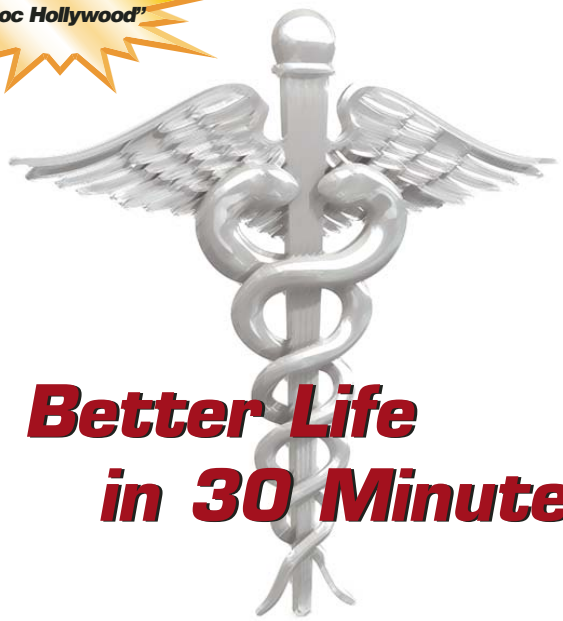
Cord Blood Essentials

Dr. Neil Shulman & Dr. Jonathan L. Liss

Author of "Doc Hollywood"



A Better Life in 30 Minutes

By Jonathan L. Liss, M.D.

A Better Life in 30 Minutes:

Cord Blood Essentials

Neil Shulman, MD
Dr. Shulman has educated and entertained millions with his authorship of Doc Hollywood, Your Body's Red Light Warning Signals, The Germ Patrol, and What's in a Doctor's Bag?

Jonathan L. Liss, MD
Dr. Liss has built a national following for his highly acclaimed lectures and is also a widely published researcher and practicing physician. Additionally, he is a National Director for Stork Medical, a private cord blood storage company that has been twice honored by the United States Congress.

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7196 North Lake Dr., Suite A, Columbus, GA 31909.

THIS BOOKLET IS NOT INTENDED AS A SUBSTITUTE FOR THE MEDICAL ADVICE OF PHYSICIANS. IT IS STRONGLY RECOMMENDED THAT YOU CONSULT WITH YOUR HEALTH CARE PROVIDER PRIOR TO MAKING ANY CHANGES IN YOUR HEALTH CARE. THE READER SHOULD REGULARLY CONSULT A PHYSICIAN ABOUT MATTERS RELATING TO HIS OR HER HEALTH AND PARTICULARLY REGARDING ANY SYMPTOMS THAT MAY REQUIRE DIAGNOSIS OR MEDICAL ATTENTION.

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INTRODUCTION

Few medical procedures offer as much hope, as little risk, and as much health protection as umbilical cord stem cells. Yet, not every doctor or every medical organization encourages private cord blood storage. To make matters more difficult, our parents, who are often our most trusted advisors, are of very little help, since these options were never possible during their time of pregnancy. Add to this the reality that most young couples have very little extra income and it makes it especially important to have enough information to make a fully informed decision. This booklet is designed to quickly give you the necessary knowledge to have a comprehensive understanding of cord blood storage and also provides the important questions that should be answered before choosing a storage company.

WHAT ARE STEM CELLS?

Stem cells are the basic building blocks of our bodies. They are cells that can become any tissue type within us. In other words, they can become blood cells, heart cells, brain cells, kidney cells, skin cells etc. They are similar to a blank canvas waiting to be painted. This is their great value and great promise.

Before umbilical cord stem cells were discovered, it was thought that only an embryo contained these cells. It was believed that once the baby was born, each cell had already made an irreversible choice as to what kind of tissue to become. In other words, the painting had already been completed. However, in the early 1980's these stem cells were found in the placental blood of newborns. All of a sudden, a risk free and pain free opportunity to obtain stem cells was found. However, one had to wonder, "Would they ever be useful?" After all, just because a blank canvas and paint are available does not mean that art will be created.

How are stem cells collected and processed?

