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The Implications of Federal and State Laws Regarding the Storage, Use, and Donation of Cord Blood

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The Implications of Federal and State Laws Regarding the Storage, Use, and Donation of Cord
Blood

by

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A thesis submitted in partial fulfillment of the requirements for the Honors
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ABSTRACT

Cord blood storage, use, and donation is a rising trend. The cells found in the blood of the umbilical cord can be used to treat various life threatening diseases. It has been shown that the use of these cells can produce results that are just as effective as a bone marrow transfusion.

The yield of cells from a sample of cord blood is not always enough to be effective for a transfusion in adults. As such children are the primary demographic for cord blood transfusions. For this reason, prospective parents are taking notice of the trend.

Currently, federal and state statutes are set up to promote the introduction of cord blood use. What current law fails to recognize is that cord blood is in use and has a lot of potential. For this reason laws need to be updated to better reflect the current market. A more proactive approach needs to be taken to better utilize the potential of cord blood.

As the trend is popularized there is an increasing notion that informed consent is not uniform enough, state laws do not adequately promote cord blood use, and there is a discrepancy between the standards of public and private cord blood banks. In order to improve upon these issues it is necessary to review the laws that are currently in place and then expand upon them so that they better reflect the storage, use, and donation of the blood. If umbilical cord blood becomes more than medical waste, as is projected to happen, then there is a need for an adequate legal foundation that protects the interests of all parties involved, especially prospective parents.

DEDICATIONS

To my mentors, Abby Milon, Kathy Cook, and Latarsha Chisholm, thank you for your guidance and your willingness to explore this new topic with me. I appreciate your support.

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INTRODUCTION

It is estimated that there is a birth every eight seconds in the United States (United States Census Bureau, 2014). In 2010 alone there were 3,999,386 births documented (Births and Natality, 2014). Each birth that occurs without complications allows for the collection of umbilical cord blood which can be stored and, if kept properly, used later to treat many diseases (Verter, 2013).

Umbilical cord blood transplants began in 1988. The first documented treatment was provided to a patient with Fanconi Anemia (Ballen, 2013). This marked the start of the transition from considering umbilical cord blood waste to being potentially useful. This transition gave rise to banking the cord blood.

Cord blood use and banking has gained the attention of prospective parents. This trend has been sparked because of the ability to use the stem cells from cord blood to treat certain diseases such as leukemia, lymphoma, and other immunodeficiency diseases (Mohapatra, 2013). Umbilical cord blood contains stem cells which can develop as other cells in the body, which is why it is able to be used and is an effective alternative to bone marrow transplants (Pinch, 2001). The stem cells in the umbilical cord blood, when used in a transfusion, basically take over the defective cells in a sick patient and begin to produce healthy cells (Pinch, 2001). It is important to note that umbilical cord blood stem cells are not the same as embryonic stem cells. The cord blood trend is a separate and less politically charged entity.

Embryonic stem cells are derived from an embryo for the sole purpose of retrieving cells to provide a remedy to an illness and then typically discarding the embryo afterwards. Unlike

embryonic stem cell collection, cord blood collection derives from the umbilical cord being clamped and the blood then being extracted. The collection process is painless for both mother and child. If done properly it can yield stem cells suitable for transplants (American Pregnancy Association, 2014). Aiding in the rising trend of cord blood use is the fact that it is a painless procedure and that the cells are readily available for use after collection and screening.

Although the use of stem cells from cord blood is possible, at this point transplants are primarily performed in younger children. Cord blood transplants are primarily only done in children due to the fact that a sample of cord blood does not always contain enough cells to be considered an effective treatment for adults (Moninger, 2006). Considering children are the primary audience it makes sense that parents are the target of marketing strategies employed by public and private blood facilities.

Generally, the options available for the expectant parent are to either store the cord blood in a private blood bank, donate the blood to a public cord bank for use in research or as a potential treatment for an unrelated individual, or to discard the blood as medical waste. While discarding the blood is still common practice, medical research is advancing in this area of study which is why other, more useful, options are becoming available to parents.

Despite the primary audience being children, the medical community is still researching ways to improve transplant availability to adults. A large reason for using stem cells retrieved from the umbilical cord is that the cells are immature which reduces the necessity of having a closely matching donor (Chen, 2013). In an effort to improve research, especially to help increase availability to adults in need of a transplant, and to expand the amount of cord blood available for transplants the federal government enacted the Stem Cell and Therapeutic Research

Act of 2005. The enactment of the Stem Cell and Therapeutic Research Act really focused in on the potential of cord blood.

The law is aiming to match the needs and demands set forth by the increasing trend for the use of cord blood. As this is a newer trend the storage, use, and donation of cord blood has been met with many questions and concerns, especially from a legal perspective. Research in this field is advancing and as a result the laws and regulations regarding umbilical cord blood are also evolving in an attempt to ensure the protection of the market and consumers of cord blood.

BACKGROUND

While the law currently covers the general use of cord blood it cannot feasibly address every issue that is cropping up as a result of increased use. As storage, use, and donation of cord blood expands, there is a prime opportunity to ensure sustainability of resources, accountability of those involved with the storage of specimens, and the uniformity of collection and consent.

Laws regarding the storage, use, and donation of umbilical cord blood can be found on a federal level and on a state level in most states (Folger, 2008). Congress initiated interest in the use of cord blood when they enacted the Stem Cell and Therapeutic Act of 2005. From there the Food and Drug Administration became the primary federal regulating agency for the use and storage of cord blood.

The FDA has proposed regulations and guidelines for both public and private cord blood storage for facilities within the United States and for those which are outside the United States but distribute the cord blood within the United States. (Wall, 2010). The Food and Drug Administration also outlined the steps necessary to be able to use cord blood in a transplant. This framework provides the basis for the workings of public and private facilities.

