

References

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The miracle of stem cells

A simple introduction to stem cell banking



Dear parent-to-be,

The world of umbilical cord blood and tissue stem cell banking is as exciting as ever.

If you didn't know, your baby's umbilical cord is a rich source of potentially lifesaving stem cells and saving their umbilical cord blood and tissue following birth is a once in a lifetime opportunity to capture them.

Over the past 10 years we have witnessed extraordinary developments in medical science which have accelerated the odds of benefiting from stem cell treatment to 1 in 200¹ for transplant medicine and it is estimated the chance could be as high as 1 in 3² for regenerative therapies.

Far too often, we (stem cell storage providers) are approached by parents who were disappointed to learn of umbilical cord blood and tissue banking for their second or third child and not their first so we have decided to join forces in a bid to help spread the word. As a result we have specifically tailored this brochure to the needs of prospective parents like you, providing a comprehensive overview of cord blood banking for both the private and public sector from a parent's perspective.

If you have any unanswered questions, queries or concerns, please feel free to consult with your healthcare provider or chosen stem cell storage provider.

With best wishes,

The Cord Blood Storage Team



Why umbilical cord stem cells?

Umbilical cord stem cells are considered to be one of the most promising sources of future medical treatments. Stem cells can be obtained from the remaining blood in the umbilical cord (cord blood), or from the umbilical cord itself (cord tissue) and could not only provide access to treatments today, but also to future regenerative therapies for strokes, diabetes, heart disease and many more.

Although it is possible to extract stem cells from a variety of different sources in the human body, umbilical cord (cord blood and cord tissue) stem cells have a number of distinct advantages:

Collection is simple, painless and carries no risk to the donor unlike collection from other, adult sources. For example, the collection of bone marrow is carried out under general anaesthetic and can cause donors to experience temporary, short term lower back pain though this usually disrupts normal activities for no more than two days. An alternative source of adult stem cells is peripheral blood, the collection of which carries less risk than bone marrow as it done without anaesthetic and simply involves inserting a needle into the donor's arm to allow the blood to pass through a special machine for 4-5 hours. The only associated side effect with this collection method is mild flu-like symptoms.

Matching between tissue types is much easier with umbilical cord stem cells as they are less developed than other, adult stem cells. This means there is a higher chance cord blood samples can be used for someone other than your child such as family members or unrelated patients in need of treatment.

Risk of GVHD (Graft vs. Host Disease) is reduced when using umbilical cord stem cells. GVHD occurs when stem cells are transplanted into a patient unrelated to the donor and the stem cells start to attack the transplant recipient. On average, this occurs in 60-80% of all unrelated transplants³ and can be a potentially fatal condition. Using naïve stem cells from the umbilical cord can reduce the chance of this happening.

The miracle of stem cells

What are stem cells?

Stem cells are our bodies' "building blocks" and also act as our "repair system". Essentially, their job is to make sure we continue to develop, grow and remain healthy throughout our lives.

Although our bodies comprise over 200 different cell types, each of these cells are very specialised and only know how to undertake a particular number of functions. For example, a cardiac muscle cell knows only how to work with other heart muscle cells to pump blood around the body and similarly, red blood cells are programmed to carry oxygen through the blood stream. Stem cells however, are very different.

Unlike the other 200+ specialised cell types, stem cells are naïve, or unspecialised, and have the unique ability to self-renew and multiply. More importantly still, stem cells actually have the potential to transform into any other cell type which means we may not need a cardiac muscle cell to repair a damaged heart, or nerve cells to repair the nervous system as stem cells could be used instead. A stem cell has truly remarkable properties and it is for these reasons that they are so valuable to modern day medicine.



Are cord blood and cord tissue stem cells the same?

Cord blood and cord tissue actually contain different stem cell types, each of which can be used to treat different things. When looking to save your baby's stem cells you should be given the option to save their cord blood, cord tissue or both so it is important to understand the differences between the two and the treatment options available before making your final decision.

Cord blood contains a large number of rare Hematopoietic Stem Cells (HSCs). HSCs can convert themselves into other blood cells such as red blood cells, white blood cells and platelets, and are used routinely in the treatment of blood related disorders such as leukaemia. In fact, there have been over 30,000 transplants worldwide using cord blood⁴, treating more than 85 serious diseases and disorders.

Cord tissue contains a very high concentration of Mesenchymal Stem Cells (MSCs), a recent discovery that has sparked great interest. This particular type of stem cell has been proven to produce connective tissue such as bone and cartilage but more astonishingly, MSCs have also been shown to rehabilitate damaged skin, liver and neurological cells. These discoveries are very much in their infancy with such treatments still in clinical trial though many parents still opt to save their baby's cord tissue in the hopes it will provide access to these regenerative therapies in the future.

