

CORD BLOOD DONATION

BY

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A PROJECT

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Abstract

“Before your baby is born, the umbilical cord is a lifeline. After your baby is born, that lifeline can give birth to hope for others,” (Be the Match, pg. 1). Adults and children whose lives have been altered due to leukemia, lymphoma, and other blood disorders are now being saved through cord blood donation. Although cord blood is saving lives, many public cord blood banks in the industry have reported significant financial stress and have expressed concern regarding the long-term trajectory of the industry (Kapinos, 2017). Strengthening aspects of the industry by making changes to payment, knowledge sharing, and research funding is crucial to the future of umbilical cord blood banks and donation.

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Umbilical cord blood stem cells were first successfully used for transplant in 1988 on a 5-year-old boy suffering from Fanconi's Anemia in Paris, France. The transplant was performed using the umbilical cord blood of his sister. As of 2005, the boy was healthy with a well-functioning transplant (Skabla, 2010). Since then, more than 20,000 umbilical cord blood transplants have been performed worldwide (Petrini, 2014). According to the National Cord Blood Program, "An estimated 10,000 to 15,000 patients cannot find a donor that is a sufficiently close match among the millions of volunteer donors listed on registries around the world. Other patients do not have enough time to find an unrelated bone marrow donor due to the rapid progression of their disease. Cord blood is now another option," (NCBP, 2015, pg.1). Cord blood transplants are now an approved therapy for over 80 medical conditions (Peberdy, 2016). The effectiveness of umbilical cord blood transplants continues to grow with the increasing number of clinical trials, and donations of cord blood for research purposes.

Purpose Statement

The purpose of this proposal is to identify current challenges in the cord blood industry as well identify research and future implications of umbilical cord blood use.

Significance of the Project

A personal experience as well as trying to donate at the University of Kansas Hospital during my 2nd pregnancy drew me to this topic. A family friend was diagnosed with an extremely rare form of lymphoma called Grey Zone lymphoma. Although he did not receive his transplant from cord blood, a fellow friend he met during his journey did. During my 2nd pregnancy, I tried to personally donate to a national public cord blood bank, LifeForce Cryobanks, which is discussed later, and ended up not being able to donate. Due to these situations, my interest was

piqued and a passion was formed to bring about awareness to umbilical cord blood donation and banking.

Project Objectives

Objectives to this project include producing a flyer that can be given to OBGYN offices and potential donor hospitals. The goal is to have the University of Kansas Hospital partner with the St. Louis Cord Blood Bank to become a participating donor hospital

Literature Review

When a patient needs a transplant, their physician determines the source of blood-forming cells that best meet their needs and would be suitable for them. Most commonly heard of are bone marrow and peripheral blood stem cells (PBSC). Typically thrown away after the baby is born, umbilical cord blood is being used as an alternate for bone marrow or peripheral blood in stem cell transplants. Umbilical cord blood contains the same blood-forming cells, known as hematopoietic stem cells, as bone marrow and peripheral blood stem cells. In some cases, umbilical cord blood may be better suited for a patient needing a transplant. After transplantation, hematopoietic stem cells create new bone marrow, which is the body's factory for producing red blood cells, white blood cells, and platelets. Transplanted hematopoietic stem cells can replace a patient's native bone marrow and go on to develop into normal, healthy blood-forming cells. (Kapinos, 2017).

For the past two decades, umbilical cord blood has been used for the treatment of blood, immune system and metabolic disorders. Promising research also suggests a wide range of other possible applications of hematopoietic stem cells including trauma repair, organ replacement, and treatment of more-prevalent conditions such as diabetes or traumatic brain injury (Kapinos,

2017). In addition to its direct therapeutic value to patients, cord blood is used for basic research on blood, blood stem cells, and immune cells (Kapinos, 2017).

Cord blood units differ from other hematopoietic stem cell sources in that they must be stored prior to use. With the expanding usage of umbilical cord blood as well as FDA-regulated clinical trials being performed, umbilical cord blood banking has grown considerably. In 1991, the New York Blood Center became the site of the first unrelated public umbilical cord blood bank developed by Dr. Pablo Rubenstein (Ballen, 2015). Using a unit from this bank, in 1993 the first umbilical cord blood transplant in the United States was performed at Duke University in a 4-year old boy with relapsed T-cell leukemia. Since that time, over 160 public umbilical cord blood banks have been established worldwide and there are 730,000 umbilical cord blood units available for public use (Ballen, 2015). Today, 14% of transplants receive cord blood that has been generously donated to a public cord blood bank (Be The Match, 2017).

