



UMBILICAL CORD BLOOD BANKING

A guide for parents

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This guide has been elaborated by the
Council of Europe European
Committee on Organ Transplantation
(CD-P-TO).

For more information, please visit
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INTRODUCTION

The cells contained in the umbilical cord blood have therapeutic value for the treatment of blood disorders and immune diseases.

The collection and storage of umbilical cord blood when a baby is born is becoming increasingly common. The reason is that the cells contained in the umbilical cord blood have therapeutic value for the treatment of malignant and non-malignant blood disorders and immune diseases. Cord blood has been used in transplant medicine since the first allogeneic cord blood transplant was performed in 1988 and, over the last 25 years, this activity has grown rapidly.

Allogeneic cord blood transplantation in children has similar survival rates compared to transplantation of haematopoietic stem cells from other sources (e.g. bone marrow), and results for adults continue to improve.

In recent years, the number of cord blood banks offering families to store the cord blood of their babies for possible future private uses against up front and yearly fees has grown. Parents are nowadays facing the question of whether to donate their cord blood for public use, to store it for private use, or discard it after birth.

If you are about to become a parent, you may find it useful to review this information so you can make an informed decision

DID YOU KNOW?

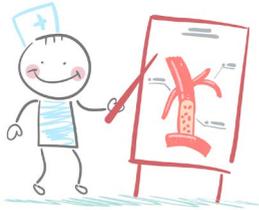
More than 730,000 cord blood units are available worldwide to be used for any patient in need, and about 35,000 cord blood transplants have been performed.

on what to do with your baby's cord blood.

This guide has been prepared by the Council of Europe European Committee on Organ Transplantation, composed of internationally recognised experts, to provide clear, accurate and balanced information about the use of cord blood in medical treatment and to guide parents through their blood storage options.

What is cord blood?

After a baby is born and the umbilical cord is cut, some blood remains in the blood vessels of the placenta and the portion of the umbilical cord that remains attached to it. After birth, the baby no longer needs this extra blood which is called umbilical cord blood or “cord blood” for short.



Cord blood contains all the normal elements of blood - red blood cells, white blood cells, platelets and plasma. But it is also rich in haematopoietic stem cells, similar to those found in the bone marrow.

Stem cells have the remarkable potential to develop into many different cell types in the body during early life and growth. They serve as a sort of internal repair system, dividing more or less without limit to replenish other cells as long as the person is still alive. This is why they may offer treatment options for a variety of diseases.

Haematopoietic stem cells are the blood cells that give rise to all the other blood cells. Blood cells are vital to the human body. There are three types of blood cells:

- Red blood cells, which transport oxygen throughout the body;

VOCABULARY

Cord blood is the blood that remains in the **umbilical cord** connected to the placenta after childbirth.

- White blood cells, which are part of the immune system involved in defending the body against both infectious diseases and «foreign» materials, like tumour cells;
- Platelets, which are involved in the physiological process that stops bleeding.

Every year, thousands of patients are diagnosed with malignant or non-malignant haematological diseases that can be treated using haematopoietic stem cell transplantation as part of the therapeutic regime. When transplanted, haematopoietic stem cells repopulate the patient's bone marrow, proliferate and differentiate into mature and functional blood cells.

How is cord blood obtained?

The blood from the umbilical cord and the placenta is no longer needed by the baby or the mother after birth.

Once the baby is delivered, the umbilical cord is clamped. The blood from the umbilical cord and the placenta is then no longer needed by the baby or the mother. At this point, the cord blood can be collected, either before or after the placenta is delivered, depending on the procedure at the hospital. If the cord blood is not collected for storage purposes, it will be thrown away and incinerated like other

DID YOU KNOW?

The storage life is still unknown, but studies have shown that cord blood units stored for longer than 23 years might still be viable.

biological products in accordance with national and international regulations.

Cord blood is collected in a sterile bag, which is referred to as a cord blood unit. In order to collect enough cells that can be used for transplantation it is important to collect an adequate volume of cord blood (some countries recommend at least 70 ml).

The bag is then sent to a cord blood bank, where tests and controls are performed (cell count, absence of transmissible diseases, HLA typing). Many collected cord blood units however, end up not being stored for transplantation because they do not contain enough blood or cells to be transplanted into a patient.