What can these stem cells be used for?

There are two main areas of therapy available when saving umbilical cord blood and tissue; these are transplants and regenerative medicine. Generally speaking, whilst transplant medicine requires the HSCs found in cord blood, the MSCs in the tissue are instead used for regenerative medicine.

HSCs are used routinely in transplant medicine and form part of standard therapies for...

Acute Leukaemia

e.g. Acute Lymphoblastic Leukaemia, Acute Myelogenous Leukaemia

Chronic Leukaemia

e.g. Chronic Myelogenous Leukaemia, Juvenile Myelomonocytic Leukaemia

Lymphomas

e.g. Hodgkins Lymphoma, Non-Hodgkins Lymphoma

Anaemias

e.g. Aplastic Anaemi, Fanconi Anaemia (first cord blood transplant)

MSCs do not yet form part of standard therapy, though extensive research is underway for...

Autism

Phase 1 Clinical Trial

Cerebral Palsy

Phase 1 & 2 Clinical Trial

Diabetes Type 1

Phase 1 & 2 Clinical Trial

Rheumatoid Arthritis

Phase 2 Clinical Trials

Crohn's Disease

Phase 2 & 3 Clinical Trial

Cardiac Repair & Recovery

Phase 3 Clinical Trial

... and many more.

There are still over 300 therapies in clinical trial or late stages of research using umbilical cord stem cells, and it is believed many of these will become reality for the lifetime of a child born today.

Clinical Trial Key:

- Phase 1:** Safety study to see if the procedure or drug is well-tolerated.
- Phase 2:** Larger study to measure effectiveness against a control group.
- Phase 3:** Even larger study to compare effects of various parameters (dose, administration... etc.) and to monitor any possible side effects.
- Phase 4:** Post-marketing studies to learn even more about risks, benefits, and optimal use.



Family or public banking - your options explained

What are my options?

There are three options available to you for your baby's umbilical cord blood and tissue. So that you are able to make the best decision for your baby, it is important to make sure you have all the information you need for each option.

To help make the process easier, we have outlined your options below and provided further information on each.

Family banking also referred to as private storage, this option allows you to save your baby's stem cells with a private stem cell storage bank. This gives your baby direct access to their own stem cells should the need for treatment ever arise.

Public banking also referred to as donation, allows you to donate your baby's stem cells to a public bank for possible use by an unrelated patient if ever required.

Disposal as medical waste.

Family Banking

Why should I consider family banking?

I'm sure if you ask you will be given a plethora of reasons why you should choose to save your baby's stem cells with a family bank, but the reality is different parents choose to do this for a number of different reasons. In our experience these may be:

Family illness

Cord blood is used routinely to treat a variety of life-threatening diseases such as leukaemia as well as blood, immune and metabolic disorders. Having a perfectly matched, easily accessible source of stem cells could prove an invaluable resource for your family.

Regenerative medicine

With over 300 therapies in clinical trial or late stages of research, the possibility of using stem cells to treat ailments such as brain injuries, diabetes and heart disease are fast becoming reality. In fact, it has been estimated that almost 1 in 3 people could benefit from regenerative medicine.

Chances of finding a match

There is no guarantee a public bank will be able to source a matched cord blood sample for treatment. In fact, 'only 60% of patients can find the best possible match from a stranger, and this drops dramatically to 20.5% if you're a patient from a black, Asian or ethnic minority background'⁵. Family banking guarantees a 100% perfectly matched cord blood sample for your baby and a 1 in 4 chance of a match between siblings. Both of these statistics are conservative as they are based on a 100% perfect match. It is possible to use umbilical cord stem cells effectively with only a good match (67%) as they are so naïve, so the chance of a match may be higher still.

Adoption or donor ovum/sperm

It is not always possible to have access to a biologically related family member following adoption or the use of donor ovum/sperm. Many parents therefore believe family banking is a unique opportunity to save these stem cells in order to guarantee a 100% match for their baby in case treatment is ever required.

Family Banking

Is there anything I need to be aware of?

Family banking can be expensive, especially when you still have un-ticked items on your baby essentials shopping list. Most family banks do fully understand how expensive this time can be so to help make things a little more manageable they offer spread payment plans, usually over 6, 12, 18 or 24.

How does it work?

Once you have made your decision to store with a family bank, you need to check that your chosen hospital will allow the collection to take place and if so, whether their staff are trained and licensed to collect for you. If staff aren't trained and licensed don't worry, all family banks are able to arrange or put you in touch with a third party technician (phlebotomist) to attend the hospital (day or night, weekday or weekend) to perform the collection on your behalf.

The good news is, most family banks work in the same way and the sign up process has been designed to be as easy as possible. To contract your chosen family bank, simply complete their Statement of Consent and Storage Agreement before arranging payment of the initial deposit. Your collection kit (containing everything needed to do the collection) will then be sent to you, usually for delivery the next working day.