“Currently, with more than 50,000 cord blood donations, the New York Blood Center’s National Cord Blood Program can, on average, find a matched cord blood graft for approximately 85 percent of patients who request a search,” (NCBP, 2015, pg.2). Currently, the odds of finding an appropriate-matched, publicly donated, unrelated cord blood unit is quite high and those numbers continue to improve as the donations to public cord blood banks grow. It is important to note that most public banks only work with selected hospitals in their community. With the number of public cord blood banks declining, donation hospitals in the United States also continue to decline. “Currently, public cord blood banking is available in fewer than 200 hospitals in the United States” (Kapinos, 2017, pg. 12). Exports are going down, even at large hospitals, and costs are going up.

The St. Louis Cord Blood Bank is one of the largest banks in the world with 190,000 umbilical cord blood units being donated to their blood bank. Due to technical specifications discussed later in this report, only 28,000 units are available for transplantation (slcbb.org, 2017). Although they are one of the largest banks in the world, they too are seeing their donation hospitals reduce from 28 currently, to 8 starting November 1, 2017. Kathy Mueckl, nurse coordinator of the St. Louis Cord Blood Bank stated “The St. Louis Cord Blood Bank has small donor hospitals, 360 miles away, and this is just not feasible anymore” (personal communication, October 25, 2017). To provide transport to such small facilities that have possibly one donation every week or couple days, is just not in their best interest, or affordable anymore. They want their donor hospitals to be the biggest and provide the most donations. K. Mueckl also stated they are currently in the process of merging with another cord blood bank. This is due to the lack of funding provided to the bank and the need to replenish the inventory that cord blood banks have. She also stated in months to come we will see about five public cord blood banks placed strategically nationwide (personal communication, October 25, 2017). Kapinos (2017) stated “A mistake was made in the beginning in terms of facilitating a multitude of banks. It is not cost efficient. There should be banks of excellence. There should be less than ten public cord blood banks nationwide. Those ten, should be a powerhouse of creating high-quality grafts around the country” (pg. 30).

The Cord Blood Donation Process

Cord blood donation is free. There is no cost for collection or public storage of the cord blood. Collection of umbilical cord blood is painless to mother and baby and does not pose a risk during or after delivery. Immediately after birth, the umbilical cord is cleansed and a needle is put into the cord, and blood is drawn out. Volume and cell preservation are key in this step of the process. After the blood has been drawn out, it is transferred to the lab for specialized testing and then sent to a public cord blood bank for potential matching for a patient in need. Once it arrives at the public cord blood bank, it is tissue typed. It is then frozen in a liquid nitrogen freezer and stored. Once stored, it is listed on a donor registry, “Be The Match” registry, and a database that is accessible to physicians to search for patients in need. Another name for the “Be The Match” registry, is the registry of the C.W. Bill Young Cell Transplantation Program (HRSA, 2017). Size is a crucial factor for “Be The Match” and other donor registries worldwide. The larger their registry, the greater the probability of finding a clinically useful match between donor and recipient (Kapinos, 2017). “More than 90 percent of cord blood units distributed for transplant in the United States are distributed through the “Be The Match” registry” (Kapinos, 2017, pg. 16).

When deciding whether or not to donate cord blood it is important to know there are four options to donating: The donor may donate the baby’s umbilical cord blood to a public cord blood bank. The donor’s cord blood will be listed on the national registry and available to anyone in need. The donor may store the baby’s cord blood in a private or family cord blood bank where it is reserved for their own family for a fee. The donor may save their baby’s cord blood for a biological sibling who has a medical need. Lastly, the donor may choose to do nothing: the umbilical cord blood will be thrown away after birth.

Theoretical Framework

Public cord blood banks compete not only with one another to provide cord blood to transplant centers, but with other hematopoietic stem cell sources, such as bone marrow and peripheral blood. When selecting the most appropriate source of hematopoietic stem cells, transplant centers weigh a variety of factors. Patient disease stage, patient comorbidities, prior treatments, the level of match between donor and recipient, and timing and availability of each different source are all factors considered when deciding which type of transplant would be best for the recipient.