When the cord blood unit is considered to be suitable for transplantation, it is given an identification number and frozen for long-term storage in the bank. Normally, cord blood units are stored in liquid nitrogen or in the vapour phase of liquid nitrogen to keep them at -150°C or lower.

Once collected and stored in a public bank, the cord blood unit is listed in a registry and made available for patients.



What is cord blood used for?

Haematopoietic stem cells used for transplantation can be obtained from:

- Bone marrow
- Peripheral blood
- Cord blood

Transplantation of haematopoietic stem cells is currently the only available treatment for patients with blood and immune system disorders such as myelomas, leukaemia, lymphomas and myeloproliferative syndrome.

In these conditions, the patients receive large doses of chemotherapy or radiation therapy to kill all the sick cells in their own blood. Doctors will then use haematopoietic stem cells to repopulate their bone marrow with healthy cells.

Haematopoietic stem cells used for transplantation may be obtained from different sources:



VOCABULARY

Allogeneic transplantation: carried out with another person's cord blood.

Autologous transplantation: carried out with the person's own cord blood.

- **Bone marrow.** Collected from the pelvic bone. This has been the main source of haematopoietic stem cells for the last few decades. The first bone marrow transplantation was reported in 1957 by Dr E. Donnall Thomas, who later received a Nobel Prize for his pioneering research.
- **Peripheral blood.** To collect haematopoietic stem cells from the blood, the donor has to receive a pharmacological treatment to make the haematopoietic stem cells leave the bone marrow and enter

the blood stream, where they can be easily collected by a procedure called apheresis.

- **Cord blood.** The first transplantation using haematopoietic stem cells from cord blood was performed in 1988 by a team led by Dr E. Gluckman to treat a five-year-old boy suffering from Fanconi's anaemia.

National registries are linked worldwide to increase the chance for doctors to find the most suitable donors for their patients.

Haematopoietic stem cell transplantation can be carried out using another person's cells (either a family member or an unrelated donor). This is known as an "allogeneic transplantation". Alternatively, the transplantation can be carried out using the patient's own haematopoietic stem cells. This is called "autologous transplantation".

Bone marrow and peripheral blood stem cells are obtained from living donors, who can either be family members or unrelated volunteer donors. Volunteer donors are generous people who altruistically register in national bone marrow donor registries in case a compatible patient may need their cells. National registries are linked to international registries to increase the chance for patients to find the most suitable donor.



DID YOU KNOW?

There are currently more than 28 million adult donors recorded in registries worldwide.

Cord blood is an alternative source of haematopoietic stem cells, which has been

widely used for patients lacking a compatible donor. Contrary to bone marrow and peripheral blood stem cells, which are only collected from the donor when a patient needs them, cord blood units are collected and stored in advance and can be readily available for any patient in need of an urgent transplant. Since a baby's immune systems is less mature, when their blood is used as a source for haematopoietic stem cells, it allows for less stringent donor and recipient matching than when the stem cell donor is an adult. Therefore, when transplanting haematopoietic stem cells from cord blood, the risk of the patient developing graft versus host disease (GVHD), a condition in which the haematopoietic stem cells from the donor attack the tissues and organs of the patient, is much lower than when using stem cells from peripheral blood or bone marrow.

For a cord blood unit to be used in a transplant, it must contain enough stem cells. The quantity and quality of cells in units stored at a cord blood bank differ, and these factors are influenced by natural variation in the cord blood itself and the way that the cord blood is collected, transported, processed and stored. Well-controlled procedures during all phases of cord blood banking are important to the success of a cord blood stem cell transplant.



CORD BLOOD BANKING MODELS

Public use banking

Public cord blood banks collect, process and store cord blood units for allogeneic transplantation. These banks are often financed by the national health systems and store cord blood units altruistically donated by parents for potential use by any patient in need.

Public banks also store samples for “related allogeneic” use – i.e. transplantation in a sibling of the donor – if, prior to the birth of the baby-donor, the sibling is diagnosed with a disease that could be treated with cord blood.

