred CB units stored worldwide, and only a small number of courageous pioneering transplant teams who offered this source of hematopoietic support to patients who often had no other options.

In 2008, NetCord will have accomplished a number of its initial goals: the creation of a modern communica-



Joan Garcia

tion network, the strong support of quality banking through the development of standards and an accreditation system, and continuous medical and scientific contributions to the field.

Today, NetCord's strength is derived from its members: 25 high-quality and active international CB banks, with a total inventory that exceeds 150,000 CB units. More than 200 transplant teams use our services. Importantly, the majority of transplants performed in the world come from our inventory, with 50% of units used in adults. This indeed reflects the confidence in the quality of our units.



E. J. Shpall

This year a new board of directors and officers were elected to continue the stewardship of NetCord.

This is an extremely exciting time to be involved in CB banking and transplantation. The field is experiencing unprecedented growth due to maturing clinical data demonstrating the success of CB transplantation. Several landmark trials have reported clinically equivalent results with CB compared to unrelated bone marrow. Double CB transplants and reduced intensity conditioning regimens have opened new therapeutic windows. CB transplants are successfully applied to an increasing number of dis-

eases and patients of all ages. Finally, promising research on cord and placental stem cells supports their potential use in tissue regeneration.

Commercial autologous CB banking is also a growing parallel activity, frequently competing with public donation programs. This has been a subject of concern for NetCord and stimulated the development of our policy statement on the topic, reported elsewhere in this issue.

We are entering the second decade of NetCord's life with the goal of maintaining our founding principles, while expanding our mission to promote the use of CB for the maximal benefit of patients. Optimally this will be a shared mission with our sister organizations. In this regard, we are strengthening synergistic collaborations with several registries and scientific/medical organizations including Eurocord, the National Marrow Donor Program, and Asiaccord. We strongly believe that if these global collaborations succeed, many transplant teams will benefit and, ultimately, patients needing a suitable donor will substantially improve their chances of long-term survival.

Leadership

NetCord Officers

President

Joan Garcia, MD
Barcelona, Spain

Vice-President

Elizabeth Shpall, MD
Houston, USA

Secretary

Eliane Gluckman, MD
Paris, France

Treasurer

Yves Beguin, MD, PhD
Liege, Belgium

Immediate Past-President

Peter Wernet, MD, PhD
Dusseldorf, Germany

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Joanne Kurtzberg, MD
Durham, USA

Riitta Kekomaki, MD, PhD
Helsinki, Finland

Cristina Navarrete, MD
London, United Kingdom

Paolo Rebulli, MD
Milano, Italy

Pablo Rubinstein, MD
New York, USA

Calendar

BMT Tandem Meetings

Feb. 13-17, 2008
Manchester Grant Hyatt Hotel
San Diego, California, USA
www.asbmt.org

EBMT Annual Meeting

March 30-April 2, 2008
Fortezza da Basso
Florence, Italy
www.ebmt.org

International Society for Cellular Therapy

May 17-20, 2008
Hyatt Regency Hotel
Miami, Florida, USA
www.celltherapysociety.org

American Society of Clinical Oncology

May 30-June 3, 2008
McCormick Place
Chicago, Illinois, USA
www.asco.org

Annual International Umbilical Cord Blood Transplantation Symposium

June 6-7, 2008
Los Angeles Airport Marriott
Los Angeles, California, USA
www.cordbloodsymposium.org

International Society for Experimental Hematology

July 9-12, 2008
Renaissance Boston Waterfront Hotel
Boston, Massachusetts, USA
www.iseh.org

International Society of Hematology

October 19-23, 2008
Bangkok Convention Centre
at CentralWorld
Bangkok, Thailand
www.ishworld.org

Board of Directors Approves Policy on Banking of Cord Blood for Autologous Use

The private banking of a baby's cord blood for possible future use has long been a concern of NetCord-member banks.

The greatest problem is that a unit of

cord blood put in private storage no longer is available for public use. Based on current medical knowledge, the likelihood that the privately stored unit ever will be used is remote and theoretical.

