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Cord Blood Collection in Pregnant Women for Stem Cell Research

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CORD BLOOD COLLECTION IN PREGNANT WOMEN FOR STEM CELL RESEARCH

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Abstract

Umbilical cord blood (UCB) stem cells form commonly banked types of human tissue. Confusion remains about sources of stem cells and their use. Birth is a once in a lifetime opportunity with 74 million births per year in the world and four million occur in the United States. Cord blood contains hematopoietic stem cells and pluripotent mesenchymal cells (Moise, 2005). There is a surge of interest in the clinical use and research investigation of umbilical cord blood for transplantation and regenerative medicine. Clinicians need increased awareness and education of options for private versus public donation and banking of cord blood at birth to present to pregnant patients.

The aims of this research were to describe decision-making readiness and communication with mothers and their partners during her pregnancy using the Transtheoretical Model (Prochaska, J.O. and DiClemente, C.C, 1982). Describe the relationship between age, pregnant women's level of parity, gestational age, highest level of education, marital status, race, religion, economic status, and plan of payment for prenatal care to their *sources of knowledge*, their *beliefs and knowledge regarding cord blood transplantation.* Perceptions of pregnant women's cord blood use and their understanding of the difference between public and private cord blood storage banks and use. The partner's perceptions of cord blood use and their understanding of the difference between public and private cord blood storage banks and use.

The voluntary sample consisted of 30 participants of convenience from two obstetrical clinics from a local clinic. The design was a quantitative method staging an algorithm for Cord Blood Donation using a Decision of Readiness Scale along with notification of significant other. The Cord Blood Survey measured sources of knowledge,

beliefs, and knowledge of cord blood transplantation. The Statistical Package for the Social Sciences (SPWS 18.0) was used to perform an analysis of data. Descriptive statistics were used to summarize the demographic variables and to identify central tendency, variability and percentages of key variables. One-way ANOVA and *t*-test were computed on the quantitative questions. Qualitative measures from randomly selected post interviews of 1/3 of the sample were completed.

The barriers to understanding what umbilical cord blood donation options and how pregnant women make decisions regarding umbilical cord blood donations are explored. The implications for nursing research are: overcoming the barriers to understanding the difference between private and public banking and the ramifications of each option; add to nursing knowledge by understanding when and how women make decisions about umbilical cord blood donation; and future studies could investigate ethical implications of umbilical cord blood donation and best nursing practice guidelines for approaching pregnant women and their partners on umbilical cord blood donation options.

Dedication

I would like to dedicate this research and the written dissertation to women and their babies who have shared their experience of pregnancy and birth with me throughout my nursing career as a Family Nurse Practitioner and as a Certified Nurse-Midwife. There is no other time in a couple's life that is so private and intimate than the birth of their child. This is a sacred time they will remember all of their life until death do us part.

Equally important, I dedicate this effort to my loving husband, Paul D. Zalusky, who has been so very patient and been there for me every step of the way on this long journey. My gratitude to my parents, Mary and Boxie who have loved me and my other four siblings, three sisters and one brother, without any reservation and taught us to always work hard and practice the "Golden Rule": treat others as you would want to be treated. They taught me to never give up on any closed door as another will always open and with God's grace I will do on this earth what I was meant to do here.

Acknowledgements

I would like to extend my heartfelt gratitude to my dissertation chair, Jane Georges, PhD, RN, for her unceasing support and guidance through the many challenges, surprises and successes throughout the entire academic program. The commitment, courage and sharing moments of the feminist perspective and the understanding of the hermeneutics philosophy has brought me a guiding light and great appreciation to understanding a way to look at the world and our life within it. I will never be able to repay her but can only hope to honor her in future work.

The USD PhD Nursing Program Director, Dr Patricia Roth, was a dissertation committee member and has shown me tremendous kindness and compassion that guided me through the transformation into a novice nurse scientist, never letting me believe that I could not complete the journey I began. I can only aspire to help other nurses on the scale that she has helped hundreds of doctoral students.

I would like to thank Dr Kathy James for her expertise and support as dissertation committee member. Her strength as a nurse, teacher and researcher has been an inspiration to me.

The recognition of thanks to Ruth Bush, PhD, for her assistance on my statistical analysis has allowed me to be enriched immeasurably by her process and guidance. She spent many hours guiding me through the statistical analysis of the data allowing me to really look at my data to see what my participants where saying to me.

Finally, with much gratitude I want to thank the medical librarian, Charlotte McClamma, MLS, for teaching me how to really "*dig deep*" for knowledge and to come to appreciate the "Foundation of All Knowledge." I am committed to her and the quote by Benjamin Franklin, "The doors of wisdom are never shut!" which is hung on her front door. What a most appropriate place for a librarian, don't you think?

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Chapter I

Introduction

Stem cells from umbilical cord blood form one of the most commonly banked types of human tissue. Birth is a time when stem cell collection is an option through umbilical cord blood collection. Despite over 74 million births per year in the world and of those four million of which occur in the United States (World Watch Institute, 2006, p.75), many people remain unaware of human umbilical cord blood collection (Cryo-cell, 2006). Who would have known thirty-five years ago, when this researcher a new graduate nurse routinely collecting cord blood at a birth to determine the baby's blood type, some day one would be collecting it for stem cell research on a baby. To make the decision to bank cord blood for stem cell collection is a life experience one can only capture at a timely moment……..Birth!

The debate over embryonic stem cell research continues in the news headlines over the last two decades. Despite this, many people remain unaware that the human umbilical cord blood and other noncontroversial stem cell sources, such as the placenta, are routinely used in medical treatments. Tremendous confusion and lack of understanding about the different sources of stem cells and their use affects members of the government, public, and medical community. It is important to note that embryonic

tissue is not the only source of stem cells and is not part of this study (see Appendix A: Sources of Stem Cells). Until 1988 (Smith & Thomson, 2000) and April, 2006 (Cryo-cell, 2006), blood that remained in the umbilical cord and placenta, respectfully, after delivery used to be routinely discarded. Now several studies have confirmed with similar results this blood is known to contain hematopoietic stem cells and pluripotent mesenchymal cells (Moise, 2005); undifferentiated cells that can develop into virtually any type of blood cell in the human body; and provides a better alternative to bone marrow transplantation to treat an expanding list of malignant, benign, and inherited disorders (Perlow, 2002) (see Appendix B showing a list of diseases potentially treatable with stem cells from umbilical cord blood). As a result, a surge of interest in the clinical use and research investigation of umbilical and placental stem cells in transplantation and regenerative medicine has evolved in the science of stem cell research.

Background of the Problem

Until President George W. Bush signed a bill December 20, 2005, the Federal Drug Administration (FDA) had no control over some of the standardizations for collection and processing of cord blood in public banks (Institute of Medicine, 2005 & 2006; Perlow, 2006). The debate regarding private banking of autologous blood for "biological insurance" versus public banking for access by the general public continues today. Lack of knowledge and expense remain as barriers to umbilical cord blood collection and placenta stem cell collection. Opportunities to educate patients and obstetrical providers in these areas need to be pursued if one is to make a true informed decision (Perlow, 2002). Obstetrical providers need to support acquisition but many do not even have a basic understanding of newborn stem cell research derived from post-

delivery stem cell banking. Patients are poorly informed about options in umbilical blood banking, especially in ethnic minorities (Perlow, 2006), and unless a parent, relative, or friend opens the internet specifically to download umbilical cord blood collection or placental stem cell collection and obtains the information somewhat easily, this process of collection is virtually unknown to the public. Many people, including medical professionals, are eager to learn more about newborn stem cell (NBSC) banking, yet they are unaware of recent regenerative medicine research or the many diseases that are currently treatable with stem cells. Pregnant women, who not only decide the fate of their newborn's wardrobe colors, and ultimately the choice to collect stem cells, frequently look to their clinicians for guidance in evaluating their options to collect stem cells or not to collect stem cells and how to go about it! In addition, many health care professionals are unaware of the federal legislation to establish nationwide cord blood banks. They have never initiated a discussion with a patient about cord blood banking and are unprepared to answer an expectant mothers' question (Young, 2006). As more pregnant women become aware of the importance of cord blood stem cells, it is increasingly necessary for clinicians to be well informed. Considering the accessibility and availability of large quantities of newborn stem cells (NBSC), it seems likely that much of the future of stem cell therapy may depend heavily on newborn stem cells.

Originally stored for the treatment of hematological disorders stem cells have now been found to be more versatile for potential use in the treatment of a broader range of disorders and diseases and may be particularly valuable in cell therapy and regenerative medicine (Gunning & Holm, 2006, p.17; Waldby, 2006). The storage of umbilical cord cells has not been without controversy and there is rapidly growing private sector

involvement. Over the last two decades umbilical cord blood has proved an effective substitute for bone marrow in the treatment of blood disorders, and most nations in the developed world have public programs for the harvesting and storage of cord blood for allogenic transplantation (Garcia & Torrabadella, 2006; Waldby, 2006). Yet, a number of ethical issues continue to be debated involving questions of regulation and quality assurance, ownership and commercialization, patenting, and the financial constraints could make this unreachable for marginalized populations in the United States. The researcher will first present the historical background of *related* and *unrelated cord blood* to establish the legitimacy of the science, *public* versus *private banking*, regulation and quality assurance of banking and the worldwide influence cord blood banking has on regenerative medicine.

Purpose of the Study

The study researched and investigated issues surrounding knowledge by healthcare providers and patients' perceptions of cord blood collection or newborn stem cell collection (NBSC) and banking. From a philosophical perspective this appears to be a source of hegemony where the issue is dominated from a white male power base whose only voice seems to matter in the present situation. However, this researcher would like to take a postmodernist viewpoint and approach it with a critical/feminist theory where everyone has a place in the dialogue. Habermas a major contributor to critical theory and stressed: human beings in dialogue with each other are the foundation for emancipatory social thought and we all need to have a voice in this through the truths claimed and communication shared about the issues (Finlayson, 2005, page 59; J.M. Georges personal communication, September 7 & 14, 2006).

This purpose of the study investigated pregnant women's knowledge of cord blood collection and what decision-making process they experience to donate cord blood at their birth. **The research question:** ***What characteristics during a woman's pregnancy are possibly related when making a decision for cord blood donation at birth?***

Specific aims for this inquiry are as follows:

1) To *describe the readiness of decision-making and communication* to her significant other during a given time in a pregnant woman's gestational age.

2) To *describe* pregnant women's age, weeks of pregnancy (gestational age), level of parity (number of pregnancies), marital status, race, religion, highest level of education, economic status and method of payment for prenatal care.

3) To examine the *relationships between* women's age, weeks of pregnancy (gestational age), level of parity (number of pregnancies), marital status, race, religion, highest level of education, economic status and method of payment for prenatal care.

4) To examine pregnant women's *perceptions* of cord blood use, difference between public and private cord blood storage banks and use.

5) To examine pregnant women's *partner's perceptions* of cord blood use, difference between public and private cord blood storage banks and use.

Conceptual Framework

The transtheoretical model (TTM) of change provides an alternative way of grouping patients according to their stage of readiness to learn and adopt new beliefs and behaviors (Prochaska & DiClemente, 1998). Recent research suggests that by understanding the clients' *readiness to change* one can design intervention to increase the

chance of successful implementation (Haslam & Haslam, 2000). The dimensions described in the model, the stages, processes, context, and markers of change, are designed to assist in picturing and understanding the process of change (Prochaska & DiClemente, 1984; DiClemente & Prochaska, 1998, pp.3-24; DiClemente, 2003). Transtheoretical Model (TTM) incorporates elements of various theories of therapy, learning, and behavior change, hence the term 'Transtheoretical'. The model, however, does not try to resolve all the conceptual issues and conflicts among the various theories incorporated in the model. It simple tries to identify and describe important elements of the process of intentional behavior change (DiClemente, 2007) (see Appendix C for figure of Stages of Change Model).

Scope and Delimitations of the Study

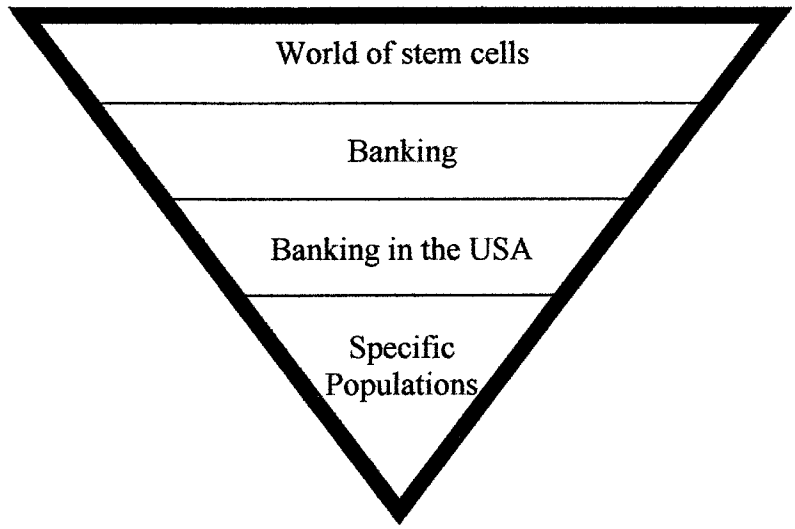
Umbilical cord cell transplantation has evolved over the last 15 years from being an experimental procedure to an accepted treatment for a number of hematological diseases and genetic disorders. Presently it is used, for example, in treatment of Acute Myelogenous Leukemia, Chronic Myelogenous Leukemia, Acute Lymphoblastic Leukemia, Chronic Lymphocytic Leukemia, Juvenile Myelomonocytic Leukemia, Hodgkin's Lymphoma, Non-Hodgkin's Lymphoma, Myeloma (cancer of plasma cells) and Wiskott - Aldrich Syndrome to name a few (see Appendix B). During the evolution of banking cord blood as human tissue it has increased exponentially around the world. The proliferation of private cord cell banks has been particularly strong in the USA and Asia while, in Europe, where there are one or two old established private banks, the emphasis has been on public cord cell banking (Agarwal, 2006; Greenwood, 2006). But, whether in the private or public cord cell banking sector, there remains alternate quality

assurance standards that need addressing. This will become particularly important if cord blood stem cells are to play an important part in the cellular therapies of regenerative medicine in the future (Greenwood, 2006) (see Appendices D and E). As the utility of these cells increases countries may have to consider whether cord blood should be collected from all newborns. This will be a costly process if only obtained by the private banks and may be the promotion of public cord blood donation but with the acknowledgement that one has the right to private storage may prove a practical way forward. It is also clear within this frontier of science that new ethical questions will continue to arise.

Outline of Proposal

Following this introduction, a review of current relevant literature in the area was presented. The conceptual model was discussed as how it is related to this study by laying the framework for the area of inquiry. Operational definitions were reviewed.

Explanation of the dissertation's importance to the advancement of knowledge, nursing science, and nursing practice were addressed. The methods to be used in this study were then described, including a detailed description of the research procedure and proposed data analysis plans.



Chapter II

Overview

Just as the "interests and welfare of the human being prevail over the sole interests of science and society so does society and the culture of healthcare send us into new technology", (Gunning & Holm, 2006, p.7, Chap. 2). This section briefly describes the milestones reached in umbilical cord blood transplantation. The researcher will first present the historical background of *related* and *unrelated cord blood* to establish the legitimacy of the science, *public* versus *private banking*, then expand on the regulation and quality assurance of banking and the worldwide influence cord blood banking has on regenerative medicine.

Historical Background

Stem cell research started in 1925 (Maximow, 1925, pp.47-113) and has been a very controversial subject when connected to embryonic stem cell research. However, umbilical cord blood and placental stem cells are not considered embryonic but are embryonic-like and are now classified currently under *newborn* stem cell research. The study of umbilical cord blood began in 1982, when discussions between Broxmeyer and Boyse led to laboratory experiments suggesting umbilical cord blood contained hematopoietic stem cells that might be suitable for transplantation (Broxmeyer, 1998, (a);

Broxmeyer & Smith, 1998, (b).The concept of using umbilical cord blood as a source of stem cells was first proposed by Edward Boyse in 1983 (Wagner, 1993).

Because of the need for quick access when patients were seeking a match for transplantation with their blood an organized blood banking system soon seemed to be the answer. Broxmeyer and Boyses' (Smith & Thomson, 2000) laboratory-based research led to establishing umbilical cord blood banking and was first successful at Indiana University to harvest cells from the siblings of children needing transplants. One of these units was used to perform the *first related* sibling transplant with umbilical cord blood in a 6 year-old boy with Fanconi anemia in 1988 in Paris, France (Gluckman et al., 1989). Gluckman further described this as a trans-Atlantic collaborative effort as the cell processing was done in the USA and hand carried to the patient in France. It was after this case that cord blood banks were established in the early 1990's first in New York in 1993 and then in Europe through the London Cord Blood Bank, the first in the UK set up in 1996 (Waldby, 2005). Subsequently, over 35 cord blood banks have been established in 21 countries and today there are over 150,000 cord blood units worldwide both in the public and private sectors (Bone Marrow Donors Worldwide, 2003, Chap. 3; Agarwal, 2006)

One year later in 1989 Harris and colleagues performed the first umbilical cord blood transplant matched to a *related* sibling in Cincinnati (Gluckman, 1989; Smith & Thomson, 2000). Kurtzberg and colleagues at Duke University in Durham, NC, performed the first successful *unrelated* sibling umbilical cord blood transplant in the United States in 1993 (Kurtzberg, Graham, Olson, Stevens, & Rubenstein, 1994). The possibility to use *unrelated* donor cord blood grafts stimulated the need for a storage bank

of *unrelated* donor cord blood units. To address this need, Rubinstein and colleagues at the New York Blood Center created the first *public umbilical cord blood bank*, designed to test the safety and efficacy of collecting, testing, cryopreserving, and dispersing umbilical cord blood collected from *unrelated* donors to transplant centers (Rubinstein, Rosenfeld, Adamson, & Stevens, 1993; Rubinstein, Taylor & Scaradavou, 1994; Rubinstein, Carrier, & Scaradavou, 1998).

The first *private cord blood bank*, Biocyte Corporation, was set up in Connecticut in 1993 (Holden, 1993) and now private cord blood banks operate throughout the USA, Europe and Asia. Wagner published the first series of cord blood recipients in 1995 representing the Placental and Umbilical Cord Blood Registry (Wagner, Kernan, & Steinbach, 1995). They reported the transplant results for 44 related, sibling cord blood grafts. This was followed in 1996 by Duke University's center reporting 25 unrelated donor cord blood transplants (Kurtzberg, Laughlin, & Graham, 1996) and in 1997 by Gluckman's report of the European experience with 78 *related* and 65 *unrelated* donor cord blood transplants (Gluckman, Rocha, & Boyer-Chammard, 1997). In 1998 Rubinstein reported the results of 562 *unrelated* donor cord blood transplants that were facilitated by the New York Blood Center's cord blood bank in New York City which is the largest series of cord blood transplants reported to date (Rubinstein, Rosenfeld, Adamson, & Stevens, 1993; Rubinstein, Taylor & Scaradavou, 1994; Rubinstein, Carrier, & Scaradavou, 1998). Recently, April 2006, Cryo-cell and Gen-cell were the first to initiate the collection of placentas for placental stem cell research (Cryo-cell, 2006). The reports provide important and encouraging results on cord blood obtained from *related* and *unrelated* donors establish a basic foundation for the science of stem cell research

and hope for parents who desire information on this issue. The replication of the science sets a firm bases on which to set a practice of use worldwide (see Appendix F: Historical Milestones of Umbilical Cord Blood Banking and Transplantation).