Cord blood collection is completely pain free and virtually risk free. After the umbilical cord is cut and the mother is given her baby to hold, the obstetrician or midwife has the choice of collecting the cord blood while waiting to deliver the placenta or performing the collection after the placenta is delivered. The healthcare provider will clean the umbilical cord and then place a needle into an umbilical vein. Over the next couple of minutes, the blood from the placenta will slowly drain into a sterile collection bag that contains chemicals to keep the blood from clotting. The collection bag is then labeled and placed in the transport box provided by the cord blood company. A few hours before or after the baby's birth, the mother must undergo a standard blood draw to fill three small tubes.

Once the cord blood and mother's blood has been collected and packaged, a courier service provided by the cord blood storage company, is contacted for sample transport. Nearly all storage companies use overnight transportation and therefore the cord blood is typically processed in less than twenty-four hours.
At the lab, the stem cells are separated from the other blood products and slowly frozen to minus 197 degrees in liquid nitrogen or its vapor. The remaining blood products, along with a sample of the mother's blood, are tested for numerous infectious diseases.

How will these cells be used?

Currently, cord blood stem cell storage is viewed as an insurance policy for both the baby and close blood related relatives. In the 1980's, only one sample out of every 40,000 was used medically. Today, it is still unlikely that the stored cells will be used, but the numbers are far more intriguing. It is estimated that one out of every 2,700 babies will use his/her own stored cord blood and one out of every 1,400 samples will be used to treat a sibling or other close relative. If this trend continues, over the next twenty years, the usage rate will be approximately one out of every one hundred samples.

There are now more than seventy diseases for which cord blood is now used for treatment. These diseases include most leukemias, many cancers, and a host of relatively rare metabolic diseases. A list of these diseases can be found on pages 24–28. Researchers are currently testing these stem cells on virtually every major disease. In fact, the University of Florida is currently giving these cells back to children who have developed insulin dependent diabetes and Duke University is hoping to add cerebral palsy to the list of treatable diseases by giving previously stored cord blood stem cells back to children who have developed cerebral palsy. One such toddler, who appears to have been cured of his cerebral palsy through Duke's efforts, was featured on numerous television shows. Videos of his miraculous fifteen minute treatment show dramatic improvement in this child's speech and motor skills in just five days. This video can be found on YouTube directly or a link can be found on Stork Medical's home page: www.stork.md.

CBS's Sixty Minutes not only documented the cure of a young man's sickle cell disease, but an actual change of his blood type. This young man no longer has sickle cell disease.

There is also extensive research into limb and organ regeneration. Stem cells of various types are already being used to replace damaged bladders, nasal cartilage, and to re–grow severed finger tips. Creating a better layer of skin to replace burned areas is also an expected near term break though. Because of these advances, Stork Medical has made a $60,000,000 charitable pledge to make cord blood storage more affordable for our military. They have done this with "The hope, prayer, and expectation that the cord blood stem cells of a soldier's newborn will one day be used to repair wounds sustained in battle." Both Democrats and Republicans have honored Stork Medical for its commitment to our soldiers and their families.

Whether or not these cells prove to be a cure for these dreaded diseases on a large scale and whether or not they become the treatment of choice for such diseases as Diabetes, Alzheimer's disease, and Multiple Sclerosis, remains to be seen.

Public Versus Private Storage

There are an ever increasing number of both public and private cord blood stem cell banks. The major difference between the two comes down to ownership of the sample. Those people that store privately own their cells and retain them for personal use. They are banking a perfect genetic match for their baby and a very close match for the baby's siblings. Cells stored in public banks are considered a donation. They are used on a first come, first serve basis. Public banks typically charge about $25,000 to distribute a sample. Private banks charge families to collect and store their cells, but typically do not charge for their retrieval.

It is possible that one day there will be a wide enough array of stored cells in public banks that acceptable matches will be commonplace. However, this is likely to be many decades in the future. As the New England Journal of Medicine noted, stem cells from unrelated donors are less likely to be helpful than one's own cells.

CONTROVERSIES

Why are there so many stem cell controversies?

There are both real and imagined controversies in the stem cell world. As mentioned in the introduction, not every doctor or healthcare organization recommends private cord blood storage. There are at least three important reasons for naysayers:

First, it is the belief of the American College of Obstetrics and Gynecology (ACOG) that if large numbers of people choose to store their baby's cord blood privately and therefore for personal use, then the public banks will fail to flourish. In other words, this organization is asking families to put the common good of the national community above the personal protection that parents typically practice for their families.

