

# Cord Blood Banking: Ethical Considerations

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## Abstract

Umbilical cord blood (UCB) is a valuable source of both hematopoietic and pluripotent stem cells. It is a readily available, easily collected source that does not cause inconvenience or harm to the donor. It has been shown to be useful in the treatment of several serious neoplastic and non-neoplastic diseases. Umbilical cord blood transplants have proven to be life saving in many of these conditions. Umbilical cord blood transplants result in better survival rates and fewer cases of graft-versus-host disease (GVHD) than the traditional bone marrow transplants. It probably can fill the gap that is caused by the lack of a suitable bone marrow match. Umbilical cord blood can be collected and cryopreserved in blood banks for at least 15 years. The family, when donating cord blood, chooses whether it prefers a public or private blood bank. Health-care providers should provide detailed and balanced information to aid the parents in their decision. Health authorities should support the development of the public banks, because by their nature they do not make money and they provide the much-needed help to those who cannot afford private banking. Ethical concerns, including proper informed consent, linkage of the donor to the donated units, truth in advertising by the private banks, and distributive justice, are discussed. Also discussed is the question of the appropriateness of selective conception of a baby to be a potential donor. There is no ethical or moral objection to its use. Umbilical cord blood donation should be encouraged.

**Key words:** Umbilical cord blood, cord blood bank, medical ethics, regenerative medicine, cord blood transplants, stem cells

Stem cells are undifferentiated cells that through replication have the capacity of both self-renewal and differentiation into mature specialized cells. There are two types of stem cells: embryonic stem cells (ESCs) and adult stem cells. Human embryonic stem cells (hESCs) are isolated from the 4- to 5-day-old postfertilized blastocyst.

Human embryonic stem cells are capable of indefinite *ex-vivo* proliferation, and they can differentiate into any specialized cell in the human body. Adult stem cells are located in tissues throughout the body and function as a reservoir to replace damaged or aging cells. Under physiologic circumstances they differentiate only into the cell lineage of the organ system in which they are located. Umbilical cord blood (UCB) is a source of “adult” stem cells. It was discovered about 30 years ago to have hematopoietic stem cells. These cells were found to be functionally comparable to those in the bone marrow. They

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have been used in marrow transplants and in the treatment of leukemias and other hematologic diseases. This raised the possibility of using UCB for the treatment of the same. The first successful transplant using UCB was done in Paris in 1988 to treat Fanconi anemia in a sibling.<sup>1</sup> Since then UCB transplants were successfully used in a multitude of hematologic and immunologic diseases.<sup>2</sup>

While hESCs offer the greatest promise and versatility, they are the subject of great ethical controversy, as obtaining them entails the destruction of 4- to 5-day-old human pre-embryos, even though they are usually extras developed during the process of *in vitro* fertilization (IVF) and, in most cases, would have been discarded.<sup>3</sup> In any event, this controversy resulted in attempts to secure other sources of stem cells to be used for both research and therapy. Umbilical cord blood seems to be a promising such source. In this paper, the discussion is limited to UCB as a source of stem cells.

As mentioned above, UCB has already been used to treat a variety of life-threatening malignant and nonmalignant hematologic and immunologic conditions. Scientists continue to expand research efforts on other pluripotent cells present in the cord blood, specifically, the ability of the mesenchymal cells to differentiate beyond their tissue lineage into other types of cells e.g. neurons, hepatocytes, myocytes, and pancreatic islet beta cells, a process called transdifferentiation. When successful, this will pave the way to treat various chronic diseases that heretofore have no cure; for example diabetes type 1, cerebral palsy, Parkinson disease, Alzheimer disease, other neurologic diseases as well as spinal cord injury, etc., heralding a new field of medicine i.e. regenerative medicine.<sup>4-13</sup> These lofty goals have not yet been achieved, but research continues.