Nevertheless, the reality is that some parents will choose to put cord blood into private storage. Recognizing this, the NetCord Board of Directors adopted the following position statement in October:

Position Statement on Cord Blood for Autologous Use

- Placental and umbilical cord blood stem cells have unique properties that make them useful in the treatment of certain life-threatening blood disorders and genetic diseases by hematopoietic stem cell transplantation.
- Cord blood stem cells may be collected and preserved in a bank for any of four reasons.
 - The cells may be donated to a bank for potential match to any patient who has a disease treatable with allogeneic hematopoietic stem cell therapy. This is a proven and increasingly common practice and has important social value.
 - The cells may be collected and preserved for a biological sibling who has a disease treatable by allogeneic hematopoietic stem cell transplantation. This also is a proven medical practice.
 - The cells may be collected and preserved on the speculation that the donor may need them in the future for a disease treatable by autologous hematopoietic stem cell transplantation. The possibility of such a disease in the donor is very low. Allogeneic (not autologous) hematopoietic stem cell transplantation is the standard care for most such diseases. Moreover, the stored cord blood may contain the same malignant cells that caused the disease.
 - The cells may be collected and preserved for possible future use to regenerate tissues. At present, there is no evidence that cord blood cells can be used therapeutically for this purpose. There are unique cell populations in cord blood that may have potential for regenerative medicine, but it is not yet clear that those properties would be any more favorable than the patient's own peripheral blood or bone marrow.
- Regardless of the reason for the collection and preservation of cord blood stem cells, two principles are firmly held.
 - The process of collecting, processing, testing, banking, selection and release of cord blood stem cells must meet professionally recognized international standards, such as those developed by NetCord-FACT. This can be assured by FACT-NetCord accreditation of the cord blood bank.
 - The information given to an adult donor, or the parents or guardian of an infant or minor donor, must be complete, unbiased and balanced. In particular, the informed consent process shall include the purpose of the stem cell collection, the possible benefits and risks, and the likelihood that the cells may be used for that particular purpose. Donors shall not be misled about the potential for cells to be used to treat future disease in that donor or to regenerate tissue. Conflicts of interest must be disclosed.
- This policy will be reviewed periodically and updated when warranted by evidence-based clinical and laboratory research.

Summary

Since the therapeutic benefit of allogeneic cord blood transplantation has been convincingly demonstrated, NetCord primarily promotes banking for allogeneic stem cell transplantation.

Banking for autologous purposes may be considered if such storage is part of a program whose primary mission is the use of cord blood units for allogeneic stem cell transplantation.

FACT Begins Native Language Demonstration Project

FACT-NetCord, the accrediting agency for cord blood banks, has launched a pilot project for accreditation of banks in their native language. Spanish will be the language in the demonstration project.

From time to time, some banks have expressed concern that inspections for FACT-NetCord accreditation are conducted only in English. The standard operating procedures (SOPs) have to be translated into English for the accreditation review and inspection, but then never are used again by bank personnel who don't speak English.

To respond, the FACT-NetCord Accreditation Office, located in Omaha, Nebraska, has begun a one-year demonstration project for Spanish-language accreditation review and inspection of cord blood banks. The objective is to evaluate the process

of conducting reviews and inspections in the native language of the cord blood bank that is seeking FACT-NetCord accreditation.

The following progress was reported to the NetCord Board of Directors when it met in October in Paris:

- FACT has hired a bilingual (English and Spanish) accreditation coordinator. The new staff member is employed full-time for the duration of the demonstration project to assist with translating documents in the Accreditation Office, as well as accompanying the inspection teams to serve as a translator and conduct a portion of the inspection.
- The accreditation coordinator has spent a week at the M.D. Anderson Cord Blood Bank in Houston, Texas, to observe all aspects of cord blood banking.

- Current Spanish-speaking lab inspectors will be trained to perform cord bank inspections. FACT will organize for all its current Spanish-speaking hematopoietic progenitor cell (HPC) inspectors a two-day training session, including a mock inspection.
- The HPC inspectors will then accompany a team of current cord blood inspectors on an upcoming inspection.
- In the spring, an actual re-inspection of a bank in a Spanish-speaking country will be conducted by a team of seasoned cord blood bank inspectors, accompanied by the newly trained Spanish speaking-inspectors.

The FACT Accreditation Office, together with the FACT Board of Directors, will evaluate the success and any challenges of the process to determine further expansion of the project.



January 2008

Member Profile

Belgian Cord Blood Bank Has Facilitated Nearly 200 Transplants

By Etienne Baudoux and Yves Beguin

The Belgian Cord Blood Bank was started in 1994. A yearly fund-raising television program focused on leukemia and called Télévie has allowed the National Fund for Scientific Research to finance a cooperative project based in three French speaking university centers (ULB-Institut Bordet and UCL-St Luc, Brussels, and ULg-Université de Liège, Liège).

