

# COLLECTING AND STORING CORD BLOOD: IN THE WORLD AND IN LEBANON



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Expectant parents are faced with a lot of important decisions before their baby is born. These include the basics, such as what to name the baby, which Pediatrician to go to, breastfeeding or formula feeding, etc. however, nowadays, they have to consider also the issue of whether or not to bank their baby's umbilical cord blood.

What wouldn't parents do to make sure that their baby grows up to be healthy?

From ads in parenting magazines, direct mailings, and flyers in their obstetrician's office, expectant parents are repeatedly told of their 'once-in-a-lifetime chance' to save their baby's umbilical cord blood for possible use later to save his life.

Since it doesn't hurt to take a baby's umbilical cord blood that would be discarded anyway, it would appear not to be much of a question. There is the issue of what blood-banking system to use. A private cord blood bank for a family's own use is to be compared with the option to donate it to a free public bank. Furthermore, the major point is that this decision is to be taken at least a few weeks before birth.

## Tissue Collection

Following the birth of the baby and delivery of the placenta, a qualified healthcare professional cleans the umbilical

cord and draws venous and arterial blood into a special sterile collection bag. The blood should spontaneously flow into the bag by gravity. After sealing and labeling, the blood bag is handed to a special courier to be transported as soon as possible to the bank knowing that the interval between collection and storage is crucial for the viability of stem cells.

However, with the need to store a large volume of cord blood, there is the possibility that clamping of the cord might be done prematurely to secure an even 'extra' quantity. But most of this newborn's own blood is important for its immediate benefit to decrease the risk for anemia. That is why the umbilical cord should not be clamped before it stops pulsating, assuring good neonatal iron storage.

Before final cryopreservation and storage the cord blood should undergo viral testing (including HIV and Hepatitis B and C), tissue HLA and blood group antigen (ABO & Rh) typing and also examined for cell viability, nucleated cell count, molecule cluster (CD34), along with bacterial & fungal cultures.

Data of similar maternal tests should be adequately documented with the baby's tissues.

An intact segment of the umbilical cord may also be similarly handled.

## What to store

Cord blood can be stored as such.

Umbilical cord tissue may undergo extraction of stem cells before cryogenic storage. This has the advantage to yield minimally-manipulated cells that are treatment ready; however, this eliminates the option of using future developments in extraction modalities.

Still this is pure speculation and there is no guarantee that they will result in successfully retrieving more viable stem cells from a previously frozen cord.

## PRESENT STATUS OF STEM CELLS BANKS IN THE WORLD

Successes of academic and scientific research in stem cell therapies, along with the increasing health care awareness created an ever growing demand on stem cells banking. Now, government administrations regulate stem cell and tissue banking. Different standards have been drawn and updated for all the successive steps: collection, processing, storage, labeling and packaging. Also, distribution of cord blood stem cells and the manufacture of manipulated stem cells products with biologic function are subject to more regulatory standards.

Universities, pharmaceutical and other scientific institutions may have their own tissue banks they run for academic and scientific research. These are not normally available for the general population who has the choice of another two types of tissue banking: Public or Private. Cord blood can either be donated to a public bank or preserved in a private bank for the personal and family's potential future use. Parents who want to save the cord blood must choose between those two options. It is important to understand the differences before making the decision.

## Public

Public banks do not charge storage fees. Also, health care providers who typically charge a collection fee at delivery of the newborn, usually waive it if the parents are donating their baby's cord blood

Customarily, the mother is required to register by the 34th week of pregnancy with the public bank. She must also pass medical eligibility guidelines. If the donation meets the size threshold for transplant use, it will be saved and listed on a registry that can be searched by patients. From then on, the bank will own the stored cord blood and will decide solely on who will receive it. There is no guarantee that the cord blood you donated or a suitable match will be available if a family member should need it.

Because of the high costs required to establish and maintain them, they are mostly limited to governmental institutions

Public banks provide suitable cord blood to help people in need, free of charge.