Umbilical cord blood stem cells also can be potentially used in gene therapy. Normal genes can be introduced *ex-vivo* in cord blood stem cells of an infant born with a genetic defect of the bone marrow or blood, and then infused into the patient. This has been effective in children with severe combined immunodeficiency syndrome, although some patients developed serious complications. Nevertheless, devising new approaches continues.<sup>14</sup> Recently, it has been estimated that approximately 10,000 UCB transplants have been used in the treatment of more than 70 diseases, including cancers of

the blood and immune system, bone marrow failure, and genetic diseases such as hemoglobinopathies, inborn errors of metabolism and immune deficiencies.<sup>15</sup> The National Institutes of Health (NIH) web site, [clinicaltrials.gov](http://clinicaltrials.gov), lists 236 clinical trials involving the use of UCB.<sup>16</sup>

### **Current Applications of UCB Transplants**

The traditional hematopoietic stem cell transplant involves stem cells harvested from bone marrow. Because of the shortage of suitable bone marrow donors, efforts have been made to use unrelated or related donors whose human leukocyte antigen (HLA) is only partially matched with the recipient, with less-than-optimal results. With the availability of UCB, the gap can be filled with UCB transplants. Actually, UCB offers more advantages over bone marrow. Umbilical cord blood is more easily obtained; does not cause pain or inconvenience to the donors, in contrast to bone marrow donors requiring aspiration of their marrow; and UCB cells are more easily harvested and more readily available, and, most important, are immunologically naïve. Bone marrow cells are more difficult to harvest, take months to procure, and are more mature immunologically, making them more prone to cause graft-versus-host disease (GVHD), specially the more severe types (grades 3 and 4). While in bone marrow transplants 6/6 match of HLA loci are required, only a 4/6 or even 3/6 match is acceptable in UCB transplantation. In a study by Rocha et al, comparing the incidence of both acute and chronic GVHD in patients receiving hematopoietic stem cell transplants, they reported that both were significantly less in those who received UCB than in those who received bone marrow transplants.<sup>17</sup> Beatty et al using low resolution HLA typing reported a 75% chance that a sibling will be at a least a 3/6 haploidentical match, which is the threshold of transplantation, a 40% chance of at least a 4/6 haploidentical match, and a 25% chance of being a perfect 6/6 match with a sibling.<sup>18</sup> An additional advantage of UCB over bone marrow transplantation is that it can be virtually free of cytomegalovirus (CMV), which in the past has been responsible for 10% of deaths following bone marrow transplantation.<sup>19</sup>

Broxmeyer et al in a study suggested that UCB can be frozen and stored for at least 15 years with highly efficient recovery of viable and highly func-

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tional human stem cells, which are needed for successful UCB stem cell transplants.<sup>20</sup> More recent data suggest that longer-term storage is feasible and does not compromise the quality of the engraftment ability of the UCB unit.<sup>21</sup> The great therapeutic potential of UCB and the demonstration of the feasibility of cryopreserving collected units and their utility for up to 15 or more years led to the development of cord blood banks.

One important disadvantage of UCB use is that relatively fewer stem cells are present in a unit. However, the use of combined units allows it to be used for adult hematopoietic transplants. Studies are now underway to evaluate the feasibility of *ex-vivo* expansion of the units. In a study by Jaroscak et al, they showed that this is possible using an automated continuous perfusion culture device. There was a 2.4-fold increase in the number of nucleated cells and an 82-fold increase in the number of colony-forming units. The administration of the *ex-vivo*-expanded cells was well tolerated by the 28 patients they studied.<sup>22</sup>

### Collection of Cord Blood

Cord blood is collected at the time of delivery. The cord is wiped clean and held slightly away from the perineum to avoid contamination with maternal blood. It is then prepped with povidone iodine and alcohol. A large bore needle is then inserted in the umbilical vein. This is connected to a closed collection bag that contains an anticoagulant (citrate-phosphate-dextrose). As much blood as possible is obtained, without changing the timing of cord clamping routine. Usually, 60 mls can be obtained. The procedure is the same for collection of blood at cesarean section deliveries with obvious attention to the sterile technique. Cord blood is usually not collected from pregnancies less than 34 weeks gestation because of the smaller volume of blood that can be collected. Also excluded are multiple pregnancies because of the possibility of cross contamination and issues of the proper labeling of the cord blood units (from which fetus the blood is collected). Cord blood should not be collected if chorioamnionitis, active genital herpes is suspected, in the presence of a malodorous placenta, or in extensive vaginal or perineal condylomata. Any major structural abnormality or known chromosomal anomaly contraindicate cord blood collection. If more subtle anomalies that have

been associated with congenital hematologic disorders are discovered on physical examination of the newborn, the collected unit should be disqualified.<sup>23</sup>