What is Public Banking vs. Private Banking?

Information regarding umbilical cord blood (UCB) banking is surfacing at an accelerated rate in the past few years. The messages, with the predominate target towards vulnerable populations as pregnant women, women of childbearing age and women, encourage mothers-to-be to bank their child's umbilical cord blood. Because UCB stem cells must be collected at birth, women should decide what to do with their child's umbilical cord blood well in advance. To discard, donate for research, publicly store or privately store UCB stem cells—these are potential choices that have to be made. As anticipated, a growing number of Internet sites and magazines advertisements are cautioning women that storing a newborn's UCB is a once-in-a-lifetime opportunity and probably an investment that can save their child if it were to become necessary. When this researcher downloaded on Google "*cord blood banking*" in the Summer of 2008 there were over one million seven hundred thousand entries compared to Winter 2006 when there were approximately seven hundred thousand (Carr, I. personal computer search, February, 2006 to July 10, 2008). Now that stem cells harvested from UCB have been successfully used for hemopoietic stem cell transplantation in *unrelated* adults (Laughlin et al., 2004; Rocha et al., 2004; Sanz,2004; Kharaboyan, Knoppers, Avard, & Nisker, 2007) they are actively being sought by families and researchers. Stem cells harvested from UCB have been used to substitute for bone marrow as a source of hemopoietic stem cells for transplants in the treatment of genetic disease, blood

malignancies, and immune deficiencies (Kharaboyan, Knoppers, Avard, & Nisker, 2007). The dedicated promise of private banking, coupled with pleas from public banks asking mothers to donate UCB for altruistic purposes, can become confusing for pregnant women as well as the general public. The empirical conclusion would be: Women who know more about UCB banking are more likely to make appropriate choices for both themselves and their families (Kharaboyan, Knoppers, Avard, & Nisker, 2007) and that would be by deciding to donate umbilical cord blood. This researcher wants to know: do they really do that and if they do, what is their understanding when they are making that decision?

Banking is of two types i.e. public and private. A woman can donate cord blood for an *unrelated* recipient to public banks (unrelated allogeneic transplantation). Private (commercial) banks, on the other hand, offer expectant parents the option to store cord blood for possible future use by that same child (autologous transplantation) or familial use. Women and mothers-to-be need to have a balance of information presented to them about private and public cord blood banking so they will feel comfortable to make an informed decision.

Before deciding to privately bank UCB, women should be advised of both the benefits and limitations of private banking. Considering one can guarantee easy access to their own stem cells for themselves or for a family member with an actual need of stem cell transplantation, it is equally important to inform mothers that presently it is highly unlikely for a family with no history of blood diseases to ever need the banked UCB (Fisk, Roberts, Markwald, & Mironov, 2005; Kharaboyan et al., 2007). This is in agreement with The American Academy of Pediatrics (American Academy of Pediatrics

[AAP], 1999 & 2007) who is against the private collection of cord blood as the need is minimal. One of the reasons would be the research shared where two estimates calculating the possible likelihood one would need the same blood given by the donor (autologous) to range from 1:2,700 (Moise, 2005 and 2006) and another from 1:1,000 to 1:200,000 (Witte, 2005). This fact was recently addressed by Kingsbury (2008) in a popular public news journal in the health section of that resource through the following comment:

"Cord blood transplants also require a less perfect match in unrelated people, opening up a broader spectrum of potential donors, and recipients' bodies are less likely to reject a transplant" (Kingsbury, 2008, pp.2-3).

The issue of private banking has generated controversy in recent years due to the aggressive marketing tactics of some private collection-and-banking facilities. Large numbers of organizations worldwide have started discouraging autologous or *private* banking. In addition to the American Academy of Pediatrics (AAP) and American College of Obstetrics and Gynecologist (ACOG), the Royal College of Obstetricians and Gynaecologists' Scientific Opinion condemned the practice of private cord blood blanking (Royal College of Obstetricians and Gynaeocologists, 2001, p.2), and the French National Consultative Ethics Committee and European Group on Ethics in Science and New Technologies are discouraging its use (Agarwal, 2006;). Italy has completely banned autologous and private banking (Rendine et al., 2000) by law and it is forbidden by the Ministry of Health in China. Canada takes a similar view and has published guidelines (Canadian Institutes of Health Research [CIHR], 2005; Armson, 2005). The Global Biopolitics Research Group out of Sydney, Australia has written a

working paper titled: *Umbilical Cord Blood: from Social Gift to Venture Capital* which is reflected by C. Waldby (2006):

Private cord blood banking has been largely condemned by bioethical and medical professional bodies, on the grounds that the likelihood of any particular individual needing a cord blood transplant is very low, and that public, redistributive banking is a more efficient use of resources (p.2).

The advantages and limitations to public banking of UCB should be clear before making a decision. Public banking of UCB is to initiate use to a human resource for the greater good of all. *Public* banks collect units from patients of a wider ethnic diversity. Even though public banks are designed to improve donor matches for minorities, a recent study revealed that cord blood donation from minorities has remained low. An American Red Cross survey in 2001 showed that 64% of donors are white, 16% African American, and 12% Hispanic, 4% Asian, 1% Native American, and 3% other (Ballen, Hicks, & Dharan, 2002). In an effort to increase minority units, the IOM (Institute of Medicine) report advised that 100,000 new quality umbilical cord blood units could be collected in a national cord bank system (Institute of Medicine, 2005). For the marginalized patient, the cost of personalized cord blood collection and storage is prohibitive and will be addressed in detail in another section of the dissertation. When the studies keep introducing and replicating the science of cord blood transplants from *unrelated* donors coming from public banks which may succeed with one or two HLA mismatches (Moise, 2005), as novel therapies in the treatment of cystic fibrosis (Sueblinvong, Suratt, & Weiss, 2007), transplantation for primary immunodeficiency (Gennery & Cant, 2008), indications and donor selections for allogeneic stem cell transplantation in children with

hematologic malignancies (Handgretinger, Kurtzberg, & Maarten Egeler, 2008), or issues to consider for successful vaccinations in children with hemopoietic stem cell transplantation (Patel, Chisholm, & Heath, 2008), one may start to agree that this is safe and ethically the right option for some families. Mothers may donate cord blood at the time of delivery at no charge and are given access to suitable matches if the need ever arises for immediate family members (Lui, 2006).

Insufficient Number of Hemopoietic Stem Cells in Umbilical Cord Blood

The problem with insufficient number of precursor stem cells found in cord blood can explain why familial use is unlikely going to be an advantage. Kurtzberg (2005) conducted research showing that stem cells found in a unit of cord blood would not suffice to treat adults weighing more than 110 pounds (Kurtzberg, Drapkin, & Sugarman, 2005). A major limitation when using cord blood grafts for transplantation in adults is the concern that the grafts have a low number of stem cells as compared with bone-marrow grafts (Laughlin et al., 2004). Reports of cord blood transplantation in adults suggest that hematopoietic recovery is faster with higher cell doses (Laughlin, Barker, Bambach et al., 2001; Sanz, Saavedra, Planelles et al., 2001; Ooi, Iseki, Takahashi et al., 2002; Laughlin, 2004). However, researchers are actively developing techniques to expand the number of stem cells in a unit of cord blood, using them in clinical trials, and reporting that cord blood transplantation in adults with leukemia and acute leukemia suggests that hematopoietic recovery is faster with higher cell doses (Laughlin et al., 2004; Rocha et al., 2004; Kharaboyan et al., 2007). Laughlin (2004) and Rocha (2004) were both observational studies with expected limitations which are inherent in this environment. In both, the effect of the stem cell source on various outcomes was analyzed by multivariate

methods to allow for a controlled comparison and the two investigations differed in their study populations and other methodological issues which may have influenced their results (Sanz, 2004). With much of the work in laboratory technology progressing to expand the UCB hemopoietic stem cells, the science is evolving so that this could solve the issue of reduced number of stem cells in a unit and hopefully increase transplantations to treat degenerative conditions such as rheumatoid arthritis and multiple sclerosis in adults (Sanz, 2004; Copeland, 2006).

Another concern when a child is in need of an HLA (human leukocyte antigen) - matched hematopoietic progenitor cell transplant (HPCT), but no match is available; the affected child's parents can use Pre-implantation Genetic Diagnosis (PGD) to conceive a child who is an HLA-matched sibling (Verlinksy, Rechitsky, Schoolcraft et al., 2001). The sibling then can act as an umbilical cord blood donor for the child in need of the transplant (Bick & Lau, 2006). This may not be the ethical choice of some parents and thus is not a reliable alternative method for them to consider.

Information about Testing Diseases and Family History

Most diseases are the result of the interactions of multiple genes and environmental factors. As genetic technology develops and tests become widely available, it has been suggested that testing be carried out on umbilical cord blood stem cells to identify pre-symptomatic diseases or disease susceptibility (McCullough et al., 1994; Institute of Medicine of the National Academies, 2005, p.22, p.169, pp.180-183, pp.185-187). Delay in reestablishing normal immune functions as donor cells restore recipient development of new lymphocytes, lymphohematopoiesis, plus immunosuppressive therapy places patients at high risk for bacterial, viral, and fungal

infections. In the case of donor-patient HLA (human leukocyte antigen) disparity, infection is an even greater problem (Eastlund, 1995; Institute of Medicine of the National Academies, 2005; Kharaboyan et al., 2007). Usually as a general rule the tests that are applied are the same series of test used for the deferral criteria as that of whole blood donors for risk factors. To reduce the risk of transmission to the recipient the criteria to determine which units are suitable for banking and the tests that umbilical cord blood subjected to include: ABO and RH type determination, newborn screening retention samples, infectious disease markers, HIV/AIDS, Hepatitis A, Hepatitis B, Hepatitis C, CMV by culture or DNA PCR testing, *Treponema pallidum* (syphilis), human T-cell lymphotropic virus, West Nile virus, parasitic blood diseases, hemoglobinopathy screen such as test negative for homozygous hemoglobinopathies, microbiology tests as positive CFU growth, normal genetic screen to mention a few (Warwick, R & Armitage, S. 2004; IOM, 2005).

Umbilical Cord Blood transplantation requires a careful and thorough review of the mother's medical and social history to exclude those with a transmissible disease (Ballen, 2005). This may involve inquiry into the mothers' symptoms of potential infectious diseases as listed above or the mother has engaged in behaviors or received a medical treatment that increases the risk of contracting these diseases. In addition, if there is a lack of family medical history of inherited genetic disorders or diseases, if there is inappropriate affirmative responses to questions from risk behavior questionnaires, or if there is refusal to answer maternal and baby health questionnaire eligibility these may affect inclusion or non-inclusion criteria for the bank when one is desiring to send the UCB unit (Institute of Medicine of the National Academies, 2005, pp.168-171). When

information about banking is shared with this population from a health care provider, especially public banking, health professionals must inform mothers about what infectious disease agents are being tested for, possible genetic testing the unit will undergo, and how they plan to be informed if the results are positive. This is a critical part in the intake process of public banking. This may reveal information about paternity, infectious diseases and predisposition or susceptibility to certain genetic diseases.

If confidentiality is not properly protected, respected, and safeguarded the results of testing can have psychological and social implications for the parents and potentially put children at risk of suffering insurance-, education-, and employment-related discrimination (Kharaboyan et al., 2007). It is essential to respect the privacy and the health needs of women and their children as well as the privacy of the patients receiving the transplants (IOM, 2005). Knowledge of individual risk does not always lead to better health but it will allow better prevention, diagnosing, and more avenues of approach in treatment (Guttmacher, Collins, & Carmona, 2004). This will ensure that increased knowledge leads to opportunities of choice affecting improved health outcomes.

Today, with medicine at the crossroads in the era of the genomic frontier, the valuable tool is the family history (Guttmacher et al., 2004; Rich, Burke, & Heaton, 2004; Scheuner, Wang, Raffel, Larabell, & Rotter, 1997). Computerized software allows clinicians the advantages of standardizing the family history and helping to overcome the gaps in obtaining and organizing the data. Linked records allow donors and recipients to be found, informed, and referred for care if infectious or genetic diseases detected after UCB stem cells have been transplanted (McCullough et al., 1994). Doctors are allowed to retrace the donated UCB in the event that a child requires an autologous transplant. Also,

in the event where a new genetic or infectious disease test becomes available, access to linked stored samples would allow providers to recontact donors who have previously agreed through informed consent to permit conducting tests on their previously donated samples, giving them the possible benefit of early diagnosis and treatment (Pinch, 2001).

Many observers worry that recording the family history may lead to genetic discrimination in employment or health insurance (Guttmacher et al., 2004), especially when anything that is noted about the family members in the medical record is potentially discoverable as publicized in the Fall 2003 Veterans Administration Electronic Medical Record scandal (personal communication with Paul D. Zalusky, September, 2003) and witnessed by this researcher May, 2008 with medical records stolen from University of Utah Medical Center, Salt Lake City, Utah. Many states have laws in place to prohibit such discrimination (see www.genome.gov/policyethics/legdatabase/pubsearch.cjm for a state-by-state listing of such laws) (Guttmacher et al, 2004), and national legislation has been passed to incriminate those who violate the law. Beginning in 2004 are documented surveys that gives one reason to believe many people will welcome efforts to make the family history a more available tool. P. Yoon and M. T. Scheuner from the Center for Disease Control and Prevention, Office of Genomics and Disease Prevention had a personal communication with Dr. Alan Guttmacher from the National Human Genome Research Institute at the National Institute of Health where they asked more than 4000 people the question "How important do you think knowledge of your family's health history is to your personal health?" Seventy-three percent of the survey respondents thought it very important, and 24 percent thought it somewhat important. However, only

30 percent of the respondents reported that they had actually collected health information from relatives in order to develop a family health history (Guttmacher et al., 2004).

A more recent example of this is a timely initiative, July 16, 2008, where there was a national launch of "My Records at MinuteClinic", a secure website that allows patients to view their MinuteClinic medical records online. This is the first retail clinic to partner with Google Health to help patients manage their medical information online. With the celebration in November 2007 seeing one million patients as a marker in the retail clinic competition, they are anticipating this successful. When a patient joins "My Records at MinuteClinic", they can also link their MinuteClinic records to a personal Google Health account. This was tested over several weeks in the Chattanooga and Knoxville markets and they have seen significant and positive interest from patients. This is done by offering the service at the patient sign-in kiosk and collecting their email address if they wish, however, it is not required to obtain health services. The patient is given a card with information how to access this website and to follow steps to register online securing two passwords to link them on their individual record. Partnering with the secure website, Google Health, it reassures those who fear a potential breach of confidentiality is far less likely to occur (personal communication on July 16, 2008 with Alex Bollman, Project Manager, MinuteClinic, 920 Second Ave. S., Suite 400, Minneapolis, MN 55402).

Financial Commitment

The financial commitment is an issue to consider. *Private Banking*, sometimes found in the literature as commercial or family banking, fees include an upfront fee for families in private banking between $1,100 and $1,975 and an annual charge for ongoing

storage about $115 to $125 (Gajilan & Gupta, 2005; Gunning, 2006; Young, 2006; www.cryo-cell.com/resource-center retrieved on October 18, 2006). *Public Banking* fee is initially free to the parents but the cost for the initial processing of cord blood is about $1,000 per unit stored. The bank incurs this initial cost and may try to recover some of the costs later. They can charge the insurance companies for units used with transplants once the need ever arises for the individual. Fees usually average $15,000 to $35,000 per unit (Gunning, 2006; Moise, 2005; Young, 2006) (see Appendix G for a comparison between the *public banking* systems of the United States and Europe with the *private banking* systems of the United States and Europe).

The Asian and Indian scenario with public and private banking is a little more limiting. Table 1 of Appendix D gives the picture of umbilical cord stem cell banking and transplants in Asian countries. In India, there are no public umbilical cord blood banks available, although, attempts have been started in New Delhi and Chandegarh. In the private sector there are a few of them. Public banking would be more useful as it would benefit all, it would be cheaper as the costs are likely to be provided by government agencies and it may be useful for the minor ethnic groups. Private banks are useful for one who can bear the costs and hence it is expensive. It is not available to others including minor ethnic groups. Reliance Life Sciences (RLS) established the country's first umbilical cord blood bank (cord blood repository-CBR) in 2002. It has two programs i.e. Relicord A which collects donor umbilical cord stem cells for *unrelated* allogeneic transplants and Relicord S which collects for *related* sibling transplants. There are banks located at Bangalore, Chennai and other places. With the education status of mothers in India being poor, most of the women are not involved in decision-making and therefore

legally valid consent remains a rarity. Only 34 % of deliveries occur within the infrastructure of health facilities and skilled personnel attend to only 42% of deliveries (Agarwal, 2006).

Regulation and Quality Assurance

The cord blood banking industry has been unregulated during its inception in the early 1990's when umbilical cord bank processing and cryopreservation activities had markedly evolved from laboratory activities (McCullough, McKenna, Kadidlo, Schierman, & Wagner, 2005). Since 1995, the Food and Drug Administration (FDA) engaged in thorough public discussion regarding a proposed regulatory approach for hematopoietic stem/progenitor cells obtained from placental/umbilical cord and peripheral blood (Harvath, 2000). In February 1997, the FDA announced its "Proposed Approach to Regulation of Cellular and Tissue-Based Products" (Food and Drug Administration, 1997). This plan was a comprehensive, risk-based system of regulation for cellular and tissues through innovative cellular and gene therapy products (Harvath, 2000). Because standards have evolved over time, cord blood banks contain units that have different levels of quality. Some units have been placed in the usable inventory with incomplete test results and/or documentation and may not meet the bank's own current criteria:

"There is a tension between private cord blood banks, which store blood for autologous or family use, and public banks, which store blood for unrelated use. There is an inference that private banks are taking out of circulation cord blood units which might otherwise be used for unrelated recipients. It is not clear that this is the case since public banks restrict their collection to a local network of hospitals and it is difficult for women

outside their target population to donate. Private banks have no such restrictions" (Gunning & Holm, 2006, p.19).

In January 2005, Bone Marrow Donors worldwide reported the U. S. inventory of public cord blood banks from *unrelated* donors to be in excess of 87,000 units (Moise, 2005). It is estimated that half of these units did not meet the criteria for a usable unit based on cell count and other collection issues (Institute of Medicine [IOM], 2005). One of the problems is the lack of enough quality cells and volume to benefit a treatment for adults. Since that time, the problem of cell count is being address mostly validated in mouse models (Encabo, Mateu, Carbonell-Uberos, & Minana, 2003; Jaroscak, Martin, & Waters-Pick, 1998). One of the initial studies addressing cell count out of The Chinese University of Hong Kong by Tsang et al., (2001) where a comparative laboratory trial with dextran added to bags containing umbilical cord blood (UCB) occurred. This was followed by sedimentation for 30 minutes pre and post sample in a semi-closed system which enabled volume reduction of UCB without significant quantitative and qualitative losses of nucleated cells (Tsang et al., 2001). There is a surge of science that is trying to address this issue (Bornstein et al., 2005).