They should accumulate enough samples of donor tissue to be able to provide efficient services. The necessary vol-



ume of this stock depends on the population and area they serve. Usually, it should be in tens of thousands.

The stored cord blood is available to any recipient when matching criteria are met. It even provides cord blood for parents who actually stored their baby's cord blood in a private bank, but find that they are not able to use it. 70% of patients do not have a matching donor in their own family. Because cord blood does not have to be matched as closely as adult donors' blood, it is especially helpful to patients from minority ethnic groups.

Occasionally, public banks may provide stored cord blood for medical research.

With much of the collection being sequestered in private banks for possible autologous use, there is a reason to expect that public banks may not be able to provide for the demand in coming years as use of cord blood for treatment of patients with diseases such as leukemia and lymphoma continues to increase.

Unfortunately, cord blood banks that allow you to donate cord blood aren't yet widely available. Interested persons wishing to donate their baby's cord blood to a public cord blood bank should talk to their doctor to see if there is one available in their area.

**Private**

Private Cord Blood Banking allows anybody to store baby's cord blood exclusively for personal and family use. Since many parents think this is a good idea, they would likely jump at this opportunity of doing something to keep their baby healthy and possibly save their life. The idea is that it is better to have cord blood stored and never need them, rather than need them and not have them.

The private sector jumped into this potential market. Contrary to the public banks, the client here owns the collected cord blood and decides alone on who uses it. If the child will need a stem cell transplant in the future, there will be no need to search for a suitable donor. (However, in cases of genetic diseases, a transfusion using a person's own cord blood may not be the best appropriate solution.) Again, if a family member will need it, there is a higher chance that this stored cord blood will be a suitable match. The success rates of cord blood transplants using cord blood from a family member are twice that of transplants using a public donor's cord blood.

This is most important for ethnic minorities.

Moreover, the activities of the private sector spread also in all the related fields; from storage, to stem cell therapies, covering research and development in tissue engineering and regenerative medicine. The most serious enterprises are hiring thousands of scientists and researchers providing them with all the needed support personnel and most up-to-date equipments. Aggregate expenses of the private sphere that are allocated for this are in billions of US Dollars; with an annual growth rate in the 2-digits. Most activity started in the United States. Recently, a notable similar trend is seen in the emergence of strong commercial activities outside the US too.

The private sector is working in parallel with academic institutions and universities. In this venture, benefit is mutual and they complement each other. However, the private sector is more driven by financial interests who at times cause conflicts with pure science. Their vision is more profit-oriented. But, on the other hand, they are more adept at risk management and follow a more resilient organization. They stress the more achievable results with the available technology and under existing the regulatory guidelines.

**Decision Making**

Parents are faced with a difficult dilemma when they are to choose between a public and a private bank. Would they go to serve the "greater good" of the community or should

they pay the high cost of a private bank? Even those parents who can afford it often find something else to do for their baby with that money; like start a college fund. Especially when they consider how unlikely it is that they would ever need to use that banked cord blood.

The reasoning may be a bit different for ethnic minorities who find it more challenging to obtain a stem cell match for potential treatments through public banks

In some studies, most women supported the donation of cord blood to public cord blood banks for potential transplantation and research, many citing altruism as the reason for this choice. A smaller proportion would feel guilty by not investing in a private bank.

Interested 'clients' choosing private storage will be faced by the huge amount of banks to choose from. They all claim "Scientific and Gold" standards. Here are some points to look for in a particular cell bank:

1- Reliability and commercial viability of the enterprise as assessed by its history.

2- Credentials of the bank (proper and ongoing accreditation and licensure).

It may be providing some additional and other procedures besides what it was originally accredited for. Also be aware of the time duration and period of renewal of the accreditation.

3- Clear contract (with no 'fine print') stating explicitly that the cord blood belongs to the donors with all the rights and privileges one would reasonably expect from such ownership.

No ambiguity should be left open as for future use.

