Saving the Leftovers: Models for Banking Cord Blood Stem Cells

Kimberly J Cogdell, North Carolina Central University

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I. Introduction

The use of embryonic stem cells is a highly publicized, politically-charged topic which implicates many ethical, legal and moral issues. But cord blood stem cells have not received this same level of media attention. Cord blood stem cells exhibit many of the same therapeutic qualities as embryonic stem cells, with fewer ethical problems. The purpose of this article is to: 1) distinguish between cord blood stem cells and embryonic stem cells for non-scientists; 2) highlight the opportunities that exist to collect more cord blood stem cells; 3) propose consent models for their collection; and 4) provide guidance for future legislation. Often cord blood stem cell publicity relates to private cord blood banking which is a very individualistic approach while public banking is based on a population approach. By emphasizing the utility of cord blood stem cells as a therapeutic and research resource, providing a framework for the collection consent and drafting suggested guidelines for legislation this article lays the groundwork for creating a comprehensive program that will benefit many Americans.

Each year there are over 4 million live births in the United States. As a result of each birth, umbilical cord blood stem cells are produced which are usually thrown away by the hospital. Rather than discarding this valuable resource, the cord blood should be banked and used for research and therapeutic purposes. Models for biobanking biological and genetic materials can be found around the world and many of the ethical, legal and social considerations have been identified. Processes for collecting material to be stored can be seen in the numerous biobanks which already exist. The ability to use cord blood stem cells for transplantation in ways that benefit populations often

1 Kimberly Cogdell, JD, MPH, Assistant Professor, North Carolina Central University School of Law; Co-Founder and Deputy Director, Biotechnology and Pharmaceutical Law Institute, I would like to thank my research assistant Paige Jones for her help.


underrepresented in traditional donor registries can be harnessed. Establishing a framework which can be followed for obtaining consent to cord blood donation, this will facilitate the collection of large numbers of samples which can be used. Avenues are already in place to collect cord blood stem cells.

The New York Blood Center’s National Cord Blood Donor Program is a public bank of umbilical cord blood established in 1992. The purpose of this program is to investigate the uses of cord blood as a possible substitute for bone marrow. Umbilical cord blood could provide a solution to the critical health need of finding matching donors for hematopoietic transplants in patients who have no matching bone marrow donors. Creating a system of universal systematic donation to a public bank will greatly increase the number of donors. Such a system would facilitate the use of new technologies, and transplant procedures while providing an opportunity for treatment to individuals who would otherwise not be able to find suitable donors.

New technology such as genetic manipulation has become increasingly more popular and the by-products of these types of research activities, therapies and medical treatments are often discarded as trash. The popularity of the use of artificial reproductive technology is increasing. After the process of in vitro fertilization is complete and the couple has achieved their goal of childbirth, often there are unused embryos. The couple often has the choice of whether to donate the unused embryos to other infertile couples or to have them destroyed. Embryo adoption/donation is a new term used to describe the process by which couples with unused embryos may donate or transfer them to others for in vitro fertilization. However, advocates of embryonic stem cell research would prefer to see some of the frozen embryos used for research purposes. A similar situation occurs with unused umbilical cord blood. Often families are unaware that the umbilical cord blood contains stem cells. There is the option of storing the cord blood privately, donating it for research, or for others or simply discarding it. Generally, the umbilical cord blood is


5 Malinowski, Michael J. and Rao, Radhika, Legal Limitations on Genetic Research and the Commercialization of its Results, American Journal of Comparative Law, 54 Am J Comp. L 45 (2006).


7 Embryo Adoption Awareness Campaign, Nightlight Christian Adoptions, http://www.embryoadoption.org/about_a_e.html

discarded rather than stored.\(^9\)

When faced with the challenges of what to do with unused biological materials many legal, ethical and moral questions arise. This article proposes a solution to collect umbilical cord blood and store it in a national public biobank for research and transplantation purposes. First, background will be given for biobanking and the materials sought to be banked. Next, parallels will be drawn between discarded biological materials and other generally discarded materials, and recommendations will be made about the type of consent necessary for placing these materials in a public bank. Two models are proposed for the consent process in collecting and storing these materials: presumed consent and informed consent during prenatal treatment on delivery intake. The informed consent process includes giving the potential donor sufficient information to determine whether or not to donate. This consent process will occur during visits to the doctor prior to birth or when the woman checks in to the hospital for delivery. The classification of the material to be donated will affect the type of consent needed to store it. By classifying the material like “trash”\(^10\) or genetic material donated for research,\(^11\) this forms the basis for establishing the consent process for biobanking.