Second, the American Academy of Pediatrics is concerned that young mothers might fall prey to the emotional blackmail and feelings of guilt that are common when a parent is made to feel that she has not done everything possible to protect her family.

Third, given that most samples will go unused, some feel that the benefit of storage does not outweigh its financial burden.

The other area of controversy is rooted in confusion about where stem cells come from. There are three sources of stem cells: placenta\umbilical cord, embryo, adult harvests. Of these, the only one that has garnered widespread criticism is embryonic stem cell collection.

To begin with, placental cord blood stem cell science is a non–controversial topic from the standpoint of morals and ethics. The vast majority of members of both the conservative and liberal parties of our government are in favor of cord blood storage and usage. In 2007, the Catholic News Service reported that Pope Benedict XVI endorsed umbilical cord stem cell research and therapy. Given this, the question "Should I or shouldn't I store my newborn's cord blood" comes down to the value of the service. These cells are available at every birth and are either stored or thrown away. The baby is never in any danger, Other than the mother experiencing a blood draw, it is a painless and risk free procedure.

As opposed to cord blood storage, embryonic stem cell storage raises highly emotional and difficult issues. It is not possible to collect these stem cells without ending the life of the embryo. Thus, your belief system as to when life begins and the government's interpretation of this charged issue has to be considered.

From a purely scientific standpoint, there are also a few very important differences between the stem cells derived from the placenta compared to those of the embryo. First, the science and treatment for cord blood stem cells is two to three decades ahead of embryonic stem cells because multiple United States Presidents have banned the experimentation and use of these cells. Perhaps more importantly, when receiving stem cells from your own body or from a close relative, you have a good understanding of the genetic heritage. On the other hand, if embryonic cells are taken from an embryo destined to one day have a serious genetic disease, then the recipient of these cells will also likely contract this disease and pass it on to his/her offspring. Recently an experiment such as this went terribly wrong in Russia. In this case, a child was given embryonic stem cells to treat his brain tumor. Unfortunately, this experiment has ended badly with the child developing numerous new lesions.

Adult stem cells are a more recent advancement. Stem cells from multiple areas of the developed body have now been found. At this time it remains uncertain if they will be as flexible or as useful as umbilical cord cells.

Another controversy surrounding umbilical cord stem cells is most closely associated with midwifery. Some midwife's feel that as much placental blood as possible should be given to the newborn. Therefore, the newborn is not cut from the cord. Instead, once the placenta is delivered, it is held high so that the blood will transfuse into the newborn. For most non–midwife obstetric practices, the cord is cut within seconds of delivery and therefore no such issue exists.

Can my baby's stem cells help other family members? With your permission, your baby's stem cells can be used to help any family member. The closer the blood relationships to your baby, the more likely these cells are to be effective. In a sense, when you choose to protect your baby's future, by storing these cells, you are also adding future health protection for the baby's parents, siblings, and to a lesser extent, other family members as well. The ability to use stored cord blood stem cells depends in part on the disease being treated, the volume of cells successfully frozen, and the size of the patient. In other words, a larger volume stored will allow a larger person to be treated. Your health care provider should be encouraged to collect as much cord blood as possible, but sometimes only small quantities are available.

STEM CELL TRANSPLANTS

What is a stem cell transplant?

The term "transplant" conjures–up a variety of unpleasant images. In reality, this is often a very simple procedure. There are different kinds of transplants. The easiest is a simple blood transfusion. In this procedure, the blood is simply infused into a vein over about fifteen minutes. If the cord blood is going back to the donor, there is essentially no chance for a reaction and therefore no risk. For others who receive this type of transplant, pretreatment with medications to reduce the risk of an allergic reaction is sometimes undertaken.

The other main type of transplant is a bone marrow transplant. In this case, the cord blood stem cells are injected in the bone marrow with the hope that they will replace the diseased bone marrow. This is also a quick procedure. It hurts a little more than a simple IV, but in the hands of a skilled practitioner, it is not a very difficult ordeal.

Choosing a Private Cord Blood Company

Let the American Association of Blood Banks (AABB) and the Food and Drug Administration (FDA) do your work for you.