### Umbilical Cord Blood Banks

There are two types of blood banks for collection and storage of UCB: public and private. The first public bank in the United States was established in the New York Blood Center in 1991. Several others were established since then. The cord blood units are donated, collected, and stored for public use. There are no fees charged to the donor's family and thus the expectant mother/donor family has no ownership rights. In 1999, the National Bone Marrow Donor Program (NBMDP) established a network of these banks listing their units for potential transplants. It also established the Center for Cord Blood in 2005.<sup>24</sup> In the United States, federal legislation was passed in December 2005 to provide funding for the establishment of a national inventory of cord blood units. Subcommittees have been formed to address standards, quality improvement, donor recruitment, collection, testing, and processing methodology.<sup>15,23,25</sup> Public banks promote allogenic (related or unrelated) donation, analogous to the current collection of whole blood units in the United States. These banks are typically associated with a local network of obstetric hospitals that send their units of collected cord blood to a central processing facility. A minority of public banks accept units of cord blood from any provider through shipment via overnight express couriers. Umbilical cord blood units collected for public banking must meet rigorous standards of donor screening and infectious disease testing as outlined by U.S. Food and Drug Administration (FDA). It does not accept units that are <60 mls. Some will require the presence of at least  $1 \times 10^9$  total nucleated cells. The criteria are so strict that approximately half of the collections are discarded (or used for research). Initial HLA typing allows these units to be entered into computerized registries so that a specific unit can be rapidly located for a patient when the need arises. The main objective of public blood banks is to archive the UCB units that they collect, so that these units are available to any patient. Some public banks restrict their activities to support research on stem cell biology or on therapeutic uses of the stem cells. The UCB donated to those banks is used for research and not for

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transplantation. The cost of UCB collection, processing, and cryopreservation in U.S. dollars is about \$2,000 per unit. The banks partially retrieve their expenses by charging the transplant institution \$25,000-35,000 per unit transplanted. They also sell the unqualified units to research labs or centers and receive grants and/or donations.<sup>23</sup>

Private blood banks, on the other hand, store blood for autologous use i.e. for use by the same individual from whom it was obtained at birth, if he or she develops a treatable disease later in life, but also can be used for another family member. The family pays a fee (\$1,100-1,750) for the initial collection, processing, and storage and an annual fee for storage (\$115-125).<sup>23</sup> While an autologous unit can be used in a multitude of conditions, it cannot be used for the treatment of inborn errors of metabolism or other genetic diseases in the same individual, because the genetic mutation would already be present in the stem cells. They cannot be used for the treatment of childhood leukemia because chromosomal translocations in fetal blood have been detected in some children who ultimately develop leukemia.<sup>25</sup> In addition, the use of autologous stem cells will negate the beneficial graft-versus-leukemic effect that occurs with allogenic stem cell transplants.<sup>25,26</sup> The chance that a donor will use the donated blood is difficult to estimate. Prior estimates of the probability of using an autologous unit have ranged from 1 in 2700 to 1 in 200,000.<sup>14</sup> Private cord blood banks claim a higher possibility than seems to be likely. Some quote unrealistic odds. One private bank cited a frequency of 1 in 27.<sup>23</sup> Private banks do not perform all the screening tests that are performed by the public banks, specifically HLA typing. They do not have a stringent minimum volume requirement. If the day comes that a unit is required to be transplanted to the donor (or to a family member), the transplant physician may decide not to use it because it fails a test e.g. contaminating bacteria or a hepatitis virus, etc., or it is of poor quality, i.e. if the volume is <40 mls or if it is between 40 and 60 ml, but the nucleated cell count is <6 x 10<sup>8</sup>.<sup>23</sup> On the other hand, the transplantation of UCB stem cells from a related donor (guaranteed by banking in a private bank) is associated with a better outcome in terms of survival rates and the risk of GVHD.<sup>27</sup> This study involved 143 transplants, 78 from related sources and 65 from unrelated sources over the course of 8 years in 45 European transplant cen-