In addition to determining classification of the genetic material, there are two other areas which affect the consent necessary for obtaining cord blood stem cell donations: the donors expectations of privacy and the donors beliefs about retaining ownership rights in the donated material. If there is no expectation of privacy in discarded materials, analogous to the trash classification this supports the presumed consent model. This parallel will be discussed further in Section VI. Similarly, if there is some consent to donate material for research purposes this supports the model for obtaining consent during prenatal screening. Establishing a uniform system for consent to deposit cord blood stem cells in public biobanks will facilitate the use of these samples within ethical and acceptable legal standards.

II. Biobanking – A General Overview

Biobanking is not a new concept. Many countries around the world have some form of biobank including the United States, the United Kingdom, Iceland, Canada and Estonia.\(^12\)

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\(^10\) *California v. Greenwood*, 486 U.S. 35, 1988

\(^11\) *Greenburg v. Miami Children’s Hospital Research Institute*; *Washington University v. Catalona*

\(^12\) Bregman-Eschet, Yael, Genetic Databases and Biobanks: Who Controls our Genetic Privacy, Santa Clara Computer and High Technology Law Journal, 23 SCCHITLJ 1, 2 – 3, November, 2006 (these counties have genetic databases)
In fact biobanking is gaining more popularity and the word is being used in many different ways to mean different things. There are banks for storing different kinds of body tissue such as brain and breast tissue as well as banks for storing tissues used to study diseases such as AIDS, Alzheimer’s and other mental illnesses. For purposes of this article, the term biobank is used to describe a collection of biological or genetic material, stored in a common facility, organized by sample and accessible to some entity. When referring to cord blood stem cell biobanks the term biobank is narrowed to only storage of cord blood stem cells. There are several different kinds of biobanks including government sponsored banks, private industry sponsored banks, and academic and non-profit banks. Many biobanks store biological materials for research purposes in response to the growing demand for clinical samples. Biobanks differ in that some allow access to the stored material to researchers while others do not. In fact, it has been suggested that the reluctance of some biobank owners to allow access to samples for research is financially motivated because owners want to discover genes for patenting. Gene patents generate large amounts of money so there is an incentive to limit access. One of the concerns with these types of patents is that the owner of the gene patent can charge large sums of money for the tests to detect mutations in the gene.

Currently there is a national cord blood program affiliated with the National Marrow Donor Program which has partnerships with cord blood banks and cooperative registries. The initiatives of the Center for Cord Blood are focused on five areas:


15 Id


17 Id. at 23


access, assurance, expertise, support, and science.\textsuperscript{21} Currently there are 15 states which have hospitals which actively collect cord blood for the Center for Cord Blood.\textsuperscript{22} Many of the hospitals participating in this program are affiliated with a local or regional cord blood bank. For instance, in 1998,\textsuperscript{23} the Duke Comprehensive Cancer Center opened the Carolinas Cord Blood Bank which now collects samples from 8\textsuperscript{24} local hospitals.\textsuperscript{25} Some states such as New Jersey receive funding from the state legislature to collect and store cord blood stem cells for transplantation to all state citizens.\textsuperscript{26} Though progress has been made, U.S. banks are fragmented.\textsuperscript{27} In 2005, a committee established through the Institute of Medicine in response to a needs assessment request by the Heath Resources and Services Administration (HRSA), recommended the establishment of a national cord blood stem cell bank program within HRSA.\textsuperscript{28} Congress passed legislation to promote cord blood stem cell banking in 2005.\textsuperscript{29}

In addition to the public biobanking, there are numerous private biobanking companies. However, private banking is expensive and therefore impractical for many women. One private cord blood bank charges almost $2,000 for the first year of storage.\textsuperscript{30} Private cord

\textsuperscript{21} Id

\textsuperscript{22} Id

\textsuperscript{23} Duke Opens 3rd U.S. Cord Blood Bank, Durham Herald Sun, Durham, NC, Wednesday, April 1, 1998

\textsuperscript{24} National Marrow Donor Program, Cord Blood Participating Hospitals, http://www.marrow.org/ABOUT/NMDP_Network/Cord_Blood_Banks/CB_Participating_Hospitals/nmdp_cord_blood_hospitals.pl#NC (Memorial Hospital at the University of North Carolina, Duke North Hospital at Duke University Medical Center, Durham Regional Hospital, Western Wake Hospital, Women’s Hospital of Greensboro, Rex Hospital)

\textsuperscript{25} Carolinas Cord Blood Bank, http://www.cancer.duke.edu/ccbb/

\textsuperscript{26} Corielle Institute for Medical Research, http://www.coriell.org/index.php/content/view/53/104/


\textsuperscript{28} Meyer, Emily A., Hanna, Kathi., Gebbie, Kristie, Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program, Report, Institute of Medicine, April 14, 2005