On a state level, most states have enacted some type of law regarding cord blood. The legislation does not generally provide in depth regulations, but are more concerned with ensuring that parents receive information about their options for the cord blood (Parents Guide to Cord Blood, 2013). The primary goal of the state laws is to inform parents, rather than protect them should something go wrong when storing, donating, or using cord blood for a transplant. Information is great, however, this falls short when the information is not consistent and is not mandated.

Other issues being discussed include who legally owns the cord blood and what constitutes informed consent. Both of these concerns are important for future liability issues that can arise. Informed consent topics are relevant at the moment because for the most part "consent policies and practices are not uniform" (Vawter, 2002). From a business perspective this can detract from operations. From a parental perspective this can cause discrepancies between expectations and actuality.

Cord blood storage, use and donation is becoming an important component of the medical field. Like many new trends the law must also change to meet new demands. The subsequent sections will outline some of the current federal and state laws as they stand now and how they can be improved upon. Additionally, review of public and private banking practices, and the concerns that arise from each will also provide a basis for where the law needs to address growing concerns.

FEDERAL LAW

Stem Cell and Therapeutic Research Act of 2005 and the Reauthorization Act of 2010

The Stem Cell and Therapeutic Research Act of 2005 was the initial congressional interest in the use of cord blood as a means for research and for use in patients with life threatening illnesses. The bill was enacted as Public Law 109-129 on December 20, 2005 after being signed by President George W. Bush. The purpose of the bill was to “provide for the collection and maintenance of human cord blood stem cells for the treatment of patients, and to amend the Public Health Service Act to authorize the C.W. Bill Young Cell Transplantation Program” (Govtrack, 2005).

The C.W. Bill Young Cell Transplantation Program was designed to expand on the Stem Cell Act to increase the availability of stem cells derived through bone marrow and cord blood. The focus for the program is on patients who require an unrelated donor for their transplantation. Finding an unrelated donor can be an arduous task and this program attempts to streamline information, to effectively communicate with patients, and to increase the odds of finding a suitable donor (United States Department of Health, 2014).

The Stem Cell and Therapeutic Research Act was an important step by Congress, allowing for increased funding for research and availability of cord blood for research and transplant purposes. The goal was to collect and maintain 150,000 new units of cord blood. This baseline number would allow for greater research and transplant options. In turn, it also allows for a larger resource should there be increased demand.

If samples that are received are not viable for transplantation the bill further stipulated that they should then be available for “peer-reviewed research” (Govtrack, 2005). All of the provisions in the bill were made to help provide more options for patients and to gather data that can be used to show the effectiveness of cord blood. Additionally, furthered research can improve the procedures necessary to increase collection and ultimately benefit adults as equally as children.

The Stem Cell and Therapeutic Research Act of 2005 is important because it is the first step in ensuring a patient has the option to receive a transplantation if necessary. Having a set baseline will allow for availability of supply in relation to demand. This bill was effective in achieving the outlined goals at the end of its prescribed term and for this reason was reauthorized in 2010 by President Barack Obama.

The Stem Cell and Therapeutic Research and Reauthorization Act of 2010 maintains the same premise of the 2005 Act. However, it does expand upon the initial goals of units of cord blood to be collected. Additionally, it provides the possibility for qualified cord blood banks to extend their initial contract lengths.

This is an important addition so that the banks can continue their work in research and finding donor matches. In addition, funding for qualified banks is more clearly defined in this bill and an extension of funding was granted through 2015 (Govtrack, 2010). Clarification is necessary so that there is an understanding of who qualifies and how they are funded during the prescribed term lengths.

Ultimately both the 2005 and 2010 bills were concerned with availability of resources. Availability of cord blood allows for research and transfusions and an allocation of funding helps

solidify that research can continue. As cord blood use is still an emerging trend there needed to be a two-fold “insurance” for resource availability.

Regulating Public and Private Cord Blood Facilities

The Food and Drug Administration is the main regulating agency for both public and private cord blood facilities. They have procured a framework that enables the process of storage and use to be possible. While basic blood and tissue practice must be followed, the involvement of the FDA in the public and private facilities varies.

When cord blood is donated to a public facility the blood is classified as a drug. Cord blood falls under the drug classification because of the therapeutic benefit derived through a cord blood transfusion. For this reason when the blood is donated and further used in an unrelated recipient the public cord blood bank will need to apply for a licensure.

Typically public cord blood banks will have to have the cord blood “licensed under a biologics license application” or the cord blood will have to go through an “investigational new drug application” prior to being used for treatment in unrelated patients (Food and Drug Administration, 2012). This is an important regulatory establishment for the protection of the patient. By filing for the licensure the blood must go through testing to help reduce risk of translating disease. Approval for a biologics license and an investigational new drug application can vary. For an investigational new drug application though there is usually a thirty day waiting period prior to approval (U.S. Food and Drug Association, 2014). If the application is submitted promptly upon receipt of the cord blood this time frame is suitable because the need for that exact specimen may not be present yet.

Public donation facilities are held to a slightly higher standard than the private counterparts. Private donation facilities must comply with standard blood and tissue practice. This includes testing for infectious diseases. However, they do not have to go through the same licensure process. The cord blood is still considered a drug but because the private facility stores the blood for personal use the licensure is deemed unnecessary. Even if the specimen is used for a family member, the familial relation supersedes the need for approval prior to use. This is not to say though that private facilities are not regulated.

In addition to standard practice, private banks must also follow other regulatory provisions. This includes establishment registration, donor testing, and compliance with current good tissue practice regulations (Food and Drug Administration, 2012). The framework set forth by the Food and Drug Administration is a basic skeletal model that allows for the practice of using cord blood to be established.