Unequivocal spelling out of the rights to request termination of storage and verify destruction of the samples. Some banks revert ownership to the bank if the client cancels the contract or fails to pay maintenance fees acquiring the right to discard or to use the sample(s) at the bank's sole discretion.

4- What cell types are stored: Whole Cord Blood, Cord Tissue, other extracted specific sub-types of stem cells, Hematopoietic Stem Cells (HSCs), Mesenchymal Stem Cells (MSCs), Very Small Embryonic-Like Stem Cells (VSELs), and Unrestricted Somatic Stem Cells (USSCs). Consider that only some specific sub-types of stem cells have presently successful and meaningful use, but some other types may be discovered in future times to be of additional value to have other uses for other diseases.

5- Accessibility and location of the bank.

It is definitely safer to have the specimen split and stored in more than one physically and geographic separate area.

Also initial splitting into several containers allows multiple sample usage at different occasions without manipulation and maybe damage of the whole original specimen.

6- Time-Interval between the collection of neonatal samples and actual cryopreservation.

Real 24/7, 365 days per year availability is crucial.

7- Valid documentation of stem cells and maternal blood testing.

To include maternal virus testing.

8- Care during transportation and handling of specimen between (to and from) the bank and the healthcare facility. Special consideration where there is some international courier and custom constraints.

9- What volume of cord blood is stored; the sample may be too small to be usable, especially for adults because of their larger body mass.

10- Besides the fee that is paid initially for the collection and storage, there is the additional cost to retrieve cells for transplant and / or other uses. Normally, insurance companies and other guarantors do not cover for cord blood collection and banking. However, they may do so if there is a history of family disease.

11- Duration of paid-for storage, with the option and conditions to renew.

Though it is widely accepted in the scientific community that long term cryogenic storage can be indefinite, 25 years is the limit generally accepted at present as safe with the current experience with technologies for freezing and keeping viable and useful stem cell tissues.

12- Keeping the client updated (best thru a one-to-one) communication with respect to possible changes of bank facilities, status of the sample and pertinent recent stem cells research.

13- Most important is to know that in cases of genetic diseases, a transfusion using a person's own cord blood may not be the best suitable.

**RECOMMENDATIONS**

The probability of usage of cord blood for personal use is very small, unless when there is. Thus, they promise more than they can deliver. The activities of such banks raise serious ethical criticisms." This is done for a purely speculative purpose that some have termed as "biological insurance."

For those at low risk, private storage of one's own cord blood is unlawful in some countries, discouraged or strictly regulated in some others.

There is almost a general consensus among medical societies and organizations encouraging the general population to donate cord blood to public banks rather than storing them in private establishments.

The American Academy of Pediatrics (AAP) and many physicians do not recommend private cord blood banking. They only accept it as a "directed donation" in cases where a sibling or other family member already has a current need or a very high potential risk of needing an allogeneic transplant (mostly bone marrow).

That doesn't mean that the AAP is against umbilical cord blood banking though. Instead, they actually 'encourage' parents to donate their baby's cord blood to public cord blood banks. This can provide 'another source of hope for patients who have no matching donor in their own family, no unrelated donor in bone marrow donor registries that is a suitable match or no time to find a donor.'

The European Group on Ethics in Science and New Technologies (EGE) has also adopted a position on the ethical aspects of umbilical cord blood banking. It is of the opinion that "support for public cord blood banks for allogeneic transplantations should be increased and long term functioning should be assured." They further stated that "the legitimacy of commercial cord blood banks for autologous use should be questioned as they sell a service which has presently no real use regarding therapeutic options."

The Medical Letter On Drugs and Therapeutics also recently addressed aspects of public and private cord blood banks, asking the question: "Does Private Banking Make Sense?" they concluded that: "At the present time, private storage of umbilical cord blood is unlikely to be worthwhile. Parents should be encouraged to contribute, when they can, to public cord blood banks instead."