\textsuperscript{30} The Cord Blood Registry charges $1975 for the first year of storage plus registration
blood banking has been criticized for attempting to market the cord blood as being used for the child it was collected from or a family member. However, often times this isn’t the case because if the child develops a disease, the disease is likely present in the cord blood as well.31

Creating public biobanks is not always viewed as favorable by private cord blood banks.32 If there are more public banks people will not pay to store in the private banks. However, some public banks use the samples for anyone who needs them not just for the individual family that donated the sample. The American Academy of Pediatrics has published useful guidelines for determining when to bank publicly or privately.33 For instance, cord blood donation is encouraged when the samples are donated to a public bank, private banking should be encouraged when there is knowledge that a sibling in the family has a medical condition34 that could potentially benefit from cord blood banking. If banking for personal or family use, parents should know that most conditions that might be helped by cord blood stem cells already exist in the infant’s cord blood and would not be used,35 and storing cord blood as “biological insurance” should be discouraged because there currently is no scientific data to support autologous36 transplant.37

Private biobanking focuses on the benefit to the individual. The mother who stores her baby’s cord blood may be able to use this cord blood for another child in her own family. Public banking assumes a benevolent purpose and can be viewed through a more fee. http://www.cordblood.com/cord_blood_banking_with_cbr/pricing_domestic.asp


34 Malignant or genetic

35 Premalignancy changes in stem cells

36 Autologous transplant refers to using an individual’s own stem cells for transplantation.

37 American Academy of Pediatrics, Frequently Asked Questions, http://www.aap.org/advocacy/releases/jan07cordbloodfaq.htm (Private cord baking is storing the cord blood for use by a family member of the donor or for the donor, should the need arise. Alternatively, public cord banking, or donating means that the cord blood is stored in a cord blood bank and is available to anyone in need of a transplant who is a match).
population based approach. Donations to the public bank will likely not be used for one’s own family but if cord blood is necessary, samples from others would be available to anyone in need.

While biobanks are useful for the storage of genetic materials, there are ethical and legal problems associated with the process. One of the most common problems deals with the informed consent gained when obtaining the samples. Donees often consent to donating for one purpose; however their samples may be used for purposes not indicated on the original consent. For this reason, when developing guidelines for existing biobanks and creating new biobanks, it is important to keep in mind issues related to informed consent. In addition to consent issues, issues arise around confidentiality, discrimination, exploitation and globalization. \(^{38}\) Another problem with biobanking is that to create a sufficiently useful bank, samples are required from donors who will likely not be the direct beneficiaries of the research the samples are used for. \(^{39}\) Additional law and policy related concerns arise as well, such as ownership of samples, privacy, confidentiality, discrimination and exploitation of groups. \(^{40}\)

III. Stem Cells and Biobanking

The biological materials to be stored using the consent model described are stem cells. It is important to distinguish the different types of stem cells. These distinctions change the lens through which to view the consent model for donation. Two general characteristics which define stem cells are “the ability to self-renew for long periods of time and the potential to differentiate into the specialized cells, which constitute body tissues and organs, and repopulate them according to need.” \(^{41}\) Three types of stem cells discussed are embryonic stem cells, cord blood stem cells and adult \(^{42}\) stem cells with the specific focus on cord blood stem cells. Embryonic stem cells are pluripotent \(^{43}\) and adult stem

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\(^{38}\) Michael J. Malinowski, Technology Transfer in Biobanking: Credits, Debits and Population Health Futures 33 JLMEDETH 54, Journal of Law, Medicine and Ethics, Spring, 2005

\(^{39}\) Id. at 59

\(^{40}\) Id. at 58


\(^{42}\) Id

\(^{43}\) Pluripotent cells can produce new cells that come from the three germ layers: endoderm, ectoderm and mesoderm. They are different from totipotent cells which have the ability to form an embryo and membranes and tissues because pluripotent stem cells cannot form the complete embryo.
cells are multipotent, however new evidence suggests that the possibility of transdifferentiation exists which may negate these classifications. Adult stem cells have the ability of self-renewal and are traditionally found in bone marrow, peripheral blood, brain, spinal cord, blood vessels, skeletal muscle, liver, pancreas, lung, skin, gut epithelia, cornea, retina and tooth pulp. Some experiments have shown that adult stem cells can also be pluripotent and can differentiate into cells of types which are different than their tissue of origin.

Cord blood stem cells are different from adult stem cells and produce higher yields when grown in culture. This makes cord blood stem cells useful for research. Cord blood stem cells are pluripotent and can differentiate into different types of tissue including: cardiac, neurologic, pancreatic, and skin tissue. There are several advantages to using umbilical cord blood. There is a large supply, the collection is non-invasive and the donor is unaffected by the donation because the cells are discarded after childbirth. Other advantages are: cord blood is more rapidly available than bone marrow, it is less risky to collect, there is a decreased risk of graft-versus-host disease, and the risk of transmission of infectious disease is diminished.