STATE LAW

For the most part, the purpose of state legislative acts is to inform expectant parents about their options for cord blood. In the majority of states the legislative acts “mandates/encourages physicians to educate expectant parents about all forms of cord blood banking” (Parent’s Guide to Cord Blood, 2014). There are some states however that have notable differences in their provisions.

Notable Differences in State Legislative Acts

There are currently twelve states that have varied the approach to the cord blood trend. It is important to note these differences because they either go beyond what most states have enacted, or they are entirely silent on the issue. Where this plays a key role is in the overall lack of uniformity which can cause disruptions in information output and what standard practice is considered. Highlighted here are a few with the most distinguished differences in their legislative acts.

The first few states mentioned herein address the public awareness aspect of promoting the cord blood trend. Virginia and Florida address the same concerns as the majority of states in that they encourage physicians to talk with parents. They however address the concern of what information to provide because they “explicitly endorse the use of educational materials from Parent’s Guide to Cord Blood Foundation” (Parent’s Guide to Cord Blood, 2014).

Florida has implemented within its legislation that, “The Department of Health shall make publicly available, by posting on its Internet website, resources and an Internet website link to materials relating to umbilical cord blood which have been developed by the Parent's Guide to

Cord Blood Foundation, Inc.[...]" Fla. Stat. § 381.06016 (LexisNexis 2014). Virginia has nearly identical statutory language which is that, "[...] the Commissioner shall make publicly available, by posting on the public website of the Department of Health, resources relating to umbilical cord blood that have been developed by the Parent's Guide to Cord Blood Foundation[...]" Va. Code Ann. §32.1-69.4 (LexisNexis 2014). Having states specifically endorse certain outlets for information is a step towards standardization. Having one or two specific sources for information adds to the overall ease of research that parents must conduct and ensures that everyone is receiving either the same or relatively the same information.

Maryland's legislative act regarding distribution of information is limited. They merely prescribe that "The Department, in consultation with obstetricians, the Maryland Hospital Association, and interested groups, shall develop educational materials concerning the values, uses, and donation of umbilical cord blood [...]" and that "[e]ach obstetrician and hospital that provides obstetrical services shall distribute the educational materials [...] to pregnant patients" Md. Code, Com. Law §19-308.7(f)(1-2). While they do not necessarily have one source of information they are notably different because they require that the educational materials be distributed to all pregnant patients.

Wisconsin and New Mexico are important to mention as well. In their legislative act they state that physicians are encouraged to inform parents about public donation options. This is an important contrast because States typically encourage a balanced release of information between public and private options. Wisconsin's statute states that "the principal prenatal health care provider of a woman who is known to be pregnant shall, before the woman's 35th week of pregnancy, offer her information on *options to donate*, to an accepting and accredited cord blood

bank, [...], *if the donation may be made without monetary expense* for the collection or storage to the woman” Wis. Stat. §146.343(2) (2014). The last part concerning monetary expense would further prohibit discussion of most private storage options. New Mexico has similar language though they do not expand on the ‘donation only’ mentality by including a monetary expense portion to the statute. Their statute states that “all health care providers providing health care services to a pregnant woman during the last trimester of her pregnancy, which health care services are directly related to her pregnancy, shall advise her of *options to donate* umbilical cord blood following the delivery of a newborn child. [...].” N.M. Stat. Ann. § 24-27-4 (LexisNexis 2014). Considering umbilical cord blood use is a new practice it is reasonable for a state to focus on public donation options as public donation can help expand research opportunities which can further develop cord blood uses.

Arkansas includes in their legislative acts a provision that allows individuals to contribute tax refund dollars so that an establishment of a public and/or private cord blood bank can be created. It is part of their Newborn Umbilical Cord Blood Initiative and Ark. Code. Ann. § 26-51-2508 authorizes a “tax check-off program” to be created that allows for a “means by which an individual tax payer may designate a portion or all of his or her income tax refund to be withheld and contributed [to the initiative fund].” Very few states offer this making it a comparatively progressive idea.

Recognition of a need is important but means nothing if there is not a way to support it. Arkansas has taken initiative to provide funding sources outside of the typical allocation of state funds. This offers a way for the budget to be increased without reducing funds from other parts of the state budget. Of all the aforementioned states Arkansas is one of the few that strikes a

balance between recognition of potential and implementation of means to explore the potential. Most states right now are not at that point.

Mississippi: Taking the Use of Cord Blood One Step Further

On April, 23, 2013 the state of Mississippi announced the approval of House Bill 151 which requires physicians and midwives to collect the cord blood of a child born to a mother under the age of 16 who fails to name the father of the child. The state is stating that in this type of circumstance that there is a suspicion of statutory rape. The cord blood is to be collected so that a DNA test can be run to determine the father and possibly pursue a statutory rape case against the father (Hess, 2013).

In the statute it is stated that “[w]hen a minor who is under sixteen (16) years of age gives birth to an infant, umbilical cord blood shall be collected, if possible, in accordance with rules and regulations adopted pursuant to this section if it would be reasonable to suspect that the minor's pregnancy resulted from a sex crime against a minor” Miss. Code Ann. § 97-5-51(5)(a)(ii)(LexisNexis 2014). Additionally they provide that “[a] health care practitioner or health care facility shall be immune from any penalty, civil or criminal, for good-faith compliance with any rules and regulations adopted pursuant to this section” Miss. Code Ann. § 97-5-51(7)(LexisNexis 2014). While the statute prescribes penalties for those convicted based on the evidence of the cord blood it is silent in regards to whether there is a penalty if the cord blood is not collected.

The theory behind this statute is that through its enactment the number of teen pregnancies will be reduced in the state. While the potential to reduce the number of teen pregnancies is plausible, there are associated legal concerns through the enforcement of the

statute. For starters, the mother has the right to not name the father. Additionally, taking possession of the cord blood would invade upon the privacy of the mother and father. If the state steps in as it plans to there is an infringement on rights that the mother and father both should have.

