

Public and Private Cord Blood Banking - The CordTrack Concept

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Public or Private? - The Cord Blood Debate

Cord blood is a unique cell therapy scientifically proven to cure a variety of diseases. In addition to successfully treating rare diseases involving blood-forming cells in bone marrow, stem cell enriched cord blood also serves as a therapeutic treatment for chronic diseases. These may include diabetes mellitus, heart disease and neurological disorders such as strokes and spinal cord injury. Cord blood's unique stem cells possess biological features only now being thoroughly explored and understood. Educated parents wise enough to take advantage of the one-time opportunity to collect this genetic resource, face the difficult decision of storing their baby's cord blood publicly or privately. Both options provide substantial benefits for their child directly and indirectly.

Parents relinquish ownership of their baby's cord blood when they donate to a public cord blood bank. The suitability of their baby's cord blood will be evaluated based primarily on the number of cells collected. Family consent allows the bank to utilize the product for research, processing applications or clinical use. Clinical use cord blood is employed in allogeneic transplant protocols to treat severely ill patients unrelated to the donor. Products not meeting the stringent criteria necessary for use in unrelated

transplantation have other valuable uses. Such as basic research investigating and promoting a better understanding of cord blood stem cell biology or even used for studies designed to improve collection methodologies. Through research additional insights can be gained into transport, processing, cryopreserve (freeze in liquid nitrogen), and the distribution of cord

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blood products for clinical use. Public Storage is a donation from the family and there are no charges or fees to the family should they meet the dynamically changing collection criteria, and rigorous quality standards for collection.

Families retain product (cord blood) ownership when stored privately. It is also accessible for future use to directly benefit the person donating the cord blood. It may also be used to treat a genetically related sibling or parent such as the mother. The cord blood unit is specifically classified as a product "directed" for use in the donor or a genetically related family member. Private storage is not subject to the same stringent public bank regulatory requirements and third party quality standards oversight. Families also pay a fee for private cord blood storage. Presently, the American College of Obstetricians and Gynecologists, American Medical Association (AMA), and American Academy of

Pediatrics do not endorse private cord blood banking. Their concerns focus on “relaxed” unregulated quality standards that could render privately stored cord blood unsuitable for clinical use, as well as unsubstantiated claims regarding the therapeutic potential of cord blood. Future endorsements by these groups are contingent on these issues being addressed directly as well as widespread clinical use of privately stored cord blood by transplant physicians. Fortunately, new scientific discoveries in cord blood stem cell biology justify numerous potential therapeutic applications for cord blood. Moreover, additional steps are needed to ensure a “level of quality” of cord blood products that are stored in private banks. Consistency in standards must be verified in order to gain support for future clinical trials designed to explore the novel uses of cord blood cell therapy.

The CordTrack Concept

CordTrack was founded to “level the playing field” bridging quality standards and operating principles between public and private cord blood banks. CordTrack enforces the highest quality standards and “state of the art” procedures to collect, transport, process, characterize and cryopreserve cord blood. Ultimately, CordTrack will provide families the option for public or private storage.

The vitally important first-step to obtain a high-quality product is the sterile collection of an adequate number of viable cord blood cells from the attached umbilical cord and placenta.

One of the key concepts behind the CordTrack approach is obstetricians (OB’s) and their staffs, these highly trained licensed medical professionals, are recognized by CordTrack as invaluable partners in the cord blood collection process. By providing both educational materials and training in cord blood donor recruitment, donor evaluation and cord blood collection, CordTrack enables the

OB’s team to better assist families in deciding to store their cord blood either publicly or privately based on their “personalized needs”. Additionally, CordTrack will provide the OB with a detailed “report card” about cord blood product composition, maternal infectious disease testing and other information impacting product quality for communication with the family. CordTrack enables obstetricians a full circle long-term relationship with their patient’s family in the cord blood preservation process.