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44 Multipotent cells usually differentiate into specific tissue or organ cell lines. This is different from pluripotent cells which can differentiate into different types of cells.


46 Self-renewal refers to producing identical copies of itself.


48 Id. at 220


Cord blood stem cells have been researched for over a decade\textsuperscript{53} as a possible source for hematopoietic stem cells.\textsuperscript{54} The uses for these cord blood stem cells have far reaching implications. Some examples of predicted uses and benefits are to virtually eliminate the need for bone marrow donors,\textsuperscript{55} providing a disease free source of hematopoietic cells, transplants for patients who have no clinically approved donors, and freedom from graft-versus-host disease.\textsuperscript{56} Cord blood stem cells can be used to treat individuals afflicted with leukemia and immune disorders.\textsuperscript{57} Additionally, diseases which cause conditions such as malignancies, hemoglobinopathies, bone marrow failure, immunodeficiencies, and inborn errors of metabolism can be treated with umbilical cord blood stem cell transplants.\textsuperscript{58}

In addition to the physiological differences between types of stem cells, there are many ethical and moral issues when dealing with embryonic stem cells as opposed to umbilical cord blood stem cells. The use of embryonic stem cells for research is often criticized because in most cases to collect the stem cells the embryo must be destroyed and therefore, no child can develop from it. Anti-Abortion and Right-to-Life advocates equate this to the destruction of human life. Using the embryonic stem cells for research, further strengthens the lack of personhood of an embryo which supports abortion rights.


\textsuperscript{55} In situations where cord blood stem cell transplants can be used in place of bone marrow transplants


\textsuperscript{58} Cord Blood Banking for Potential Future Transplantation, Pediatrics, Vol. 119, No. 1, pp. 165 - 170, January 2007 (Table 1) (Policy Statement, Section on Hematology/Oncology and Section on Allergy/Immunology, American Academy of Pediatrics).
If the embryo is considered to have rights similar to a living child, using the popular religious belief that life begins at conception, any use of the embryonic stem cells leading to the destruction of the embryo is murder. Morally, questions of how much is too much manipulation arises. While there are some embryos in fertility clinics that will be destroyed, these numbers pale in comparison to the umbilical cord blood which is discarded. Harvesting stem cells from umbilical cord blood does not have the same difficulties as embryonic stem cell collection. The mother and the baby are not harmed by the collection. The stem cells are not taken from material which could later become a life. Some of the moral issues about genetic manipulation exist but these issues are far less caustic than the related abortion issues.

IIIA. Examples of the Beneficial Uses of Cord Blood Stem Cells

One key area of focus for the use of cord blood stem cells is as a replacement for stem cells found in bone marrow used in bone marrow transplants. The main problem with bone marrow transplants is that genetic matching must be high and transplants from non-sibling unmatched donors often develop graft-versus-host disease because of the mismatches. This is problematic because only 20 – 25% of patients have an HLA matched sibling. Transplants using cord blood stem cells do not require the same level of HLA-matching. The incidence of graft-versus host disease was decreased by 10-fold using cord blood stem cell transplants.

59 Bone Marrow Transplant and Peripheral Blood Stem Cell Transplantation: Questions and Answers, National Cancer Institute Fact Sheet, http://www.cancer.gov/cancertopics/factsheet/Therapy/bone-marrow-transplant, (Stem cells in allogenic transplants may come from a family member or an unrelated donor which is distinguished from autologous transplants where the patients receive their own stem cells) (Last referenced, July 7, 2007).


61 HLA is a common abbreviation for human leukocyte-associated antigens which are proteins found on the surface of cells.


63 Cord Blood Banking for Potential Future Transplantation, Pediatrics, Vol. 119, No. 1, pp. 165 - 170, January 2007 (Table 1) (Policy Statement, Section on Hematology/Oncology and Section on Allergy/Immunology, American Academy of Pediatrics).

64 Kurtzberg, Joanne, Lyerly, Anne D., and Sugarman, Jeremy, Untying the Gordian Knot: policies, practices and ethical issues related to banking of umbilical cord blood,
A major benefit of storing cord blood stem cells in public biobanks to be used for therapeutic purposes is that these cells can be used for transplantation in place of a bone marrow transplant. Benefits cited by the National Marrow Donor Program for donating to a public bank include: the availability of the donation to any patient in need of a transplant, if the donation does not meet the criteria for transplant it can be used by researchers to develop new and more effective uses for cord blood stem cells, and the donation is typically free, because the public bank will cover the cost of processing and storage. Thousands of bone marrow transplants are performed in the United States each year. To those who undergo the procedure, the physical experience of the bone marrow transplant is a painful one.