In addition to privacy rights, the mother, despite being a minor should still have the right to retain possession of the cord blood for private banking or for donation to a public bank. Based on the statute, suspicion of statutory rape is enough to require collection of the cord blood for use in a paternity test. If the pregnancy raises suspicion of statutory rape, is the mother still required to forgo her right to retain possession of the cord blood so that the state can identify the father?

On a more practical level, there is a question of whether testing on the cord blood will destroy the possibility of the child or public being able to use the cells. Cord blood stem cell collection is still a relatively new practice. As of now the number of stem cells found in the cord blood is low and as such the yield of stem cells can traditionally only provide benefit to children.

If the state steps in and requires testing of the cord blood can they guarantee that the full potential yield of cord blood stem cells is still achievable? If it is not, this may reduce the opportunity for the child to receive an effective therapeutic reaction to the transfusion. Assuming the child could have used his/her own cord blood said child may now need to rely on a public donation facility rather than his/her formerly viable cord blood specimen. In this case the child is at a greater disadvantage.

In addition to these issues, it is still widely debated whether the cord blood belongs to the child or to the mother, but there is yet a mention of the cord blood belonging to the state. The only time the state can really claim things removed from the body is if it is to be regarded as

medical waste. For this reason is it even ethical that the state mandates the collection of the cord blood? The state certainly does not own the cord blood or truly have a vested claim to it, so the state dictating what must be done with the cord blood in this situation seems contrary to the rights of the mother. This statute in particular is troubling, especially if other states begin to follow Mississippi's lead prior to an establishment of the true extent that the provisions can be applied.

PUBLIC VS. PRIVATE CORD BLOOD BANKS

Unlike embryonic stem cell testing, umbilical cord blood is fairly non-controversial. The largest debate surrounding cord blood is the issue of storing it privately or donating it publicly. Each situation has its merits but very few are willing to concede that private storage is a better option.

Public cord blood donation facilities are a benefit to society as a whole. This is because cord blood donated publicly have the potential to be used for any HLA matched recipient. Private donation facilities on the other hand serve an individualized need. The following sections will outline the standard operation of public and private cord blood banks and whether private or public cord blood banks are a better option.

Public Cord Blood Banks

Public cord blood banks allow for the collection of umbilical cord blood that can later be used for unrelated patients in need of a transplant. The benefit of public cord blood banks is that there are more samples to choose from in the collective pool. This means that patients with life threatening diseases have access to more viable options for their transplants.

The purpose of public donation facilities is to enable research and further to provide a diverse selection of specimens for transfusions. Diversity of blood specimen in a public facility is important so that every individual theoretically has the possibility of finding a matched donor. Public cord blood banks look to the collective good for society.

A parent has the option to donate the cord blood of their child to public banks, but this option is not always discussed with parents. Many prominent organizations, such as the

American College of Obstetricians and Gynecologist, (furthermore ACOG), support donation of the umbilical cord blood.

In a statement released in February 2008, the ACOG advised that “physicians should give balanced information to their pregnant patients who are considering cord blood banking, presenting both the advantages and disadvantages of public vs. private cord blood banks” (ACOG, 2008). They also recommended “that physicians disclose that there is no reliable estimate of a child's likelihood of actually using his or her own saved cord blood later” (ACOG, 2008). While the ACOG states that they are not for or against cord blood banking, it is reasonable to assess that based on the recommendations made they are more inclined to public storage options.

Public donation is important in order to further study the benefits of cord blood. However, donation is not always a feasible option. Firstly, there is a lacking number of public donation collection sites. Not every hospital has the resources to collect the cord blood on behalf of a public facility. According to Be the Match, only twenty-four states have hospitals that partake in the collection of the umbilical cord blood for public donation. Of those twenty-four states, half have five or less participating hospitals that will collect the cord blood for public donation. Due to the lacking availability of participating hospitals, parents will likely have to travel farther distances to a hospital if they wish to donate the cord blood. There are a select few public donation facilities that will accept mail-in donations, though typically they only accept donations from residents of the state in which the facility is located.

There is a quick turn-around time for donation. The cord blood needs to be properly stored to remain viable. As such, the donation facility in which arrangements have been made to

donate to typically need to be notified within a few hours after the cord blood has been collected so that a courier can be sent out within the next day. This quick turnaround is necessary so that the blood remains properly stored and is able to be processed.

Parents will have to do a lot of research and preparation if they choose to proceed with donation. An expectant parent may not have the time, either they are too far into their pregnancy or for other reasons, or energy to research and plan. This is an added stress to the parents and can discourage prospective donors. If they do proceed with donation though there is generally no costs associated with the donation. It is possible that the collecting physician may charge for the collection of the cord blood, but the donation facilities generally do not charge for a donation.

Second, from an operations standpoint the costs associated with a public donation site are high. There is no cost for the parent to donate the blood which means that the public cord blood facility bears all of the costs. They “pay for the collection, testing, and storing of umbilical cord blood” and do not recoup their initial expenses until a unit of cord blood is used by a future recipient (Health Resources and Services Administration, 2014).

A unit of cord blood can run upwards of \$30,000, but this expense can be covered by a patient’s insurance. This means that even when a sample is used there is not a guarantee of any immediate payment. A further look into the numbers shows a logical reasoning for limited public donation facilities.

It is estimated that a public bank will incur costs between \$1,500 and \$2,500 per unit of cord blood collected. These numbers are prior to licensure requirement costs. Typically, the reimbursement by the federal government is only about \$1,282 of the initial incurred costs.

These numbers alone show why operating a public bank can be costly and therefore there is slow progress in implementing more public cord blood banks (Verter, 2013).

