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US Public Cord Blood Banking Practices: Recruitment, Donation, and the Timing of Consent

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Abstract

BACKGROUND—Cord blood has moved rapidly from an experimental stem cell source to an accepted and important source of hematopoietic stem cells. There has been no comprehensive assessment of US public cord blood banking practices since the Institute of Medicine study in 2005.

STUDY DESIGN AND METHODS—Of 34 US public cord blood banks identified, 16 participated in our qualitative survey of public cord blood banking practices. Participants took part in in-depth telephone interviews in which they were asked structured and open-ended questions regarding recruitment, donation, and the informed consent process at these banks.

RESULTS—13 of 16 participants reported a variably high percentage of women who consented to public cord blood donation. 15 banks offered donor registration at the time of hospital admission for labor and delivery. 7 obtained full informed consent and medical history during early labor and 8 conducted some form of phased consent and/or phased medical screening and history. 9 participants identified initial selection of the collection site location as the chief mode by which they recruited minority donors.

CONCLUSION—Since 2005, more public banks offer cord blood donor registration at the time of admission for labor and delivery. That, and the targeted location of cord blood collection sites, are the main methods used to increase access to donation and HLA diversity of banked units. Currently, the ability to collect and process donations, rather than donor willingness, is the major barrier to public cord blood banking.

INTRODUCTION

In the two decades since the first successful cord blood transplant in 1988, cord blood has moved rapidly from an experimental stem cell source to a widely accepted alternative to bone marrow as a source of hematopoietic stem cells.^{1, 2} Cord blood transplantation is now a standard practice treatment option in pediatric transplant and is growing as a major stem cell source for adults.^{3, 4} Evidence that long-term survival after cord blood transplantation for both children and adults is comparable to that of bone marrow transplantation makes the increasing utilization of cord blood transplant and banking likely.^{5–8} Because of the greater histocompatibility of cord blood transplants relative to bone marrow transplantation, cord

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blood also extends transplant access to racial/ethnic minorities currently under-represented on donor registries worldwide.⁹ With adequate funding to increase cord blood inventories, cord blood has the greatest potential to provide a stem cell source for transplant patients regardless of race or ethnicity.⁹ Moreover, cord blood recruitment allows an opportunity (in addition to recruitment of marrow and hematopoietic stem cell donors) to add inventory more likely to match minority patients. Despite its immense potential as a collective resource, cord blood from approximately 96 percent of the four million births in the US annually is discarded, and fewer units are banked publicly than privately.^{10, 11}

In response to the recognition of the clinical value of cord blood, public and private cord blood banks were established in the mid-1990s in the United States and internationally.¹² Private banks market cord blood storage to expectant parents as biological insurance for potential autologous or family use for transplant or regenerative medicine. Public banks collect cord blood for allogenic use in stem cell transplants of unrelated individuals or for biomedical research. Although the US still lacks a well funded, well-publicized system of public donor banks, the number of public cord blood banking programs in the United States is growing. The American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the American Medical Association, and the American Society for Blood and Marrow Transplantation have recently issued new or revised guidelines that encourage public cord blood banking and cord blood education laws have been passed in 27 states.^{13–17} In 2005, Congress passed the Stem Cell Therapeutic and Research Act.¹⁸ The act, reauthorized in 2010, includes the C.W. Bill Young Cell Transplantation Program to encourage cord blood research and build a national public cord blood inventory to address inequities in the access of minorities to transplant by funding public banking programs that target minority donors.¹⁹ Thirteen banks are currently under contract to contribute cord blood units to the National Cord Blood Inventory, with each contract specifying by racial and ethnic group a specific goal of bankable units.²⁰

Early commentary on the practices of public cord blood banking emphasized the need to meet two ethical imperatives: (1) considerations of justice, which require that “mechanisms be created to ensure that all potential participants have a fair opportunity to participate in UCB banking” in order to provide equal access of minority patients to stem cell transplants, and (2) respect for donor autonomy, as reflected in the need to obtain fully informed consent of donors.²¹ In the first decade of public cord blood banking, practices regarding recruitment, consent, collection, storage and use varied, with the most disputed being the question of when to obtain maternal consent.^{22–24} The timing of consent was controversial because it embodied the tension between the ethical goals of justice and autonomy. Policies that required consent to cord blood donation to be obtained during the prenatal period denied access to women who received no prenatal care or were not informed of the option to donate before hospital admission for labor and delivery. Yet educating potential donors at the time of admission for labor and delivery raised the question of how fully informed such donor consent could be.