Although many procedures are performed and save lives, seventy percent of individuals in need of a transplant do not have a suitable donor. According to the National Marrow Donor Program, it is difficult for ethnic and racial minorities to find suitable donors because the most likely matches are from the patient’s ethnic or racial group. Specifically, “American Indian and Alaska Native, Asian, Black and African American, Hispanic and Latino, Native Hawaiian and Other Pacific Islander, and multiple-race patients face a greater challenge in finding matched donors or cord blood than White patients.” By comparison, Caucasians have an 80% chance of finding an unrelated


66 Bone Marrow Transplant Information, Colombia Presbyterian Medical Center, Herbert Irving Comprehensive Cancer Center, http://cpmenet.columbia.edu/dept/medicine/bonemarrow/bmtnfo.html (stating that over 7,500 people underwent bone marrow transplants in 1991); (Last referenced, July 7, 2007).

67 Id

68 Id


donor\textsuperscript{71} while African Americans find matches less than 30% of the time.\textsuperscript{72} This makes it especially difficult for African-American patients; Thousands of African-Americans are diagnosed with a life-threatening blood disease, many of which could be treated by a bone marrow or cord blood stem cell transplant if a matching donor could be found.\textsuperscript{73} By increasing the number of donors from ethnic and racial minority groups, patients from these groups will have a greater chance of finding suitable donors. As awareness increases and targeted programs are developed, the situation for ethnic and racial minorities is improving. In 2006, 26\% of all recipients from these groups received cord blood stem cell transplants.\textsuperscript{74}

IV. Legal Arguments: Property Rights, Informed Consent and Ownership

In this section, the legal property and ownership classifications of different kinds of materials will be examined; namely discarded and donated materials. The classification affects the type of informed consent required to collect and store the sample. It is important to note however that the way consent should be obtained for different types of banked specimens is in dispute.\textsuperscript{75} When donated samples containing genetic materials can be identified and linked back to original donors, potential problems occur. One problem is that in some settings to be useful, biobanks must have both the physical samples plus the medical information about the subject who donated the samples.\textsuperscript{76} Genetic material

\textsuperscript{71} For patients suffering from leukemia, lymphoma and other disorders treatable with transplantation

\textsuperscript{72} Glasgow, Mary E., and Bellow, Gerald, Bone Marrow Donation: Factors Influencing Intentions in African Americans, Oncology Nursing Forum, Vol. 34. No. 2, (2007).

\textsuperscript{73} Black Patients Need Donors, National Marrow Donor Program, http://www.marrow.org/ABOUT/Connecting_Patients_w_Donors/Community_Outreach_Partnerships/Unite_Commit/Black_Patients_Need_Donors/index.html (describing the community outreach and partnership activities in the Black community and the need for more donors); (Last referenced July 7, 2007).


\textsuperscript{75} Evans, Barbara J., Meslin, Eric M., Encouraging Translational Research Through Harmonization of FDA and Common Rule Informed Consent Requirements for Research with Banked Specimens, Journal of Legal Medicine, 27 JLEGMED 119, 120, June, 2006

\textsuperscript{76} Henry T., Population Participation and Other Factors that Impact the Compilation and the Utility of Resulting Databases, Louisiana Law Review, 66 LALR 79, December, 2005
can be used to provide information about family groups, community groups and other broad classifications and can often be used for years after the samples are collected. For instance, ethical concerns about stigmatization, discrimination and exploitation may arise if harmful information is discovered from research done with donated samples which can be identified to the donee.

The first step in determining what type of consent is necessary to bank a sample is to decide how it is classified through a property context. When to obtain the consent is a controversial issue resolved in different ways by different banks. Some banks obtain consent before collection while others ask after the collection where the collection is successful. Determining the appropriate consent can be especially difficult when dealing with cord blood stem cells collected after childbirth because they aren’t donated in the traditional sense like other biological materials donated for research purposes. Because there is no exact classification, the property rights must be examined from perspectives which have been previously classified. Cord blood stem cells have characteristics similar to donated materials in that the mother knows that when the material is removed, it will normally not be returned to her. These materials are also similar to a more basic ownership classification, trash, because the mother knows that the material will be discarded after the birth. By examining these two scenarios, the models for presumed consent or consent during prenatal appointments for biobanking cord blood stem cells arise.