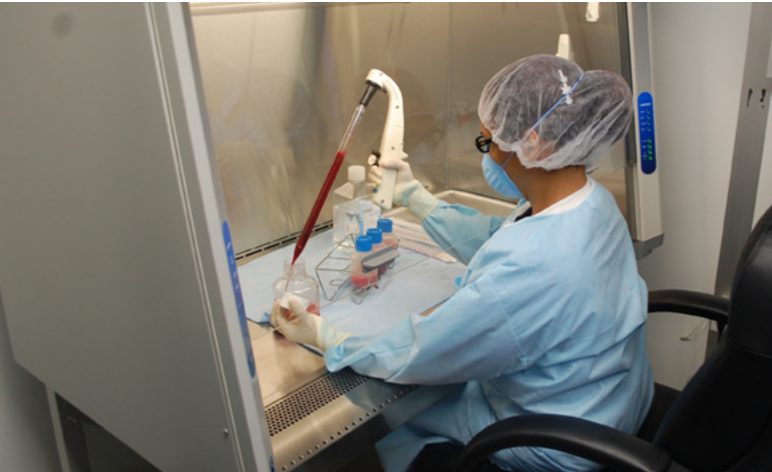
**WARNINGS**

A boom in unproven procedures and stem cell therapies is worrying scientists.

Many clinics are offering stem cell treatments making claims about what stem cells can and cannot do that are not supported by present understanding of science.

Science, in general, is a long and involved process. Understanding what goes wrong in disease or injury and how to fix it takes time. New ideas have to be tested first in a





research laboratory, and many times the new ideas don't work. Even once the basic science has been established; translating it into an effective medical treatment is a long and difficult process. Something that looks promising in cultured cells may fail as a therapy in an animal model and something when it works in an animal model, it may still fail when it is tried on humans.

When new therapies are tested in humans, ensuring patient safety becomes a critical issue. This means starting with very few people until the safety and side effects are better understood.

If a treatment has not been carefully designed, well studied and gone through the necessary preclinical and clinical testing, it is unlikely to have the desired effect. Even more concerning is that it may prove to make the condition worse or have dangerous side effects.

#### **Currently, there are very few widely accepted stem cell therapies.**

The range of diseases where stem cell treatments have been shown to be beneficial in responsibly conducted clinical trials is still extremely restricted. The best defined and most extensively used is blood stem cell transplantation to treat diseases and conditions of the blood and immune system, or to restore the blood system after treatments for specific cancers. Some bone, skin and corneal diseases or injuries can be treated with grafting of tissue that depends upon stem cells from these organs. These therapies are also generally accepted as safe and effective by the medical community.

#### **There is something to lose by trying an unproven treatment.**

Some of the conditions that clinics claim are treatable with stem cells are considered incurable by other means. It is

easy to understand why people might feel they have nothing to lose from trying something even if it is unproven. However, there are very real risks of developing complications, both immediate and long-term, while the chance of experiencing a benefit is likely very low. In one publicized case, a young boy developed brain tumors as a result of a stem cell treatment.

Also cost is high. There are long-term financial implications for the patients, their families and communities. And if travel is necessary add to that the added expenses and other considerations, not the least of which is being away from family and friends.

Moreover, participating in an unproven treatment may make a person ineligible to participate in upcoming clinical trials. Responsibly-conducted clinical trials are critical to the development of new treatments as they allow us to learn whether these treatments are safe and effective.

#### **Just because stem cells came from your body doesn't mean they are safe.**

Every medical procedure has risks.

While you are unlikely to have an immune response to your own cells, the procedures used to acquire, grow and deliver them are potentially risky. As soon as the cells leave your body they are subjected to a number of manipulations that could change the characteristics of the cells.

If they are grown in culture, the cells may lose the normal mechanisms that control growth or may lose the ability to specialize into the cell types you need.

The cells may become contaminated with bacteria, viruses or other pathogens that could cause disease. The procedure to either remove or inject the cells also carries risk, from introducing an infection to damaging the tissue into which they are injected.

#### **Be wary of patient testimonials.**

Just because people say stem cells helped them doesn't mean they did.