Limitations of Cord Blood Donation

Research has proven there is a lack of education and knowledge among healthcare providers and potential donors. Many people are able to donate but it is never mentioned to them during their pregnancy. Nor, do they understand the process of donation. Many people hear about cord blood donation via internet, television, or simply a personal story from a friend who received a transplant. From lack of patient and provider knowledge to a lack of government funding, there are limitations to cord blood donation.

Lack of patient and provider knowledge. One of the greatest limitations of cord blood donation seems to be lack of patient and provider knowledge. Outside of this lack of knowledge, once umbilical cord blood is donated it must meet donor-screening criteria as well as technical specifications. It is important to know the life-saving stem cells in umbilical cord blood are not embryonic stem cells. The umbilical cord blood cells are taken from the baby's umbilical cord and placenta, not from an embryo. The stem cells found in cord blood are rich with blood-forming cells that have the ability to cure a patient's blood, immune system or metabolic

disorder. Many mothers do not donate due to the lack of education on the type of cells being donated.

A recent study by Peberdy (2016) reported that evaluation of a group of midwives and maternity nurses revealed that both groups were aware that cord blood was used in the treatment of hematological disorders but only two thirds were aware of other conditions for use such as autoimmune disorders, degenerative conditions, genetic diseases, and research (pg, 4). Many transplant physicians have little or no experience with cord blood, so therefore will not use it and will chose other transplant sources. Education and training remain vital among healthcare professionals.

Technical specifications. After the first transplant took place in 1988, umbilical cord blood donation and banking emerged quickly due to it being a proven treatment option for pediatric patients in need. Over time, it was realized that umbilical cord blood could also be used in adults. The U.S. Food and Drug Administration (FDA), and government, issued guidance in 2010 for public umbilical cord blood banking when research proved that units could be used in people of all ages. The FDA developed an approach to licensure of transplant products that allowed cord blood manufacturers to apply for a Biologic License Application (BLA). The FDA, under this guidance, will accept BLAs from hematopoietic cord stem cell manufacturers that can demonstrate compliance with its recommendations for assurance of safety, purity, potency, and effectiveness (Wells, 2010). This licensure, which is now a requirement for public cord blood banks, is extremely costly. Unfortunately, this also changed many of the technical aspects of collection.

The total nucleated cell count (TNC) of a cord blood unit is one of the most important measures used when determining if a cord blood donation is suitable for transplant. Kapinos

(2017) states that “half of the current national inventory is made up of cord blood units that have TNC counts of less than 1.25 billion cells per unit, whereas the probability that a cord blood unit with that cell count will be used in a given year is about one-tenth of a percent. Relative to a 1-3 percent change that a cord blood unit with a TNC of more than 1.5 billion will be used in a given year, or about a 61 percent chance that it will ever be used” (pg. 4). Greater cell doses correlate with increased engraftment success, decreased time to neutrophil and platelet recovery, and longer disease-free survival (Skabla, 2010). When only used in pediatric patients, donations did not have to contain such large volume and cell counts. At that time, 50%-60% of donations processed were not appropriate for donation due to technical specifications not being met (Kapinos, 2017). Currently, public banks are only able to process about 10% of donations they receive due to technical specifications. Typically, umbilical cord blood units do not contain enough cells to treat an adult, a problem that can be overcome by combining two units. (K. Meuckl, personal communication, October 25, 2017). The game has changed to wanting bigger volume units and bigger cell counts due to treating people of all ages. Current research indicates that a higher TNC count can offset some degree of HLA mismatch. The downside of only collecting higher TNC count units is that doing so will result in fewer units being added to the national inventory. This could have a negative impact on improving the genetic diversity of the national inventory (Kapinos, 2017).

Collected cord blood must contain enough blood-forming cells, be free from infection or disease, and must be large enough. Inadequate volume has proven to be the primary reason umbilical cord blood units are unsuitable for transplants (Skabla, 2010). The volume and cell count used for transplant is simply the amount the cord blood bank determines is present in the unit or units used. Sometimes, more than one unit is used in adult patients to make sure the

required volume and cell count is present. With bone marrow and peripheral transplant units, the recipient always get the volume and cell count they need based on the amount being given by the donor.