At first glance, the case of California v. Greenwood, seems to be unrelated to the issues of banking cord blood stem cells. But upon closer review, a parallel can be drawn between the material placed on the curb to be collected as garbage and the material removed during childbirth to be discarded by the hospital. Greenwood deals with the search and seizure of materials obtained from a warrantless search and whether the use of this material violated the Fourth Amendment. By placing the items on the curb the original owners had no expectation of privacy in them and therefore the items could be used for purposes other than trash. Several state supreme courts have addressed this issue and the cases had mixed results. Similarly, by agreeing to discard the birth related

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81 Hawaii. State v. Tanaka, 701 P.2d 1274 (Haw. 1985) (the police trespassed on the private property of the defendants workplace and seized evidence. A search warrant was
materials\textsuperscript{82} opens the door to the idea that these materials may be used for purposes other than just discarding. There are several distinctions between the expectations of privacy when dealing with government warrantless search and seizure and when dealing with birth related materials. It should be noted that the obvious difference is the latter is a non-government action and there are heightened expectations of privacy in relation to genetic materials. Yet when an individual discards hair from a brush, finger/toenail clippings, a blood soiled bandage or other such material carrying genetic or identifying information is there an expectation of privacy? The door is open to interpretation. Here no consent process is used to obtain this information. The presumption is made that if you throw something in the trash, it is opened up to the public. If the owner of the article, item or material did not want it to be accessible to others, it could be burned, shredded or any number of other ways of discard that would render the items useless.

As opposed to trash, the easier connection is to materials donated for genetic research. If a person participates in a research study and donates a biological sample, they have been told of the risks and how the sample will be used. However, even when consent is given, every aspect of the use of the material does not have to be spelled out. This was the case in \textit{Greenburg v. Miami Children’s Hospital Research Institute}.\textsuperscript{83} The subjects involved in this research donated genetic material to be used for the study of Canavan disease. While the researchers did do research on Canavan disease, they also obtained a patent based on the research done with the materials donated by the subjects in the study which was ultimately profitable. The subjects argued that the use of the material to obtain the patent and the economic interests of the researchers exceeded the consent given. Based on a variety of legal theories including informed consent, fiduciary duties, and fraudulent concealment the donors brought the action and were unsuccessful.\textsuperscript{84} In fact, they went so far as to say that “the property right in blood and tissue samples also evaporates once the

\begin{quote}
obtained based on this evidence. The Supreme Court of Hawaii held that under the Hawaii Constitution the defendants had a reasonable expectation of privacy in their trash bags therefore the police officers seizure without a warrant violated the prohibition against unreasonable searches and seizures); New Jersey. \textit{State v. Hempele}, 576 A.2d 793 (N.J. 1990) (The Supreme Court of New Jersey found that a person has a reasonable expectation of privacy in garbage left at curbside); Washington. \textit{State v. Boland}, 800 P.2d 1112 (Wash. 1990) (The Supreme Court of Washington held that the defendant’s private affairs were unreasonably intruded upon when the police removed garbage from the defendant’s trash can); Vermont. \textit{State v. Morris}, 680 A.2d 90 (Vt. 1996). (Supreme Court of Virginia found that a person has an objectively reasonable privacy interest in garbage).
\end{quote}

\textsuperscript{82} Referring to the placenta, cord blood stem cells and other birth related fluids and materials routinely discarded after childbirth


\textsuperscript{84} Id
sample is voluntarily given to a third party.  

As recently as 2006, research participants were deemed to be donors and the biological materials given for the research study constituted an inter vivos gift. The court used the elements of the inter vivos gift: 1) present intention of the donor to make a gift; 2) delivery of property by donor to donee; and 3) acceptance by donee whose ownership takes effect immediately and absolutely. By viewing the genetic material donated for research as a gift, then the third element extinguishes ownership rights in the material of the original donor.

Comparison: Organ Donation and Stem Cells

A practical comparison can be made between the donation of cord blood stem cells and organ donation. Donations of organs and stem cells have different ethical issues but there are basic similarities. With both organs and cord blood, individuals must choose or consent to be donors. The donation is of some biological/body part which can be used for therapeutic purposes in others. However, organ donation is more highly regulated and has a longer history. Statistics available for both organ donation and cord blood stem cell donation indicate that there is a shortage of donees. In other words, there are more people who need donors than there are people who donate.

By examining the state of organ donation and models of donation around the world and in the United States, a framework can be developed for ways of making cord blood stem cell donation more efficient and viable. In July of 2007, there were over 96,000 individuals on the waiting list for an organ donation. In the Prefatory Note of the Uniform Anatomical Gift Act website,

“according to the Scientific Registry of Transplant Recipients in 2005 when there were about 90,000 people on the organ transplant waiting list, there were 13,091 individuals who died under the age of 70 using cardiac and brain death criteria and who were eligible to be organ donors. Of these, only 58% or 7,593 were actual donors who provided just over 23,000 organs. Living donors, primarily of kidneys, contributed about 6,800 more organs. Between them about 28,000 organs were transplanted into patients on the waiting list in 2005.