As mentioned earlier until recently there has been virtually no regulation of cord cell banks. In March 2004 the European Directive (2004/23/EC) on setting standards for quality and safety for the donation, procurement, testing processing, preservation, storage and distribution of human tissues and cells came into force (Gunning & Holm, 2006, p.21). This tissue banking directive would apply to all biobanks, including cord cell banks in the public sector. In the UK the Human Tissue Act 2004, which meets the Directive requirements, came into force on April 1, 2006. Other countries, notably

Australia, Germany, and France already impose good manufacturing practice (GMP) standards. Most other locations standards apply which have been developed by bone marrow transplant organizations or blood services such as the Foundation for the Accreditation of Cellular Therapy (FACT) and the American Association of Blood Banks (Gunning, 2004, pp.10-15). Gunning (2006) also mentions there have probably been over a dozen organizations around the world setting quality standards for cord blood banking, all varying slightly, and accreditation has been voluntary.

Cord blood banking involves: recruitment, consent, testing of maternal donors, collection, processing, cryopreservation, testing, and releasing cord blood unit to a transplant center. In the USA protocols have been established for these (Rubinstein, Dobrila, & Rosenfield, 1995) and updated in 2005 with the establishment of a National Cord Blood Stem Cell Program funded by the Health Resources and Services Administration with $10,000,000 (Institute of Medicine, 2005) but this expenditure will await a report on the issue from the Institute of Medicine. Meanwhile there is disagreement between cord blood banks and registries as to how the program should work (Reed, A. from *New York Times*, May 29, 2004). The establishment of the program would allow for easy access to donors of different ethnic and racial populations. Units in public banking would be registered in a computerized program and able to be located in a search without the initial cost as in private banking. The units are tested for viruses, transmissible infectious diseases, and bacterial contamination during the prep for banking, so all is available in a shorter time interval. Relocation of the parents is a barrier to this process. The rational to contact the parent of the donor is to identify any serious

illness identified since the birth of the donor. The parents have the right to decline to participate (Witte, 2005).

Even though public banks are designed to improve donor matches for minorities by helping serve those patients who have a more difficult time finding donors through the National Marrow Donor Program (NMDP) and other international registries, a recent study revealed that cord blood donation from minorities has remained low. An American Red Cross survey in 2001 showed that 64% of donors are white, 16% African American, 12% Hispanic, 4% Asian, 1% Native American, and 3% other (Ballen, Hicks, & Dharan, 2002). In an effort to increase minority units, the IOM (Institute of Medicine) report advised that 100,000 new quality umbilical cord blood units could be collected in a national cord bank system (Institute of Medicine, 2005). As of May 2005 the racial/ethnic composition of the NMDP cord blood registry 52% white, 5% African American, 13% Hispanic, 5% Asian, 12% multiple race, 1% Native American, and 12% other or unknown (Ballen, 2005). This implies an increased recent attention to minority recruitment has resulted in more diverse cord blood units.

On December 20, 2005 President Bush signed into law H.R. 2520. Congress passed the Stem Cell Therapeutic and Research Act (Lui, 2006). The bill renames the National Marrow Donor Program the C.W. Bill Young Cell Transplant Program (Moise, 2006). Along with this, $34 million in 2006 and $38 million between 2007 and 2010 are appropriated to establish a national cord blood inventory of 150,000 units. The belief is that would then be enough diversity that 90% of Americans who might need stem cells would be able to find a match (U.S. Congress, 2005). The bill also tasks the FDA with the development of licensing requirements for cord banks that will contribute units to the

inventory. In early 2006 the California Assembly Initiatives, Assembly Bill (AB34) Portantino-Umbilical Cord Banking, Pilot Project was effective July 1, 2007. This was a pilot project that would seek to diversify the umbilical cord blood supply collected in public blood banks. It would require the Department of Public Health to identify 5 hospitals, in ethnically diverse areas, as voluntary participants to collect, secure a patient's consent for donation of, and partner with specified entities to store umbilical cord blood (A Publication of the Regional Perinatal Programs of California, 2007). In addition Senate Bill, SB1555: Speier-Umbilical Cord Blood Banking, Education, Screening which will provide awareness, assistance, and information regarding umbilical cord blood banking options in multiple languages should be an introduction in trying to change the social and cultural perspectives of this practice in California.

Cord Blood Banking in Regenerative Medicine

The aspect of umbilical cord blood banking has gained particular impetus from the field of regenerative medicine. Regenerative medicine seeks to identify the mechanisms of self-production involved in auto-regeneration and to enhance and develop them into therapies for those tissues that do not regenerate spontaneously. Research is being conducted to find ways to culture cord blood stem cells so they can be "expanded" in the same way as embryonic stem cell lines (Egan, 2000) and to induce transdifferentiation into multipotent stem cells, rather than stem cells committed to the production of the blood system (Anderson, Gagae & Weissman, 2001). Umbilical cord blood is being used for unrelated bone marrow replacement, for example the report out of Japan (Mugishima, Takahashi, Nagamura, Asano, & Saito, 2002). The cord blood bank

industry is open to paths of stem cell research and wants to participate in alternative options (Tse & Laughlin, 2005; Klatz, 2005; Henning et al., 2004).

Although traditionally associated with industrialized nations, epidemic levels of non-communicable diseases, such as diabetes, cardiovascular diseases and cancer are rapidly increasing in low- and middle-income countries (Cryo-cell, 2006) on top of the persisting threat of infectious disease such as in India with malaria and anemia (Bhattachary, 2006). Now threaten by the developing world and straining health systems that are still struggling with persisting levels of infectious disease cord blood banks may be an asset. It is like there is a "double-burden" on these countries. The emerging field of regenerative medicine may provide new opportunities to address these health needs if employed with the goal of improving global health over all (Greenwood et al., 2006). Greenwood further implies several developing countries themselves have recognized the potential of regenerative medicine and have initiated Research and Development work in this field. This phenomenon of the "double burden" is so severe that the World Health Organization refers to non-communicable diseases in the developing world as "neglected epidemics" (World Health Organization [WHO], 2003, p.15). "Worldwide, non-communicable diseases now account for more deaths annually than infectious diseases", (http://www.who.int/dietphysicalactivity/publications/facts/chronic/en. Retrieved May 10, 2007). By 2020, it is estimated that 7 out of 10 deaths in developing countries were due to non-communicable diseases (Boutayeb & Boutayeb, 2005).

In Greenwood (2006) he discusses based on the literature regarding health innovation in developing countries (Juma & Yee-Cheong, 2005; Morel, 2005), as well as experience in studying successful biotechnology sectors in developing countries

(Thorsteinsdottir, Quach, Daar, & Singer, 2004), how he and his colleagues believe that building capacity and encouraging local innovation in regenerative medicine can help developing countries capture benefits to address some of the health needs presented by this "double burden" of non-communicable and infectious diseases. Five areas where assessed: dedicated government funding, goods (e.g. bioengineered skin) and services (e.g. umbilical cord blood banking available for purchase), companies, publications, and academic institutions (see Appendix E for a reflection of a survey of regenerative medicine activities in 31 low- and middle-income countries). Greenwood further presents a more detailed descriptive narrative of six countries currently active in regenerative medicine: Argentina, China, India, Iran, Malaysia and South Africa. These countries were chosen because they show interesting and diverse activities in regenerative medicine, as well as representing various geographic regions of the world. The information in the narratives is well beyond the scope of this paper; however, the results of this survey of regenerative medicine activities in developing countries demonstrate that even though regenerative medicine is still an emerging field worldwide, developing countries are actively engaged in its pursuit. The survey identified 31 low- and middle-income countries and is a first step towards understanding how developing countries are building capacity in regenerative medicine and using it to address some of the health needs such as diabetes, cardiovascular disease and cancer. An understanding such as this can facilitate the development of health and policy both in developed countries and developing world needs.

Unique Problems with Umbilical Cord Blood

In an earlier portion of the study this researcher described the issue of umbilical cord blood being discarded at the birth as waste material (Gluckman, 2000; Kingsbury, 2008). With education and the science evolving over the years on the use of UCB for treatment of multiple diseases (Perlow, 2002, Moise 2005) the collection rate is improving but it still needs to improve (Institute of Medicine of the National Academies, 2005). Especially if infectious disease or genetic testing indicates that a child's cord blood is not suited for storage and transplantation or when the volume or quantity of cells collected is insufficient, the units may be considered not useable and then discarded (Kharaboyan et al., 2007). Ballen (2005) reported a common reason for approximately half of the cord blood units intended for banking after successful collection are not frozen and stored for transplant use due to a low-volume in the unit (Ballen, 2005). Now one is trying to educate hospital managers and obstetrical providers such as physicians/nurse-midwives/nurses to re-think this and instead of discarding these units, stem cells scientists have requested access to them to advance research in stem cell therapy (Héma-Québec, 2006). This possibility should be discussed with women when obtaining informed consent before the banking process (Institute of Medicine of the National Academies, 2005; Gunning, 2006, Chapter 3, pp.17-25).

The problem has surfaced where reports of some private companies collecting umbilical cord blood are presenting themselves as "*Public Banks*" (Gunning, 2006; (Saginur, Kharaboyan, & Knoppers, 2004). One of the tactics reported by Hundley (Hundley, 2003) is that they store blood in *gratuitously* and then sell compatible matches to research companies as well as to patients in urgent need of transplantation who are

willing to pay close to $15,000.000 per unit. Hundley goes on further by indicating the incentives to recruit women have been reported to pay obstetricians a fee for collecting cord blood from their patients (Kharaboyan, 2007, Gunning, 2006). The provider ought to fully disclose their personal commercial interests as well as those of the company with whom one chooses to store the cord blood (Institute of Medicine of the National Academies, 2005, Chapter 5, pp.106-119; Gunning, 2006).

It is ethically important to obtain informed consent for the donation of any cord blood unit regardless of the timing of collection or the potential use of the unit. Informed consent procedures for the donation of cord blood should follow a consistent set of protocols that educate the donor about the various options for cord blood use. The requirements should be modeled on already established criteria for transfusion of whole blood and other unfrozen products (Fernandez, 1998; Institute of Medicine of the National Academies, 2005, p.107). Different consent methods have been used by different cord blood banks (Institute of Medicine of the National Academies, 2005, p.108).

The most optimal manner to promote and ensure respect for a pregnant woman's autonomous choice, her informed consent for the collection, storage, and use of her cord blood should be given prior to the labor experience and after adequate disclosure of information on the uses of the donated cord blood. This is especially important in the alternative of public banking, in which the patients may often not initiate the donation process. Almost all the women polled in Sugarman's (Sugarman, Kurtzberg, Box, & Horner, 2002) study expressed the opinion that the information about the collection of cord blood should be presented before the third trimester of pregnancy and could be

included in the informational packets that are given to others during prenatal visits. On the other hand, knowing that situations for optimal conditions may not occur in the labor and delivery area, the American Red Cross Cord Blood Program, North Central region, investigated a phased consent policy (Vawter, Rogers-Chysler, & Clay, 2002). The phased consent approach is a 3-step process involving (1) targeting information about cord blood banking to pregnant women; (2) allowing early labor consent to the ex utero collection, which is the collection from the placenta shortly after the birth experience, and temporary storage of cord blood; and (3) permitting post collection consent to the permanent storage, donation, and testing of the cord blood. Mothers who were eligible for intrapartum labor consent had to meet strict eligibility criteria including dilation less than 7 cm, age older than18 years, more than 36 weeks gestation, and no use of narcotics.

Theoretical Model

The transtheoretical model (TTM) of change provides an alternative way of grouping patients according to their stage of readiness to learn and adopt new beliefs and behaviors (Prochaska & DiClemente, 1998). Recent research suggests that by understanding the clients' readiness to change we can design our intervention to increase the chance of successful implementation (Haslam & Haslam, 2000). The dimensions described in the model, the stages, processes, context, and markers of change, are designed to assist in picturing and understanding the process of change (Prochaska & DiClemente, 1984; DiClemente & Prochaska, 1998, pp.3-24; DiClemente, 2003). TTM incorporates elements of various theories of therapy, learning, and behavior change, hence the term 'Transtheoretical'. However, the model does not try to resolve all the conceptual issues and conflicts among the various theories incorporated in the model. It

simple tries to identify and describe important elements of the process of intentional behavior change (DiClemente, 2007). Central to this model is the idea that people move through pre-defined stages when trying to improve health-related behavior. The stages are:

- Pre-contemplation (no consideration of changing)
- Contemplation (thinking about changing)
- Preparation (making plans to change)
- Action (actually in the process of changing)
- Maintenance (working to prevent relapse)

Targeting interventions according to a person's readiness to change is not a new idea in the world of health promotion. Prochaska and DiClemente (1982) developed the "stage of change model" in the field of psychotherapy in the 1980's. The model was originally seen as a linear model but now is often considered as cyclical because most people attempting to change their health behavior will have to repeat stages in order to learn how to maintain their behavior. The cyclical model is shown in the diagram in Figure 1, Appendix C (Prochaska and DiClemente, 1982; Prochaska & Levesque, 2001).

This model is often used to design a course of action to encourage people to give up smoking. For example, a smoker who is in the pre-contemplation stage will need to be given graphic information about the health risks (Haslam et al., 2000) and may benefit from shock tactics. However, those smokers in the preparation stage will benefit from encouragement, practical advice on how to change, information to reinforce their motivation and perhaps skills training.

The same principles can be used for pregnant women learning about cord blood collection, banking and storage of her infant's blood at the time of birth. If she has asked for assistance in understanding the process, we could presume that she is past the pre-contemplation stage. However, if she is seeking information to make a decision regarding public or private banking she may be further in the stages of readiness to change through preparation (making plans to change) or action (actually in the process of changing) thus making a decision.

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making a decision. A Stage of Readiness Scale was used and adapted from Prochaska et al., (Prochaska, Velicer, & Rossi, 1994; Quinn, Alexander, Hollingsworth, O'Connor, & Meltzer, 1994) (see Appendix H, Table 1).

It is important to address any assumptions or motivations the donors might have. The attitudes of mothers toward the collection of cord blood units generally reflect their level of knowledge of the process (Sugarman, Kaplan, Cogswell, & Olson, 1998; Fernandez, Gordon, Van den Hof, Taweel, & Baylis, 2003). Perceptions about the collection process can be misleading, the associated risks, and the availability and access of units, should they be needed in the future, are common among cord blood donors. In one study, women failed to appreciate their alternatives to donating cord blood to a public bank. Almost thirty-three percent (33%) did not understand that they had the option of discarding their cord blood at delivery, whereas just over fifty percent (50%) were aware of the option of placing cord blood units in a private bank (Sugarman, Kurtzberg, Box, & Horner, 2002). Another study showed that ninety-five percent (95%) of new mothers say had they known about public cord blood donation, they would have donated per a recent report (Kingsbury, 2008) of a National Marrow Donor Program (NMDP) survey.

"The potential is so significant," says Dr. Jennifer Willert, a stem-cell transplant specialist at the Rady Children's Hospital in San Diego. "Not to have families know about the possibility of banking, that's tragic." (Kingsbury, 2008)

Other donors view public banking as a less expensive way to preserve and gain access to their children's cord blood in the future rather than contracting with a private bank. Almost one-half of the respondents indicated that the reason they chose to donate their cord blood to a public bank was to protect their child's future health (Sugarman et

al., 2002; Institute of Medicine of the National Academies, 2005, p.111). Not having a property claim on public donation of cord blood is an important issue parents need to comprehend at the time of informed consent.

The researcher was interested in examining whether the variables of age, gestational age, level of parity (number of children), marital status, race/ethnicity, religion, highest level of education completed, economic status and method of payment for prenatal care are *predictors of knowledge of cord blood donation.*

Umbilical cord cell transplantation has evolved over the last 15 years from being an experimental procedure to an accepted treatment for a number of hematological diseases and genetic disorders. During the evolution the banking of this human tissue has increased exponentially around the world. The proliferation of private cord cell banks has been particularly strong in the USA and Asia while, in Europe, where there are one or two old established private banks, the emphasis has been on public cord cell banking. But, whether in the private or public cord cell banking sector, there remains alternate quality assurance standards that need addressing. This will become particularly important if cord blood stem cells are to play an important part in the cellular therapies of regenerative medicine in the future. As the utility of these cells increases countries may have to consider whether cord blood should be collected from all newborns. This will be a costly process and maybe the promotion of cord blood donation but with the acknowledgement that the right to private storage may prove a practical way forward for some and not for others. It is also clear within this frontier of science that new ethical questions will continue to arise.

Implications to the Body of Nursing Science & Gaps in the Literature

Essentially the limited or absence of nursing science, theory building and research in this field of contributing stem cells in cord blood collection, donation, and future outcomes needs to be recognized and further supports the need for this study. The following are areas where there is a gap in the literature supported by my prior literature review:

- Knowledge deficit on types of banking for cord blood: Private and Public
- Knowledge deficit on what process of regulation matches private versus public blood banks
- Disagreement on insufficient number of hemopoietic stem cells in umbilical cord blood and how it needs to be packaged
- Discrepancies regarding information related to testing for diseases and what is needed in the family history
- Discrepancies related to the financial commitment
- Issues surrounding what are the required regulatory and quality assurance issues of collection, donation, and storage
- What avenues of disease treatment and regenerative medicine are presently occurring and what is to come in the future.

(Kingsbury, 2008; Institution of Medicine(IOM), 2005 & 2006; Kurtzberg, Drapkin, & Sugarman, 2005; Eastlund, 1995; Kharaboyan et al., 2007; Gunning & Holm, 2006; McCullough et al., 2005; Greenwood, 2006).

Chapter III

Methodology

Method reflects the researcher's philosophical beliefs about the nature of reality and is situated in, and flows from, one's world-view and the nature of the question being researched. According to van Manen, "Lived experience is the starting point and the end point of phenomenological research" (van Manen, 1997, p.36). Lofland addresses the lived experience when he stated, "Today's solutions may become tomorrow's problems; tomorrow's problems may provide special research opportunities the day after" (Lofland, Snow, Anderson, & Lofland, 2006, p.32). The research process begins with the awareness of a phenomenon as it exists in the world. Who would have known thirty-five years ago when this researcher a new graduate nurse routinely collecting cord blood at a birth to determine the baby's blood type that some day one would be collecting it for stem cell research on a baby. This researcher has chosen to do a quantitative method because qualitative results are inadequate by themselves. When the researcher assesses the initial quantitative results the qualitative data are needed to help explain or build what is really going on with the sample (Creswell & Plano Clark, 2007, Chap. 4 & 5). The researcher has chosen to do a Survey Design which may hopefully lead to research opportunities in the future with a mixed method as an Explanatory Design.

The purpose of this chapter is to describe the quantitative design and methods chosen to conduct this research. The qualitative analysis was limited to only 11 interviews out of the total, thirty in the population, for this study and there was limited time to go into depth due to time constraints and financial limitations. This is an area the researcher needs to explore in the future. This section begins by addressing the research questions and hypotheses, the specific research design implemented, including the desired sample, recruitment of participants, and measurement instruments. This includes a discussion of descriptive and inferential statistics used to analyze the data, data collection procedures, and data management and analysis. Issues related to human subjects discussed, which includes confidentiality, consent, risks/benefits, and communication with participants.