The most compulsive parents–to–be agonize over the quality of the processing and storage laboratory. For some, many hours on the telephone and computer are being spent to make certain the best lab has been chosen to process and store the cells. You can avoid this lengthy and tedious task by simply asking if the lab is fully licensed by the AABB and is it fully compliant with FDA standards. Both of these credentialing agencies have rigorous standards. The AABB inspects every step of the process from labeling of the specimen at your hospital to the final storage. Their process includes the back–up or fail safe systems available in the laboratory all the way to laboratory security. In short, their process is extremely thorough. Thus, if the lab has been licensed by the AABB, you can take it on faith that you have chosen a highly professional and capable lab.

IMPORTANT QUESTIONS

Important Questions to Ask Your Prospective Cord Blood Storage Company. These questions will be broken down into four categories: Quality, Service, Cost, Corporate Stability.

Quality

Is your company FDA registered?

FDA registered companies must comply with current and future federal guidelines. This is helpful oversight on your behalf.

Does your laboratory have full AABB accreditation?

As noted elsewhere, the seal of approval from these agencies virtually guarantees you are working with a reputable and highly skilled laboratory. It does not guarantee that the company you hire is of high quality, only the laboratory they use.

Are your storage bags segmented so that a partial sample can be retrieved?

This is becoming an industry standard. If you have a large sample, it is possible that you will only want to use a portion. Make certain that your sample is stored in at least two separate compartments. More than two compartments are not necessary as it is extremely unlikely that enough cord blood can be collected to treat three maladies.

Are the stem cells separated or is the entire collection stored?

a.Low budget companies will take your entire sample and place it into nitrogen without any processing of the stem cells. This is a very bad practice and should be avoided.

Does the courier specialize in tissue transport?

To reduce costs, lesser companies will hire package delivery companies to transport your cord blood. Thus the sample may sit inside a hot metal truck next to a case of paper clips while the delivery truck goes through an entire day's route.

Is the cord blood kept at room temperature during transportation?

This is a must. Keeping these cells at room temperature is the single most important issue related to cell viability. Even on the most temperate of days, a package in the storage section of a large metal truck will do quite poorly. Thus, eliminate any company that does not use a courier service that specializes in tissue transportation. Most of the major cord blood companies use AirNet® for transport. AirNet sometimes uses its own airplanes and other times contracts with commercial airlines. When transported by air, it is typically arranged for biologic specimens to be the last items loaded and the first items unloaded to maintain temperature control.

Will I be informed of the quantity of cord blood collected prior to storage?

The more cord blood stored, the larger the person can be who uses the cells. Thus, if only a tiny amount is collected, only a tiny person can be treated. Even with small amounts, some people will still choose to store the cord blood as there may one day be processes invented to duplicate the cells so that any amount will be helpful. However, these processes do not currently exist and therefore reasonable people may choose to discard the sample prior to processing. In our experience, most families will choose to store their cord blood even if they have small volumes. However, as your baby becomes an adult, if therapies have not been developed to duplicate these cells, you may choose have them discarded rather than continue to pay annual storage fees.

How many transplants has your laboratory accomplished?

If the laboratory is FDA & AABB approved, this is less important as their processes have been shown to be adequate. Still it is nice to know that you are dealing with an experienced company.

Service

Is the cord blood picked–up from the hospital room?

Since high quality companies typically offer this service, there is no reason to settle for less. If the courier comes to your room, no bonding time is lost for any of your loved ones.

Can I Speak to a Doctor to have my cord blood medical questions answered?

This is a free added service provided by several companies. Even if you do not have any current questions, it can be comforting to know that you do not have to rely on the medical knowledge of a salesperson.

If I leave my contact information, am I going to receive unsolicited and unwanted sales contacts?

It is important to ask this question before requesting further information from a company. Unfortunately, several companies will hound you with repeated sales calls.

Cost

Do you have a total out–of–pocket cost guarantee until my baby's first birthday? If so, how much? Is it in writing?