When the parents donate their cord blood to a public use bank, they sign an informed consent form giving the bank permission to list their child’s cord blood on a national registry that can be searched to find a match for a patient. The cord blood is listed purely by its tissue type, with no information about the identity of the donor. Success in finding compatible donors depends on the size and diversity of the available cord blood stocks. That is why all national registries worldwide are connected and share information about their stored units. This helps to find the most suitable and compatible donor for

DID YOU KNOW?

Different types of cord blood banks exist and it is important to understand the differences between them to make informed decisions.

any recipient in need.

Public use banks are subject to national regulations and they need to follow strict protocols to obtain safe and high-quality cord blood units with high cell numbers since they aim to bank as many cord blood units as possible for use in established treatments. It is only then that their units can be included in the national registry. In some countries an international accreditation (FACT-NetCord or AACBB) is additionally required. Furthermore, such accreditation is compulsory for cord blood banks listed in the global donor registry.

The Council of Europe, in its **Recommendation (2004)8 on autologous cord blood banks**, recommends to member states that cord blood banks should be based on altruistic and voluntary cord blood donation and used for allogeneic transplantation and related research. The establishment of cord blood banks for autologous use should not be supported by member states or their health services.

Family use banking

Family use cord blood banks collect, process and store cord blood units for autologous or family use, which means that these cord blood units will be stored for the exclusive use of the donor, or someone in his/her family, should they develop a disease requiring haematopoietic stem cell treatment in the future.

Most of these banks are private institutions and they function on a for-profit basis. In these banks, the family pays a fee to collect and to store the cord blood of their baby and these units will not be made available for public use through national or international registries.

In order to be authorised, all cord blood banks have to comply with general national regulations on good manufacturing practices and marketing. However, some key quality criteria for the storage of cord blood units to be used in transplantation (i.e. the volume of blood to be collected, the maximum time between collection and processing and the number of cells per unit) are not always addressed in national legislation but rather in the standards developed by specialised international accreditation organisations (e.g. FACT-NetCord or AACBB). Therefore, parents should also study if the bank has any other accreditations by international accrediting bodies.

Furthermore, parents should verify with the bank what would happen to their cord blood unit if the bank were to close down for any reason.

Additionally, they should also be aware that, in most family use banks, cord blood units will be discarded if storage payments from the parents cease.



Alternative cord blood banking schemes

Nowadays, alternative cord blood banking options are being offered to the public. For example, hybrid cord blood banks offer families the option of privately storing their unit or donating it for public use. Whatever

their choice, the unit will be stored in the same facility.

In addition, in some countries legislation permits private storage of cord blood units for autologous or family use but they must be made available for allogenic transplantation if during a search they are found to be a good match for a non-related patient.

DID YOU KNOW?

When considering hiring the services of a family use bank, parents should carefully study if the bank has all the authorisations required by the national law and if it has any accreditations from specialised international accreditation organisations (e.g. FACT-NetCord or AACBB).

UNDERSTANDING THE DIFFERENCES BETWEEN PUBLIC DONATION AND FAMILY USE STORAGE

Donation to a public use bank is a source of hope for patients who have no matched bone marrow donor in their own family and increases their chances of finding a compatible donor in international registries.

If a mother meets the eligibility requirements for collection and her baby's cord blood is fully qualified for transplantation, it can be stored in a public use bank.

Donation to a public use bank is done mainly for the benefit of others and has the potential to save the life of any person for whom the unit is a good match. It is a source of hope for patients who have no matched bone marrow donor in their own family and increases their chances of finding a compatible donor in international registries.

Public banks will store only high quality cord blood units that are likely to contain enough cells for a transplant since they aim to bank only those cord blood units that have the highest chance of contributing to a successful clinical outcome. Indeed, as many as 80% of the units collected in maternity hospitals are discarded by public use banks because they do not contain enough cells, have become contaminated and/or have lost viability when transported from the collection site to the bank, according to the quality standards set by the international accreditation organisations.



DID YOU KNOW?

In most cases, when a patient needs cord blood transplantation, cells from a healthy donor are preferred to his own cord blood since his/her cells may carry the same genetic or congenital disorder that caused the disease.