Cord blood cannot take too long to be delivered to the cord blood bank for processing. Cord blood needs to be at the bank, frozen, and stored, within 36-40 hours of collection. (K. Mueckl, personal communication, October 25, 2017). While cord blood is in transit, time and temperature affect the viability of the cord blood (Kapinos, 2017). “Studies have reported a 1-percent drop in cell viability for every 4-hour increase in transit time” (Kapinos, 2017, pg.13). If the cord blood takes too long to arrive at the cord blood bank, or temperature is affected, it may not be suitable for transplant but can still be made available to use for research with the parents’ permission.

Screening and medical history. A thorough screening and medical history of the mother will be conducted. Informed consent must be obtained from the mother prior to delivery. The mother’s health history and the results of her blood sample test must meet eligibility guidelines. On the day of delivery, a small amount of blood will be drawn from the mother to insure she is free from any type of infectious diseases. The blood is only taken from the mother, not the baby. Donors must be 18 years of age or older, although some states have laws that allow donations from younger women. The donor must be expecting a healthy, single birth, and expecting a delivery of at least 34 weeks gestation. If expecting twins, one may not donate due to each umbilical cord having different tissue types and it is possible the two cord blood units could be mixed up during collection. In the United States, currently a mother must be signed up by the 34th week of pregnancy. Ideally, the cord blood bank should be called between the 28th and 34th week of pregnancy to discuss the options and steps involved for donation. Mothers are often turned away

because they do not inquire about donation until it is too late. It is important to note that labor or delivery is not changed in any way when a mother decides to donate umbilical cord blood.

Names of cord blood donors are also never shared. The cord blood is listed purely by its genetic type, with no information regarding the identity of the donor. The mother and baby's name are protected and kept private. Although confidentiality is maintained after donation, donated umbilical cord blood is always traceable and may be available to the donor should the need arise, unless it has already been released for transplant to another patient (Petrini, 2014).

Other banking options. Parents may also choose to store the cord blood in a private cord blood bank. Parents can choose to do this regardless of there being a medical reason known to do so at that specific time. Companies have termed this “biological insurance”. The fee for private storage differs, but averages around \$1500 required up front, and \$100 per year after for storage. “An estimated 4.0 million umbilical cord blood units have been saved for private or family use” (Ballen, 2015, pg.1). The organization providing this service has a profit margin on each unit banked, and thus the provider is making money in real time and does not have to wait years to break even when units are released for use (Ballen, 2015). There is also less government regulation of private versus public banks. Private banks are not required to hold FDA licensure or to hold accreditation (Kapinos, 2017). With a profit margin, less government regulation, and not having to hold licensure, this has allowed private banks to grow much faster and achieve sustainability over public banks (Ballen, 2015). Public banks incur greater costs than private banks because of the extra testing necessary to match units with unrelated recipients. The financial burden on public cord blood banks limits the number of collection sites and the education provided. “As of December 1, 2014, an estimated 4.03 million cord blood units have been stored in private banks worldwide, including 1.26 million in the United States. Compared to

the most recent count in public cord banks at 713,000 units worldwide, and 216,000 in the United States” (Ballen, 2015, pg. 3). In summary, through the end of 2014, the amount of cord blood inventory in private banks worldwide is about 6 times more than in public banks, yet the public banks have released 30 times more units for therapy (Ballen, 2015). Private storage therefore can even be seen as damaging the public interest, it removes units from network resources that could otherwise be of therapeutic benefit to persons other than the donor (Petrini, 2014).

Parents should know that a child’s own cord blood is rarely suitable for a transplant for that child due to the cord blood stem cells carrying the same affected genes, and if transplanted, would confer the same condition. For example, in most cases of childhood leukemia, cells carrying the leukemic mutations are already present at birth and are established in the cord blood. There is no effective way to remove those mutations at this time, thus allowing those pre-leukemic cells being given back with transplant (NCBP, 2015)

Parents may also choose to store the cord public in a family (private) cord blood bank for the use by a family member with a current condition with a high potential of needing a bone marrow or stem cell transplant. Units held in private banks remain the property of the child, under the guardianship of the parents. They may, however, be made available to other family members, so that most “private” umbilical cord blood banks are effectively “private/family” umbilical cord blood banks. (Petrini, 2014). It is important to know, there is only a 25% change that siblings will match each other (Be The Match, 2017). The American Academy of Pediatrics only recommends private cord blood banking as a “directed donation” for a biological sibling or family member in need of the cord blood. With directed donation, the collection and storage is offered at little or no cost (NCBP, 2015).