On the day of birth, and following the successful delivery of your baby, your baby's cord blood and/or tissue will be collected. A small volume of your blood (maternal sample) will also need to be collected before everything is transported to your family bank's laboratory. The maternal sample will be tested for specific disease markers (such as HIV, Hepatitis B, Hepatitis C... etc.) and both the cord blood and tissue will be tested for viability and bacterial contamination. All test results should be notified to you and assuming everything passes without issue, your baby's cord blood and tissue stem cells are then placed into long-term storage and will remain there until they may be required.



How do I choose a family bank?

There are several family banks to choose from in the UK, all of whom offer different services and different benefits. When choosing a family bank, we recommend you check the following before making that all important decision:

Do they offer volume reduction or whole blood storage?

There are two cord blood storage methods available to you; volume reduction and whole blood. Whilst both methods allow you to capture the HSCs in the cord blood, there is much debate surrounding which is best. In line with most public banks worldwide, the majority of family banks in the UK have adopted volume reduction. Although the dominant storage method worldwide, we do still recommend you research this in more depth before making your final decision.

Do they hold a Human Tissue Authority (HTA) license?

Every tissue bank operating in the UK, both family and public, is required by law to hold an HTA license (www.hta.gov.uk). The regulations and guidelines enforced by the HTA ensure the quality and safety of your baby's stem cells are maintained from collection, processing and testing to long-term storage and any future use.

Do they hold other accreditations?

Some family banks choose to not only hold an HTA license but also partake in other regulatory programmes such as the MHRA (www.mhra.gov.uk) and the ISO Quality Management System (www.iso.org). Although participation is not mandatory, it is important to consider this when making your decision as it can be indicative of a family bank's devotion to continual improvement.

How long have they been operating?

Although most family banks in the UK have been operating for over 10 years and have a wealth of experience in the processing, testing and storage of these invaluable stem cells, some family banks are still relatively new to this practice and may not have the same level of experience. We therefore recommend you consider this before making your decision.

How many samples have they released?

This is an important question to ask as it gives you peace of mind that your chosen family bank is experienced in the preparation, release and transportation of samples for treatment. We recommend you ask why samples have been released (standard therapy, clinical trial or experimental treatment) and what the results of treatment are.



Public Banking

Why should I consider public banking?

Choosing to donate your baby's cord blood could help an unrelated patient in need of transplant in the UK or anywhere in the world.

Combined, the public banks in the UK have an inventory of at least 20,000 cord blood units⁶ of which 480 have been used in transplantation. Despite this resource and those provided by other public banks across the world, there are still challenges in the rapid identification of suitably matched cord blood units. By donating your baby's cord blood however, you are helping to increase public stocks and give someone a better chance of survival.

Is there anything I need to be aware of?

Donated cord blood samples are made available for public use and are not kept specifically for your baby or family.

Should a cord blood transplant ever be required for a patient with leukaemia, lymphoma or other blood disorder, the public register will be searched for the most appropriate sample with the best match. This means should your baby's cord blood prove a match for someone else, their sample will be released for the treatment of that specific patient.

You also need to be aware that until world supplies are increased, there is still a chance that finding a matched cord blood unit may take time or that you may not find one at all. On average, where matched cord blood units are available, it takes 3 months from starting the formal search process to the day of transplant⁷.

How does it work?

You will need to register with your chosen public bank prior to the arrival of your baby, though you don't need worry too much about this as cord blood programme staff are on hand to help at each designated hospital. Once registered, the public bank will arrange for a trained technician or healthcare professional to collect your baby's cord blood following delivery. A small maternal sample will also be collected and together, they will then be transported to a designated laboratory.

On receipt of the samples, testing will commence to assess suitability of storage. If after this testing the cord blood sample is accepted, it will be uniquely coded and stored anonymously for future use.

Which public bank should I choose?

There are two public banks operating in the UK; Anthony Nolan and NHS Blood and Transplant (NHSBT). Both public banks are not only licensed by the HTA but also hold NetCord-FACT accreditations (www.factwebsite.org). When opting to donate your baby's cord blood, you need to be aware both public banks operate in a select number of hospitals across the UK which means you can only donate if you are due to give birth at:

Anthony Nolan

Birmingham Women's Hospital
King's College Hospital
Leicester Royal Infirmary
Leicester General Hospital
Nottingham City Hospital
Queen's Medical Centre, Nottingham
The Royal Free Hospital
St Mary's Hospital, Manchester

NHSBT

Barnet General Hospital
Luton and Dunstable Hospital
Northwick Park Hospital
St George's Hospital
University College Hospital
Watford General Hospital

Both public banks have chosen to limit the number of hospitals they operate in to maximise resources. Each of these hospitals enjoy a high birth rate and diverse population which results in a large number of donations with a wide variety of tissue types.