On the other hand, family use banks store units for the use of the donor or a family member. Private family use cord blood banks may not follow the same strict acceptance criteria as those in public use banks and they can store cord blood units even if they do not meet the critical characteristics (i.e. the volume of blood and number of cells) that need to be fulfilled in order to be used for successful transplantation of future adult patients.

Many parents could think they are buying a “biological insurance” for their child when they contract these services and may feel that the peace of mind afforded by private storage is worth the costs. However, parents should be aware of the low probability of using one’s own cord blood for autologous transplantation. Numerous studies are available on the probability of autologous use, which is estimated at between 1:20,000 and 1:250,000. Additionally, a single cord blood unit may not always contain enough haematopoietic stem cells to treat grown up children and adults. In these cases, the privately stored unit will not be enough and additional units (most probably from an unrelated donor and stored in a public use bank) will still be needed.

Furthermore, taking into account that the possibility of a cord blood unit being released over a period of 15 years is very



low, there is a very high probability that, should the donor or a family member (sibling) of the donor need a transplant in the future, the unit would still be available even if it was stored in a public use bank.

Parents should pay special attention to advertisement practices used by certain family banks. Data given to the parents is sometimes incomplete or inaccurate, not supported by scientific evidence, and could lead them to a non-informed choice. Many family use banks advertise possible future uses not currently established. There are many on-going research protocols and clinical trials using privately stored cord blood units in regenerative medicine. However, they have not so far shown any significant scientific evidence to support a definitive cure of conditions such as diabetes, heart disease, cerebral palsy or autism. Furthermore, every such future therapy might also be achieved with stem cells obtained from other sources such as bone marrow and blood, and at a lower cost than privately storing cord blood.

The Council of Europe supports and recommends the development of altruistic and voluntary donation and the public banking of cord blood for allogeneic transplantation.

Many international organisations, authoritative institutions and scientific societies all over the world speak out against speculation over the possible future uses of cord blood. Instead, they promote the altruistic donation of cord blood to public use banks. These cells are made available to treat patients with specific diseases

and medical conditions, a practice which has proven to save thousands of lives worldwide. Banking of cord blood for public use ensures international solidarity and is a very efficient way of storing cord blood stem cells.

Can all mothers donate their cord blood?

Every healthy mother with a normal pregnancy can donate cord blood.

But, under certain conditions, mothers are not allowed to donate cord blood. Some of the conditions are:

- Twins or multiple births: twins and other multiples are typically smaller and do not have enough umbilical cord blood for transplants;
- Premature births: small babies typically do not have enough cord blood for transplants, and these births often involve complications;
- When the baby's mother, father or siblings have had some type of cancer;
- When the mother has diabetes and takes insulin that contains animal products (bovine insulin);
- When the mother has received an organ or tissue transplant in the last



DID YOU KNOW?

Cord blood collection is performed only in the case of a normal pregnancy, full-term delivery and in the case of a healthy new-born baby. In this situation, cord blood donation carries no risks for the mother or the child.

12 months;

- When the mother has an enlarged risk for acquiring a blood transmitted disease (i.e. has had a recent tattoo or piercing in which shared or non-sterile inks, needles, instruments or procedures were used;
- When the mother has lived in a part of the world where certain diseases that are carried in the blood are more frequently contracted.

The purpose of these restrictions is to protect patients in need of a transplant and the donors themselves. The physicians or midwives who conduct the health screenings can answer any questions you may have about your specific situation.

The decision to donate is a personal one and must be based on good information and advice which can be given by the health authorities and your doctor.

Will I be tested before I can donate?



Yes, if you choose to donate your cord blood for public use you will be asked to complete a consent form and a mother and family health questionnaire. You will also need to provide a small sample of

your blood to be screened for infectious diseases, including hepatitis and HIV/AIDS.

In the unlikely event that any test result is positive, your doctor will contact you to offer appropriate advice.

What do I need to do if I decide to donate?

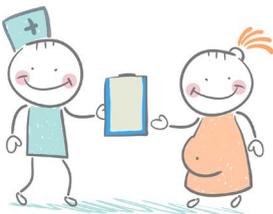
Donating cord blood to a public-use bank involves talking with your doctor or midwife about your decision to donate.

Not all hospitals and clinics are able to be part of the public-use donation system. You should check with your Health Authority, doctor or midwife about the national or regional list of available centres. Also, every national and regional health centre has a different collection protocol.