It can be a very frustrating exercise to determine the final cost of everything necessary to store your baby's cord blood. It is also a completely unnecessary irritation. Finding a company with transparent pricing and a plainly stated price guarantee that includes all costs is important. If they do not offer this, it is likely that extra costs are coming your way. For instance they might list that the doctor's fee is included. However, that doesn't mean that your doctor's entire fee is included. Other companies will list a large number of services included but do not include the first year of storage. Some companies add surcharges for last minute enrollment or overnight transportation etc. A written total price guarantee takes away all of the guessing and potential anxiety. You should insist on this.

What is the annual cost after the first year?

If you have not contracted for a multiyear storage plan you will receive a new bill upon your baby's first birthday. Make certain you are paying a reasonable rate. This annual rate ranges from approximately $99.00/year to $350/year for exactly the same service.

Is stem cell retrieval free?

If and when the cells are needed for use, most companies will offer to retrieve them for free. This however does not include transportation charges.

What is your refund policy?

Given the uncertainties of when labor will occur, how much cord blood will be available and the partner's ability to remind the health care provider to collect the blood, it is important to know the refund policy for the company you choose.

Will I be given the option to decline storage?

This is an important question that is directly linked to a company's refund policy. As mentioned previously, it is not unusual to only collect a very small sample of blood. There are many companies that will store this sample without informing you of the small volume. These tend to be the companies that offer a full refund. They make this offer because they never expect to actually give you a refund. By storing the sample without your input, they are never in a position to offer a refund. Thus, if it looks too good to be true, it may be too good to be true.

Stability

How stable is your company?

Since it is possible that these cells will be stored for a lifetime, it is important to use a stable company. The issue of stability is difficult to define. Those companies that own their own laboratory promote this as a sign of their commitment and stability.

Companies that lease the services of well established labs brag about the fact that two separate corporate entities would have to go bankrupt for there to be a problem with your storage. Both are reasonable arguments. However, given that we are in an age where no business is too big to fail, the more credible argument probably favors companies that do not own their own lab. If the storage company goes out of business, the laboratory still has the responsibility to protect your cells. If the laboratory were to go out of business, then the storage company would have the responsibility to transfer the cells to an equally reputable laboratory at their cost.

CONFUSING QUESTIONS

It is sad to say, but part of the marketing strategies for some cord blood companies is to make the process seem so overwhelming that you do not compare companies on the critical questions listed above and therefore become willing to spend more money for meaningless issues where they create false choices. The following is a list of common questions that should be viewed as an intentional sales distraction.

Do you store the cells in liquid or vapor nitrogen?

This is sometimes discussed in terms of contamination potential. Some will say that the nitrogen vapors can carry bacteria from one sample to another. This is complete nonsense. All samples are sealed in sterile bags without any way for outside contaminates to enter. Since the samples are all stored at –197 degrees, no organism can move to gain entrance. Either method is completely acceptable.

What preservative do you use?

There are standard chemicals used by all reputable labs to store stem cells. If the AABB has accredited the lab, you can have confidence that the preservative is appropriate.

Do you store in bags or vials?

It makes no difference if your stem cells are stored in vials or blood bags. Both storage methods are acceptable. You do however want to make certain the blood bags have two or more compartments so that partial samples can be retrieved.

Do you use a gravity method or a suction method to collect the cord blood?

The suction method for cord blood collection uses a syringe to suck the blood from the placenta. The gravity method simply lets the blood drain from the placenta into the bag. Both methods are acceptable. Most OB's prefer the gravity method because it is easier. At first thought, it would seem that more blood can be collected if it is sucked out. However, the vacuum created tends to force the wall of the vein to collapse, thereby blocking the flow of blood into the bag.

Does your lab use red cell depletion?

There is a standard procedure used to process stem cells. If the AABB have accredited the lab, you can have confidence that the lab is practicing excellent ways to maximize the number of viable cells harvested for storage.

Do you have special collection bags for caesarean section?

Virtually all companies use collection bags wrapped in sterile foil. Thus, they are all acceptable for cord blood collection in surgery. Recently, a collection bag manufacturer began a marketing campaign that implies only their special bag is acceptable. This is untrue, but has generated the confusion that seemed to be intended.

ESTIMATING COSTS

What are the estimated costs of cord blood stem cell storage.

The best quality companies all perform the same services for a price that ranges from $1,700–$2,400 for the first year. After the first year, annual storage rates range from $99–$300/year. Payment plans and pre–paid multi–year storage discounts are typically offered.