When costs are high, and incurred without guarantee of payment or reimbursement there is a difficulty presented for the implementation of these storage facilities. The business model itself is counterproductive to the overall goals. While public cord blood banks are highly regarded, and are inherently the goal of the Stem Cell and Therapeutic Research Act, they are not a prominent option at the moment due to the high funding costs required to operate and maintain the facilities in accordance with current FDA regulations.

Private Cord Blood Banks

Storing cord blood in a private bank is often times the option that expectant parents are bombarded by. Private cord blood banks are costly to store the cord blood in. To segue around the high costs, operators of private blood banks capitalize on the emotional vulnerability of expectant parents.

Many private cord blood banks have persuasive advertising which can easily lead expectant parents to believe that they are providing “insurance” for their child by storing the cord blood. When presented with the idea that their child can be cured from leukemia, lymphoma, and other diseases there is little hesitation for making the decision for storing the cord blood. When looking at such advertisements, parents are lulled into believing that money is not an object when it is possible to save their child from potential life threatening diseases.

What parents often do not realize though is that the claims made by private cord blood banks are over exaggerated. In fact it is estimated that the likelihood of a child using his/her own cord blood is less than a 0.04 percent chance (Mohapatra, 2013). In addition to this it is also

possible that should the child need the cord blood he/she will not be able to use it because the genetic defect causing the illness is present in the cord blood sample as well (Mohapatra, 2013).

As mentioned in an article released by Parents.com, a woman stored her child's cord blood in a private bank. When she learned that her son was diagnosed with a potentially fatal disease, and one that using the cord blood would be effective against, she requested that the stored blood be used for treatment. What doctors ultimately told her was that the umbilical cord blood could not be used because what was causing the illness in her child was found in the genetic material of the blood, meaning that even if a transplant occurred it would not help to eradicate the illness (Moninger, 2013). Up until that point she was unaware that this could happen and did not find out until after having stored the cord blood. This is not an uncommon occurrence.

Misleading advertising is not the only problem that parents face when storing the cord blood in a private bank. Issues of failed health inspections and lack of maintenance of the cord blood units, mislabeling of blood units and other discrepancies contribute to a child not being able to use the cord blood when it is needed.

In these situations one may ask how it is possible for the privatized cord blood banks to continue in this manner. The simple answer is that they should not be able to. The Food and Drug Administration does have regulations that the private banks are to follow. They require that private banks follow current FDA regulations "including establishment registration and listing, donor screening and testing for infectious diseases (except when used for the original donor), reporting and labeling requirements, and compliance with current good tissue practice

regulations” (FDA, 2015). Where the problem lies though is that some of the privatized cord blood banks simply do not follow the regulations.

The Food and Drug Administration will conduct health inspections and ensure that current practice standards are met. If they are not being met they can force the shutting down of the private banks, but by the time it reaches that point the blood bank in question is likely already severely noncompliant. This can mean anything from the cord blood bank failing to maintain proper temperatures in the facilities, failing to maintain a clean facility, or abandoning the facility altogether. What this causes is the inability to use the cord blood that is stored in such facilities because the samples will have been compromised. It is for the compilation of aforementioned reasons, (low odds of personal use and noncompliant facilities), that many high ranking health organizations, such as the American College of Obstetricians and Gynecologists and the American Association of Pediatrics are hesitant to recommend the utilization of private storage facilities.

While there are issues that face private banking, Congress realizes that private storage is as much a part of the cord blood trend as public donation is. As such, H.R. 3673, the Family Cord Blood Banking Act, was introduced on December, 5 2013. The purpose of this bill is “[t]o amend the Internal Revenue Code of 1986 to treat amounts paid for umbilical cord blood banking services as medical care expenses” (Congress.gov, 2013).

Providing the incentive of a tax break would be a benefit to the individual who is storing the cord blood. There are high costs associated with private storage so being able to write it off as a medical expense could help mitigate this. However, because cord blood use is still an emerging practice, the main focus right now should be on public donation. The purpose of the

Stem Cell Therapeutic Act of 2005 (2010) was to increase the donated supply of cord blood and other stem cell specimens. As of this writing there is not a tax incentive for donation of cord blood, nor is there a proposed tax incentive for donation of the cord blood. So, it is very possible that people will further consider storing blood in a private bank over donating to a public bank. This could have a negative effect to the initial goal of the Stem Cell and Therapeutic Act of 2005 (2010). This tax incentive proposal would be better suited for a time when the benefits of private storage begin to either equal or outweigh those of public donation. Until that point though efforts should remain concentrated on public donation.

OTHER LEGAL CONCERNS REGARDING CORD BLOOD

The main controversy surrounding umbilical cord blood is the debate over private v. public storage. This is not the only issue that has arisen as a result of cord blood use. Ownership rights and informed consent are also prevalent. It is also important to shed light on the privacy rights of the mother and child.

Ownership of Cord Blood

Ownership rights is a pressing issue for both public donation and private facilities. In the public sector the mother must consent to donation of the umbilical cord blood. If the mother donates the blood then there is an expectation that she does, at one point, have ownership of the cord blood. It is common thought that at the point of relinquishment that the limited property interest in the blood is relinquished.

This is an important note because if the donation facility uses the cells in a manner that the mother was not anticipating a court will likely deem that the mother has no interest in the blood and therefore the facility is within its rights to do with the sample as they please without the full consent of the mother (Kirchenbaum, 1997). It is important for a mother to understand that after donation she no longer has a claim to the umbilical cord blood. If her child requires the blood at a later date the sample may not be available.

In the private sector ownership rights stem from whether the mother or child owns the blood. The arguments made are that the umbilical cord and the blood within are entirely a part of the baby as it is growing and developing deeming it the child's property. However, adult stem

cells can be found within the cord blood and that once the cord is cut it is the mother's property (Petrini, 2010).