ters. They reported a two-fold increase in one-year survival rates and a two-fold decrease in the risk of GVHD with the use of the former.<sup>27</sup>

## **Ethical Issues**

### ***UCB Donation is a Virtue***

Up until recently, the placenta and its content of blood was considered a waste byproduct of the birth process and was discarded. Knowing what we know now, cord blood is a valuable product that is potentially life-saving. Donating cord blood is a generous gift that basically does not cause harm or inconvenience to the donor and may save or improve the quality of someone's life. We as Muslims should encourage UCB donation. The Qur'an reminds us that

“... and if anyone saved a human life it would be as if he saved the life of all mankind... .”<sup>28</sup>

Physicians, specifically obstetricians, should encourage families to bank cord blood at birth. This should be seriously considered when there is a specific diagnosis of disease known to be treatable by stem cell transplant in an immediate family member. However, there is an important ethical concern that is related indirectly to UCB donation. A case in point is that of a baby who was specifically conceived to serve as a donor for his sister who was suffering from the hereditary fatal Fanconi anemia. The mother conceived through IVF. The resulting embryos were subjected to preimplantation genetic diagnosis (PGD). Only the embryo that tested negative for the disease and was an adequate HLA match to the sick sister was implanted. At delivery UCB was obtained from the newborn and was successfully used for the treatment of his sister.<sup>19</sup> Bioethicists in that institution ruled that this was ethically acceptable. The question is whether the child was used as a commodity. But is bringing a human being to life while in the process saving another life (especially that the newborn did not encounter any risk) Islamically acceptable? In my opinion it is acceptable as long as we accept that IVF is permissible and that most Islamic scholars agree that PGD is also acceptable.<sup>29</sup> However, this may be a subject of further debate.

### ***Whether to Donate to Public or Private Banks?***

The merits of each type have been discussed. The



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families should be given detailed information of the therapeutic potential, realistic expectation of the benefit that can be derived to their families if they decide to donate to a private bank as well as the great reward from Allah ﷻ if they donate to a public bank, ensuring that the human resource they are donating will serve the greater good for mankind rather than only a small possibility of benefit to themselves. This amounts in my opinion to Ihsan (a higher level of virtue). It is estimated in a study by Johnson in 1997 that if 200,000 UCB units are stored for the exclusive use of the donor (autologous transplant), only 74 units will be so utilized, and the remaining 199,926 units would be taken out of circulation for use by patients who need allogenic transplants.<sup>26</sup>

### ***Truth in Advertising***

Private banks, being for-profit entities, are involved in aggressive marketing. They should not be promising “biologic insurance” for the newborn or use the slogan “stop cord waste.” Ironically that is what is happening with random autologous storage.<sup>26</sup> The issues of the possibility of future use, quality control, long-term availability, and cost should be addressed in their literature and marketing. The American College of Obstetricians and Gynecologists (ACOG) committee opinion in 1997 states “Parents should not be sold this service without realistic assessment of their likelihood of return on their investment.”<sup>30</sup> It has been stated that private banking is really indicated for families with a child who is already afflicted with a disease treatable by stem cell transplant only and for families where the two parents are known to be heterozygous for a potentially lethal disease treatable by stem cell transplantation even if they have not yet had an affected child.<sup>26</sup>