85 Id


87 Id.

88 http://www.mayoclinic.org/transplant/organ-donation.html (approximately 97,000 people in the Us are waiting for organ transplants; 17 people die each day waiting for transplants that cannot take place because of the shortage of donated organs)


These data indicate that the current system allows the loss of many organs that could be used for transplant to decrease the shortage. The beneficial aspects of organ donation systems in countries with highly successful programs, could be used to create a cohesive organ procurement system. In the same way, while examining donation systems that work, this will provide insight into how to develop a donation scheme for cord blood stem cell donors. First, the system in the United States will be described followed by a few other international systems.

Organ donation in the United States is governed by two legislative acts, the Uniform Anatomical Gift Act (UAGA) and the National Organ Transplant Act (NOTA) and is based on an altruistic model through volunteerism. There is tremendous support of the volunteer type program yet in comparison, there is much less participation. Individuals may donate by donor card or by expressed wishes to donate. If the decedent’s wishes were not known and there is no representative to offer the organs for donation, the UAGA proscribes conditions which must be met in order to procure the organs. One problem suggested with the U.S. model is that the physicians and emergency personnel are responsible for obtaining the consent. In response to this difficulty some states have adopted novel approaches to obtaining consent. For example, Ohio implemented an online registry where donors could make an informed decision based on information and

referenced July 8, 2007).


92 Id. at 1683

93 Id. at 1687

94 Uniform Anatomical Gift Act

95 Next of kin, Uniform Anatomical gift Act of 2006 §9, (representatives that can make a gift - agent of the decedent can make the gift, the spouse of the decedent, adult sibling of the decedent, adult grandchildren of the decedent, grandparents of the decedent, an adult who exhibited special care and concern for the decedent, guardian of the decedent at the time of death, or any person having authority to dispose of the body)

96 Uniform Anatomical Gift Act (the coroner or medical examiner in possession of an unclaimed body may make an anatomical gift)

clearly state their commitment to donate by signing up.98 As of June 2006, there were 3.5 million licensed Ohio drivers registered through the donor registry.99

By contrast, many countries around the world use a presumed consent model for organ donation.100 And when compared to other organ procurement programs, countries with the presumed consent model have higher levels of donation.101 Notable presumed consent models can be found in France, Belgium, Austria, and Spain all with varying requirements but using the same basic principles.102 Factors which may affect donation include cause of death, religion, characteristics of patients, staff training and availability of surgeons and facilities.103

The Spanish model is one of the most successful in Europe.104 They have a highly organized system of trained transplant coordinators which are a part of the Organización Nacional de Transplantes (ONT).105 A key feature of the Spanish system is that the potential donors are tracked and the transplant coordinators discuss the options of donation with potential families.106 The coordinators have been so successful that in

105 Id.
106 Id.
many cases a family that originally rejected donation changed their minds after speaking to the transplant coordinators and having the process explained to them. Training videos are used to train the transplant coordinators. The coordinators use role play to practice situations which may occur. They carefully talked to the patients explaining the benefits of the donation. It is remarkable how quickly they are able to talk to the patients and how crucial the timing of these conversations are in the whole process. In addition to the training video, other videos exist describing the national network and the process that occurs after the organ is collected, including transporting the organ, and contacting the recipient. Additionally, the intensive care unit where the transplant recipients are housed and treated is very structured. Overall, the process and people are very professional and organized.

The Models

Based on the lack of classification of cord blood stem cells in traditional legal theory, a uniform system for consent to donate to public banks is the obvious answer. By looking at the strengths and weaknesses of other donation systems, a system of consent can be developed. A multifaceted approach designed to reach many individuals in different places is necessary. In order for any systematic approach to be successful, the level of awareness must be raised in the entire population. Public service announcements, newspaper and magazine ads, documentaries, or other forms of information dissemination should be used to teach the masses about the benefits of cord blood stem cells and to dispel any misconceptions that may exist. There must be buy-in by stakeholders including, physicians, advocacy groups, and grassroots organizations. By creating a program which incorporates these aspects a universal consent process can be developed. Two approaches can be taken for consent to donate cord blood stem cells.

Informed Consent

The first more traditional approach is a standardized form and pamphlet which can be distributed by the physicians or nurses at individual offices and clinics during prenatal
classes or prenatal visits. The women would have the opportunity to read the information prior to delivery and make an informed choice about whether to donate. A national website should also be created specifically to inform women about the process and the benefits of donating. Until then, women can be directed to existing websites to get more information. The final consent can be obtained during intake at the hospital when the baby will be delivered.