Hybrid banking, a private/public bank option in which umbilical cord blood units can be used for either public or private use, has been proposed as a solution to promote umbilical cord blood transplant. Hybrid banks are inviting primarily because the private side can compensate for the financial losses incurred on the public side. Kapinos (2017) states, “many hybrid bank owners are able to generate revenue on the private side to cover expenses or losses incurred on the public side” (pg. 41). The regulations surrounding private vs. public cord blood banks are different, especially in the United States and differences in quality have been documented.

Government involvement and funding. Funding is also a major hindrance in cord blood donation and banking. “A 2015 investigation by the World Marrow Donor Association found that only 11 percent of public cord blood banks are financially breaking even” (Kapinos, 2017, pg.6). Public umbilical cord blood banking is financed through a combination of government grants and private donations (Petrini, 2014). K. Mueckl stated that in 2009, the Food and Drug Administration (FDA) got involved in the licensing of public cord blood banks. By law, as of 2009, all public cord blood banks must be licensed and accredited to ensure that they meet quality and safety standards. It costs public cord blood banks initially over \$1 million dollars to obtain and go through the process of licensure and ongoing annual costs of more than \$100,000 (personal communication, October 25, 2017). Once eligible cord blood units are listed on The Registry, public cord blood banks receive a subsidy for cord blood collection, processing, and storage. This subsidy does not cover the entire costs for cord blood collection, processing, and storage, but it does help fund some of these costs (Kapinos, 2017). “Average annual over costs total from \$1.2 million to \$4.5 million, depending on the size and setup of the cord blood bank. These costs consist of equipment, maintenance, rent, utilities, office supplies, and other related expenses” (Kapinos, 2017, pg. 56).

Public cord blood banks absorb much of the cost during the entire donation through transplant process. This means during donation at participating hospitals, all costs are absorbed by the public cord blood bank that stores the donation. Also, the collection, processing, and storing of the cord blood are all covered by the cord blood bank. Cord blood banks must collect and store inventory for years without any assurance that their inventories will be used. Cord blood banks only receive a fee from transplant centers when a unit is withdrawn for use, which could be years after it was collected. Cord blood banks charge the same fee per cord blood unit regardless of size and HLA type, so there is strong financial reason to bank only the cord blood units with the highest odds for use. If cord blood banks were able to charge more for a rare HLA-typed unit or a larger cord blood unit, the market would allow incentives for the collection of rare cord blood units. Kapinos (2017) stated “In the United States, fees charged per shipped cord blood unit average \$36,000” (pg. 57).

K. Mueckl stated that there was a pilot program recently that was trying nationwide banking. They were only seeing 1.5% of units suitable for donation, which ended this program due to the immense cost (personal communication, October 25, 2017). Due to limitations of funding, it is not possible at this time to donate cord blood at every hospital. According to the National Cord Blood Program (2015), they are expanding their own program to encourage federal funding to help all qualified public cord blood banks in the United States build a large national inventory of cord blood units. Two acts were passed by Congress in the past twelve years to build support for umbilical cord blood transplant and research: The Stem Cell Therapeutic Act of 2005, Public Laws 109-129, and the Stem Cell Therapeutic and Research Reauthorization Act of 2010, Public Laws 111-264 (HRSA, 2017). The Stem Cell Therapeutic and Research Act of 2005 provided the initial funding for the “collection and maintenance of

150,000 new units of high-quality cord blood to be made available for transplantations through The Registry. The Act authorized the National Cord Blood Inventory to receive \$15 million in federal funds for each fiscal year, from 2007 to 2010 to help meet this goal. The Act's Reauthorization Act in 2010 changed from 150,000 new units to "at least 150,000" units and allotted \$23 million from years 2011 through 2014 and \$20 million in year 2015 (Kapinos, 2017).