Method

Research that includes uncovering meaning from a feminist perspective is a beginning step towards understanding a woman's lived birth experience. Because much of a woman's lived birth experience is hidden due to privacy and it being one of the most intimate moments in her life, a *feminist hermeneutic phenomenological perspective* was used to provide deeper understanding of the lived experience of women and the decision to donate cord blood at her child's birth. The Survey Design is well suited to this study because it is a step toward how to assess a woman's knowledge in the use of this method of stem cell collection. The design is suitable as the researcher wants to form groups based on quantitative research (Morgan, 1998; Tashakkori & Teddlie, 1998) and the researcher will use the quantitative participant characteristics to guide purposeful sampling for a qualitative phase (Creswell, Plano Clark, Gutmann, & Hanson, 2003) in

future research opportunities. The researcher anticipates one may need qualitative data to explain significant or non-significant results, outlier results, or surprising results (Morse, 1991).

Stem cells from umbilical cord blood form one of the most commonly banked types of human tissue. Birth is a time when stem cell collection is an option through umbilical cord blood collection. Despite over 74 million births per year in the world of which four million in the United States (World Watch Institute, 2006, p.75), many people remain unaware of human umbilical cord blood collection (Cryo-cell, 2006). Originally stored for the treatment of hematological disorders these stem cells have now been found to be more versatile for potential use in the treatment of a broader range of disorders and diseases and may be particularly valuable in cell therapy and regenerative medicine (Gunning & Holm, 2006, p.17;Waldby, 2006).

The storage of umbilical cord cells has not been without controversy and there is a rapidly growing private sector involvement. Over the last two decades umbilical cord blood has proved an effective substitute for bone marrow in the treatment of blood disorders, and most nations in the developed world have public programs for the harvesting and storage of cord blood for allogenic transplantation (Garcia & Torrabadella, 2006; Waldby, 2006). Yet, a number of ethical issues continue to be debated involving questions of regulation and quality assurance, ownership and commercialization and patenting. In this paper the researcher will first present the historical background of *related* and *unrelated cord blood* to establish the legitimacy of the science, *public* versus *private banking*, regulation and quality assurance of banking and the worldwide influence cord blood banking has on regenerative medicine.

Tremendous confusion remains about different sources of stem cells and their use in the minds of the government, the public, and the medical community. Until 1988 (Smith & Thomson, 2000) and April, 2006, (Cryo-cell, 2006) blood that remained in the umbilical cord and placenta respectfully after delivery used to be routinely discarded. Now several studies have confirmed with similar results this blood is known to contain hematopoietic stem cells and pluripotent mesenchymal cells (Moise, 2005); undifferentiated cells that can develop into virtually any type of blood cell in the human body; and provides a better alternative to bone marrow transplantation to treat an expanding list of malignant, benign, and inherited disorders (Perlow, 2002) (see Appendix B for a list of diseases treatable with stem cells from umbilical cord blood).

The purpose of this study is to investigate pregnant women's knowledge of cord blood collection and what decision-making process they experience for a decision on donation of cord blood. **The research question:** ***What characteristics during a woman's pregnancy are*** *related when* ***making a decision for cord blood donation at birth?***
The following hypotheses were tested and are listed below:

Hypotheses:

1) Women are not *knowledgeable* about their options to store infant's cord blood (CB) with a storage bank for possible future use by the child or other family members.

The transtheoretical model (TTM) of change provides an alternative way of grouping patients according to their stage of readiness to learn and adopt new beliefs and behaviors (Prochaska & DiClemente, 1998). Recent research suggests that by understanding the clients' readiness to change we can design our intervention to increase the chance of successful implementation (Haslam & Haslam, 2000). The dimensions

described in the model, the stages, processes, context, and markers of change, are designed to assist in picturing and understanding the process of change (DiClemente, 2003; DiClemente & Prochaska, 1998, pp.3-24; Prochaska & DiClemente, 1984). The cyclical model is shown in the diagram in Figure 1, Appendix C (Prochaska and DiClemente, 1982; Prochaska & Levesque, 2001).

The same principles can be used for pregnant women learning about cord blood collection, banking and storage of her infant's blood at the time of birth. If she has asked for assistance in understanding the process, one could presume that she is past the pre-contemplation stage. However, if she is seeking information to make a decision regarding public or private banking she may be further in the stages of readiness to change through preparation (making plans to change) or action (actually in the process of changing) thus making a decision. A Stage of Readiness Scale used adapted from Prochaska et al. (Prochaska, Velicer, & Rossi, 1994; Quinn, Alexander, Hollingsworth, O'Connor, & Meltzer, 1994) (see Appendix H, Figure 2).

The researcher is interested in examining whether the variables of age, gestational age, level of parity (number of children), marital status, race/ethnicity, religion, highest level of education completed, economic status and method of payment for prenatal care are *related characteristics to the knowledge of cord blood donation.*

Research Design

This research presents a survey with a descriptive correlation design using convenience sampling, utilizing a cross-sectional design to assess factors that may lead to cord blood collection, banking and storage. The design will use *t-test for independent means and Analysis of Variance* (ANOVA) for analysis. The design and method are

intended to determine if the knowledge level of two factors: public cord blood banking and storage OR private cord blood banking and storage is clearly understood by pregnant women and their partners. Since the goal is to predict values of the dependent variable, cord blood banking (public or private), which is categorical and dichotomous, the researcher is attempting to predict membership into one of two or more "groups". The researcher is testing if there is statistical significance between the differences of the two sample means. A statistician named William Gosset developed the *t-test* for exactly this type of situation (Fred Pyrczak, 2010, p.119). As a test of the null hypothesis, the *t-test* yields a probability that a given null hypothesis should be rejected. When the *t-test* yields a low probability that a null hypothesis is correct, the researcher usually rejects the null hypothesis. There are three basic factors which interact with each other in determining the probability level: 1) The larger the samples, the less likely that the difference between two means created by sampling errors. When large sample are used, the *t-test* is more likely to yield a probability low enough to allow rejection of the null hypothesis than when small samples are used. 2) The larger the observed difference between the two means the less likely that the difference created by sampling errors. 3) The smaller the variance among the participants, the less likely it is that the difference between two means created by sampling errors and the more likely the null hypothesis rejected (Fred Pyrczak, 2010, p.120; Shott, 1990, pp.122-125).

The other analysis which was used was the One-Way ANOVA. *Analysis of variance* (ANOVA) is a closely related statistical procedure to the *t-test* but is used to test the difference(s) among *two or more means* (Holcomb, 2009, p.149; Fred Pyrczak, 2010, p.127). The *t-test* cannot give you the difference among more than two means. When

ANOVA is done, the result also uses similar methodology to the *t-test* to determine if there is a statistically significant difference in means by calculating in *F*-value.

One advantage of the research design is the ease which the use of the instruments will provide, as well as their brevity. Another potential advantage includes patients understanding of private versus public banking and the process in each bank. It will minimize potential confusion to pregnant women and their partner's regarding the potential capability of stem cells in *private* and *public cord blood banks* that are advertized in many different venues including the internet. A potential disadvantage would be possible discourse between pregnant women and their partner's due to differences in the final decision to donate cord blood or not donate. Finally, the worst disadvantage would be the decision not to donate at all with a possible disadvantage to their lives should they need it.

Sample Size and Power Analysis

A power calculation determines the needed sample size to detect a particular effect. Based upon the rule of thumb 15-20 subjects per independent variable, approximately 45 to 80 participants required to achieve sufficient power. The three independent variables measured from the questionnaire are: 1) patients' *sources of knowledge* about cord blood donation, 2) patients' *beliefs* about cord blood collection, storage and use, and 3) patients' *knowledge about current indications* for cord blood transplantation.

The power of the test of the null hypothesis is "the probability that it will lead to the rejection of the null hypothesis" (Cohen, 1988, p.4) and (Munro, 2005, pp.141-143). A power of 0.80 means there is an 80% chance of rejecting the null hypothesis. The

higher the desired power, the more subjects required. Cohen suggests that for the behavioral scientist, a power of 0.80 is reasonable, given no other basis for selecting the desired level (Munro, 2005, p.141).

The effect size for the *t* test is the difference between the means of two groups divided by the standard deviation for the measure. Cohen's moderate effect size is set at 0.5, which means half of a standard deviation unit. Given an effect size of .70 and a power of .80 the Cohen table indicates this researcher will need 33 subjects (Cohen, 1988, p.55).

Each time an ANOVA test is conducted one runs the risk of a Type I error (rejecting a true null hypothesis). The probability level that sets the point at which one rejects the null hypothesis also is the level of risk with which one is comfortable. When calculating multiple *t-tests* on independent samples that are being measured on the same variable, the rate of error increases exponentially by the number of tests conducted. Instead of using a series of individual comparisons, we examine the differences among the groups through an analysis that considers the variation across all groups at once. This test is the *analysis of variance* (ANOVA).

Using ANOVA an effect size of .30 (Cohen, 1988, p.355 defines a moderate effect size as .25, which with two groups is still half of a standard deviation unit) and still using a power of .80 we would need to have 27 subjects in the group (Munro, 2005, p.154; Cohen, 1988, p.384).

However, the researcher will also attempt to use Pearson's correlation coefficient and when determining the sample size for comparison of two normally distributed interval variables there are three needed elements as well. They are *effect size, alpha, and*

power. Effect size is the absolute value of the difference between the expected correlation and a correlation of zero. For example, if this researcher expects the correlation to be –0.4 the effect size would be 0.4. ($|-0.4 - 0| = 0.4$). The absolute difference is used because for a sample size calculation it does not matter whether the correlation is positive or negative. The *alpha level* is the probability of falsely rejecting the null hypothesis, that is rejecting the null hypothesis when it is actually true (Type I error). There is no correct alpha level. The researcher will choose an alpha level based on what is reasonable (Katz, 2006, pp.132 & 135). Most studies accept a 5% chance of rejecting the null hypothesis when it is really true. Therefore, the researcher will usually specify alpha as 0.05. The *power* is the probability of rejecting the null hypothesis if the actual effect is as large as the estimated effect size. Although this researcher would like a 100% chance of rejecting the null hypothesis when it is false there is no sure bet this will happen. Usually one settles for a 0.80 or 0.90 probability (80% to 90% chance) of rejecting the null hypothesis if it is false (Katz, 2006).

Sample

The research design involves assessment of women who voluntarily want to inquire about the pros and cons of cord blood donation in the San Diego county area. Methodology will include use of instruments, or standardized measures, to assess sources of *knowledge about cord blood donation*; *beliefs about cord blood collection, storage and use*; their *knowledge about current indications for cord blood transplantation;* This was measured using the Fox Questionnaire (Fox et al., 2007) and a Readiness for Change Scale (Prochaska & DiClemente, 1998) titled as the Cord Blood Collection Survey. Basic demographic information and data concerning age, gestational age, number of children

(parity), marital status, race/ethnicity, religion, highest level of education completed, economic status, and method of payment for prenatal care was analyzed. The factors were analyzed in their relationship to women's knowledge level of cord blood collection, banking and storage (donation).

Because there was a concern about obtaining enough women for the sample size, several options were explored. A convenience sample was recruited through the placement of adds in a local newspaper, *San Diego Union Tribune,* and a flyer available in local church congregations to allow for a convenience sample by volunteering and non-randomization. There were flyers in the waiting rooms of two multicultural clinics where most of the women were of childbearing age. This was the first method at obtaining participants. The inclusion criteria searches for pregnant women; the majority of participants were English speaking women even though some were bilingual. However, there were translators available for Spanish and Arabic translation if needed. The *advantage* of the sampling technique was ease in implementation and it was preferred that a naturally formed group of volunteers participate in the study. The *disadvantage* was that this was not randomized to all women. The research procedure process was available to conveniently include a marginalized population of English and non-English speaking women; it did not eliminate the possibility of systematic differences among the participants and the environment of the experiment could have affected the outcomes. However, the researcher believes this was a representative sample of women potentially in their childbearing years who were delivering at our hospitals in the geographical area. The local newspaper advertisement would be read by those women who are literate, seek an interest in participating in this research, and it was distributed to

a wide net of subscribers as well as availability of the newspaper on the internet. In order to obtain additional participants this was advertised in local church bulletins. The researcher included church going women as they are usually family oriented and may be representative of the pregnant population. To maintain anonymity and confidentiality the surveys and questionnaires were coded with the individuals last 4 digits of their phone number. All information was secured by the researcher using password protected files and locked storage.

Operational Definitions

Dependent Variable: the decision to collect cord blood (1) or not collect cord blood (0) and it will be to a private bank (1) or public bank (0). This was measured by the score on the Cold Blood Collection Survey. So the total score of each individual was the dependent variable.

Dependent variable: Stages of Readiness as described in the transtheoretical model (TTM) by Prochaska & DiClemente (Prochaska & DiClemente, 1998):

Pre-contemplation (no consideration of changing)

Contemplation (thinking about changing)

Preparation (making plans to change)

Action (actually in the process of changing)

Maintenance (working to prevent relapse)

Independent Variables: The main independent variable (IV) was the patients identified by their gravida as primigravida OR multigravida. Additional variables which included: A) Patients' *sources of knowledge about cord blood donation*; B) Patients'

beliefs about cord blood collection, storage and use; and C) Patients' *knowledge about current indications* for cord blood *transplantation.*

Demographic Variables or Control Variables for Logistic Regression (these contain a mix of continuous and categorical variables): age; gestational age in weeks calculated from last normal menstrual period OR confirmed by 16-20 week ultrasound; level of parity (number of children); marital status; race/ethnicity; religion; highest level of education completed; economic status; and method of payment for prenatal care.

Data Collection Procedures with Instruments

Each participant completed a self-administered *survey* on her first encounter with the researcher at anytime during the gestation of the pregnancy along with the incentive that at completion of the survey they would be enrolled in a lottery and be eligible to win a gift certificate valued at $100. All surveys were cross-sectional, self-administered and collected by the researcher. The baseline survey includes a staging algorithm designed to assess individuals' stage of cord blood donation intention, and a second staging algorithm designed to assess individuals' stage of communicating their cord blood donation intention with their partner. Staging algorithms were adapted from previous research with other health behaviors (Prochaska, Velicer, & Rossi, 1994). Wording for these staging algorithms is presented in Figure 2 in Appendix II. The subject will circle the comment that most represents the intent of the individual and will circle the comment that most represents the status of communication with the individual spouse or father of the baby (FOB).

An explanation of the study was provided followed by obtaining informed written consent. All women who enter into the study were offered an anonymous *questionnaire*

to complete. The Fox Questionnaire (Fox et al., 2007) includes multiple choice questions regarding the sources of information about cord blood, whether they plan to have their cord blood collected and stored, whether they plan to donate to a *public* bank or store with a *private/commercial bank*, the reasoning behind these decisions (*sources of knowledge*, independent variable 1), the *beliefs* about the potential uses for cord blood collected (independent variable 2), and their *knowledge about current therapeutic uses of cord blood transplantation* (independent variable 3). The questionnaire was developed to collect demographic characteristics, (Table1); Patients' sources of knowledge about cord blood donation, (Table 2); Patients' beliefs about cord blood collection, storage and use, (Table 3); and Patients' knowledge about current indications for cord blood transplantation, (Table 4) (see Appendix I, Tables 1-4). The researcher conducted a face-to-face *interview* with each participant to establish a positive rapport with them only before answering the questionnaire. The participants self-administered the survey. No information was offered at that time regarding education on the differences between *public* versus *private cord blood* donation. Every third participant in the survey was selected to participate in a one-on-one 60 minute interview using the Interview Guideline for Cord Blood Donation (see Appendix K). Consent Assent is in Appendix L (see Appendix L).

Measures

The instrument, Readiness for Change, used for the survey in Table 1 (see Appendix H), was adapted from a tool in the public domain created by Prochaska and DiClemente (1982). It is a staging algorithm for readiness to change. This tool has consistently demonstrated high reliability and validity for general population use, as well

as with patients with behavior changes, and used quite proficiently throughout the research community today for studying all types of clinical trial with patients in use of any type of decision-making process. When doing my literature search the tool came up 262 times on the internet. The tool meets *content validity* as the items measure the content they were intended to measure such as the individuals' stage of cord blood donation intention, and a second staging algorithm designed to assess individuals' stage of communicating their cord blood donation intention with their partner. This gave a discrete dichotomous variable on the survey with only two classifications (Yes/No) to answer the stage of readiness.

The questionnaire used in Table 1, 2, 3, 4 of Appendix I is adapted from Nathan Fox (Fox et al, 2007) and for purposes of clarification this titled the Fox Questionnaire. This questionnaire a reflection of categories in age, gestational age, level of parity (number of children), marital status, race/ethnicity, religion, highest level of education completed, economic status and method of payment for prenatal care. There was categorical, nominal, ordinal, interval, and odds ratio scales of measurement. This is the bases of the *descriptive statistics* intended to support the results reflective in the frequency distribution of the mean, median, and mode in each category (see Appendix I, Table 1). These measures of central tendency will be represented in standard deviations (sd) of the sample and not the population (SD) to describe the variability. The variability is the amount by which participants vary or differ from each other. In other words, the standard deviation, (sd), of the sample will be compared to the population, (SD), in the literature to examine variability.

The Fox Questionnaire will also reflect the patients' sources of knowledge about cord blood donation; patients' beliefs about cord blood collection, storage and use; and patients' knowledge about current indications for cord blood transplantation. This will allow one to assess pregnant women regarding their basic understanding of cord blood donation, beliefs, and knowledge on current indications for transplantation. This will then be compared to Stages of Readiness placing them in categories of an ordinal scale (see Appendix J, Table 5). The *inferential statistics* will allow one to make inferences about the characteristics of the population from knowledge of the corresponding characteristics of the sample.

The questionnaire/survey met reliability as the answers were from the individual without a third party asking the questions for possible bias or misrepresentation unless a translator was used and this did not occur with this researcher in this population. *Content validity* was assessed because the items in the questionnaire/survey where measured on a scale unique to each individual which is what the questionnaire/survey was intended to measure. The *predictive or concurrent validity* was assessed, i.e. that the more pregnancies one experiences the more knowledgeable one would be regarding cord blood donation and use. *Construct validity* was assessed in the questionnaire/survey by the items which measure hypothetical constructs or concepts regarding pregnant women's beliefs regarding cord blood collection, storage and use.

Data Management and Analysis

The descriptive statistics will describe the distribution of the independent variables such as age, gestational age, level of parity (number of children), marital status, race/ethnicity, religion, highest level of education completed, economic status and

method of payment for prenatal care by using measures of central tendency and of variation. This was done with a frequency distribution from which the mean, median, and mode were derived. The computer program in this study used the PASW Statistics GradPack 18 for Windows®/Mac® (Arbuckle, 2009) on the Fox Questionnaire (see Appendix I).

The inferential statistics will have multiple analyses using *t-test* and ANOVA using PASW Statistics GradPack 18 for Windows®/Mac® (Arbuckle, 2009). To begin the researcher assessed using a null hypothesis:

H_0 = There is no difference in the mean score of Cord Blood Collection (CBC) Survey

μ_1 = Pregnant women who speak with their obstetrician

μ_2 = Pregnant women who do not speak with their obstetrician

$H_0 = \mu_1 - \mu_2 = 0$

By using the *t-test* one seeks to disprove the null hypothesis with different variable means: that is, there is no difference between the two means. The *t-test* is (Katz, 2006, p.84) calculated as the difference between the two means divided by the standard error of that difference:

$$t = \frac{\text{mean of sample 1} - \text{mean of sample 2}}{\text{standard error of difference between mean 1 and mean 2}}$$

The computer produces the equal (pooled) variance formula and the unequal (equal variances not assumed or separate) variance formula. The first task is to look first at the Levene's test. If the significance level exceeds .05, the equal variance (pooled) results are used; if the significance level is less than .05, the unequal (separate) variance

results will be used (Munro, 2005, p.143) and I would reject the null hypothesis (Katz, 2006, p.85).