### ***Linkage of the UCB Units to the Identity of the Donor***

The primary purpose of this linkage is to assure that unsafe units are identified and not used for transplantation. For example, if the donor develops a disease, metabolic or infectious, which was not identified at birth and that may be detrimental to a potential transplant recipient, that unit would be disqualified. Or if a new genetic test is developed, the donor can be tested to rule out this particular genetic disease. This implies the family is responsible for notifying the blood bank of this development, and

the blood bank is responsible for inquiring about the health of the donor. The blood bank should also notify the family about the advent of new tests. That is why the identity and contact information of the donor/family should be kept. It also implies that UCB units are to be quarantined for a certain time, usually 6-12 months, before being released. The length of this period has to be balanced with the advantage of having the unit available for use soon after procurement. Linkage is thus important, but it has to be noted that it does pose a risk to the privacy of the donor. The donor may be contacted at a later date to solicit a bone marrow donation of his or her “unique” stem cells. It is recommended that demographic data should be kept separate from other data while linkage is maintained.<sup>31</sup>

### ***Consent***

The expectant mother should be given detailed and accurate information about the utility of donating the cord blood and clearly given the option of not donating it. She should be counseled about the pros and cons of private versus public banking. The health-care provider who is providing prenatal care and who is going to be present at the time of delivery is the best person to give this information and obtain consent. The best time to do this is during the third trimester, and it is best affirmed during labor. There may be a question about who actually owns the cord blood. Is it the mother’s or the newborn’s? As far as the consent this question is immaterial because parents are custodians of their children and can make health decisions for their newborns. In the United States, the consent of the expectant mother is all that is needed, especially since she has to give a blood sample at the time of delivery for various tests. In Muslim countries, both parents probably would be involved in this decision.

### ***Distributive Justice***

Another aspect of private banking is that it allows the “privileged” parents to pay for the collection of stem cells for their “own,” while the less financially able society members would have no access to this valuable resource. This concern, combined with the many units of UCB that are potentially wasted in the autologous donation approach promoted by the private banks, tilts the balance in favor of public banks.

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In a measure to support public banks and to address this issue of unequal access, the Stem Cell Therapeutic and Research Act was passed in 2005 in the United States. This bill established a network of cord blood banks to facilitate the use of cord blood for transplantation and appropriated \$79 million between 2006 and 2010 to establish a national inventory of 150,000 UCB units. The bill also calls for the U.S. Federal Drug Administration (FDA) to develop licensing requirements for cord blood banks that will contribute cord blood units to the inventory. It is hoped private banks will also abide by these regulations.<sup>23</sup>

The American College of Obstetrics and Gynecologists (ACOG), in its latest committee opinion on the subject issued in February 2008, did not express a recommendation for or against private banking but argued for the need for provision of balanced and accurate information regarding the advantages and disadvantages of public versus private banks. It further stressed that the remote chance of an autologous UCB unit being used (1:2700) should be disclosed to the expectant mother.<sup>25</sup> The American Academy of Pediatrics suggested "...Private storage of cord blood for biologic insurance is unwise."<sup>32</sup> Private blood banking has been banned in Italy since 2002.<sup>3</sup> The Royal College of Obstetricians and Gynecologists states that "Routine directed commercial cord blood collection and stem cell storage cannot be recommended at this time ..."<sup>33</sup> The French National Consultative Ethics Committee recommended that the decision makers "encourage a considerable extension of cord public banks for essentially allogenic purposes, rather than subscribing to the creation of private banks for strictly autologous purposes..."<sup>34</sup> In March 2004, the European Group on Ethics in Science and New Technologies stated its position: "The legitimacy of commercial cord blood banks for autologous use should be questioned as they sell a service that has presently no real use regarding therapeutic options. Thus, they promise more than they can deliver. The activities of such banks raise serious ethical criticisms."<sup>35</sup> The Maternal/Fetal Medicine Committee of the Society of Obstetricians and Gynecologists of Canada recommended that "altruistic donation of cord blood for public banking and subsequent allogenic transplantation should be encouraged when UCB banking is considered by childbearing women ..."<sup>36</sup>