In an effort to answer the question of ownership a typical private cord blood agreement will dictate that the mother is engaging in the contract on behalf of the child, acting as an agent. Once the child reaches the age of majority it is deemed that control of the sample is appropriated to the child. For example, in a contract found through Cryo-Cell international, the language of the agreement states that "Cryo-Cell does not have a contract with the child" but that "When [the] [c]hild has reached the age of 18, [the] [c]hild has ownership claims [...]" (Cryo-Cell, 2015). This would suggest that the mother is acting as an agent on behalf of the child and that the child actually owns the specimen.

Where this becomes controversial is if a sibling needs to use the cord blood for a transfusion. Depending on the language of the contract, the mother may not have full authority to allow the cord blood to be used for a transplant in a sibling. It is generally not specified if the mother has any right to the blood at all other than to ensure that it is stored. This would be the point in which the court would be called to step in for the determination of whether the mother has the ability to consent to the treatment.

While there is not current case law that focuses on the consent of cord blood transfusions in siblings there is plenty regarding organ transplant. When it comes to an organ transplant and the donor is either a minor or incompetent the parents may not have authority to consent to the transplant. When left to the discretion of the court they will look for signs of whether the transplant will benefit the donor and donee. They take into consideration familial ties and bonding, and if they do not see that there are strong ties they will likely state that the operation

should not take place (Kirchenbaum, 1997). For example, *Strunk v. Strunk* 445 S.W.2d 145 (1969) was a case that came out of the Court of Appeals of Kentucky. A mother and father had two sons. Tommy Strunk was considered to be legally competent and was suffering from a fatal kidney disease. The other son, Jerry Strunk was 27 and considered to be incompetent, having the mental age of a six year old. However, he was a donor match for the ill brother and the parents petitioned the court to allow them to act on the son's behalf so that the kidney transplant could occur. The court looked to the brother's relationship and determined that if Tommy were to die it would be more traumatic on Jerry than if he were to undergo surgery for the kidney transplant. It was the emotional attachment between the brothers that ultimately persuaded the court to grant the parent's the right to act on behalf of Jerry Strunk. Other cases have since followed citing to *Strunk v. Strunk* when the determination for parental consent for a procedure on behalf of a minor or incompetent child is needed.

If cord blood transplants between family members follows this same schematic it would be reasonable to assume that the parents do not have authority over the cord blood sample that they are merely ensuring its protection until the child it was retrieved from reaches the age of majority. It may be possible them to make decisions if they are regarding the child that the sample was taken from, but beyond that it may be a matter for the courts to resolve.

If the aforementioned holds regarding cord blood transfusions then it would also be reasonable to assume that there are limited property rights associated with the cord blood. This presents another problem. If there are limited property rights then no one actually owns the cord blood and the questions regarding medical decisions remain unanswered.

If for arguments sake the mother is the owner, then many of these questions are foregone. The mother can consent to the use of the cord blood for medical treatment in a sibling without issue. Considering that the purpose of storing the blood is for potential later use, this only adds to the overall benefit of storing the blood. Additionally, if it is deemed that the mother owns the blood then there is little recourse that can occur if the mother chooses to donate the blood.

To the contrary, if it is the child's property then there can be concern that by the mother donating the blood for public use there is a "contradiction to the principle of the autonomy of the child and the donation is being done without the child's knowledge" (Petrini, 2010). What this means is that, while the mother has guardianship of the child, the child in the future may not approve of what the mother has done with the cord blood. This line of thought can ultimately unravel the entire prospect of donating to a public cord blood bank.

These questions call for clear legislation regarding the potential issue of ownership. What can be defined is whether ownership rights should be established and who then owns the blood. If these concerns are mitigated through legislation then cord blood use is one step closer to operating at a more efficient level.

What Constitutes Informed Consent

By definition, informed consent is the "consent of a patient or other recipient of services based on the principles of autonomy and privacy" (Medical Dictionary, 2015). For the purposes of cord blood collection it is important to keep this in mind. While important, it can be hard to reconcile textbook definitions with practice.

A consent form must be signed by the mother in order to either donate or store the cord blood for future use. In terms of donation, the form traditionally states that the donor understands how the collection process works and that there are issues that can arise through the collection and use of cord blood. Typically an expectant parent should be informed and give consent prior to “the onset of labor when the donating mother is able to fully understand what is involved and is not distracted or under anesthesia” (AABB, 2014).

It is determined that informed consent should take place at some point during the third trimester prior to labor. This however is not a steadfast rule. When donating publicly, the timing of informed consent is important. Once the donation is made any claim to the blood is relinquished by the mother. The mother needs to be fully aware of what she is doing when donating the sample and understand that once the donation is made the cord blood may not be available to her any longer. This is important so that if there is ever a dispute regarding whether the mother was made fully aware the public facility is covered and allowed to continue to operate.

In an ideal situation consent will be rendered prior to labor. However, this is not always possible. If a mother has stated that she would like to donate the cord blood but goes into labor prior to giving consent, the donating mother can sign a “‘mini’ consent form allowing collection of the cord blood during labor, and administrators will “meet with her after she recovers from the delivery to educate her and obtain full informed consent” (Kurtzber, 2005).

Unlike public donation, private cord blood banks allow the donating mother to sign an agreement and consent form at any time. Typically they will be signed prior to labor but this does not have to occur in order for a storage facility to accept the agreement and consent form as

valid. So long as everything is in order prior to storage the mother has some time to consider her options.

There are additional challenges that informed consent brings outside of timing. The donating mother needs to be aware that by donating the cord blood she herself, and the cord blood, will need to be tested so that there is a documented medical history. This is an extensive testing for the presence or pre-disposition of disease. Any genetic information garnered from the testing is attached to the sample and kept for the record. Testing of the cord blood is also done by a private facilities. The information is gathered so that it can be determined whether the child will be able to use the specimen. Due to the extensive medical and genetic data collected through the testing of the cord blood it is imperative that a consent form addresses what the data is going to be used for.