This successful operation has given the program extensive financing, for infrastructure as well as for staff, through years 1994-2002.

The program includes three storage centers working together with maternity networks in their area. From the beginning a common body of procedures has been shared regarding inclusion criteria, processing methods, storage as well as release. For instance, three storage centers use the same integrated and automated system for cryopreservation, storage and retrieval of units. Identical electronic records tools and data transfer are in use. The current stock contains 5,032 validated units.

Data of validated units from the whole program are collected and transferred through Liège Cord Blood Bank to NetCord inventory. Searches into that inventory are done in the NetCord Virtual Office and coordinated by the national hub registry (Marrow Donor Program-Belgium).

So far, 190 units have been released for transplantation to patients around the world, and 31 units are in the process of recruitment. The number of units delivered per year has been steadily increasing since 2001.

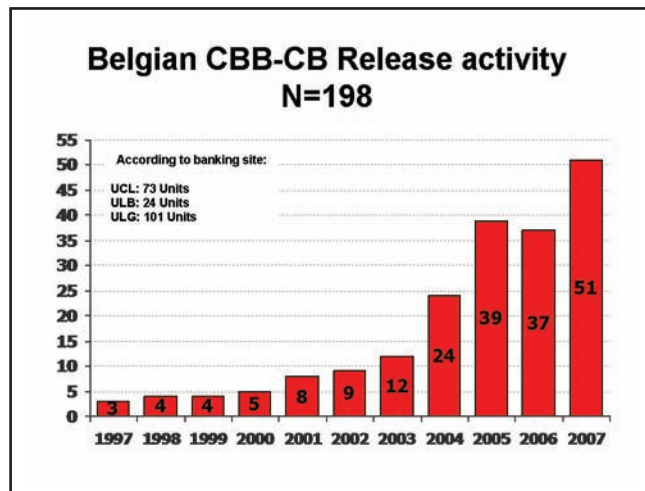
The Belgian Cord Blood Bank does a continued analysis of post-thaw and post-transplantation data to monitor properties of end products in terms of post-thaw, as well as post-transplant, recovery. Post-thaw results are stable over time and satisfactory with a median TNC recovery of 82 percent.

Despite a limited amount of available data, recovery of patients who have been transplanted with units from the bank is comparable to what has been published in the literature. Despite best efforts, limited feedback is given by transplant centers, and most of the post-transplant information is from Eurocord in Paris.

To remain an active member of NetCord, the Belgian bank has been working since 2001 to upgrade the activity to the most recent NetCord-FACT Standards. The bank's storage

site in Liège was inspected by a team of FACT inspectors in June 2004, and the bank was granted FACT-NetCord accreditation in September 2005 for cord blood collection, processing, testing, banking, selection and release limited to allogeneic directed and non-directed donations.

The two remaining parts of the program, (UCL-St Luc) and (ULB-Institut Bordet), are still in the process of applying for accreditation and can be reasonably expected to achieve that this year.



Belgian Cord Blood Bank Team

Virtual Office Report

Transplant Coordinators Increase Traffic to NetCord's Database

By Holger Gressmann

Transplant centers can search for cord blood units by several methods. NetCord offers a unique system for transplant coordinators to find the best available matched units from cord blood banks around the globe.

The online search system maintained by the NetCord Virtual Office solves several problems that can arise with a growing volume of cord blood searches of the joint inventories of more than 150,000 units in NetCord-member banks.

There is no cost to transplant centers for registration and preliminary searches of the NetCord inventory.

The Virtual Office can be accessed at www.netcord.org.

Presented below is a statistical summary of this year's activities in the NetCord Virtual Office:

- Currently 317 transplant centers are registered.
- 1,520 new patient data entries were added from January through mid-November 2007. Together with new