Testing the association of a nominal variable with an interval parametric variable (e.g., the association of ethnicity and Cord Blood Collection Survey score) is similar to testing the association of a dichotomous variable with the interval parametric variable (e.g., the association of Cord Blood donation "Yes/No" with the Cord Blood Survey score). In both situations one will be comparing means. The difference is that with a nominal variable, there are three or more groups. In such situations, use ANOVA (Katz, 2006, p.88).

An ANOVA tests the null hypothesis that there is no difference in the means of different groups; "in other words, any differences between the means are due to random variation" (Katz, 2006, p.88) and indicates the probability that the null hypothesis is correct (Patten, 2007, p.127). According to the null hypothesis, all groups were from the same population (a local prenatal care/obstetrical clinic) and each of their scores come from the same populations of measure (Cord Blood Collection Survey). Any variability of the scores can be seen in two ways: First, the scores vary from each other in their own group; this variation is called "*within-group variation*". Second, the groups vary from each other; this variation is call "*between-group variation*". Together, the two types of variation, prenatal patients characteristics and Cord Blood Collection Score, add up to the total variation (Munro, 2005, pp.154-157).

ANOVA produces an F-value. The F-value is the ratio of the between-groups variance to the within-groups variance (Katz, 2006, p.88).

$$F = \frac{\text{between-groups variance (variance calculated based on entire sample)}}{\text{within-groups variance (variance calculated separately for each group)}}$$

Because one-way ANOVA calculations are extremely detailed the margin of error is high and it is easy to make mistakes when doing them by hand. Therefore computer output is recommended and the researcher here is using PASW Statistics GradPack 18 for Windows®/Mac® (Arbuckle, 2009), otherwise known as the "new SPSS 18.0". Using this software the *p*-value for *F* statistic is given. The format shown in table below in Figure 3.1 is the way the one-way ANOVA results were presented.

Source	Degrees of Freedom	Sum of Squares	Mean Square
Between groups	$k-1$	SSB	MSB
Within groups	n_T-k	SSW	MSW
Total	n_T-k	SST	

Figure 3.1 One way analysis-of variance table format (Shott, 1990, p.151)

Strengths and Limitations of Methods

If the difference between the means is small or if the error in the measurement of the difference is large compared to the difference in the means, then the *t*-value will not reach statistical significance. The *t-test* may not be valid for variables with non-normal distributions. If the mean is not an accurate measurement of the center of the distribution, then a test based on the comparison of means may not be valid. The *t-test* is actually a very robust test because the statistical software is built to take into account situations when the variance may be unequal. Unequal variance is especially a problem when the sample sizes are unequal and smaller sample is associated with the larger variance. When variances are unequal, the researcher will need to perform a *t-test* for unequal variances Levene's test is one of the tests to calculate equality of variances. This is in the computer program where the *t* value is calculated two ways: assuming equal and unequal variances (Katz, 2006, p.85). If the variances are equal then report the value of the *t-test* assuming

equal variance. If the variances are unequal report the value of the *t-test* assuming unequal variance.

A limitation of the *t-test* is that it does not give the reader direct information on the numeric difference between the two groups (Katz, 2006, p.85). A useful method of calculating the difference between the two groups is to obtain the mean difference between the two groups (i.e., mean difference = mean 1 – mean 2) and then take the 95% confidence interval of that difference (Glantz, 2002, pp.200-9). The difference between the means would be considered statistically significant if the 95% confidence interval of that difference excludes zero (Katz, 2006, p.85).

When performing ANOVA with computer software it can perform one-way ANOVA calculations but it cannot determine whether independence or normal assumptions are adhered to in a reliable fashion. This is the responsibility of the researcher. If the computer is given data that violate assumptions, it will carry out the analysis anyway which could then be misleading (Shott, 1990, p.152).

Another important limitation of ANOVA is that it does not indicate where the difference lies. A large *F* just tells you that you can reject the null hypothesis that *all* the means are the same (Katz, 2006, p.89). For example, if the researcher compares three groups A, B, and C, there are a total of seven possible ways that the groups may differ from one another (Katz, 2006, p.89):

A is different than B (but not different than C)

A is different that C (but not different than B)

B is different that C (but not different than A)

A is different from both B and C (which are not different from one another)

B is different from both A and C (which are not different from one another)

C is different from both A and B (which are not different from one another)

A and B and C are all different from one another

To see where the differences lie, it is necessary to perform pairwise comparisons of the groups using a *t-test*. "The important difference is that when you use the *t-test* for pairwise comparisons you are performing multiple comparisons. When making multiple comparisons you should set more stringent criteria (i.e., a lower *P*-value) before rejecting the null hypothesis" (Katz, 2006, p.90). This is to prevent a Type I error.

There are several important issues related to the use of statistical analysis using *t-test* and analysis of variance. First, there is the issue of the ratio of participants to variables included in the analysis. Problems may occur if too few participants relative to the number of predictor variables exist in the data (Mertler, 2005). Also, post-hoc comparisons with ANOVA can be a problem as well.

Human Subjects

Risks and Benefits

Participation in research may involve risks or discomforts. Potential risks and benefits were disclosed in the informed consent (see Appendix L). Although this is strictly a descriptive correlational study, completion of the questionnaires may cause participants to experience anxiety, or discomfort and possible discourse with their significant other. To avoid this, the questionnaires were administered in a private setting within the university where the participant can answer without fear of interruption from family or other personnel. The participants were instructed that they need not answer any question they wished to omit. After the woman has finished, the participant will place the

completed questionnaires in an envelope that is labeled with a unique patient identifier, known only to the investigator. The participant will seal the envelope and give it to the researcher who will analyze the results at a later time in a private setting.

There may be no direct benefit from participation in this study. However, several possible benefits exist. One possible benefit is early identification of level of knowledge which will alert the individual mother of concerns regarding her possible selection to cord blood use and preparation for the birth of her child and her expectations. This gives her an opportunity to decide if she chooses to discuss with her significant other the pros and cons of different types of cord blood collection for use. This will allow her to see if she is ready to even make a decision regarding this important issue and what she may need to do to get the information to complete a well informed decision regarding cord blood use. All of these interventions may inform and improve the participant's health status and family preparation for future years to come.

Protecting subjects from any potential risks

To minimize potential risks the participants were volunteers and there was no coercion of any type used. If there is a question that she desires not to answer on the questionnaires she will not be eliminated from the study. If she desires more information regarding this issue after answering the questionnaires, the researcher will give written handouts explaining the information. This will not be distributed beforehand as the researcher desires to get nonbiased information in the beginning. If there is discourse between couples around this subject, a counseling service was provided for the couple as social support per their request (see consent form Appendix L and see recruitment flyer Appendix M). There was a Spanish translation of the Flyer, Consent, Readiness Scale,

Fox Questionnaire and Interview Questions done by a paid and certified linguistic assistant at a local university working towards a degree to be a psychologist in a dual track of curriculum in the College of Sciences & Engineering and the College of Arts and Letters.

Chapter IV

Data Analysis

The purpose of this study is to investigate pregnant women's knowledge of cord blood collection issues and what decision-making process and complexities they undergo regarding or in conjunction with cord blood donation at the birth of their infant. The survey assessment items were selected from the Fox Questionnaire and patient's identification of the stage of readiness in their decision regarding cord blood collection for donation at the time of the study. **The research question: *What characteristics during a woman's pregnancy are related when making a decision for cord blood donation at birth?***

The following hypotheses tested and are listed below:

Hypotheses:

1) Women are not *knowledgeable* of their options to store infant's cord blood (CB) with a storage bank for possible future use by the child or other family members.

The researcher is interested in examining whether the variables of age, gestational age, level of parity (number of children), marital status, race/ethnicity, religion, highest level of education completed, economic status and method of payment for prenatal care

are *related to knowledge of cord blood donation.* First, a descriptive profile of the sample was presented, followed by the results specific to the research questions.

The same principles in the Transtheoretical Model can be used for pregnant women learning about cord blood collection, banking, and storage of her infant's blood at the time of birth. If she has asked for assistance in understanding the process, we could presume that she is past the pre-contemplation stage. However, if she is seeking information to make a decision regarding public or private banking she may be further in the stages of readiness to change through preparation (making plans to change) or action (actually in the process of changing) thus making a decision. A Stage of Readiness Scale was used and adapted from Prochaska et al. (Prochaska, Velicer, & Rossi, 1994; Quinn, Alexander, Hollingsworth, O'Connor, & Meltzer, 1994) (see Appendix H, Figure 2).

The responses to the survey pertaining to the participants and the spouses' partners are stages of readiness: pre-contemplation; contemplation; preparation; action; and maintenance are presented in Table 4. The majority of women and their partners (52%) responded that they are in the pre-contemplation stage. Table 4.1 below reflects the outcome of the Stages of Readiness on the Stages of Readiness Scale.

Table 4.1 Stages of Readiness Scale

Stage	*Pre-contemplation*	*Contemplation*	*Preparation*	*Action*	*Maintenance*	*Total*
Women's Intention	15 (50%)	9 (30%)	4 (13%)	2 (7%)	0 (0%)	30 (100%)
Women's Spouse/ Partner Notification	16 (53%)	6 (20%)	3 (10%)	3 (10%)	2 (7%)	30 (100%)
Total	31 (52%)	15 (25%)	7 (12%)	5 (8%)	2 (3%)	60 (100%)

Table 4.2 Comparing Gravida with Stages of Readiness Scale

Gravida	*Pre-contemplation*	*Contemplation*	*Preparation*	*Action*	*Maintenance*	*Total*
Primigravida	7 (47%)	4 (27%)	3 (20%)	1(7%)	0 (0%)	15 (50%)
Multigravida	8 (53%)	5 (33%)	1 (7%)	1(7%)	0 (0%)	15 (50%)
Total	15 (50%)	9 (30%)	4 (13%)	2 (7%)	0 (0%)	30 (100%)

Women have not given any thought to being a cord blood donor 50% of the time while 30% are giving some thought to being a cord blood donor weighing the pros and cons, 13% are preparing to be a cord blood donor, 7 % have signed consent and not spoken with their spouse/partner. Given the distribution of responses, this variable was transformed into a dichotomous response of 1) no thought regarding cord blood donation and 2) thinking about cord blood donation for further analysis.

The analysis of the Readiness Scale was adjusted for parity (number of children born). Table 4.2 demonstrates that women (86%) with more than one child

(multigravidas) were in the Pre-contemplation (53%) and Contemplation (33%) stage compared to women (74%) having their first child (primigravida) with 47% in the Pre-contemplation stage followed by 27% in the Contemplation stage respectively; however more of those women who were primigravidas were in the Preparation Stage 20% of the time when it is time to decide on cord blood donation. This means they are preparing to be a cord blood donor and learning more about their consent options. They are moving further along the path to a decision they wish to make for their family regarding donation of cord blood.

Sample Characteristics

The dataset contains all responses from 30 completed questionnaires from the 35 which were distributed through volunteer encounters over an 11 month period, August 2009 to June 2010. This was a response rate of 86%. None of the participants had made a decision to collect cord blood at the time of the questionnaire. The demographics of the study participants are listed in Table 4.3.

Table 4.3 Demographic Characteristics of Study Participants

Table 4.3a	*Range*	*Mean (Standard Deviation)*
Age (years)	14-45	26
Gestational Age (weeks)	16-40	24

Table 4.3b	*Group*	*N (%)*
Number of Living Children	None	15 (50%)
	1 or more	15 (50%)
Marital Status	Single	18 (60%)
	Married	12 (40%)
Race	Hispanic	17 (57%)
	Caucasian	7 (23%)
	Other	6 (20%)
Religion	Christian	4 (13%)
	Catholic	11 (37%)
	Other	15 (50%)
Highest level of Education	HS Diploma	16 (53%)
	More than HS Diploma	14 (47%)
Total Household Income/yr.	Less than $50,000	24 (80%)
	Greater than $50,000	6 (20%)
Method of Payment for Prenatal Care	Self-Pay	1 (3%)
	Insurance	5 (1%)
	Medi-Cal	24 (80%)
Discuss CBC w/ OB/CNM?	Yes	9 (30%)
	No	21 (70%)
If not, do you plan to discuss CBC w/ OB/CNM?	Yes	14 (47%)
	No	16 (53%)

Overall, the participants had a minimal education level of a high school education (53%) but 14 (47%) had either completed or entered an undergraduate university. Of these, 4 (28.5%) entered and completed a postgraduate degree. This may be attributed to the severe economic recession in the USA, December 2007 to June 2009. The fact that so many women with an advanced age were seen at a community clinic can be attributed to this too. San Diego, which is considered a service economy, sustained official unemployment rates greater than 10% during this time period (Bureau of Labor Statistics, 2010) and many of the employed and under employed lost health insurance coverage.

The participants age ranged from 14 to 45 years of age and gestational age were evenly distributed from 16 weeks to 40 weeks. There were two groups that clustered at 23 weeks and 33 weeks. The majority of the sample (57%) was Hispanic (17) which reflected the clinics location as a predominantly Hispanic area in San Diego which has grown during the last 20 years. The remaining component reflected the areas diversity: 23% Caucasian (7), 20% Other (6) of which broke down specifically to: (1) Asian/Pacific Islander, (2) Black, (2) Iraqi, and (1) other. Since 2000 there have been economic struggles for many families and there an estimate of 2,000 people who used Arabic as their main language who migrated to San Diego from Iraq, Jordan, Lebanon, and other countries of the Middle East (Coalition, 2010). San Diego is the largest metropolitan area west of Detroit, Michigan which houses more than 80,000 members of the Middle Eastern population in the last 4 years (Coalition, 2010). However, because my sample was small this may not have influenced this at the time but may if future study leads to a large sample of the population.

The predominant religious groups were 13% Christian (4), Catholic 37% (11) and Other as 50% (15). Many included the description for being Caldean and "not Catholic" by preferring to be identified as the option of Other.

Method of payment for prenatal care was predominantly in one of three groups. Self-pay 3% (1), Insurance 17% (5), and Medi-Cal (California Medicaid) which was 80% or (24).

*The null hypothesis: "There is no difference in the CBC (Cord Blood Collection) Score if one had talked with their obstetrician/CNM OR had not talked with their Obstetrician/CNM. AND, if they had not talked, did they plan to talk with them. The CBC Score was calculated on a scale of 10 questions. The higher the number out of 10 the higher the subject scored the more perfect the total score. A *t-test* for *independent* means compared for two samples that were independent of each other. This method (*independent*) is used to indicate there is no relationship (no matching or pairing) of scores from one sample to the other. The selection of individuals for the groups had no bearing on the selection of individuals for the control group, the two samples were said to be independent. In other words, they were separately and independently drawn from the population of participants.

When measuring the CBC Score with the *t-test* for independent means on two categories of age: the *mean* for **Group 1** (Less than 24 years of age) and **Group 2** (24 years of age or more) the *mean* for **Group 1** ($m = 2.26$, $sd = 2.49$) is lower than the mean for **Group 2** ($m = 3.13$, $sd = 2.94$) at the .194 level ($t = -.869$, $df = 27.2$). Because the variances were different, a *t-test* that did not assume equality of variances conducted with a confidence interval (CI) = .95. Therefore, there is no significant difference.

When measuring the CBC Score with the *t*-test for independent means for two categories number of living children: the *mean* for **Group 1** (No living children) and **Group 2** (1 or more living children) the *mean* for **Group 1** ($m = 2.3$, $sd = 2.46$) is lower than **Group 2** ($m = 3.06$, $sd = 2.9$) at the .143 level ($t = -.733$, $sd = 27.0$). Because the variances were different, a *t-test* that did not assume equality of variance conducted with a confidence interval (CI) = .95. Therefore, there is no significant difference.

When measuring the CBC Score to Race using a One Way ANOVA for more than two means, there yields a value of F at 6.423 and the associated probability of .005. The difference among the means can be declared significant at the .01 level. For the Hispanic group, the mean reported CBC score level was 2.0 (sd =2.4). The mean reported CBC Score level for the Caucasian group was 5.4 ($sd = 1.9$) and the mean reported CBC score level for the Other group was 1.5 ($sd = 2.3$), respectively. The differences among the means are statistically significant at the .01 level (F [2, 27] = 6.423).

When measuring the CBC Score with Payment Method using a One WAY ANOVA measuring the difference between and among self-pay group, private insurance group, and Medi-Cal insurance group there yields F at 3.344 and the associated probability of .050. The difference among the payment methods and CBC score is significant at the .05 level. For the self-pay, the mean reported CBC Score .000 (sd = N/A). The mean reported CBC Score for private insurance was 5.2 ($sd = 2.167$) and the mean for the Medi-Cal insurance and CBC score was 2.3 ($sd = 2.5$) respectively. The difference among and between the means is significant at the .05 level.

When measuring the CBC Score with the participant answer to: Did you discuss CBC with your OB/CNM? If not, do you plan to discuss CBC with your Obstetrician/CNM? The following measured:

The "Sig" for "Levene's Test for Equality of Variances" is .002. Because .002 is less than .05, it is not appropriate to assume equality of variances.

The mean for **Group 1** ($m = 1.43$, $sd = 1.83$) is significantly lower than the mean for **Group 2** ($m = 3.18$, $sd = 2.93$) at the .05 level ($t = -2.7$, $df = 25.5$). Because the variances were significantly different, a t test that did not assume equality of variances was conducted. Table 4.4 is the synopses of the data.

Table 4.4 Response to Cord Blood Collection Survey by Demographic Factors

	Test	*Critical Value*	*P-value*	
Age	*t* test	-0.869	0.39	NS
Gestational Age	*t* test	-0.081	0.94	NS
Number of Living Children	*t* test	-0.733	0.47	NS
Marital Status	*t* test	0.054	0.957	NS
Race	ANOVA	6.423	0.01	*
Religion	ANOVA	0.19	0.83	NS
Highest Level of Education	*t* test	0.24	0.81	NS
Total Household Income/yr.	*t* test	-1.69	0.1	NS
Method of Payment for Prenatal Care	ANOVA	3.344	0.05	**
Discuss CBC w/OB/CNM	*t* test	1.29	0.2	NS
If no, do you plan to discuss w/OB/CNM?	*t* test	-2.71	0.05	***
Would it make a difference in a decision to CBC if you knew your OB/CNM paid a fee?	*t* test ANOVA	-0.04 0.001	0.97 0.1	NS NS
The chance that my baby would have a condition(at birth or in the future) could be used	ANOVA	2.252	0.106	NS
The chance that a sibling who is healthy would develop a condition that could benefit from CBC	ANOVA	4.713	0.01	*

For most conditions requiring cord blood therapy, could a child use cord blood from his/her own placenta?	ANOVA	0.64	0.64	NS
For most conditions requiring cord blood therapy, could a child use cord blood from a sibling's placenta?	ANOVA	0.82	0.55	NS
If your child did need cord blood therapy and you did not have cord blood stored from him/her or a sibling, what is the chance cord blood from a public storage bank could be used?	ANOVA	0.59	0.71	NS
Do San Diego hospitals have a system in place whereby you could donate the cord blood to a public cord bank?	ANOVA	0.85	0.48	NS
Age	Chi Square x^2	3.75	0.053	**(>.05)
Gestational Age	Chi Square x^2	9.6	0.002	* (>.001)

*P= @ the .01 level comparing CBC with Race

**P= @ the .05 level comparing CBC score with Payment Method

***P= .014/.012 are unequal and slightly above the .01 level therefore needs to be at the .05 level comparing the CBC score and "If one has not discussed CBC with your OB/CNM, do you plan to discuss with your OB/CNM?