The aforementioned tends to be the largest point to a consent form but certainly not the only. It is also used to ensure that the donating mother understands that there are not currently any studies that test the “long-term viability of cryopreserved cord blood” given that the use of cord blood has not had a long history (Martin, 2011). The mother also needs to know that regardless of whether she would like to donate or store the cord blood it is possible that collection may not occur if complications during labor occur.

Having informed consent not only protects the mother, but it also protects the hospitals along with the private and public cord blood banks. Having a lack of standardization in how and when informed consent is collected gives rise to the possibility of a variety of law suits. A donating mother may feel cheated, or that she did not have enough, or adequate, information to fully realize what she was doing by choosing to donate or store the cord blood.

This could have significant backlash on the hospitals and cord blood banks. Bad publicity can reduce the amount of willing donors and consequently the number of available, and useable, cord blood units. In addition to the potentially fewer donations, a public bank may not have the means to financially endure backlash from a donor. This is especially so if there is a substantial claim. A private storage facility is less likely to have the same backlash because the terms of agreement outlined in the contract tend to reduce overall liability for the private storage facility.

Who Can Give Informed Consent?

Timing of consent, and the information presented in the consent form are important. Another consideration that needs to be made though is whether a mother's consent alone is sufficient. The argument is that the father may need to consent to either donation or storage of the cord blood depending on the method of extraction.

Cord blood can be collected either in utero or after the placenta is outside the uterus. It is believed that "if the cord blood is removed while the placenta is still in the uterus, generally the mother's consent is sufficient because it is an extension of her body" however, "if the cord blood is removed after the placenta has been taken from the mother's uterus, [...], an argument could be made that the father's wishes are also relevant [...]" (Meyer, 2005).

A mother and father both have rights in deciding how best to ensure the well-being of their child. If a father's wishes were to play a role there is now another factor that a consent form must make consideration for. As previously mentioned, the purpose of the consent form is to protect both the patient and the banking facility. If it is deemed that they have not obtained adequate consent then there are consequences that will result.

Timing once again plays a role in informed consent conditions. Additionally, determination of whether both parents must consent to the collection of cord blood can tie into ownership issues. If the mother owns the blood then it would be reasonable to believe that her consent alone is adequate. If however the child owns the blood, or even if it is jointly owned between parents, then it would be reasonable to believe that the mother and father must both consent to collection. Ownership and informed consent issues have a cyclic nature in which answers to one issue can help shed light on the other.

In the Interest of Privacy

Questions regarding privacy are often raised when donating the umbilical cord blood. Extensive medical tests are performed to determine whether the mother has a disease or is pre-disposed for disease. Additionally, a mother must fill out a medical history questionnaire in order to donate. All of this information is linked with the donated specimen. The information collected is considered to be sensitive and therefore it is understandable that the mother would have concerns over maintaining her, and her child's, privacy.

In order to maintain privacy sensitive medical data is encrypted and a number is assigned to the cord blood specimen. Names are never attached. A recipient for the donation would not know the name of the mother or child, only that the blood was an HLA match. Likewise, if a specimen was utilized for research, the researchers would not have access to identifying information but only the specimen and information necessary to carry out the research.

As medical practices advance however, it may be necessary to construct new methods of ensuring privacy. There are large amounts of genetic information associated with the cord blood.

If medical practice allows the potential of constructing a visual of the donor based on the information then current privacy practices will fall short.

Privacy standards have been updated and enforced by the Health Insurance Portability and Accountability Act, (furthermore HIPAA). The purpose of HIPAA is to make sure that patients are granted their privacy and that health information is not released unnecessarily. This is important for cord blood donation and storage because of the genetic and health information associated with the specimen. It is important to note though that HIPAA may not apply to every organization. While it is typically enforced for both storage and donation practices it is not enough to assume that HIPAA will apply in every situation. For this reason it is important for the mother, or parents, to review whether the facility falls under HIPAA and how they will be protected if it does.

RECOMMENDATIONS

Umbilical cord blood can be an effective alternative to bone marrow. The efficacy of cord blood is still being tested and as such it is not yet used as part of a common medical practice. That is not to say that it never will be though. Now is the time to ensure that legal concerns are addressed for when cord blood is accepted as common practice.

Moving From Availability to Sustainability

The Stem Cell and Therapeutic Research Act of 2005 and the Reauthorization Act of 2010 have provided the basis for the availability of cord blood samples. Now that the availability is present the next step is to create sustainability. Cord blood use is becoming even more popularized and research needs to continue. As storage, use, and donation increases, availability of a cord blood supply must be ensured. Availability will also aid researchers as they can continue their work without running the risk of not having specimens to test and develop procedures from. Sustainability will be an issue that needs to be addressed both at a state and federal level.

There are increased numbers of people being born each year. This can provide both the answer to and a challenge for sustainability. More births mean more opportunities for collection of cord blood. However, it also means a larger population who may need cord blood transfusions. Public donations are the best means for servicing a larger population who may need a transplant. To follow through on increasing donations, hospitals, instead of operating under an opt-in program for collection should operate as an opt-out program. This means that unless

parents otherwise object the cord blood will be collected for public donation. This will not only help increase sustainability but will also aid in ensuring cord blood becomes more than medical waste.

The above recommendation would require that hospitals be equipped with the means to collect the cord blood and overall would be feasible to implement however there are alternatives. Congress can propose a plan to incentivize public donations of cord blood. Incentives are an effective motivator and can really increase unit availability. This incentive based program does not necessarily need to be payment for donation but could be something as simple as an increased tax credit in the Internal Revenue Code.