Ethnic and racial diversity. "Seven out of 10 people will not have a matching donor in their family for bone marrow or peripheral stem cell transplant. They depend on the Be The Match Registry to find a match" (Be The Match, pg. 4). That number for people of diverse racial and ethnic background is even lower. "For many ethnic groups, no more than 20-30% are able to find suitable matches" (Petrini, 2014, pg.88). Cord blood, is particularly useful in cases where an exact match cannot be achieved from other sources. This situation tends to occur more frequently in the United States for certain minority populations. Adding donated cord blood from diverse communities to the registry increases the probability that every patient will find a life-saving match. "In 2016, 29 percent of umbilical cord blood transplants were for patients of color" (Be The Match, 2017, pg.5). Umbilical cord blood provides a way to decrease the variation between racial groups and can accelerate the transplant process when bone marrow or peripheral blood transplants are not available (Skabla, 2010).

Delayed cord clamping. More mothers than ever before are inquiring about delayed cord clamping (DCC). This rise corresponds with the World Health Organization's (WHO) recommendation that the umbilical cord not be clamped earlier than necessary. "Delayed cord clamping is the prolongation of the time between delivery of a newborn and the clamping of the umbilical cord" (APA, 2017, pg. 2). Delayed cord clamping allows more blood to transfer from

the placenta to the baby, increasing the child's blood volume. The iron in the blood increases the newborn's iron storage, which is vital for healthy brain development (APA, 2017). DCC is typically only used with preterm infants. "The American Congress of Obstetricians and Gynecologists (ACOG) endorses delayed cord clamping in preterm infants but believes there is not enough evidence at this time to confirm the potential benefits of DCC in full-term babies" (APA, pg.3. It is important to know if a mother decides to delay cord clamping, this can have an effect on the volume and quality of cells being donated. Delayed cord clamping has had a major impact on the cord blood world. Kathy Mueckl, Nurse Coordinator of the St. Louis Cord Blood Bank has seen their number of donations drastically go down due to delayed cord clamping (personal communication, October 25, 2017).

Other transplant options. "Although there are approximately 11 million individuals registered as bone marrow or peripheral stem cell donors in the United States, these sources require a stringent match to the patient and often require significant time, pain, and additional medical costs to collect donations" (Kapinos, 2017). Umbilical cord blood is particularly useful when there is no adult donor or bone marrow/peripheral blood stem cells that are a close match. Cord blood stem cells are unique because they allow for less-precise matching of the donor's human leukocyte antigen (HLA) type to the recipient's HLA type (Kapinos, 2017). Evidence suggests that health outcomes from these less precisely matched cord blood cells are just as good as those from matched bone marrow grafts (Kapinos, 2017). Sometimes a patient cannot wait several weeks or months for a donor to be contacted and the bone marrow donation to be collected. Cord blood in this case is a great option. Units are typically collected long before they are needed and are ready to use from a public cord blood bank immediately. The turnaround time between requesting a cord blood unit and receiving it in a transplant center is very short in comparison

with the turnaround times for bone marrow and peripheral blood. Donations for bone marrow or peripheral blood require extensive coordination with potential donors. Cord blood has been proven to have a lower risk of graft-vs-host disease infection versus other sources after transplantation. Cord blood transplants have also been associated with lower relapse rates (Kapinos, 2017).

There is also the evolving field of haploidentical stem cell transplants. The St. Louis Cord Blood Bank as well as all public banks have seen drastic decreases in donations due to the emergence of this type of transplant. The advantage of haploidentical stem cell transplant is that nearly all patients have an immediately available donor. Haplo transplants are easier and cheaper to transplant with much shorter engraftment periods than cord blood. A haploidentical related donor is usually a 50% match to the recipient and may be the recipient's parents, sibling or child. The better the match, the more successful a transplant will be. For the 70% of patients that do not have an identical related donor, haplo transplant has served as an alternative option. According to Kapinos (2017) "Researchers and transplant physicians have stated haploidentical transplants may just be the latest trend. Many are concerned about the long-term outcomes of haploidentical transplants (pg. 34). Initially haplo transplants may be cheaper, but with a high risk of relapse, this can cost an additional 50 to 60 percent (Kapinos pg. 34).