Sources of Women's Knowledge

The main sources of the participant's knowledge came from seeing/reading ads in magazines/commercials regarding cord blood storage 53% of the time but only 37% read or saw literature related to private banking versus 20% on public banking. Table 4.5 reflects some other ways like discussing cord blood donation with their obstetrician or midwife. This was taken from the Cord Blood Collection Survey Table 2 on page 24 of the questionnaire.

Table 4.5 Sources of Knowledge

	Yes	*No*	*Total*
Discussed CBC w/OB/CNM.	9 (30%)	21 (70%)	30 (100%)
If no, do you plan to discuss w/OB/CNM.	14 (47%)	16 (53%)	30 (100%)
Seen/read literature distributed by private/commercial CBC companies regarding cord blood storage.	11 (37%)	19 (63%)	30 (100%)
Seen/read ads in magazines/commercials regarding cord blood storage.	16 (53%)	14 (47%)	30 (100%)
Seen/read literature distributed by a public cord blood bank regarding cord blood donation.	6 (20%)	24(80%)	30 (100%)

Women's Belief about Cord Blood Collection, Storage, and Use

Table 4.6 Women's Beliefs about Cord Blood Collection, Storage, and Use for Transplantation

F2 *Would it make a difference in a decision to store cord blood with a private/commercial cord blood bank if you knew that your OB would be paid a fee to collect the cord blood?*	YES=5 NO=16* N/A=9
F3 *The chance that my baby would have a condition (at birth or in the future) that could benefit from cord blood during his/her first 10 years of life is about:*	1 in 100=4 1 in 1000=6 1in 10,000=7 <1 in 10,000=1 N/A=12*
F4 *The chance that a sibling who is now healthy would develop a condition that could benefit from this cord blood is about:*	1 in 100=4 1 in 1000=6 1 in 10,000=6 <1 in10,000 =1 N/A=13*
F5 *For most conditions requiring cord blood therapy, could a child use cord blood from his/her own placenta?*	Always=7 Usually=8* Sometimes=6 Rarely=4 Never=0 N/A=5
F6 *For most conditions requiring cord blood therapy, cold a child use cord blood from a sibling's placenta?*	Always=1 Usually=6 Sometimes=11* Rarely=1 Never=3 N/A=8
F7 *If your child did need cord blood therapy and you did not have cord blood stored from him/her or a sibling, what is the chance cord blood from a public storage bank could be used?*	Always=3 Usually=3 Sometimes=7 Rarely=10* Never=2 N/A=5
F8 *Do San Diego hospitals have a system in place whereby you could donate the cord blood to a public cord blood bank?*	YES=6 NO=4 Don't know=19* N/A=1

When one assesses and compares the Women's Belief Model about Cord Blood Collection, Storage and Use there are numerous beliefs participants shared on the survey. The majority 49% (16) answered "NO" followed by 30% (9) as not applicable when answering the question, "Would it make any difference in a decision to store cord blood with a private/commercial cord blood bank if you knew that your OB would be paid a fee to collect the cord blood?"

When asked, "If there a chance that my baby would have a condition (at birth or in the future) that could benefit from cord blood during his/her first 10 years of life...." 40% answered "not applicable" with the second most frequent answer being 1: 10,000 at 23%. Another belief expressing the chance that a sibling who is now healthy would develop a condition that could benefit from this child's cord blood also answered 43% of the time as "not applicable" (13) and the second most frequent answer 1:10,000 (6) or 20% of the time.

The belief, "For most conditions requiring cord blood therapy, could a child use cord blood from his/her own placenta?" was answered as "usually" (8) 27% of the time compared to always (7) 23%, sometimes (6) 20%, rarely (4) 13%, never (0) 0% and "not applicable (5) 17% of the time. Another belief, "For most conditions requiring cord blood therapy, could a child use cord blood from a sibling's placenta?" answered most frequently as sometimes (11) 37% followed by not applicable (8) 27%, usually (6) 20%, never 3 (10%), always (1) 3%, and rarely (1) 3% of the time respectively.

"If your child did need cord blood therapy and you did not have cord blood stored from him/her or a sibling, what is the chance cord blood from a public storage bank could be used?" most frequently answered rarely (10) 33%, followed in descending order as

sometimes (7) 23%, not applicable (5) 17%, always (3), 10%, usually (3) 10%, and finally never (2) 7% in that descending order. Another way to look at this would be to imply that (13) or 43% had a positive understanding or belief that a public bank could help them but (17) or 57% did not believe a public bank could help them.

The last belief the participants answered was, "Do San Diego hospitals have a system in place whereby you could donate the cord blood to a public cord blood bank?", and the majority (19) 63% answered they did not know followed by (6) 20% who said yes on the survey, and (4) 13% who said no on the survey with (1) 3% answering not applicable. This is most likely true as there is clearly not a system set in place to educate the public where to obtain public banking in the San Diego municipal area. Even if you are highly educated in this group it seemed to still be a barrier for one to find the information expressed by one participant when being interviewed and she had a higher level of education with a degree as a doctor in philosophy.

Chapter V

Discussion of Findings

The Nation's labor markets were deeply affected by the deteriorating economic conditions that began December 2007 and continued for the next two years. Some have referred to this period as the "Great Recession" of 2007-2009 (Sum & Khatiwada, 2010). The National Bureau of Economic Research, the Nation's arbiter of the beginning and ending dates of recessions, has designated the recent recession as having lasted from December 2007 to June 2009.

Because of the recession, 2009 was one of the worst years for poverty in America in more than half a century. The total number of Americans living in poverty hit 43.6 million, the highest level in 51 years and the national poverty rate rose to 14.3 percent from 13.2 percent, according to data released late 2010 by the Census Bureau (NCB, 2010; Huffington, 2010). One in seven Americans is living in poverty at the time of this writing per. Mint, the personal finance site, put together an interactive chart of regional poverty rates (Mint, 2010) and California's *percent of poverty levels* range from less than 10% up to 25%-30%.

Though suburban areas are now home to one-third of America's poor, large cities have not been immune to the after math of the recession (Huffington, 2010; Mint, 2010)

(NCB, 2010). Residents of cities like San Diego have seen some of the biggest drops in personal income in the last year. Crippling poverty rates in many of America's hardest-hit regions have been accompanied by several other disturbing trends for the middle class. Income inequality hit an all-time high before the recession, according to the University of California, Berkley, economist Emmanuel Saez (Huffington, 2010). States, faced with an estimated budget shortfall of $380 Billion for 2011 (Huffington, 2010; NCB, 2010; Coalition, 2010) have started to cut crucial services and have allowed thousands of workers to be jobless.

Growing layoffs last year caused millions of Americans to lose employee-provided health insurance, leaving 16.7 % of Americans with no health insurance, the highest level since the United States Census started collecting the data in 1987 (Huffington, 2010). The ranks of *discouraged workers* and others marginally attached to the labor force also had increased during this recession 2007 to 2009. These individuals are those who wanted and were available for work and had looked for a job sometime in the prior 12 months. They were not counted as unemployed because they had not actively searched for work in the past 4 weeks. The number of persons who were marginally attached to the labor force increased sharply during the current recession, rising to 2.1 million in the first quarter of 2009 (Bureau of Labor Statistics, 2009 & 2010).

The unemployment rate in the San Diego County was 10.2 % in October 2010, and below the October 2009 estimate of 10.6%. This compares with an unadjusted unemployment rate of 12.0% for California and 9.0 % for the nation during the same period (National Bureau of Labor Statistics, 2010). This was during the time the data collection took place in San Diego.

Patient Profile

The local clinic has been providing services and programs available to all low-income residents in the community it serves since 1990 and it celebrated the Twenty Year Anniversary in 2010. Many of the patients were immigrants and refugees, many of whom were in the country legally and were forced to leave their native countries due to conflict or other upheaval as civil war and ethnic cleansing occurred. The clinic placed a high value on the support of the family and provided comprehensive programs that strengthen both the children and adults. Some patients were second or third generation families from the communities they serve. Most were struggling to survive initially when entering the United States but are now learning to build their knowledge of the community and its resources to become more self-sufficient and they all rely on the clinic not only for health care but for their non-medical needs as well.

One of the local clinics, part of the Central Region of San Diego, is a federally designated MUA/MUP-Medically Underserved Area/Medically Underserved Population. The primary service area has a population of 199,230 which is a small part of a larger extended area that includes the entire Central Region of San Diego County with a population of approximately 488, 205. The community clinics data characteristics are as follows: 64% are women (83% of those are of childbearing age). Ninety-six percent (96%) are non-white and 80% say they prefer to be served in a language other than English. An astounding 98% of them are below the Federal definition of poverty (double that of all of San Diego County, the state of California and the United States as a whole). The vast majority (92%) are either uninsured or rely on public insurance programs for partial coverage (La Maestra Community Health Centers, 2007). The location in the

community serves as a mesh of inner city challenges of poverty, unemployment, and poor access to health care or social services. Linguistic and cultural barriers compound these problems. The need for translators to be provided to health care workers caring for this population has been challenged as there are over 37 separate census tracts served by this overburden facility on Fairmount Avenue (La Maestra Community Health Centers, 2007). There are no "*County Hospitals*" in San Diego. This region of the city has a 19.22% poverty rate (Mint, 2010; Bureau of Labor Statistics, 2010; La Maestra Community Health Centers, 2007), highest teen birth rate, lowest prenatal care utilization rates, lowest health insurance coverage rates, and highest rate of reported child abuse.

El Cajon was the second area of data collection in the East San Diego County. It is a more rural desert setting and experiences similar problems to those of City Heights. In El Cajon, the majority of the population is Latino although "official" census numbers report only 26%. This was witnessed by this researcher working as a nurse practitioner and midwife over the last two to two and one-half years when she witnessed the majority of the patients coming to the clinic suddenly changed from Latino to populations from Iraq and other Middle East Countries with Arabic as their main language. Because of the high cost of housing in coastal areas, there is a migration of middle income, working people buying homes in El Cajon and commuting west. From outward appearances household incomes seem to be increasing but this development masks the fact that there is still high local unemployment, underemployment, and poverty. Many Hispanic refugees and Chaldean immigrants, who escaped from Iraq, live in El Cajon and struggle with linguistic and cultural barriers that continue to exist. There are 29 different census

tracts with a total population of 118,902 (according to the 2002 census). All of the East Region of San Diego County has a population of approximately 446,750.

In both of the clinics there is a high use of translators/interpreters due to the limited English proficient (LEP) skills of many patients. An estimated 50 million people in the United States do not speak the same language as their healthcare provider, and 23 million are considered LEP (Rousos, Mueller, Hill, Sala, Hovell, & Villarreal, 2010). This was particularly apparent with the women who present with Arabic as their main language. They preferred female translators over male translators a vast majority of the time. The attention to the role of gender during interpreted medical visits is important to improving health care and health for persons with LEP. At both clinics it is a common practice to minimize use of family members or friends for translation due to confidentiality and use bilingual staff members or professional interpreters. This was mandated by Federal Civil Rights legislation since 1964 where language assistance services became available free of charge for all LEP patients at all points of health care (Chen, Youdelmanm, & Brooks, 2007). Although the research is very limited in the use of gender with LEP patients it is hopeful that the influence of the interpreter on provider-patient communication is likely to reduce the disparities in the medical outcomes across chronic and acute illnesses (Rousos, Mueller, Hill, Sala, Hovell, & Villarreal, 2010).

Cord blood is a noncontroversial source of stem cells, yet experts estimate that 99% (Rochman, 2010), of this potentially lifesaving resource gets thrown away in the postpartum period. One may believe from this study that it is due to so many barriers present to them around concerns of communication and the options of how to ascertain the information. Unlike the stem cells in human embryos, which can morph into any kind

of cell in the body, the stem cells in cord blood have their futures largely mapped out (Powell, Hingorani, & Kolb, 2009) as blood, brain, liver or heart muscle cells for example. But researchers have shown that cord blood cells can be reprogrammed, and over the next decade, doctors hope to adapt these cells to treat heart attacks, strokes, diabetes and maybe neurodegenerative diseases too. An interview by Bonnie Rochman with Dr. Joanne Kurtzberg, director of the Carolinas Cord Blood Bank at Duke University (Rochman, 2010) she states: "Cord blood is already being used in therapy regimens for patients with cancer, sickle-cell anemia, immunodeficiency, marrow failure and genetic diseases that call for transplants". As their due date creeps closer, many pregnant women pack a "go bag" for the hospital: toothbrush, personal music selections to listen when in labor, cute outfit to dress baby in when coming home. Over the last few years savvy mothers-to-be have started tucking in one more important item: a kit to collect and donate the blood in their babies' umbilical cord. This is only accessible for the woman who can afford such a high price of $2,000-$3,000 for the kit to complete the initial processing and approximately $125 to $250 per year after that to store cord blood that can be used only by the donor's family when donating to a private bank. Or, if it is a public bank, by contrast, one can make their contents available to anyone who is a close enough match at no cost or fee.

The question this researcher posed to the marginalized population in this study: Do women know that this form of stem cell therapy is available through cord blood collection at the birth of their infant? And, if they do, can they have a choice of cord blood storage through knowing the difference between a private or public bank living in San Diego County? Of note was 70% of the women had not discussed cord blood

donation with their provider and of those, 47% planned to discuss it with their OB/CNM. This brings this researcher to the conclusion they were curious and had a plan in mind. At what level of readiness where they at the time of the survey? Women's intention was in the Pre-contemplation Stage 50% and Contemplation Stage 30% of the time. That means 80% of the population studied were ready to act on the information they had learned from at the time of the survey. Women's Spouse/Partner Notification pre-dominantly in the Pre-contemplation Stage 53% of the time followed by the Contemplation Stage 20% of the time.

When one compares gravida with stages of readiness scale one may speculate that the more pregnancies one has the more likely they are to be more in the stages of readiness such as preparation and action. What data illustrated 7 (47%) of Primigravida and 8 (53%) of Multigravida group were in the Pre-contemplation Stage and the rest were in the Contemplation 4 (27%0, 5 (33%), Preparation Stage 3 (20%), 1 (7%) and Action Stage 1 (7%), 1 (7 %) respectively between Primigravida and Multigravidas. Their sources of knowledge came from seeing/reading ads in magazines/commercials regarding cord blood storage 53% of the time but only 37% read or saw literature related to private banking versus public banking 20% of the time respectively.

When looking and comparing the women's beliefs about Cord Blood Collection, Storage, and Use most of the women answered "not applicable" to their belief questions because I believe they truly did not know. They answered "usually" for most conditions requiring cord blood therapy when the child could use his/her own cord blood from the placenta. The likelihood of this occurring has been proven in the scientific journals (American Academy of Pediatrics, 2007, pp.165-170) and range from less than 1 in 1,000

to more than 1 in 200,000 (Johnson, 1997). No accurate estimates exist of the likelihood of children to need their own stored cord blood stem cells in the future (American Academy of Pediatrics, 2007, pp.165-170). They also answered "sometimes" cord blood can be used from their siblings placenta, which is more often the case. There is only a 25% chance for identifying a full HLA match in a sibling donor (Karanes, Confer, Walker, Askren, & Keller, 2003; Wagner, 1996). The question related to the belief: "If your child did need cord blood therapy and you did not have cord blood stored from him/her or a sibling, what is the chance cord blood from a public storage bank could be used", was answered "rarely" when the literature clearly states there is a high probability in a public bank this can be found. There are more than seven million potential unrelated volunteer adult donors registered in the National Marrow Donor Program registry (Karanes, Confer, Walker, Askren, & Keller, 2003) and there are many patients unable to find a fully matched donor, which diminishes access to transplantation therapy. Nonwhite patients have a lower chance of identifying a fully matched unrelated adult donor because of genetic heterogeneity and lack of non-white donors. However, over the last decade, unrelated-donor, banked umbilical cord blood has been shown to contain sufficient numbers of stem cells for successful transplantation between unrelated, partially HLS-mismatched individuals (Kurtzberg, Laughlin, Graham, et al., 1996; Rubinstein, Carrier, & Scaradavou, 1998; Rocha, Wagner, Sobocinski, et al., 2000; Gluckman, Broxmeyer, Auerbach, et al., 1989; Migliaccio, Adamson, Stevens, Dobrila, Carrier, & Rubenstein, 2000). This means with the advances in the clinical practice of cord blood transplantation, most patients unable to find a fully matched adult donor can identify a partially matched cord blood donor. The final question: "Do San Diego hospitals have a

system in place whereby you could donate the cord blood to a public cord blood bank?" was answered by most of the participants as "don't know" and they don't know because there is little advertising in this area. The area is predominantly taken over by the for-profit cord blood banks. They learned that San Diego does not offer public banking because they have no such bank in this geographic area based on the interviews done on 11 of the participants whom were interviewed.

Shared decision making should be the commonly used process, requiring shared information among relevant care providers and a willingness and capability to communicate effectively with parents. This process also suggests the need for outcome data. Such data should be relevant to the population seeking care at a given institution. Relying on national or other reported regional or institutional data from outside a particular practice setting is not always valid, because data from different practice settings likely are neither constituted nor controlled in the same fashion. The provision of care, which is decided by local clinical and population data and the determination of best interests, or what can be viewed as effective, beneficial, and appropriate care versus ineffective, burdensome or inappropriate care, demand the availability of data from which to make these determinations with parents (Carter, 2009). Until such data are available, healthcare professionals should be frank in recognizing and communicating some uncertainty in their decisional process with parents. Conversely, although objective outcome data are important, for any given baby and their parents, the chance of a certain outcome is either 0 or 100% in their minds. Thus, discussions of relative risks, while useful for healthcare professionals may not be particularly helpful when discussing

treatment options, risks, and benefits with parents and other family members (Carter, 2009).

Why does one even care or have concern about how one gets hematopoietic stem cells transplanted from cord blood or sometimes called placental blood versus bone marrow?

Stem cells are self-renewing cells defined by two properties: (1) they can proliferate to make differentiated cell types of a tissue in vivo, and, once developed, (2) they can continue to self-renew for the lifetime of the organism. Presently the only stem cell of clinical relevance is the hematopoietic stem cell, which can reconstitute the blood system after bone marrow transplantation (Nussabaum, McInnes, Willard, & & Boerkoel, 2001).

Although bone marrow has long been the major source of transplantable hematopoietic stem cells and progenitor cells, the discovery that placental blood OR cord blood represents a rich source of hematopoietic stem cells is beginning to make a substantial impact on the treatment of malignancy and genetic diseases.