Some companies make it difficult to determine the total charges and others make it easy. When storing, you need to make certain that the following services are included in the price quoted:

- *Collection, processing, and storage through the first year.*

- *Overnight temperature controlled sample transportation that is picked–up from your labor room.*

- *Full coverage of the doctor's fee. Many companies will pass some or all of this cost onto you. This can substantially increase your initial fee.*

How does a person sign–up?

As a general rule, the entire process takes about an hour. Most companies will allow you to download their contracts from the internet and all of them are willing to send you a copy by regular mail if desired. Aside from the contract that you will need to review and sign, there are multiple health information forms that must be filled–out. These forms are mandated by the government to make certain that the cells being stored are of low risk to harbor dangerous infections, such as HIV.

Once you sign–up, a collection kit is mailed to you. This kit contains all of the materials necessary to collect the baby's cord blood and the mother's blood sample.

For couples that wish to store their baby's stem cells for family use, they must sign–up with a private cord blood bank.

There are many such banks across the country. Most offer nationwide coverage in the continental U.S. Storage can be arranged as late as a day or two prior to delivery, but as with most things, the earlier that it is arranged, the easier it is to accomplish. For families that wish to donate their baby's cord blood for public use, some hospitals will offer this service at the time of delivery while others ask you to make arrangements on your own.

Treatable Diseases

Cancers

Hodgkin's disease
Non–Hodgkin's lymphoma
Acute lymphoblastic leukemia
Acute myeloid leukemia
Chronic myeloid leukemia
Autoimmune lymphoproliferative syndrome
Burkitt lymphoma
Cytopenia related to monosomy 7
Familial histocytosis
Juvenile myelomonocytic leukemia
Hemophagocytic lymphohistiocytosis
Langerhans cells histiocytosis
Lymphomatoid granulomatosis
Myelodysplasia syndrome

Immune Deficiencies

Ataxia telangectasia
Cartilage–hair hypoplasia
Chronic granulomatous disease
DiGeorge syndrome
Hypogammaglobulinemia
IKK gamma deficiency
Immune dysregulation polyendocrinopathy
Mucolipidosis, Type II
Myelokathesis
X–linked immunodeficiency
Severe combined immunodeficiency
Adenosine desaminase deficiency
Wiscott–Aldrich syndrome
X–linked agammaglobulinemia
X–linked lymphoproliferative syndrome

Hematologic Disorders

Amegarakarocytic thrombocytopenia
Autoimmune neutropenia (severe)
Congenital dyserythropoietic anemia
Cyclic neutropenia
Diamond Blackfan anemia
Evan's syndrome
Fanconi anemia
Glanzmann's disease
Hypoproliferative anemia

Juvenile dermatomyositis
Juvenile xanthogranulomas
Kostmanns syndrome
Pancytopenia
Red cell aplasia
Refractory anemia
Schwachman Syndrome
Severe aplastic anemia
Systemic mastocytosis
Severe neonatal thrombocytopenia
Congenital sideroblastic anemia
Thrombocytopenia w/absent radius (TAR Syndrome)
Thalassemias
Alpha–thalassemia internedia (hemoglobin H disease)
Alpha–thalassemia major (hydrops fetalis)
Beta thalassemia major (Cooley's anemia)
Beta thalassemia intermedia
E–beta thalassemia
E beta + thalassemia

Metabolic Disorders

Adrenoleukodystrophy
Gaucher's disease (infantile)
Metachromatic leukodystrophy
Globoid cell leukodystrophy (Krabbe disease)
Gunther disease
Hermansky–Pudlak syndrome
Hurler syndrome
Herler– Scheie syndrome
Hunter Syndrome
Sanfilippo syndrome
Maroteau–Lamy Syndrome
Mucolipidosis Types II, III
Alpha mannosidosis
Neimann Pick Syndrome, types A & B
Sandoff Syndrome
Tay Sachs Disease

Sickle Cell Disorders

Sickle cell anemia (hemoglobin SS)
HbSC disease
Sickle Beta thalassemia
Sickle Beta + thalassemia

The list continues to grow...

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Dr. Liss *has built a national following for his highly acclaimed lectures and is a widely published researcher and practicing physician.*

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