Another creative approach, one that moves entirely away from monetary benefits, is to create a standing agreement that if a public donation of cord blood is made, and either the eligible child or eligible nuclear relative have future need for a cord blood transfusion that said individual be classified as a priority for receiving the transfusion. If that were to be a valid option additional parameters would need to be set up. For example, a time limit for the agreement to remain valid, at what point an individual must be named, and at what stage in the individual's condition that the provision for being classified as a priority can take effect. Additionally, it may be important to note that eligibility is limited to current medical practices and whether or not there is therapeutic benefit for the individual to receive a transfusion based on cord blood cells. Further definition of eligibility should also include the threshold at which the individual must meet or exceed in terms of perceived therapeutic benefit. In theory, providing an incentive, can ensure that more units are going to better uses than medical waste.

Room for Improvement: Federal and State Legislative Actions

Federal:

Cord blood can effectively be use for medical treatment. With this in mind federal regulations need to be modified so that everyone has access to this potential, that consumers are adequately protected, and that there is a clear definition of who owns the cord blood.

Improving access to cord blood can be aided by increasing sustainability of cord blood. Healthcare is a top priority, and with the vast number of births that occur each year in the United States there is a large potential yield of cord blood specimens. In order to tap into this potential though public donation facilities need to be better funded, and more hospitals need to be equipped with the potential to collect the cord blood.

Increased funding alone will not solve the problem entirely. For as long as private banking options exist there is a portion of cord blood specimens that will be deviated for an individual purpose rather than a collective one. While it is not suggested that private banking should be stopped, because there are instances where private storage is useful, federal regulation should address advertising concerns and those of reliability. Private cord blood banks need to be held to a higher standard of accountability. This can be addressed by more frequent health inspections, and more rigorous guidelines for how to properly keep a specimen, (i.e. not allowing for the movement of a specimen continuously back and forth between facilities).

Advertising regulations for private storage should also be taken into consideration because of the emotionally vulnerable state of expectant parents. Regulations should address the issue of marketing tactics that prey on the emotional state versus advertising the reality of the situation. Claiming that the cord blood is a “life insurance” of sorts but belittling the fact that the

specimen likely will not be used is a tactic that raises serious ethical concerns. A balance needs to be struck so that parents are given adequate and accurate information prior to choosing to bank privately. Until marketing tactics are addressed through regulation though private banks will continue to capitalize on the emotional vulnerability of parents.

Congress can address issues related to informed consent and ownership. For starters, cord blood needs to be identified as a unique medical treatment. This is so that ownership rights can readily be applied to the specimen. If legislation clearly notes who owns the specimen, i.e. the mother, the child, or the blood bank, then the scope of the rights of the owner can be more easily understood and represented.

In terms of informed consent, adoption of a unanimous standard will help protect consumers. A federal standard will ensure that informed consent is properly retrieved and within the appropriate time-frame. It should address which trimester consent must be garnered by. It should also address what needs to be included in the agreement. For example, it should be disclosed that the donated sample may be used for means outside of the conceived scope of the informed consent contract.

State:

Many states have established a provision encouraging physicians to educate parents on their options for the cord blood. However, there needs to be a more proactive approach. This approach needs to be a two-fold process.

Firstly, we need to move past encouraging physicians to educate parents and instead mandate that physicians inform parents of their options. Mandating that physicians educate their

patients about their options will mean that more people become aware of the benefits from the use of the cord blood which in turn can increase donation. Due to varying religions, states that mandate physicians to inform their patients about their options take into consideration religious conflicts. They do so by allowing physicians to forgo informing their patients if there is a religious conflict.

If a provision were to require a physician to educate expectant parents it would also be in the interest of the physicians to include a provision that protects them from liability if a parent is unsatisfied with their choices and tries to blame the physician. This is an emotional time for parents and a physician should not be at risk for simply increasing awareness of an emerging topic.

A discussion covering both public and private cord blood banks should occur with an objective presentation of the facts for both. If state legislators were to enact such a provision there also needs to be a standard set of information that the physician is required to pass along. This way there is not a wide variance of information based on a physician's personal beliefs. Additionally, this information should be presented to the parents prior to the third trimester.

At this time there is not a large amount of collection sites that will allow for the collection of cord blood for public donations. For this reason a parent needs time to properly plan if they decide to publicly donate the cord blood. Without proper planning and research it is possible that donation of the cord blood will not be feasible.

Having said that, the next part that state legislation should address is the lack of hospitals willing to collect cord blood for public donation facilities. This is a state issue versus federal

because each state is going to have to address their financial standing and how implementation of more collections sites can be a possibility. Whether it be physician education, funding, or both each state should look into how to increase the number of locations. What this will allow is increased availability for parents, potentially shorter commutes which reduces the risk of not making it to a collection facility, and will ultimately help improve the overall sustainability of the supply within the public cord blood facilities.

CONCLUSION

Cord blood is a viable option to replace the use of bone marrow in transfusions. It has been shown that cord blood is just as effective as bone marrow in treating certain life threatening diseases. At this point though the main audience for a cord blood transfusion is children, with the hope of finding ways to increase adult responsiveness.

The collection of cord blood is painless for both mother and child. There are many benefits adding to the favor of the use of cord blood over bone marrow. The increasing trend for collection, storage, and use of cord blood has not been met without a rise in legal issues and concerns though.

It is possible to address these concerns now. In doing so it is possible to pave the way for cord blood use to become more widespread. Overall, the umbilical cord blood is important. It is necessary to shy away from the traditional notion that it is medical waste. Cord blood stem cells do not pose the same social and political controversy that embryonic stem cells do which adds to the favor of using cord blood. As of this writing research is also being completed on how the umbilical cord itself can be used for therapeutic treatment of disease.

Right now, there are endless possibilities for cord blood, but research needs to be able to continue in this area. If stability of supply is ensured, practice procedures are standardized, and legal concerns answered now, by the time cord blood use is common practice there will be a smoother transitional period.

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