The use of cord blood has three great advantages over bone marrow as a source of hematopoietic stem cells. *First*, recipients are more tolerant with incompatible cord blood than of other allogeneic (other) donor cells. Thus, engraftment occurs even if as many as three HLA antigens are mismatched between the donor and the recipient. *Second*, the wide availability of cord blood, together with the increased tolerance of incompatible donor cells, greatly expands the number of potential donors for any recipient. The latter feature is of particular significance to patients from minority ethnic groups, for whom the pool of potential donors is relatively small. *Third*, the risk of graft-versus-host disease is substantially reduced using cord blood cells as the donor source. It is likely that the

isolation and characterization of stem cells from other tissues, including nervous system, will eventually make cell replacement feasible in a wide variety of malignancies and genetic diseases; (Arora et al., 2009; Hansen et al., 1998; Moore, 2010; Gutman et al., 2009; Kataoka et al., 2008; Koh, 2004).

Nursing Implications

The American Medical Association and the American Academy of Pediatrics recommends public banking over private, favoring private banking only when there is already an affected family member or a disease in the family that would benefit from a transplant. Many consumer cord blood banking organizations do not support one type of banking over another but recommend that parents be informed of the pros and cons of the various options (Besser, Schwartz, Romo, & Salahi, 2010).

According to Frances Verter, founder and director of the nonprofit organization, Parent's Guide to Cord Blood Foundation, the overall benefits outweigh the chance it may never be used. And, because there are only 17 public banks in the U.S. that tend to collect units from nearby hospitals, many families may not be in an area where public bank donation is as accessible. That makes it more difficult for many parents to understand their options when it comes to choosing between public and private banking. There is a problem in that there are a limited number of places that accept donations. The downside is that lots of parents want to donate, but it requires money to process the donation. There's a certain infrastructure involved that not a lot of centers have in place. Furthermore in the report it goes on to say, according to Chris Ober, co-founder of Save the Cord Foundation, besides the limited number of public banks available for parents to choose, it is often difficult to distinguish between the various options that individual

private companies offer. Everything looks great on the Internet, but there are great differences between all of the private banks. One really needs to do your homework to make sure the bank you choose is right for you (Besser, Schwartz, Romo, & Salahi, 2010).

Cord blood donation should be discouraged when cord blood stored in a bank is to be directed for later personal or family use, because most conditions that might be helped by cord blood stem cells already exist in the infant's cord blood (i.e., premalignant changes in stem cells). Another way to explain this to parents is the potential for children needing their own stored cord blood stem cells in the future for autologous (self) use is controversial at this time (Johnson, 1997). There is also not any evidence of the safety or effectiveness of autologous cord blood stem cell transplant for the treatment of malignant neoplasms. There is evidence demonstrating the presence of DNA mutations in cord blood obtained from children who eventually develop leukemia (Rowly, 1998). Therefore, autologous cord blood transplantation might even be contraindicated in the treatment of a child who develops leukemia. Care providers should be aware of the unsubstantial claims of private cord blood banks made to future parents that promise to "*insure*" infants or family members against serious illnesses in the future by use of the stem cells contained in cord blood. Although not standard of care, directed cord blood banking should be encouraged when there is knowledge of a full sibling in the family with a medical condition (malignant or genetic) that could potentially benefit from cord blood transplantation.

Cord blood donation should be encouraged when the cord blood is stored in a bank for public use. Parents should be informed that chromosomal abnormalities and

infectious disease testing is performed on the cord blood and that if abnormalities are identified, they notified. Parents need to know the cord blood banked in a public program may not be accessible for future private use.

Private storage of cord blood as "biological insurance" should be discouraged. Cord blood banks should comply with national accreditation standards developed by the Foundation for the Accreditation of Cellular Therapy (FACT), the US Food and Drug Administration (FDA), the Federal Trade Commission, and similar state agencies.

The following recommendations are suggested to minimize any barriers to parents through institutions or organizations (private or public) involved with cord blood banking:

Cord blood banking recruitment practices should be developed with an awareness of the possible emotional vulnerability of pregnant women, their families and friends. Efforts should be made to minimize the effect of this vulnerability on cord blood banking decisions such as discussions with providers well in advance of active labor.

Accurate information about the potential benefits and limitations of allogeneic and autologous cord blood banking and transplantation should be provided. Parents need to be informed that autologous cord blood would not be used as a stem cell source if the donor developed leukemia later in life. Parents need to know that cord blood is a tissue source not proven to be used as yet in regenerative medical purposes but the advancement of the science is continuing at this time.

Policy should be developed by the cord blood banks regarding disclosing to the parents any abnormal finding in the harvested blood.

Specific permission for maintaining demographic medical information should be obtained, and the potential risks of breaches of confidentiality should be disclosed.

Written consent should be obtained before onset of active labor.

If blood bank is conducting research, an institutional review board must review and approve recruitment strategies and consent forms.

Cord blood collection should not be performed in complicated deliveries. The cord blood stem cell collection program should not alter routine practice for the timing of umbilical cord clamping.

All cord blood banking programs should comply with FACT or equivalent accreditation standards.

Other professionals and physicians who recruit pregnant women and their families for for-profit placental cord blood stem cell banking should disclose any financial interest or other potential conflict of interest they have in the procedure to their patients.

Professionals affiliated with institutions or organizations that promote for-profit placental blood stem cell banking should make annual financial-disclosure and potential-conflicts-of-interest statements to an appropriate institutional review committee that possesses oversight authority.

Targeted efforts should be made to recruit underserved minorities (black, Hispanic, American Indian/Alaska Native individuals) in public cord blood banking programs to extend to them potential treatments afforded other segments of society.

Conclusion

This was a mixed method of quantitative and a small qualitative research piece. The qualitative method was limited due to financial limitations and time limitations.

Thirty of the surveys were entered into this research for analysis with one third of them, eleven, sharing an additional interview with the researcher centered on the question of cord blood donation. Two additional participants were not used as they changed their decision to participate. The respondents had a poor overall understanding of cord blood banking. There were multiple barriers to accurate information between public and private banking. Even though the majority of the respondents were Hispanic with a high school education and some even had completed two years of college, a respondent who had a doctorate degree in philosophy also had a difficult understanding between public and private cord blood banking and difficulty locating where to access a public cord blood bank. Part of the puzzle is also accessing banks that have proper funding because allocation of funding to public banks is limited. The aim of the survey was to conduct it with most of the respondents in the 22 to 24th week of pregnancy but some were conducted later in the pregnancy at approximately 32 to 36th week of pregnancy. It is unlikely that more women would have made a decision regarding cord blood storage if they had been surveyed later in pregnancy because the Cord Blood Collection (CBC) Survey and the Stages of Readiness Scale for Decision Making reflected the knowledge they had during their pregnancy at the time. Moreover, despite the high proportion of women in this survey who were in the stages of readiness, they desired to learn more and did want to donate cord blood. Many in this marginalized population did not have an opportunity to donate cord blood as they were not able to afford the financial burden of the cost through private cord blood donation. Along with this, there was not a local public cord blood bank in the geographic area of San Diego during the time of this study 2009-2011.

Future research should focus on strategies to educate women earlier in the pregnancy or during the pre-conceptual period so they are prepared to make a truly informed decision at the appropriate time. The researcher was still amazed in an industrialized country such as the United States how easy one can organize their choices in life to donate organs for end of life on their driver's license, which they are required to carry on their person, enter options for possible transplant donation before ones demise, and even arranging for breast milk banking and donation without too many barriers but the steps to take to complete a contribution to a public cord blood bank seems to continue to be a barrier throughout this advanced technology. One may see the change coming slowly but only from the consumer driven based decision to request public cord blood banking from their healthcare provider, their healthcare provider learning how to contribute through the process of public cord blood collection, and seeking the avenues for public donation can this option possibly advance to make this less cumbersome for the public at large. The future of stem cell research will depend on this and advance the technology of cord blood use in treating multiple diseases.

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Appendix A

Stem Cell Sources

STEM CELL SOURCES

	ADVANTAGES	DISADVANTAGES
ADULT	• Non-controversial and supported by legislation • More cells may be available per collection • Allows for future collections • Demonstrates some degree of developmental plasticity (ability to be molded) • Indicated as therapy for numerous human diseases and used in transplant for more than 40 years	• Less proliferative than younger cell types • Tolerant of only 1 or fewer HLA antigen mismatches • Provides older cells with shorter telemeres • Invasive collection procedure that poses some risk to the donor • Registries are subject to donor attrition • Increased rate of GVHD (graft vs. host disease) compared with use of younger cells
NEWBORN	• Non-controversial, readily available, and supported by legislation • Highly proliferative and improves the rate of self-renewal • Increased developmental plasticity, allowing differentiation into multiple cell types • Tolerant of 2 or more HLA mismatches due to immunologic immaturity • Indicated as therapy for numerous human diseases (75) and used in transplant for more than 15 years • Decreased rates of GVHD (graft vs. host disease) • Young cells with longer telomeres	• One-time collection, at birth only • Cell count limited to quantity available at birth, until expansion technologies are approved for use in patients • Delay engraftment when samples with decreased cell dose are used
EMBRYONIC	• Highly proliferative improving the rate of self-renewal • Increased developmental plasticity, enabling differentiation into multiple cell types • Involved in research that furthers our understanding of cellular development • Young cells with longer telomeres	• Controversial and heavily restricted, even for research purposes • No validation in human patients • Difficult to regulate and prone to teratoma formation (tumors)

(Young, 2006)

Appendix B

Diseases Potentially Treatable with Umbilical Cord Blood Stem Cell Transplants

Diseases potentially treatable with umbilical cord blood stem cell transplants

Acute leukemias	**Lymphoproliferative disorders**	**Histiocytic disorders**
Acute biphenotypic leukemia Acute lymphoblastic leukemia Acute myelogenous leukemia Acute undifferentiated leukemia	Hodgkin's disease Non-Hodgkin's lymphoma Prolymphocytic leukemia	Familial erythrophagocytic lymphohistiocytosis Hemophagocytosis Histiocytosis-X
Chronic leukemias	**Phagocyte disorders**	**Inherited erythrocyte abnormalities**
Chronic lymphocytic leukemia **Chronic** myelogenous leukemia Juvenile chronic myelogenous leukemia Juvenile myelomonocytic leukemia	Chediak-Higashi syndrome Chronic granulomatous disease Neutrophil actin deficiency Reticular dysgenesis	Beta thalassemia major Pure red cell aplasia Sickle cell disease
Myelodysplastic syndromes	**Liposomal storage diseases**	**Congenital (inherited) Immune system disorders**
Chronic myelomonocytic leukemia Refractory anemia Refactory anemia with excess blasts Refactory anemia with ringed sideroblasts	Adrenoleukodystrophy Gaucher's disease Hunter's syndrome Hurler's syndrome Krabbe disease Maroteaux-Lamy syndrome Metachromatic leukodystrophy Morquio's syndrome Mucolipidosis II (I-cell disease) Mucopolysaccharidoses Niemann-Pick disease Sanfilippo's syndrome Scheie's syndrome Sly syndrome, 13-glucuronidase deficiency Wolman disease	Absence of T & B Cells SCID Absence of T Cells, Normal B Cell SCID Ataxia-telangiectasia Bare lymphocyte syndrome Common variable immunodeficiency DiGeorge syndrome Kostmann syndrome Leukocyte adhesion deficiency Omenn's syndrome SCID with adenosine deaminase deficiency Severe combined immunodeficiency disease (SCID) Wiskott-Aldrich syndrome X-linked Lymphoproliferative disorder

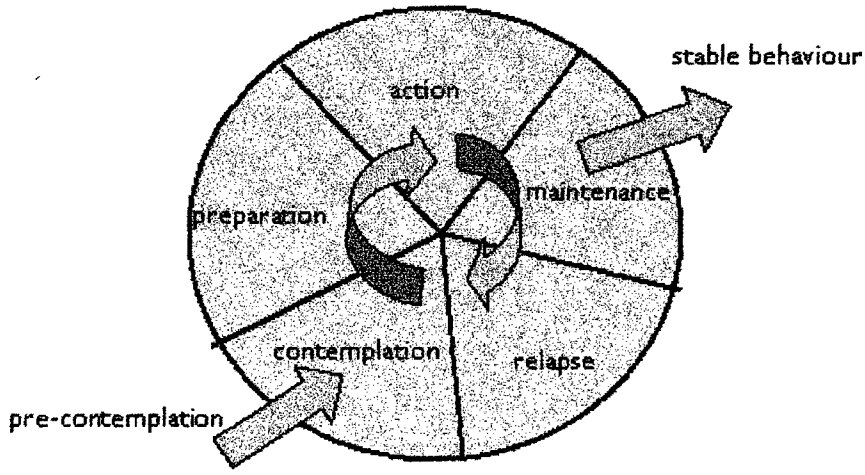
Stem cell disorders	**Other malignancies**	**Other inherited disorders**
Fanconi's anemia Paroxysmal nocturnal hemoglobinuria Severe aplastic anemia	Breast cancer Ewing sarcoma Neuroblastoma Renal cell carcinoma	Cartilage-hair hypoplasia Glanzmann's thrombasthenia Lesch-Nyhan syndrome Osteopetrosis
Myeloproliferative disorders Acute myelofibrosis Agnogenic myeloid metaplasia Essential thrombocythemia Polycythemia vera		**Platelet abnormalities** Amegakaryocytosis Congenital thrombocytopenia
		Plasma cell disorders Multiple myeloma Plasma cell leukemia Waldenstrom's macroglobulinemia

SCID = severe combined immunodeficiency disease

(Adapted from Moise, 2005; Perlow, 2002)

Appendix C

Stages of Change Model



Stages of Change Model

Figure 1: Stages of Change Model

Prochaska, J.O. & DiClemente, C.C. (1982). Transtheoretical therapy toward a more integrative model of change. *Psychotherapy: Theory, Research and Practice, 19 (3),* 276-287, (Prochaska & DiClemente, 1982).

Appendix D

Asian Cord Blood Inventory of Umbilical Cord Blood Use and Umbilical Cord Blood Transplants

Table 1: Asian UBC Inventory of Use and UCB Transplants (August 2004)

Cord blood bank	Inventory	Transplanted	Children	Adult
Beijing	5,800	44	26	70
Tianjin	5,400	15	10	5
Seoul	32,000	84	80	4
Taipei	6,700	9	9	-
Ho Chi Minh	1,076	7	7	-
Bangkok	315	1	1	-
Tokyo	5,563	277	105	172
Total	56,854	437	238	197

(Agarwal, 2006)

Appendix E

Regenerative Medicine Activities in Low- and Middle-Income Countries

Table 2: Regenerative Medicine Activities in Low- and Middle-Income Countries

Country	*Dedicated government Funding*	*Goods and services*	*Companies*	*Publications*	*Academic institutions*
Brazil	*	*			*
China		*	*		*
India		*	*	*	*
Argentina			*	*	*
Bulgaria		*	*	*	*
Chile		*	*	*	
Malaysia		*		*	*
Mexico		*	*	*	*
Poland		*	*	*	*
Slovakia		*	*	*	*
South Africa		*	*	*	*
Thailand		*	*	*	*
Columbia			*	*	*
Cuba			*	*	*
Egypt			*	*	*
Russia				*	*
Belarus					*
Hungary					
Iran					*
Latvia				*	*

Lithuania					*
Pakistan				*	*
Romania					*
Saudi Arabia				*	*
Serbia				*	
Turkey				*	*
Ukraine				*	*
Vietnam					*
Moldova					*
Philippines					*
Uganda					*

(Greenwood, 2006)

Appendix F

Milestones in Umbilical Cord Blood Banking and Transplantation

Milestones in Umbilical Cord Blood Banking and Transplantation

Year	Event
1982	Discussions between H. Broxmeyer and T. Boyse about the potential clinical use of UCB as a source of hemotopoietic stem cells.
1988	E. Gluckman and colleagues in Paris perform first related donor UCB transplant for a child with Fanconi anemia.
1989	R. Harris and colleagues in Cincinnati, Ohio, perform the first related donor UCB transplant in the US.
1993	J. Kurtzberg and colleagues at Duke University in Durham, North Carolina, perform the first unrelated donor UCB transplant.
1993	P. Rubenstein and colleagues at the New York Blood Center establish the first public, unrelated donor cord blood bank.
1995	J. Wagner and colleagues report in *The Lancet* the results of related and unrelated donor UCB transplants.
1996	The National Heart, Lung and Blood Institute of the National Institutes of Health award funding for UCB banks and transplant centers to conduct a national safety and efficacy trial.
1996	J. Kurtzberg and colleagues report in the *New England Journal of Medicine* the first large series of unrelated donor UCB transplants.
1998	P. Rubenstein and colleagues report in the *New England Journal of Medicine* results from 562 unrelated donor UCB transplants performed worldwide.
2006	Cryo-cell and Gen-cell first initiation to collect placentas for placental stem cell research by Gen-cell and Cryo-cell.

UCB = Umbilical cord blood

(Smith, 2000; Cryo-cell, 2006)

Appendix G

Financial Report of Umbilical Cord Blood Banking Private versus Public in the United States and Europe

BANKING: Private versus Public Banking in the United States and Europe

- Private donation is predominate; it's often called *Family Banking as* it may be given to a related member of that child.
- Recruitment from OB clinics, via the Internet & promotional material
- Inducements-incentives to recruiters with commission on every "sale"
- Parents in form of club membership for the child which gives entry to a sweepstakes providing access to four $10,000 college scholarships/yr
- Federal government supported by NIH grants, charitable foundations, Am. Red Cross, (Gunning, 2006)

UNITED STATES

	Private or Family	Public
Initial Fee	$1,100 to $1,975 Includes cost of kit	Free Processing fee $1,000 which the bank incurs
Storage	$115 to $225/year	$1,000/unit May charge the insurance company
Process if needed	No fee	Can be $15,000-$35,000/unit May charge the insurance company

- Public donation is predominate; parents donate their child's cord blood for unrelated use.
- Recruit from OB clinics but within a local or regional network; difficult to donate if they do not come from within the geographic area of public banking
- Ensure wide diversity of ethnic groups
- Sources of funding-Red Cross, Jose Carreras Foundation, charitable foundations *as* ADISCO (Italy), Commonwealth state and territory government research and community funding, (Gunning, 2006)

EUROPE

	Private	Public
Initial Fee	€ 175 ($150) Includes cost of kit and cost of initial processing	Free
Storage	€ 175 ($150) Includes cost of kit and cost of initial processing	Free
Processing if needed	No fee	Charge if have insurance Otherwise no charge

Appendix H

Staging Algorithm for Cord Blood Donation Intention with Readiness of Change Model

Table 1: Staging Algorithm for Cord Blood Donation Intention and Spouse Notification

Stage	Cord Blood Donation Intention	Spouse Notification
Precontemplation	I have not given any thought to being a cord blood donor.	I have not given any thought to discussing with my spouse how I feel about cord blood donation.
Contemplation	I'm giving some though to being a cord blood donor and weighing the pros and cons.	I'm giving some thought to discussing with my spouse how I feel about cord blood donation.
Preparation	I'm preparing to be a cord blood donor, learning more about consent options.	I'm preparing to talk with my spouse about how I feel about cord blood donation.
Action	I have signed a cord blood consent, but I have not yet talked with my spouse about this.	I have talked with my spouse about how I feel about cord blood donation.
Maintenance	I have signed a cord blood consent, and I have talked with my spouse about this.	I have talked with my spouse about how I feel about cord blood donation, and about how he feels about cord blood donation.

