# 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 https://go.edqm.eu/transplantation.

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# INTRODUCTION

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 blood disorders and immune diseases. Cord blood has been used in transplant medicine since 1988 and, over the last 25 years, this activity has grown rapidly.

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

Cord blood transplantation in children has similar or superior survival compared to transplantation of haematopoietic stem cells from other sources, and results for adults continue to improve.

In recent years, a number of cord blood banks offering families to store the cord blood of their babies for possible future private uses and in exchange for substantial fees have emerged. Parents are nowadays facing the dilemma of using these private services, donating their cord blood for public use or discarding 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 on what to do with your baby's cord blood.

## DID YOU KNOW?

More than 600,000 cord blood units have been stored for transplantation worldwide, and more than 30,000 cord blood transplants have been performed.

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. This blood is called umbilical cord blood: "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 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 can be used to treat many 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.

- White blood cells, which are part of the immune system involved in defending the body against both infectious diseases and foreign materials (invading micro-organisms, foreign particles or tumours);
- Platelets, which are involved in the physiological process that stops bleeding.

Every year, thousands of patients are diagnosed with diseases treatable by haematopoietic stem cell transplantation. 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 are 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 are 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 biological products in accordance with

**DID YOU KNOW?**

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

national and international regulations.

Cord blood is collected in a sterile bag, which is referred to as a cord blood unit. It is important to collect at least 70 $cm^3$ of cord blood. The bag is then sent to a cord blood bank, where tests and controls are performed (cell count, absence of transmissible diseases, HLA typing). A big percentage of donated cord blood units end up not being stored for transplantation, usually 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.

Once stored, the cord blood unit is recorded in a registry and made available for use.

# What is cord blood used for?

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

Haematopoietic stem cells used for transplantation can be obtained from:
- Bone marrow
- Peripheral blood
- Cord blood

myeloproliferative neoplasms.

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:

- Bone marrow, collected from the hip. 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 go into the blood stream, where they can be easily collected by a procedure called aphaeresis.
- Cord blood. The first transplantation using haematopoietic stem cells from cord blood was performed in 1988 by a team led by Dr E. Gluckman

## VOCABULARY

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

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

to treat a five-year-old boy suffering from Fanconi's anaemia.

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".

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

Bone marrow and peripheral blood stem cells are obtained from living donors, who can either be family members or unrelated volunteer donors. 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 doctors to find the most suitable donors for their patients.

Cord blood is an alternative source of haematopoietic stem cells that 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 stored and readily available if a patient is in need of an urgent transplant.

## DID YOU KNOW?

There are currently more than 22 million adult donors recorded in registries worldwide.

In this case, the donor's immune system was less mature (he/she was a baby), which allows for less stringent donor and recipient HLA matching than if the donor had been an adult. When transplanting haematopoietic stem cells from cord blood, the risk for the patient developing graft versus host disease (GVHD) effect, a condition in which the haematopoietic stem cells from the donor attack the tissues and organs of the patient, often with a fatal result, is much lower than when using stem cells from peripheral blood or bone marrow.

# What types of banks store cord blood?

## Public use banks

Public cord blood banks collect, process and store cord blood units for allogeneic use. These banks are financed by the national health systems and store cord blood units altruistically donated by parents for the use of any patient in need. However, their cord blood unit may also be used by including their own child if he/she later needs a cord blood transplant and the unit is still available.

The parents sign an informed consent form giving the bank permission to list

## DID YOU KNOW?

Over 600,000 units are stored in quality controlled public use cord blood banks.

their child's blood on a national registry that can be searched to find a match for a transplant 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. This is why all the national registries worldwide are connected and share their stocks. This helps to find the most suitable and compatible donor for any recipient in need.

Public use banks are subjected to national regulations and have to be accredited (FACT-Netcord or AACBB accreditation), following strict protocols to obtain high-quality cord blood units with a high number of cells.

## Family use banks

Family use cord blood banks collect, process and store cord blood units for autologous or family use, which means that the cord blood units will be stored for the exclusive use of the child, 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 banks and they function on a for-profit basis. In these banks, the family pays a fee to store the cord blood of their baby and these units

Family use banks are not subject to regulations and international accreditation, so they apply less stringent quality criteria for the storage of cord blood units.

are not available for public use through national or international registries.

Contrary to public use banks, family use banks are not subject to regulations and international accreditation, so they apply less stringent quality criteria for the storage of cord blood units. Since they charge the families for each unit stored, they try to store as many as possible, even if the likelihood of them being used in the future is extremely low.

When considering hiring the services of these family use banks, parents should also carefully study what will happen to the cord blood units if the bank goes out of business in the future. They should also be aware that, in most family use banks, cord blood units will be discarded if storage payments from the parents cease.