In conclusion, cord blood is a very valuable source of both hematopoietic and pluripotent stem cells. It is a readily available, easily collected source that does not cause inconvenience or harm to the donor. It has been shown to be useful in the treatment of several serious neoplastic and non-neoplastic diseases. Umbilical cord blood transplants have been proven to be lifesaving in many of these conditions. It results in better survival rates and fewer cases of GVHD than the traditional treatment with bone marrow transplants. It probably can fill the gap that is caused by the lack of a suitable bone marrow match. There is no ethical or moral objection associated with its use. Umbilical cord blood donation should be encouraged. It can be collected and cryopreserved for at least 15 years in public or private blood banks. The pros and cons of public and private banks have been described. The family, when deciding to donate cord blood, has to choose which type it prefers. Detailed and balanced information should be given to the parents by their health-care providers before they make that decision. Health authorities should support the development of the public banks because they are not-for-profit entities and provide much-needed help to those who cannot afford private banking. Ethical concerns include proper informed consent, linkage of the donor to the donated units, truth in advertising by the private banks, and distributive justice. Also discussed is the question of the appropriateness of selective conception of a baby to be a potential donor.

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## Appendix

### Indications of Umbilical Cord Blood Transplants

#### Thalassemias

- Hemoglobin H disease
- Thalassemia major (hydrops fetalis)
- Thalassemia major (Cooley's anemia)
- Thalassemia intermedia
- E-thalassemia
- E-B thalassemia

#### Sickle cell disorders

- Sickle cell anemia (hemoglobin SS)
- HbSC disease
- Sickle thalassemia
- Sickle B-thalassemia

#### Oncologic disorders

- Thalassemia major (Cooley's anemia)
- Thalassemia intermedia
- Acute lymphoblastic leukemia
- Acute myeloid leukemia
- Chronic myeloid leukemia
- Autoimmune lymphoproliferative syndrome
- Burkitt's lymphoma
- Cytopenia related to monosomy 7
- Familial histiocytosis
- Juvenile myelomonocytic leukemia
- Hemophagocytic lympho-histiocytosis
- Hodgkin's disease
- Non-Hodgkin's lymphoma
- Langerhans cell histiocytosis

- Lymphomatoid granulomatosis
- Myelodysplasia syndrome

#### Hematologic disorders

- Amegakaryocytic thrombo-cytopenia
- Autoimmune neutropenia (severe)
- Congenital dyserythropoietic anemia
- Cyclic neutropenia
- Diamond-Blackfan anemia
- Evans syndrome
- Fanconi's anemia
- Glanzmann disease
- Hypoproliferative anemia
- Juvenile dermatomyositis
- Juvenile xanthogranulomas
- Kostmann's syndrome
- Pancytopenia
- Red cell aplasia
- Refractory anemia
- Shwachman syndrome
- Severe aplastic anemia
- Systemic mastocytosis
- Severe neonatal thrombocytopenia
- Congenital sideroblastic anemia
- Thrombocytopenia-absent radius syndrome

#### Immune deficiencies

- Ataxia telangiectasia
- Cartilage-hair hypoplasia



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- Chronic granulomatous disease
  - DiGeorge syndrome
  - Hypogammaglobulinemia
  - IKK delta deficiency
  - Immune dysregulation polyendocrinopathy
  - Mucopolidosis, type II
  - Myelokathexis
  - X-linked immunodeficiency
  - Severe combined immune-deficiency
  - Adenosine desaminase deficiency
  - Wiskott-Aldrich syndrome
  - X-linked agammaglobulinemia
  - X-linked lymphoproliferative syndrome

**Metabolic disorders**

- Adrenoleukodystrophy
- Gaucher's disease (infantile)

- Metachromatic leukodystrophy
- Krabbe's disease
- Gunther disease
- Hermansky-Pudlak syndrome
- Hurler's syndrome
- Hurler-Scheie syndrome
- Hunter's syndrome
- Sanfilippo's syndrome
- Maroteaux-Lamy syndrome
- Mucopolidosis types II, III
- Alpha mannosidosis
- Niemann-Pick disease, types A and B
- Sandhof's disease
- Tay-Sachs disease

Modified from K. J. Moise, JR, 2007.<sup>23</sup>