Adapted from Prochaska et al. (Prochaska, Velicer, & Rossi, 1994; Quinn, Alexander, Hollingsworth, O'Connor, & Meltzer, 1994)

Appendix I

Fox Questionnaire

Table 1. Demographic characteristics of study participants

	Overall %	Donating to Private bank %	Donating to Public bank %
Age	<20		
	20-29		
	30-39		
	≥40		
	NA		
Gestational Age	<24 weeks		
	24-35 weeks		
	≥36 weeks		
	NA		
Number of Children	0		
	1		
	2		
	>2		
	NA		
Marital Status	Married		
	Single		
	NA		
Race	American Indian/ Alaskan Native		
	Asian/ Pacific Islander		
	Black		
	Hispanic		
	White		
	Other		
	NA		
Religion	Buddhist		
	Christian		
	Hindu		
	Jewish		
	Muslim		
	No religion		
	Other		
	NA		

Highest level of education completed	1^{st}-8^{th} grade 9^{th}- 12^{th} grade Undergraduate college University degree Postgraduate degree NA
Economic status	less than $50,000/year $50,000-$100,000/year greater than $100,001 up to $150,000/year greater than $150,001 up to $200,000/year greater than $200.001 up to $250,000/year greater than $250.001 up to $300,000/year greater than $300,001 up to $400,000/year greater than $400,001 up to $500,000/year greater than $500,001/year
Method of payment for prenatal care	Self-pay Insurance NA

Table 2. Patients' sources of knowledge about cord blood donation

	Yes/No	Donate to Private Bank %	Donate to Public Bank %
Discussed cord blood collection with obstetrician.			
If did not discuss with obstetrician, plan on discussing cord blood collection with obstetrician.			
Seen/read literature distributed by private/commercial cord blood collection companies regarding cord blood storage.			
Seen/read ads in magazines/commercials regarding cord blood storage. Seen/read literature distributed by a public cord blood bank regarding cord blood donation.			

Table 3. Patients' beliefs about cord blood collection, storage and use.

	Overall %	Donate to Private Bank %	Donate to Public Bank %
Would it make a difference in a decision to store cord blood with a private/commercial cord blood bank if you knew that your obstetrician would be paid a fee to collect the cord blood?			
Yes			
No			
N/A			
The chance that my baby would have a condition (at birth or in the future) that could benefit from cord blood during his/her first 10 years of life is about:			
1 in 100			
1 in 1000			
1 in 10,000			
<1 in 10,000			
N/A			

The chance that a sibling who is now healthy would develop a condition that could benefit from this cord blood is about:

1 in 100
1 in 1000
1 in 10,000
<1 in 10,000
N/A

For most conditions requiring cord blood therapy, could a child use cord blood from his/her own placenta?

Always
Usually
Sometimes
Rarely Never
N/A

For most conditions requiring cord blood therapy, could a child use cord blood from a sibling's placenta?

Always
Usually
Sometimes
Rarely
Never
N/A

If your child did need cord blood therapy and you did not have cord blood stored from him/her or a sibling, what is the chance cord blood from a public storage bank could be used?

Always
Usually
Sometimes
Rarely
Never
N/A

Table 4. Patients' knowledge about current indications for cord blood transplantation.

	Overall %	Donate to Private Bank %	Donate to Public Bank %
Does San Diego hospitals have a system in place whereby you could donate the cord blood to a public cord blood bank?			
Yes			
No			
Don't know			
N/A			
For the following conditions, please indicate whether cord blood has been successfully used as a therapy:			
Alzheimer's disease			
Yes			
No			
Don't know			
N/A			
Asthma			
Yes			
No			
Don't know			
N/A			
Blood cancer (such as leukemia or lymphoma)			
Yes			
No			
Don't know			
N/A			
Certain genetic diseases of the immune system (such as "Bubble Boy" disease)			
Yes			
No			
Don't know			
N/A			
Certain inherited diseases of metabolism (like "Lorenzo's Oil" disease)			
Yes			
No			
Don't know			
N/A			
Diabetes			
Yes			
No			
Don't know			
N/A			
Failure of the bone marrow			
Yes			
No			
Don't know			
N/A			

Parkinson's disease
- Yes
- No
- Don't know
- N/A

Red blood cell or hemoglobin disorders (such as sickle cell disease)
- Yes
- No
- Don't know
- N/A

Spinal cord injury
- Yes
- No
- Don't know
- N/A

Appendix J

Sources of Knowledge, Beliefs, Knowledge on Transplants to Stages of Readiness Scale

Table 5. Sources of Knowledge, Beliefs, Knowledge on Transplants to Stages of Readiness Scale

Questions from 3 Questionnaires	Precontemplation	Contemplation	Preparation	Action	Maintenance
Patients' *sources of knowledge* about cord blood donation					
Patients' *beliefs* about cord blood collection, storage and use.					
Patients' *knowledge about current indications* for cord blood transplantation.					

Appendix K

Interview Guidelines

Interview Guideline: Cord Blood Donation

1. How did you hear or see information about cord blood donation?
2. When did you receive information about cord blood donation?
3. Tell me what your understanding of the process in cord blood donation is and how it occurs?
4. Have you discussed cord blood donation with your obstetrician, PCP, or CNM yet? Do you plan to do so?
5. Would it make a difference in a decision to store cord blood with private/commercial cord blood bank if you knew that your obstetrician, PCP, or CNM would be paid a fee to collect the cord blood?
6. What is your understanding regarding a chance that your baby would have a condition (at birth or in the future) that could benefit from cord blood during his first 10 years of life?
7. If you chose to store cord blood in a private/commercial bank what would be your primary reason?
8. If you chose to store cord blood in a public bank what would be your primary reason?
9. Tell me how you feel about San Diego hospitals having a system in place whereby you could donate cord blood to a public cord blood bank at the birth of your child?
10. Do you have any thoughts about your future beliefs regarding stem cell research through cord blood collection?

Appendix L

Consent

Cord Blood Donation Information and Assent Form

Irene Carr, RN, MSN CFNP, CNM, doctoral candidate and student, University of San Diego is interviewing volunteers as part of her research study. The purpose of the study:

- To develop better understanding of public and private cord blood donation, storage and use.
- To obtain community members perspectives on the option of cord blood donation in the San Diego County.
- To obtain input from a broad segment of the population

Participants, couples and individuals, interested in the phenomenon of how they are making decisions to collect cord blood at the birth of their child and what is their understanding and belief about this process will be addressed in a questionnaire followed by an interview. Those willing to express their views on stem cell research from cord blood collection and how they make a decision to use private or public banking will be addressed. You will be asked other characteristics relevant to the study.

The interview will involve one interview that asks questions about your pregnancy and how you heard about cord blood collection. The interview will last about 60-90 minutes and also will include some questions about you, such as your age, gender, gestational age, number of children you have birthed, race/ethnicity, religion, highest level of education completed, financial status, and method of payment for prenatal care. The interview will take place at a time and place convenient for you. Participation is entirely voluntary and you can refuse to answer any question and/or quit at any time. Should you choose to quit, no one will be upset with you and your information will be

destroyed right away.

The information you give will be analyzed in a manner that protects your identity. That means that a code number will be used and that your real name will not appear on any of the materials used.

There may be a risk that participating in the interview may make you feel tired. Remember, you can stop the interview at any time you feel tired or for any other reason. The other risk may be discourse in your decision to donate or not donate cord blood.

The benefit to participating will be in knowing you helped doctoral nursing students learn how to ensure every pregnant woman the opportunity to make a well informed decision about cord blood donation/banking.

If you have any questions about this interview, please contact Dr. Mary-Rose Mueller at the University of San Diego, 619-260-4562.

I have read and understand this form, and agree to the research purposes it describes to me. This form is given to me for my records.

_____ _____

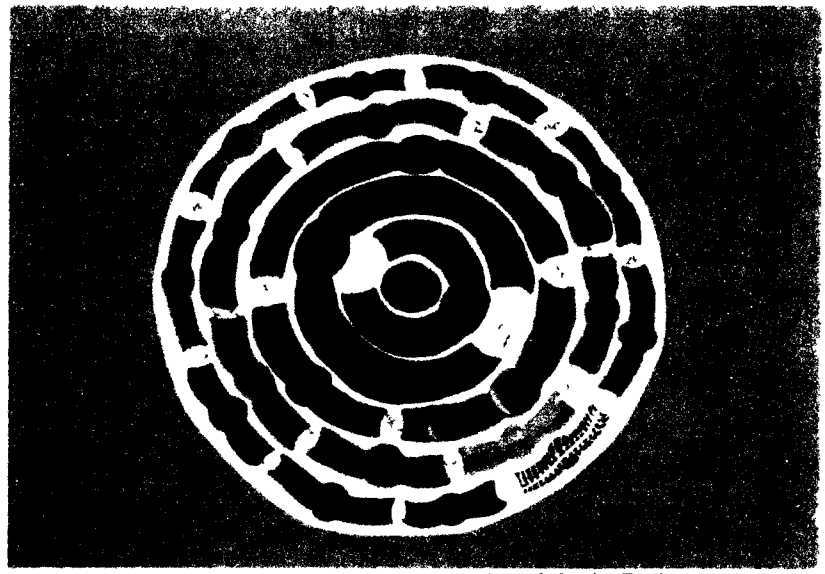
Signature of Participant Date of Interview

Appendix M

Recruitment Flyer

BANK
CORD BLOOD at Birth
SURVEY

DECISION to DONATE



Amanda Louise Emsley

Nurse researcher is actively seeking women during their pregnancy to volunteer for a survey regarding their knowledge on cord blood banking. Takes 15 minutes. Please contact Irene Carr, MSN, FNP-BC, CNM at 619-823-5650 OR 619-262-5925 for further information.

Appendix N

Bureau of Labor Statistics

Bureau of Labor Statistics
Mid-Atlantic Information Office
Suite 810 East - The Curtis Center
170 South Independence Mall West
Philadelphia, Pa. 19106-3305

Branch of Economic Analysis and Information
Phone: 215-597-3282
Fax: 215-861-5700
Web site: www.bls.gov/ro3
Email: BLSinfo_Philadelphia@bls.gov

San Diego-Carlsbad-San Marcos, CA Metropolitan Statistical Area
not seasonally adjusted data

Establishment Data	Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Annual Avg
Total Nonfarm	2009	1,251.7	1,247.7	1,245.4	1,235.5	1,235.9	1,235.3	1,216.0	1,216.1	1,217.5	1,215.9	1,219.3	1,218.5	1,229.6
	2010	1,202.7	1,205.3	1,211.9	1,215.6	1,220.7	1,225.0	1,213.6	1,206.6	1,209.2	1,214.6			
Mining & Logging	2009	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.3	0.3	0.4
	2010	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3			
Construction	2009	66.0	64.2	64.0	62.1	62.1	61.5	60.4	60.2	59.5	57.9	57.9	56.1	61.1
	2010	54.4	53.7	54.3	54.6	55.6	56.7	56.5	56.9	56.5	57.0			
Manufacturing	2009	101.2	99.9	99.5	99.5	99.3	98.1	93.6	93.1	93.1	92.3	92.3	92.2	96.4
	2010	91.6	90.9	91.3	91.7	91.6	91.6	91.0	91.2	91.1	90.7			
Financial Activities	2009	71.6	72.0	71.7	70.7	70.6	70.5	70.3	70.1	69.3	69.0	68.6	68.5	70.3
	2010	69.1	67.7	68.0	68.1	68.2	68.1	67.9	68.1	68.2	68.2			
Professional & Business Services	2009	204.0	202.6	200.1	197.5	196.9	198.0	195.9	195.7	193.5	194.2	195.6	195.7	197.3
	2010	192.2	195.0	196.8	197.2	197.3	198.2	198.4	196.4	198.1	198.8			
Education & Health Services	2009	141.2	143.1	144.6	142.5	142.9	142.8	139.7	141.5	142.9	144.9	145.0	144.9	143.0
	2010	143.8	145.2	146.0	146.6	146.3	145.5	143.0	143.7	145.2	147.4			
Government	2009	228.1	227.1	228.8	228.7	229.0	229.6	218.8	215.8	218.2	224.7	224.8	224.1	224.7
	2010	222.9	223.7	225.4	226.8	231.9	228.1	215.3	213.4	215.6	222.5			
Leisure & Hospitality	2009	152.6	152.5	153.1	154.4	156.6	158.0	158.2	160.0	157.3	153.6	152.8	152.7	155.2
	2010	149.4	149.9	151.2	153.2	155.3	157.5	157.5	156.9	155.4	152.0			
Other Services	2009	46.3	47.0	47.3	46.6	47.2	47.4	46.6	47.2	46.2	47.0	47.4	47.6	47.0
	2010	45.2	46.1	45.9	46.1	46.8	47.5	48.0	47.2	47.5	47.4			
Trade, Transportation, & Utilities	2009	204.1	200.9	199.3	197.0	196.1	196.3	196.7	196.9	196.4	196.6	196.4	196.7	198.3
	2010	194.4	193.7	194.0	193.4	193.6	194.8	195.6	194.8	195.1	196.3			
Information	2009	38.1	38.0	37.6	37.3	37.1	37.4	36.9	36.7	36.1	36.1	36.2	36.2	37.0
	2010	35.1	36.1	36.1	35.9	35.9	35.8	35.8	35.7	35.4	35.2			

Labor Force Data														
Labor Force	2009	1,562,491	1,567,371	1,566,687	1,554,381	1,549,129	1,559,805	1,568,166	1,567,270	1,561,164	1,550,138	1,550,406	1,541,327	1,557,369
	2010	1,554,032	1,555,918	1,570,244	1,568,167	1,567,343	1,573,207	1,580,726	1,575,312	1,570,607	1,566,730			
Employment	2009	1,430,388	1,431,124	1,429,450	1,416,377	1,404,566	1,405,163	1,436,130	1,436,779	1,391,231	1,386,397	1,388,419	1,382,252	1,426,070
	2010	1,381,374	1,389,173	1,396,327	1,403,482	1,409,677	1,407,611	1,438,892	1,407,550	1,403,011	1,428,201			
Unemployment	2009	131,882	136,247	141,437	137,429	144,563	154,645	132,068	130,598	159,933	163,741	162,986	159,075	131,299
	2010	172,658	166,745	173,917	165,684	157,666	165,596	142,834	167,762	167,596	138,529			
Unemployment Rate	2009	8.4	8.7	9.0	8.8	9.3	10.0	10.3	10.3	10.9	10.6	10.4	10.9	9.7
	2010	11.1	10.7	11.0	10.4	10.1	10.5	10.9	10.6	10.7	10.2			

Data for the most recent month are preliminary

Date of last update: 12/7/2010

Appendix O

Answers to Interview Questions

Interview Questions on Cord Blood Donation

How did you hear or see information about blood donation?

1. TV commercial and internet.
2. TV and @ UCSD. "I had to make a choice between circumcision and donating cord blood."
3. My PCP asked me.
4. TV
5. My doctor.
6. Television and OB, PCP.
7. From my doctors office.
8. Dr Irene Carr.
9. From my midwife.
10. OB family Nurse Practitioner... she gave her handout.
11. Information by mail & information from doctor in the office information display.

When did you receive information about cord blood donation?

1. Not applicable.
2. Papers w/last pregnancy 5 yrs ago.
3. Today!!
4. I have not information.
5. I don't know.
6. During early pregnancy.
7. Second trimester.
8. Today, 5/06/2010.
9. Today, 5/17/2010.
10. At 12 weeks gestation.
11. Continuously

Tell me what your understanding of the process in cord blood donation is and how it occurs?

1. You give consent for hospital or Party to take donation.
2. Some hospitals have kits kept there if you decide to use them. UCSD has kits. I did not get kits.
3. I would like to do this.
4. I don't have a lot of understanding because I really don't know much about it.
5. I don't know.
6. Hospital collects it, sends it to bank; if baby has leukemia in future you can use the blood from the bank.
7. I don't know.
8. "No answer"
9. I need more information regarding Cord Blood Donation to decide what my future choices.
10. Private versus Public.
11. Not very much.

Have you discussed cord blood donation with your obstetrician, PCP, CNM yet? Do you plan to do so?

1. YES.
2. Yes, as sickle cell is in my family members.
3. Yes.
4. No, haven't discussed it with my obstetrician. Maybe.
5. I have not. I don't know.
6. Yes.
7. No, But I plan to do so.
8. I need to talk with my husband.
9. I do not know much about it at this time.
10. Yes.
11. No. But maybe I am ready now. (this participant is 39 weeks GA).

Would it make a difference in a decision to store cord blood with private/commercial cord blood bank if you knew that your obstetrician, PCP, CNM would be paid a fee to collect the cord blood?

1. Yes.
2. No.
3. Don't know.
4. Don't know.
5. Yes.
6. Yes.
7. NO.
8. "No Answer."
9. Yes, it depends.
10. No difference.
11. N0!

What is your understanding regarding a chance that your baby would have a condition (at birth or in the future) that could benefit from cord blood during his first 10 years of life?

1. Little or no understanding.
2. Yes in the next ten years sickle cell may surface in my kids.
3. Don't know.
4. Don't know.
5. I don't know. I do not have any children yet.
6. I understand it can be used if your child has leukemia.
7. Pretty good understanding.
8. "No answer."
9. "No answer."
10. No idea of rates and condition.
11. I do not know what the probabilities are???

If you chose to store cord blood in a private/commercial bank what would be your primary reason?

1. It would be beneficial and free to do so.
2. For the health of my kids.
3. Don't know.
4. To benefit my child.
5. In case it is ever needed for my child.
6. For the health of my baby.
7. For private/family use.
8. For the future if my daughter would need it.
9. Is it a safe procedure?
10. Just to have it available, if one needs it.
11. To help my son if he had a disease.

If you chose to store cord blood in a public bank what would be your primary reason?

1. It would be free to do so, and it would be available to my child if needed, as well as others.
2. It's free. Everyone can use it. Many don't have money to pay for private donation.
3. Don't know.
4. To benefit my child.
5. In case it is ever needed.
6. For the health of my baby.
7. They do not offer this in San Diego.
8. Some babies may need this.
9. Is it a safe procedure.
10. The low cost.
11. I am not sure what the difference between storing privately and publically.

Tell me how you feel about San Diego hospitals having a system in place whereby you could donate cord blood to a public cord blood bank at the birth of your child?

1. I think it would be a great ideal if it were free for personal and public use. Yet, I would be against it if it was to profit financially to companies or misused.
2. Yes that would be great but they don't have one right now.
3. I think it's good.
4. Don't know.
5. I'm neutral about it.
6. Good.....it can help anyone because you don't know at the time of the birth.
7. No thoughts.
8. "No answer."
9. If it is a safe procedure I would not mind.
10. I would use it if it was available.
11. That would be great if this was available.

Do you have any thoughts about your future beliefs regarding stem cell research through cord blood collection?

1. I like the idea of stem cell research to help people and cure diseases---Yet, I do not approve of companies profiting off of donated cord blood or misuse or sale of such discoveries.
2. They should do it.
3. No.
4. No.
5. No, I do not.
6. Yes, continue to do the research and educate parents on their options.
7. I think it is a great idea.
8. "No answer."
9. I will look into it and research about it.
10. I am learning; and I am still learning.
11. It seems like a good idea if it is cost effective and safe.