# UNDERSTANDING THE BENEFITS OF PUBLIC vs FAMILY USE STORAGE – THE FACTS

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

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 do not find one in the international registries.

Donation to a public use bank is made 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 do not find one in the international registries.

Family use banks store units solely for the use of their own child or a family member. Parents should be aware of the low probability of using one's own cord blood for autologous transplantation. Additionally, a single cord blood unit will not contain enough haematopoietic stem cells to treat larger children and adults. In these cases, the privately stored unit will not be enough and units stored in a public use bank will still be needed.

Moreover, not all collected cord blood units are viable for use. Around 20% of the units do not contain enough cells, and some units may become contaminated or lose viability when transported. Ultimately,

## DID YOU KNOW?

In most cases, when a patient needs cord blood transplantation, cells from a healthy donor are used, since the cells in their own cord blood may carry the same genetic or congenital disorder that caused their disease.

a large percentage of the units collected in a public use banks are discarded (as many as 80% in some banks). However, the quality standards in family use banks do not usually follow the same strict criteria as those in public use banks, which may result in stored units finally not being fit for transplant if ever needed.

Many family use banks advertise possible future uses not currently established. So far there is no evidence to support claims that privately stored cord blood will one day be used to cure diabetes, heart disease, cerebral palsy or autism. Moreover, every future therapy that family use cord blood banks refer to in their claims could also be possible with stem cells obtained from other sources such as bone marrow and blood, and at a lower cost.

Many parents are led to believe they are buying "biological insurance" for their child and may feel that the peace of mind afforded by private storage is worth the high price. Unfortunately, they are often misinformed and misled by inaccurate information, vague promises and aggressive marketing techniques that will exploit their feelings of guilt if they "miss the unique chance of saving their child's life in the future".

Many international organisations and scientific societies all over the world speak

**DID YOU KNOW?**

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

out against speculation over the possible future uses of cord blood. Instead, they promote the altruistic donation of cord blood to public use banks, which is a reality that is saving thousands of lives worldwide.

Public banking of cord blood ensures international solidarity and is the most efficient way of storing cord blood stem cells. These cells are made available to treat patients with specific diseases and medical conditions, thereby saving lives.

## Can all new mothers donate their cord blood?

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

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

## 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.

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,
- When the mother has received an organ or tissue transplant in the last 12 months,
- When the mother has had a tattoo or ear, skin, or body piercing in the last 12 months, 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 transplanted patients and donors. The midwives who conduct the health screenings can answer any questions you may have about your specific situation.

# Will I be tested before I can donate?

Yes, public cord blood banks will ask you 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?

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

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

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 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.

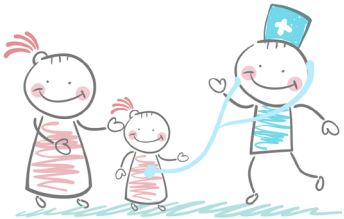
Private banking prices can vary from country to country and from one bank to another. Private banks usually charge the family between 2,000 and 2,500 euros for the process, plus 150-200 euros as an annual storage fee.

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.

**DID YOU KNOW?**

The cost of public banking is free of charge for parents while private banking costs around 2,500 euros plus annual fees.

# TAKE-HOME MESSAGE



Deciding to bank 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. Considering that:

- Public cord blood banking costs the parents nothing, but can give birth to hope for a patient in need;
- 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;
- Collection and storage costs at family use cord blood banks are high while the chance of these cord blood units being used by your child is extremely low;
- There is no evidence-based scientific data and only very weak clinical arguments to support private cord blood banking;
- When patients need a cord blood transplant, in most cases it is due to a genetic or congenital disease. However, the altered genes may

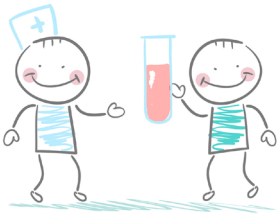
The Council of Europe and most professional associations and physicians do not recommend private cord blood banking.

Donating your baby's cord blood for public use is the best and most efficient alternative.

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;

- The quality and cell count of cord blood units stored in family use banks do not usually follow the same strict criteria as in public use banks. Additionally large child and adults will need more than one cord blood unit to be transplanted. Therefore, units stored in public use banks will still be needed in most cases;
- Because of these limitations and the uncommon occurrence of diseases treatable with stem cell transplants, there have been far fewer than 1,000 autologous cord blood transplants in the last two decades in contrast to more than 30,000 unrelated donor cord blood transplants that have been performed worldwide.

The Council of Europe and most professional associations and physicians **do not recommend private cord blood banking** and have declared the use of cord blood as "biological insurance" to be "ill-advised". **In contrast, donating your baby's cord blood for public use is the best and most efficient alternative, 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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