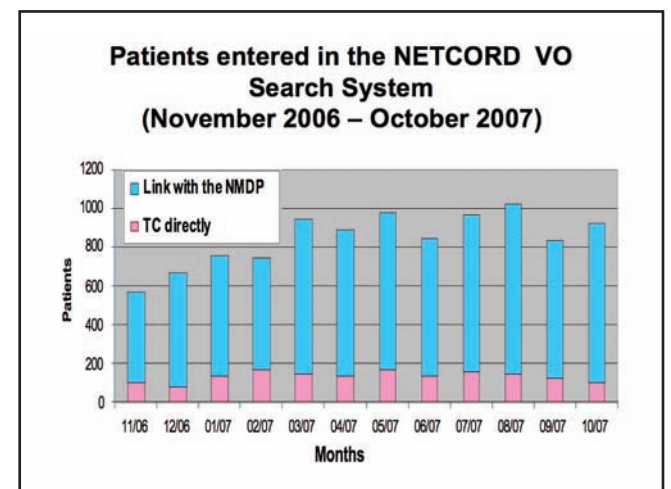
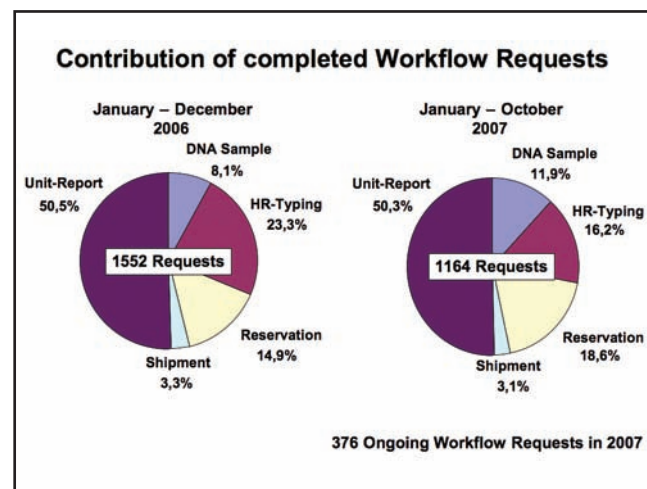
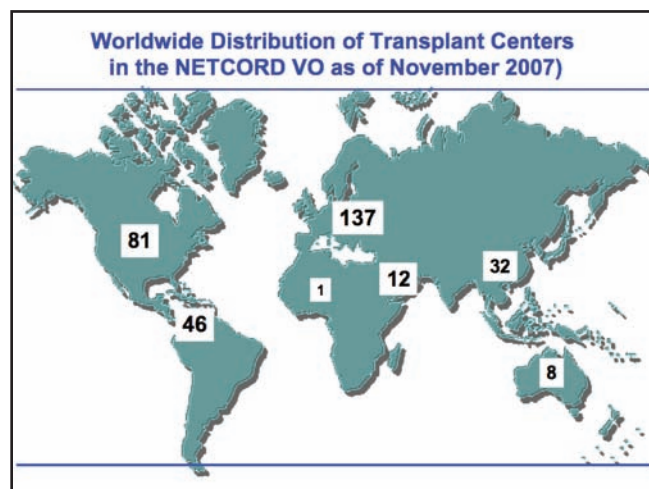
patient data entries relayed from the National Marrow Donor Program (NMDP) through a shared search agreement, the number of new patient entries was 8,178.

- 1,164 workflow requests were completed between January and the middle of November, and 376 requests were ongoing in December.
- This year the cord blood bank in Athens, Greece, began listing inventory. The inventory of banks in Mannheim, Germany, and Malaga, Spain, will be added soon.

- Since spring, the inventory of the Italian cord blood banks has been continued by the Italian Bone Marrow Donor Registry (ITCBN) in Genova.

In recent months the Virtual Office staff has focused on updating the cord blood data definition in cooperation with the NMDP.

The successful linkage of the NMDP and NetCord for combined responses to search requests has improved online information services for transplant centers, resulting in a more efficient cord blood allocation workflow.



January 2008

Eurocord Report

Eurocord-NetCord Registry Interactions Improve Transplant Outcomes

By Vanderson Rocha, Irina Ionescu, Andree Laure Herr, Federico Garnier, Wagnara Chaves, David Pacheco, Joan Garcia and Eliane Gluckman

Umbilical cord blood transplantation (UCBT) has extended the availability of allogeneic hematopoietic stem cell transplantation (HSCT) to patients who would otherwise not be eligible for this curative approach. We estimate that more than 10,000 patients have already been transplanted with cord blood as a source of allogeneic stem cell transplantation.

Progress in the field of umbilical cord blood transplantation parallels the huge interest in establishing and developing cord blood banks worldwide. Today more than 300,000 cord blood grafts are available in more than 45 cord blood banks. These banks play an important role in the process of cord blood transplantation.