FAQs, Myths & Common Misconceptions

Still have questions? Not to worry, we hope the following frequently asked questions and common misconceptions help to answer these and address any questions, queries or concerns you may have.

FAQs

How is the cord blood and tissue collected?

Collection is safe, painless and only takes a few minutes following the birth of your baby and delivery of your placenta. Once the umbilical cord has been clamped and cut, your nominated obstetrician, midwife, phlebotomist or other healthcare professional will use the equipment provided in your collection kit to clean the umbilical cord. For cord blood collections, the needle attached to the blood bag is inserted into the umbilical vein and arteries where the blood is collected, using gravity, into the blood bag. For cord tissue, a 15cm length of the umbilical cord is selected and cut before being placed it into the collection pot provided. Both samples are then packaged back into the collection kit box and passed to you to await courier collection.

What's the average volume of cord blood collected?

The average cord blood collection for family banks is around 60ml, and for public banks it's around 89ml⁸. It is worth noting most public banks set stringent acceptance criteria for the volume of cord blood collected and those that do not meet these criteria will not be stored. It is for this reason that the recorded average volume of cord blood samples stored for public banks differs from those of family banks.

Can a sample be used more than once?

It is unlikely a sample would be used on more than one occasion today because the number of stem cells present in a single sample is usually sufficient for only one treatment.

Can a lower than average collection still be used?

It is quite possible your baby's cord blood will be used if a lower than average sample is collected. When considering cord blood transplants today, doctors must take into account the weight and general condition of each patient before deciding on a dose size. In the event a single cord blood sample is deemed insufficient for treatment, the doctor may perform a 'double transplant' using the original and another unrelated cord blood sample. This is a strategy used worldwide and is fast becoming routine. Looking to the future, clinical trials are underway to develop technologies that will allow a sample to be safely increased in size. This expansion technology means small samples could be amplified to a volume sufficient for treatment without the need for a double transplant.

How long can umbilical cord stem cells be stored for?

All storage terms offered by family banks in the UK must be evidenced which is why most family banks offer an initial storage term of 25 years. Current research has shown cord blood stem cells stored, thawed and used after 23.5 years are still

therapeutically viable⁹, and that similar cell types have maintained viability after 28 years¹⁰ or even 40 years¹¹. Although research is still underway to determine the maximum storage period, experts in the scientific community strongly believe these stem cells could be stored indefinitely.

Will I have to change my birth plan if I choose to save my baby's stem cells?

No. Whether you opt for a natural delivery or caesarean section, managed or physiological third stage of labour there should be no problem collecting your baby's stem cells. In fact, you'll find most banks across the UK recommend your birth plan is not

Common Misconceptions

Collecting my baby's stem cell will interfere with the third stage of labour

The care provided to you and your baby at such a critical time is of the utmost importance so we would never do anything to jeopardise this. It is therefore standard practice to only collect the stem cells once the third stage of labour has been successfully completed and both mother and baby are safe.

If I donate, my baby's cord blood will be there for me in the future

It is important to understand that only a small number of samples donated to public banks are stored. Studies have shown as many as 71% of all donations do not meet the established acceptance criteria for public banks¹³ and for the remaining 29% that do, each donation is placed onto the register anonymously. The chance of your sample being available to you or your family in the future is therefore quite low.

Doctors won't use a person's own stem cells to treat their disease

For environmental and non-genetic diseases, this simply isn't true. It is possible to perform an autologous

altered or compromised in anyway as there a few things that will adversely affect your baby's stem cells.

If I choose delayed cord clamping, will there be enough blood left for collection?

Yes. Recent studies have shown there is no significant effect on the quality or quantity of cord blood collected following delayed cord clamping¹². With strong evidence to suggest delayed clamping may reduce jaundice and low iron stores in new-borns, it is important to know both are possible.

(using a person's own stem cells) transplant for a number of diseases such as auto-immune disorders, solid tumours, acute myeloid leukaemia and some forms of Hodgkin's lymphoma. In fact, autologous transplants are also performed to help replenish the body's bone marrow following chemotherapy treatment for non-blood related cancers.

The chance of using stem cells is so small, there's no point in family banking

Stem cell therapy is a very real possibility for both transplant and regenerative medicine. In 2008, it was estimated that 1 in 200 people will undergo a stem cell transplant before the age of 70. The transplant data used in this study is now ten years old and stem cell research has continued to develop at an astonishing rate. In fact, it is now estimated that as many as 1 in 3 people will benefit from stem cell based regenerative therapies. Today, cord blood stem cells alone are used in the treatment of over 85 diseases and there are over 300 clinical trials underway.