Involvement of the participating donation hospital. Donation hospitals also need someone who really believes in umbilical cord blood donation to allow a donor program to start. It can be viewed as a great community endeavor by the hospital as well as donors. If a hospital is not listed as a participating hospital for cord blood banking, the only way to donate would be to register for a mail-in donation program. Currently there are two U.S. public banks that will accept mail-in donations, Lifeforce Cryobanks and Saneron. The limitation to these two U.S.

public banks is that if the donor delivers their baby between Friday at 3p.m. and Sunday at 3p.m., they are not able to donate due to the lack of available transportation to get the cord blood to the bank in the appropriate time.

Implementation Plan

Within a 9 month timeline, schedule meetings and telephone correspondence with the University of Kansas Hospital Obstetrics and Gynecology department chair as well visit local clinics to discuss cord blood donation. A meeting as well as telephone correspondence will also be directed to the University of Kansas Cancer Center and Midwest Stem Cell Therapy Center. Within 18 months, the University of Kansas Hospital will partner with the St. Louis Cord Blood Bank to become a participating cord blood donor hospital.

Outcomes of the Project

The result of this project was to find out why the University of Kansas Hospital is not a participating hospital for the donation of cord blood. Phone calls were made to department chairs in the obstetrics and gynecology department and emails sent, that were not returned. I also placed multiple phone calls to the St. Luke's Organization department head of their cord blood program that were not returned as well. I attempted to learn more about the entire process and got in touch with a woman at the St. Louis Cord Blood Bank that provided me a plethora of information regarding cord blood donation and banking.

Conclusion and Future Study

Despite the complex challenges discussed, public cord blood banks continue to innovate to meet the financial challenges they face. Although congress has developed laws and allocated funding to public cord blood banks, it has not been enough for most cord blood bank to

financially break even. It has been suggested that payment to public cord blood banks could be structured similarly to the way organs are reimbursed, and although cord blood is costly to acquire, there are other significant costs related to bone marrow and peripheral blood transplants that are often overlooked. An example is costs to the donor and the cost of waiting to obtain units (Kapinos, 2017).

Having a well-established, functioning, cord blood bank system means that in the future, if technological change increases demand for cord blood, there is already a system in place. A system will not have to be built from scratch. If there is even one breakthrough therapy or treatment with cord blood for diseases such as Alzheimer's or cerebral palsy, this could result in exponential growth and demand for cord blood units. The societal benefit of having a cord blood system far outweighs its costs. It is important to emphasize there are patients who have no alternative source for transplant, umbilical cord blood is their only option making this a vital and life-saving treatment. To generate revenue, some public cord blood banks have begun locating themselves within a larger entity, such as a blood center or a biotechnology company. Cord Blood programs have said to benefit from using the couriers, labs, and hospital connections of their whole blood programs. This is a great way to offset the expenses accrued with public cord blood banking. Many public cord blood banks have also organized fundraising events or philanthropic funding. Some states have even granted a portion of income tax toward a cord blood banking program. If cord blood were to disappear as a treatment option, it would result in increased mortality, particularly for pediatric patients and minority patients. Minority patients depend on the diversity conferred by cord blood. Pediatric patients are generally smaller than adult patients and can be treated using some of the smaller cord blood units in the inventory that otherwise will not be used (Kapinos, 2017).

The success of cord blood donation relies heavily on healthcare professionals. Patients rely heavily on their health care provider(s) to provide them the most credible information when deciding whether or not to be a donor. Healthcare professionals need ample access to evidence-based knowledge on cord blood banking to provide their patients with accurate information regarding donation. In 2014, the Cord Blood Registry and The Institute for Transfusion Medicine announced the launch of a multi-year initiative to provide education and guidance to expectant parents regarding options for cord blood bank and donation. Efforts will be made by healthcare professionals to educate and inform families of the difference between private and public banking as well as current therapies and future clinical indication for treatments using umbilical cord blood. (CBR, 2014). Progress and growth in this field is dependent upon knowledge.

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Appendix A

Hematopoietic Stem Cell Sources, Advantages and Limitations

Cord Blood Stem Cells

Source Umbilical cord blood following a healthy single birth.

Advantages

- Readily available once collected and stored.
- Young cells, broad range of reproduction and differentiation capabilities.
- Less stringent HLA-matching requirements.
- Lower risk of graft vs host disease (GVHD)
- Associated with lower relapse rates.