The International NetCord Foundation was originally created on behalf of Eurocord to establish good practices in umbilical cord blood storage, facilitate donor search, improve the quality of the grafts, standardize excellence criteria on an international scale and, importantly, to establish procedures for bank accreditation in collaboration with FACT (Foundation for the Accreditation of Cellular Therapy).

The inventory of NetCord, the cooperative network of large, experienced UCB banks, currently has more than 150,000 cryopreserved UCB units ready for clinical use for unrelated recipients, and more than 5,000 grafts have been shipped. Recently, the National Marrow Donor Program (NMDP) has established a similar cord blood bank network in the USA with the financial support of the American Congress.

Collaborations between NetCord-Eurocord, the NMDP and the Center for International Blood and Marrow Transplant Research (CIBMTR) have been established with the goal of providing the most appropriate and high-quality cord blood unit for a specific patient and to collect and share high-quality clinical data to make possible prospective and retrospective

studies and to provide to all cord blood banks clinical data as a quality control of their units.

Eurocord Registry

In order to develop research in the different biological aspects of cord blood cells and evaluate cord blood transplants, the European Group for Blood and Marrow Transplantation (EBMT), with the support of the European Union, organized the Eurocord group in 1995. One of the most important achievements of the Eurocord group was the establishment of the Eurocord registry. It works in close collaboration with NetCord banks, collecting and validating clinical data of patients transplanted with NetCord cord blood units.

Thanks to this 20-year collaboration, 4,121 cord blood transplants have been reported to the Eurocord registry from 228 European transplant centers from 34 European countries (64% of cases), and 190 transplant centers (36% of cases) from other countries.

A total 481 UCBT transplants have been reported using related donors (the majority HLA identical sibling donors), mainly for children with malignant and non-malignant disorders, and 3,607 have been performed in the unrelated transplant setting for children and adults.

During the last three years, the number of unrelated UCBT reported to Eurocord has increased to more than 300 transplants per year, and since 2004 the number of adults transplanted with cord blood cells has overtaken the number of UCBT performed in children, according to Eurocord registry data.

Cord blood transplantation has been used to treat a variety of genetic, hematologic, immunologic, metabolic and oncologic disorders.

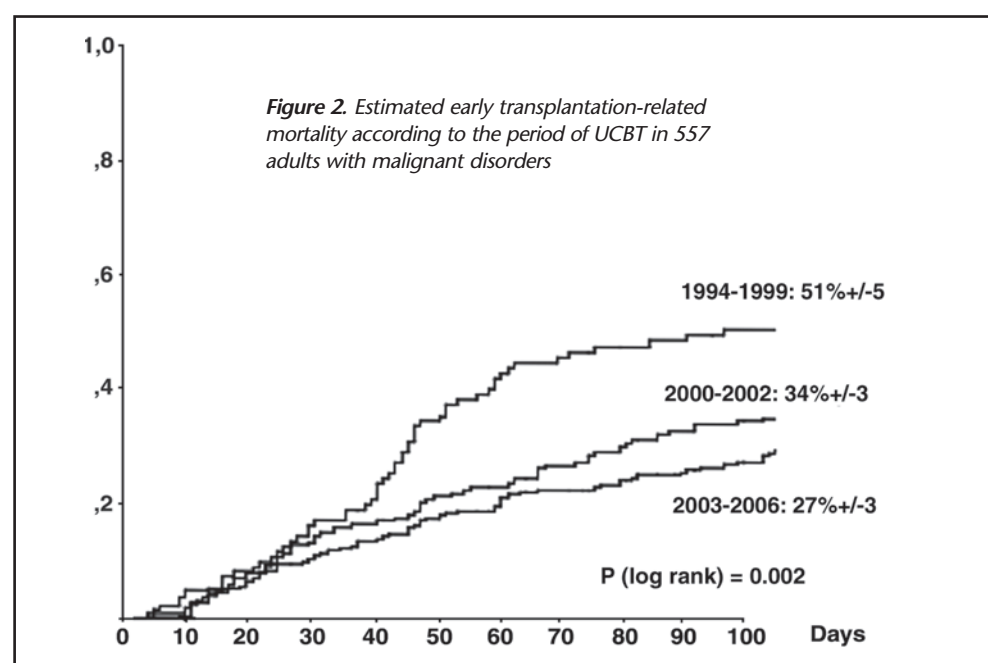
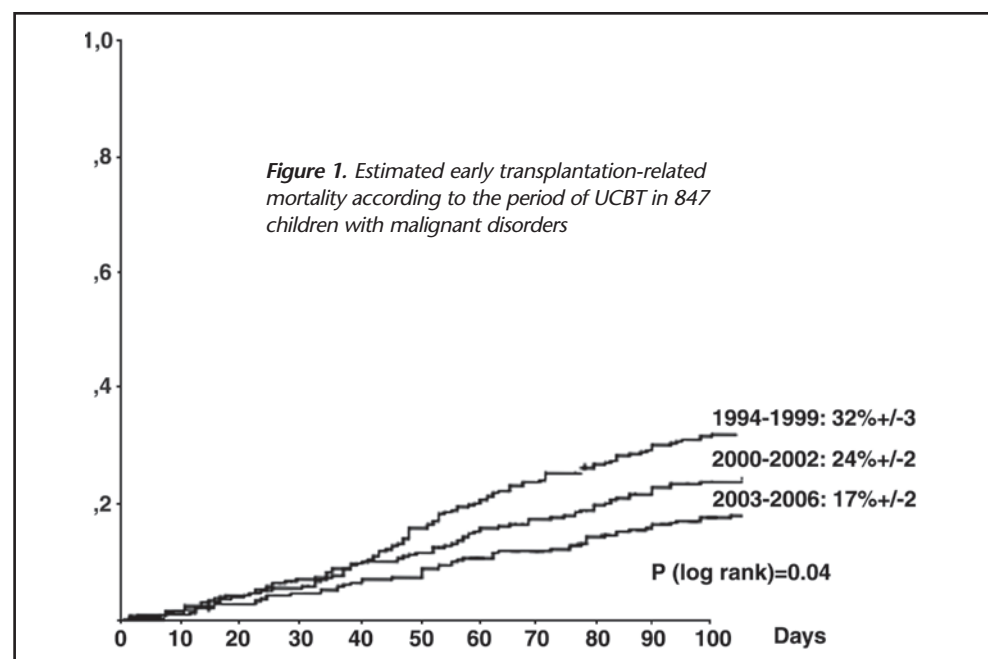
Eurocord Operations