The positive effects of this approach are the protection of individual choice, making a systematic standardized process which can be used across the nation, and increasing the awareness of new technology. However, there are difficulties with this model. Like organ donation, this method relies on the altruistic principles of volunteerism. The families would have to be proactive about seeking information. Physicians and nurses would have to take time out of their already busy schedules to facilitate the administration of the program.

Presumed Consent

The second more innovative approach is a presumed consent model. This model should be implemented over a period of time using test markets or areas to determine feasibility. A statewide initiative should be developed informing individuals of the program. All women delivering babies in public hospitals would be presumed to consent to donate unless they opt out of the program. Therefore, the choice of the individual is not foreclosed; however, rather than the assumption being viewed in the negative, it should be viewed in positive terms i.e. assuming an individual would like to donate rather than assuming that they would not like to donate. If the woman chooses not to donate, a form could be downloaded from the program website and submitted during intake before the childbirth. Forms would be available to hospitals and birthing centers, as well.

Using a presumed consent model, consent is more passive and many people may not know that they have agreed. Communicating this program to the public is essential for safeguarding the patient’s right to know. It does not require the time of the physicians and nurses to ascertain whether the person wants to be a donor just before labor. It is an equal enrollment program so those that are economically disadvantaged are not harmed by not having prenatal appointments or internet access.

With either model there are great benefits to standardizing consent to facilitate cord blood stem cell donation to public banks. Universal donation is not class conscious or gender specific, it does not see color, religion or any other categorization which divides people. When all are donors, no one is discriminated against yet everyone is helped. Individuals from minority populations will benefit by having a greater number of samples to be used for cord blood stem cell transplants. Researchers may have access to more samples to further advance research and study of ways to use this valuable resource.

Legislation

In order to ensure protection of individuals, researchers, clinicians, hospitals and all
others involved, legislation should be passed to govern the collection and storage of cord blood stem cells. There is limited federal legislation related to research using cord blood stem cells but a more comprehensive plan should be developed. The legislation should include the following:

- **Define the consent model;**
  - Using tools such as the online consent forms/opt-out forms

- **Create a statewide network of education and training for health care workers, patients and families;**

- **Define how the samples can be used**
  - 40% of the samples should be used for research and 60% should be used for therapeutic purposes
  - Samples cannot be used for human cloning
  - At all times at least 50% of all minority samples collected should remain in the bank
  - Preference should be given for research on orphan diseases as well as diseases which affect underserved populations

- **Identify who will have access to samples**
  - Public/private partnership
  - Small and public universities (as defined in the legislation) should be given preference over private entities

V. Conclusion

There are a multitude of possibilities for research using biobanks. Biobanking may have an especially positive effect for minority populations in that they provide a more structured way to study traditionally excluded groups. Overall, everyone can be a winner. Yet, efforts must be made to promote biobanking for altruistic purposes.

Some basic challenges exist in establishing biobanks. Standardization, collection and distribution were named as some issues to collecting and managing biospecimens.

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111 C.W. Bill Young Cell Transplantation Program (Established under section 379 of the Public Health Service Act 42 U.S.C. 274).


114 Biobanks: Accelerating Molecular Medicine, IBM, IDC, Special Report, November 2004, at 10, http://www-
Data integration within and between biobanks is also important.\textsuperscript{115}

In addition to logistical challenges, there are also legal issues which must be resolved in order for a national cord blood stem cell biobank to exist. Regulations like HIPAA which require privacy of information and protection of medical records will be implicated.\textsuperscript{116}

Public cord blood stem cell biobanks should be a public-private partnerships. Funding should be obtained for the program from both the NIH and pharmaceutical companies seeking to use the samples for research. No more than 50% of the samples in the biobank at any given time should be used for research and a constant amount of samples should always remain in the bank. This would encourage companies and others interested in doing research to promote donation of cord blood stem cells. This process would include educating the public, and demonstrating the benefits of these donations thought disease case studies, and individual stories. The information dissemination should not stop at potential donors, other stakeholders such as physicians, scientists, venture capital organizations and other funding sources should also be included. Use of samples for research on orphan diseases and diseases affecting minority populations should receive some additional benefit from the NIH in funding these projects.

By using either the informed consent or presumed consent model, a formalized approach should be taken to create a process for stocking public biobanks for therapeutic and research purposes.

\textsuperscript{115} Biobanks: Accelerating Molecular Medicine, IBM, IDC, Special Report, November 2004, at 16, http://www-03.ibm.com/industries/healthcare/doc/content/bin/Biobanks_Accelerating_Molecular_Medicine.pdf

\textsuperscript{116} HIPAA