Limitations

- One-time supply.
- Costly to procure, process, and store compared with other sources.
- Delayed short-term engraftment.
- Lower volume of cells than adult sources unless double units are used.
- Limited protection from prior viral exposure.

Adult Sources

Bone marrow (from a surgical procedure) or peripheral blood (nonsurgical, but requires long collection hours).

- Can be harvested more than once.
- Transmits some immune protection from donor to recipient from prior viral exposure.
- Maintain the ability to differentiate.
- Extensive historical data for use.
- Rich concentration of stem cells resulting more rapid engraftment.

- Less developmental potential compared with cord blood.
- Donor discomfort during the harvesting procedure.
- Can take time to locate donor and schedule donation.
- Greater potential for GVHD than cord blood.

SOURCE: (Kapinos, 2017, pg.5)

Appendix B
Flyer for OBGYN/potential donor hospitals

Umbilical Cord Blood Donation

- Help save lives with cord blood.

◆ Umbilical cord blood donation is **FREE**

◆ Labor and delivery are not affected in any way.

◆ Children and adults whose lives have been altered due to leukemia, Lymphoma, and blood disorders are now being saved through cord blood donation.

◆ If you are interested in donation, contact a public cord blood bank at Bethematch.org/cord between your 28th and 34 weeks of pregnancy.

◆ For more information regarding umbilical cord blood donation, please go to www.bethematch.org/cord



Give the Gift of Love



Appendix C

Transcript of telephone correspondence with Kathy Meuckl, Nurse Coordinator, St. Louis Cord Blood Bank. October 25, 2017.

Emailed me a copy of the most recently published RAND report.

Cord blood banking is in a time of financial turmoil. Has become extremely expensive since the FDA required licensure in 2009, that costs over \$1 million dollars initially and hundreds of thousands of dollars annually.

Cord blood banks only receive money for cords that get used for patient care.

St. Luke's Organization in Kansas City used to their own cord blood program and had long term storage. Now they are set up as a more of a triage center. They collect cord blood or surround participating hospitals collect cord blood and it is sent to St. Luke's, then sent to the St. Louis Cord Blood Bank. St. Luke's now serves as more a "triage center" for cord blood donations.

St. Louis Cord Blood Bank started due to a transplant physician had a child needing a transplant. Through research he found cord blood was an option to save his child's life. He did all of the leg work to get the blood bank up and running.

Effective 11/1/17, participating hospitals are decreasing from 28 to 8.

In the mid 90's, cord blood donation was new and there was no inventory established yet. They were only being used for pediatric transplants. Over time it was realized cords could be used to treat adults. 50-60% of cord blood donations that were processed at that time did not meet criteria for donation. Now cord blood banks due to federal regulations are only able to process about 10%.

Banks are needing bigger unit with larger cell counts. There is competition amongst units for the biggest and best units.

A pilot program was launched nationwide to encourage cord blood donation. They were only able to bank 1.5% of units collected. This pilot program did not last long, it was not feasible.

Units need to be to the cord blood bank within 30-40 hours after delivery.

There is a need to replenish the existing cord blood banks and place few cord blood banks strategically nationwide. STLCBB is merging with another cord blood bank in the coming months

Haplo transplants are becoming popular. A lot of relapse are noted with them. Preterm babies there has been proven benefit to delayed cord blood clamping. Full term babies there has been no proven benefit to delayed cord clamping. Has had a huge impact on the cord blood world.

Appendix D

Attempted email and telephone correspondence with Dr. Carl Weiner FACOG. K.E. Krantz Professor and Chair Associate Director, Institute for Reproductive Health and Regenerative Medicine Director, Center for Developmental Origins of Health and Adult Disease at the University of Kansas Medical Center.

September 27, 2017:

Hi Dr. Weiner,

My name is Kellee George and I am currently an employee and faculty here at KU. I am in my last semester finishing my master's degree and am completing a practicum regarding cord blood donation. I have a few questions regarding cord blood donation here at KU and why we are not a participating hospital to collect for public cord blood banks. If you have any time at all to speak I would greatly appreciate your time. Please let me know.

Thank you,

Kellee George