You can sign up to donate when you are between 28 and 34 weeks pregnant (although some hospitals will take last-minute donations). Most public cord blood banks and hospitals need several weeks before your baby arrives to check your medical history and eligibility to donate.

You will also need the cooperation of your healthcare provider.

Upon arriving at the hospital, remind the labour and delivery team that you are donating your cord blood.



What are the costs of cord blood storage?

The costs of public use banking are covered by the public health system. If parents decide to donate their cord blood, the process will be free of charge for them.

In the rare and specific case of direct donation, when there is a pre-existing medical condition in one of the child's siblings at the time of donation, the cord blood can be stored in a public bank for direct use in that sibling. The costs of this banking will be covered by the public health care system in most European countries.

Private family banking prices can vary from country to country and from one bank to another. The prices range between 900 and 2,400 euros and these include the storage fee for a certain number of years. An alternative formula that some banks propose is the payment of an annual storage fee between 50 and 150 euros plus the initial service (collection and process), which can cost between 300 and 600 euros.

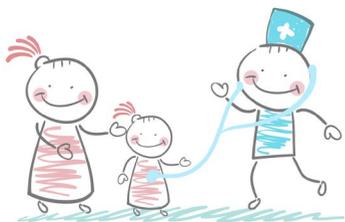


DID YOU KNOW?

Cord blood storage for public use is free of charge for the parents. On the other hand, storing privately for family use can cost up to 2,400 euros.

TAKE-HOME MESSAGE

Deciding to store your child's cord blood is a personal decision. Some people feel that the potential benefits are too few to justify the money. Others believe that it is a worthwhile investment. The key is to understand the details so you can make a rational and well-informed decision. We hope the information provided in this brochure will help families through this process.



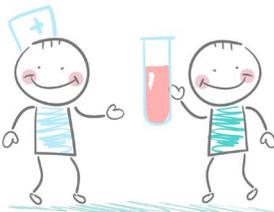
In summary:

- Public cord blood banking does not require parents to cover any costs. It is an altruistic donation that can give birth to hope for a patient in need, including your child should he/she ever need a cord blood transplantation;
- Cord blood donation to public use banks will increase the number and diversity of cord blood units available for patients of ethnic minority or multi-racial groups;
- The costs of collection, processing and storage at family use cord blood banks are paid by the parents while the chance of these cord blood units being used by the child or its siblings is extremely low;
- There are currently no evidence-based scientific data but only very

The Council of Europe and most professional associations and physicians recommend cord blood banking for public use.

weak clinical arguments to support cord blood banking for autologous use;

- When patients need a cord blood transplant, in most cases it is due to a genetic or congenital disease. However, the altered genes may also be present in the baby's cord blood, so it would not be safe as a transplant source and stem cells from a donor would be preferred;
- Grown up children and adults need more cells to be transplanted than those contained in a single cord blood unit. Therefore, in most cases, even if parents had stored a unit for family use, it would not be sufficient for a successful transplantation and additional units stored in public use banks would still be needed;
- Family use banks do not always follow the same strict criteria in terms of cell quality and number as public use banks;
- Because of the above limitations and the uncommon occurrence of diseases treatable with stem cell transplants, there have been only ~200 units released worldwide by family banks for transplantation in cases of haematological conditions, as recorded in the scientific literature. In contrast, approximately 35,000 unrelated donor cord blood



transplants have been performed through the international network of public use banks;

- There is no current evidence to support the efficacy of experimental cures other than transplantation. Therefore, families should be cautious about banking services sometimes advertised by family use cord blood banks, including potential future uses like stem cell therapies that have not been yet validated.

The Council of Europe and most professional associations and physicians **recommend cord blood banking for public use** and do not support private cord blood banking for the child or its direct family as a form of “biological insurance”.

Donating your baby’s cord blood for public use is the best and most efficient option, having the potential to provide life-saving treatment for the many patients in need.

The EDQM is a directorate of the Council of Europe, an international organisation founded in 1949 that covers almost the entire continent of Europe. The Council of Europe aims to develop common democratic and legal principles based on the European Convention on Human Rights and other reference texts on the protection of individuals.

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