Certification and Quality Assurance

CordTrack Certification process establishes partnerships only with cord blood banks who meet all regulatory requirements and who embrace the following criteria:

- An objective “patient-centered” method of donor recruitment that is not based on advertising using unsubstantiated claims of therapeutic benefits of cord blood.
- Demonstrated commitment adhering to the highest quality cord blood banking practices irrespective of costs.
- Willingness to promote progress, support and participation in the cord blood-banking field and innovative initiatives.

All CordTrack affiliate banks must be registered with the Food and Drug Administration (FDA) and compliant with all relevant current FDA

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“Good Tissue Practice (GTP)” regulations. In

addition, participating cord blood banks must comply with the regulatory standards

established by the

American Association of Blood Banks (AABB). They also must be in compliance with those promulgated by the Foundation for Accreditation of Cell Therapy (FACT). Adherence to quality practices will be verified by regular “on-site”

inspections and submission of documents. These must demonstrate maintenance of active registration, certification and continuing participation in laboratory quality assurance and external proficiency testing programs mandated by the Clinical Laboratory Improvement Act (CLIA) and College of American Pathologists (CAP).

Through an objective and consistent quality focused approach in all aspects of the process: education, donor recruitment both public and private, collection, transport, processing and storage by a certified partner lab all with third party OB oversight, CordTrack provides a viable, clinically effective product that will be available when the need arises.

Conclusions

In order to guarantee the future of cord blood as a premier source of adult stem cells for cell therapy, we must capitalize on the synergy that exists between public and private cord blood banking models. Public banks currently provide cord blood for unrelated (allogeneic) use in hematopoietic stem cell transplantation primarily to treat patients with acute leukemia. This activity accounts for the overwhelming majority of cord blood transplants performed to date and is the primary basis for the clinical experience gained thus far in the use of cord blood. The experience gained in the therapeutic use of cord blood from

public banks today is providing the critical knowledge to continue to explore future potential uses of this unique cell therapy product.

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Future uses of cord blood are anticipated to treat non-malignant chronic diseases such as diabetes, heart disease or neurologic disorders, which will be performed using an autologous transplant

protocol. For autologous transplantation, the donor and recipient is the same person. This approach is much safer than the allogeneic (unrelated) transplant approach to treat acute leukemia because it avoids the problems of immunologic rejection and graft-vs-host disease, which are significant barriers to ensuring a successful outcome and high quality of life following an unrelated transplantation.

It is vitally important to point out that only those individuals whose cord blood is collected today will be eligible for future autologous cord blood transplant protocols. We expect that virtually all of these products will be stored in private banks. Private storage is however, contingent on clinician confidence in the current quality standards used to bank those products. Supporting the synergy between public and private cord blood banking through the adoption of uniform quality standards is the catalyst for the remarkable potential of cord blood for stem cell therapy to be fully realized serving both the public and private patient recipients.

About the Author: Dr. Michael H. Creer, MD

<http://path.slu.edu/facultycvs/creer.pdf>

Dr. Creer is Professor of Pathology and Pediatrics and Director of the Laboratory Medicine Division which manages the stem cell laboratory and stem cell collection facility at St. Louis University School of Medicine. Dr. Creer is the former director of the St. Louis Cord Blood Bank, one of the largest and most well-established cord blood programs in the world. Dr. Creer has been actively involved in public (not for profit) cord blood banking for the past 9 years and played an important role in the development of the National Cord Blood Network for the NMDP (National Marrow Donor Program) where he served as co-chair of the NMDP Cord Blood Committee.

Dr. Creer is actively engaged in scientific research in cord blood stem cell biology with specific emphasis on the mechanisms which recruit stem cells to sites of tissue injury. This is the obligatory first step in getting stem cells to tissue sites where they can affect repair and understanding this process is essential to the advancement of stem cell therapy.

Dr. Creer is a committee member of the American Association of Blood Banks (AABB) Cellular Therapy Product Standards group and is actively involved in inspecting cord blood banks, stem cell laboratories and stem cell collection programs for FACT (Foundation for Accreditation of Cellular Therapy). He has also served in an ad hoc capacity as an advisor to the FDA (Food and Drug Administration) on cord blood banking and processing of other cellular therapy products.