Eurocord operates through interactions with NetCord CB banks, transplant centers, the EBMT database called "Promise" and international donor and transplant registries.

Eurocord has developed a registry of all cord blood transplants performed

a period of public comment.

The Foundation for the Accreditation of Cellular Therapy (FACT) has accredited 15 cord blood banks. These are facilities that meet or exceed the NetCord-FACT Standards, as verified through document review and on-site inspections. Forty other banks have applied for accreditation.



within EBMT and non-EBMT transplant centers, the majority performed with cord blood units coming from the NetCord network of CB banks. Eurocord is responsible for retrieving, validating and entering the clinical data into the database, assuring the high quality of the data.

Eurocord already has established a program of data exchange with Promise (the EBMT database). For this purpose, a program of validation and verification of the data has been developed, as well as comparison of the two databases. This will continue, and better ways of interactions will be discussed. Ultimately common data reporting forms will be used.

Other programs of data exchange are currently being structured, namely with the NMDP and CIBMTR, concerning CB transplants performed within the CIBMTR network of transplant centers in the United States and Canada, and with European cord blood units. Eurocord establishes close links with the cord blood banks and bone marrow registries in order to establish algorithms for donor search.

A Eurocord survey has shown an improvement of the results of cord blood transplants performed in adults

and children with malignant disorders in the recent years.

Figures 1 and 2 show that early transplantation-related mortality has decreased for children and adults transplanted with a single cord blood unit. This improvement in overall survival is a consequence of many factors related to patients, donors and transplants, but mainly is a result of better donor choice based on number of cells and HLA and better patient selection.

Standards and Accreditation

Third Edition of NetCord-FACT Standards Completed, Published

The Third Edition of the *NetCord-FACT International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release* was completed and published in early 2007.

The new standards are the result of extensive study and deliberation by members of the cord blood banking field and clinicians, and were open for

NETCORD MISSION

The mission of The International NetCord Foundation is:

- To globally unite supply and demand for umbilical cord blood.
- To promote the highest quality cord blood products through worldwide standards and an accreditation process for cord blood banks.
- To encourage and facilitate expanded uses of cord blood transplants by promoting laboratory and clinical research, as well as treatment outcome evaluation.