There are three main reasons why a person might feel better that are unrelated to the actual stem cell treatment:

1- The intense desire or belief that a treatment will work can cause a person to feel better and to even experience positive physical changes, such as improved movement or less pain. This phenomenon is called the placebo effect. Even having a positive conversation with a doctor can cause a person to feel some improvement.

2- Likewise, other techniques offered along with stem cell treatment, such as changes to diet, relaxation, physical therapy, medication, etc. may make a person feel better in a way that is unrelated to the stem cells.

3- Also, the severity of symptoms of many conditions can fluctuate over time, resulting in either temporary improvement or decline. This does complicate the interpretation of the effectiveness of treatments.

These factors are so widespread that without testing in a controlled clinical study, where a group that receives a treatment is carefully compared against a group that does not receive this treatment, it is very difficult to determine the real effect of any therapy.

#### **Worry when a treatment is offered for a wide variety of conditions.**

A single stem cell treatment will not work on a multitude of unrelated diseases or conditions. As described above, each type of stem cell fulfills a specific function in the body and cannot be expected to make cell types from other tissues. It is unlikely that a single type of stem cell treatment can treat multiple unrelated conditions, such as diabetes and Parkinson's disease.

Embryonic stem cells may one day be used to generate treatments for a wide range of human diseases. However, embryonic stem cells themselves cannot directly be used for therapies as they would likely cause tumors and are unlikely to become the cells needed to regenerate a tissue on their own. They would first need to be coaxed to develop into specialized cell types before transplantation.

## ACTUAL STATUS OF STEM CELL BANKS IN LEBANON

Most of what was said about stem cell banks in general also applies to Lebanon.

But as yet, there is no clear regulation in Lebanon to govern the status of stem cell banks. No specific rules are drawn to control the different aspects of the field.

Still, the venturing Lebanese did manage to run stem cell banks. There is a multitude of them competing in the market.

Many act simply as agents to well-known banks outside of Lebanon. The mother company can be either in the United Kingdom, in Germany or in Cyprus...

- Some are owned and run by commercial establishments, entering the market as a diversification of their business.

- Others are burgeoning project of a venturesome person with a particular vision.

- Certain stem cell banks were started by local health care professionals in the field who associated with international banks to complement their role.

- However, there is one Lebanese company that opened its facilities in Lebanon few years ago, providing public and

private tissue banking, along with laboratory and stem cell therapy services.

Costs for the private banking vary depending on the company and on the product requested. They average between USD 2,000 and 3,500. The collection fee of the health care provider is actually included by the bank.

Like any other dealing, discounts may be obtained for so many reasons, such as discounts for the second child or when a friend is referred.

The Lebanese institute that accepts public donations does this for free, covering its expenses either from a potential recipient or from assistance from NGOs.

Until the present time, a few thousand Lebanese have stored their baby's cord blood for private use. The numbers are increasing annually. Here, the obstetrician is reimbursed by the private bank for collection services; this constitutes enough stimuli for him to spend some time explaining to the parents the benefit of this procedure.

As for public banking, only a handful has donated to public banks. This is due mainly to the fact that the typical obstetrician has no incentive to spend his/her time explaining to the future mother the benefits of donating the newborn's cord blood freely to the local bank. On the other hand, even if educated and conscious parents wish to donate, they are not ready to carry the expenses of collection and transportation of the cord blood to public banks outside of Lebanon.

In Lebanon, there remains some cultural misconception regarding scientific research in general. This becomes most striking when it has to do with our own body or a family member's body. For many individuals, tissue donation and autopsy (for example) continue to be looked as taboos. They remain anxious and apprehensive of what is going to be 'really' done. All sort of doubt and exorcism come to their mind.

Considerable effort is to be spent on education about such subjects.

## APPENDIX

This is of an incomplete list of stem cell storage providers:

Cytocare  
Future Health  
Smart Cells  
Lifeline  
Cells4Life  
Cells Therapy Centers  
Transmedical for Life