There has been no comprehensive assessment of public cord blood banking practices in the US since the Institute of Medicine (IOM) study in 2005.²⁴ Since then, more public cord blood banks have been established and the demand and utilization of cord blood units have increased substantially. These developments highlight the compelling need to assess existing public banking policies and practices. Here we review the results of our qualitative survey of US public cord blood banks and examine contemporary public cord blood banking practices regarding recruitment, donation, and the informed consent process.

METHODS

Public cord blood banks were identified through an online Google search using the terms “public cord blood banking” and “cord blood units for research.” Investigators followed links found with those search terms and looked at websites of public cord blood banks and of research programs that were collecting cord blood for research only, as well as that of the Parents’ Guide to Cord Blood Foundation.²⁵ This yielded a list of 35 US public cord blood banks, including banking programs that educate potential donors and either collect or organize the collection of cord blood at collection sites but bank the cord blood elsewhere. Inclusion criteria included collecting donations for cord blood transplant and/or research in the US in 2010. One bank was excluded as it stopped collecting cord blood during the recruitment phase, for a sample of 34.

Investigators identified potential participants using publicly listed contact information from institution websites. Participants included medical directors, collection coordinators, or other personnel of participating banks who were knowledgeable regarding bank or collection site practices and procedures. Potential participants were contacted via email to request participation and were provided information about the purpose of the interview, use of results, and terms of anonymity and confidentiality. If there was no response, investigators followed up with phone calls and emails. Where no email address was available, participants were contacted by phone. Participants received a copy of the informed consent document prior to the interview. Participation was conditioned on maintenance of anonymity of the interviewee and of his/her bank.

We conducted in-depth, semi-structured interviews from July 2010 through January 2011. Interviews took 30 to 60 minutes and were conducted by phone. Participants received a \$10 gift card. Interviews were audio-recorded when the participants permitted it and were transcribed. In the one interview that was not recorded, extensive notes were taken.

Participants were asked structured questions pertaining to donation rates; timing and content of informed consent, and uses of collected cord blood, as well as open-ended questions concerning approaches to donor recruitment and education; the processes of obtaining consent and collecting donations, and uses of cord blood for transplant and research. Here we limit our discussion to donation, recruitment, and the process of obtaining informed consent. Participants were also asked to share their cord blood banks’ informed consent documents. Analysis of these documents when available allowed investigators to identify additional information regarding the banks’ current practices.

Transcripts, notes, and informed consent documents were read to analyze the content of our structured questions. Open-ended responses were coded using inductive qualitative methods to identify major thematic categories. Two independent reviewers analyzed interview materials and informed consents. Differences between reviewers were resolved through a consensus process with the entire research team. The protocol was reviewed by the Case Western Reserve University Institutional Review Board as an exempt protocol.

RESULTS

Out of our sample of 34 public cord blood banks and programs, 16 banks participated in this study. Eleven banks did not respond; 3 were unable to complete the interview, and 4 declined. Of the 16 participating banks, 12 shared their donor informed consent forms. Participants represented banks that varied in size; location; length of time in existence, and demographic composition of their donor populations.

Donor recruitment: marketing resources and methods

Pregnant women are inundated with print, online, and television advertisements for private cord blood banking, but often are unaware of public donation options.²⁶ Public cord blood banks lack funding to compete with the marketing campaigns of private banks. Instead they provide opportunities for expectant women to learn about cord blood donation by maintaining websites with information and contact information, answering phone calls, and making posters and brochures available at health fairs and in obstetrician's offices and clinics. Unable to advertise, they "really rely on the hospital staff, the office staff ... to post posters" and place brochures in prenatal packets (Interview # 3). One participant explained how the brochure about donation placed by the bank she was affiliated with in the prenatal packets patients received at a women's health center was outnumbered by advertisements for private cord blood banking. She commented:

So we have a little brochure there amongst many, many others. (Interview # 5)

Another remarked:

...as soon as a woman gets pregnant, they are bombarded by the private companies with stuff in the mail, and I've been to many a Baby Fair and Health Fair ...and they're like "Oh, I already have that information." I'm like, "No you don't, 'cause we can't afford to mail it to you. So I know you didn't receive it." (Interview # 3)

When asked if word of mouth was important in recruiting donors, one participant responded:

Very important... So I would say that probably the majority have heard about it from either their clinician, their prenatal class, or their labor nurse, but a significant number of them have heard it from friends and/or they're repeat donors so that they're already clued in. (Interview # 8)

The same participant also noted the importance of print and online media in directing women already committed to cord blood donation to collection sites, commenting:

... some of them... have ... decided that they want to do it and so they have searched the web to find ... [where they can donate.] An article will come out and ... will have a link to say Be the Match Foundation and they will then ... look through the list and ... give us a call ... so they hear about it a number of different ways (Interview # 8)

Women who learn about cord blood donation may search for opportunities to donate while they are pregnant.²⁷⁻²⁹ They can find information about public donation, including consent forms, on the websites of banks and hospitals that serve as collection sites. Programs may rely on such self-selected donors – those who initiate the donation process themselves -- rather than or in addition to an active recruitment program. One participant pointed out:

It can be the donor herself that asks for the information... A lot of them are informed, call us ... when their delivery day is imminent and they want to know how to sign up and ... we answer their questions, etc., over the phone and then they just need to ask their nurse when they go in. (Interview # 8)

Donor recruitment: staffing and clinical priority concerns

Cord blood donation is only available at approximately 180 collection sites in the United States.^{27,28} (Since our data collection was completed, a small number of hospitals have begun piloting a federal mail-in program that supplies collection kits for public donation from anywhere in the continental US, for inclusion in the National Marrow Donor Program's Be the Match Cord Blood registry.^{28, 29}) Consequently, not every woman who

would like to donate delivers at a hospital that is able to accommodate her desire. One participant commented:

We get calls all day long from people who want to donate, but don't have a place to donate. (Interview # 8)

Even at hospitals that serve as collection sites, not all women who deliver are eligible to donate, and not all eligible women are approached about donation. In addition, staff may not be available to collect donations 24/7, and those programs staffed around the clock may not be sufficiently staffed in order to collect donations from every woman who would like to donate.

Physician and staff “buy-in” affect both number of units collected and number of units that are actually bankable. Several participants emphasized the importance of “buy-in,” whether they were referring to the willingness of prenatal care providers and labor and delivery staff to inform laboring women about donation or for physicians to take the time — for which they are not always reimbursed -- to do a collection that meets volume criteria for banking. Staff that offer routine prenatal care in obstetricians’ offices and labor and delivery staff in hospitals may feel they have too much to accomplish without the additional effort cord blood banking requires and may be reluctant to take the time to inform women about donation, but their efforts are critical.^{20, 30} As one participant noted:

But in fact it's Labor and Delivery staff [who] are really key to getting ...the recruitment of these what we call walk-ins. (Interview # 6)

Staff “buy-in” also affects the percentage of collected units that are bankable at sites that rely on labor and delivery staff rather than bank personnel to do the actual cord blood collection. To be viable for transplant, samples must meet volume and cell dose specifications and pass testing for infectious disease and genetic and/or blood and metabolic disorders. Samples that do not meet criteria for transplant are designated for research or discarded. Interviewees emphasized the need for physicians to become knowledgeable about differences in collection standards for public and private banking in order to increase the percentage of viable units collected. Nationally, less than half of collected cord blood units are deemed bankable for transplant, typically because of inadequate volume and cell dose.³¹ Thus the numbers of units collected and banked for transplant differ considerably.

Donor recruitment: timing and level of enrollment

Public banks vary in their recruitment strategies, which include requiring women to enroll in the last trimester of pregnancy, encouraging enrollment prior to hospital admission, and/or accepting “walk-in” or “admit screening” donors who are approached or who ask hospital staff about donation at the time of hospital admission. Donor registration at the time of admission for labor and delivery facilitates the participation of women who were previously unaware of the opportunity to donate, should they choose to do so. We therefore asked participants if the cord blood banks they are affiliated with offer donor registration on the day of admission for labor and delivery.

Out of 16 banks that were interviewed, 14 offer same day hospital admission/cord blood donor registration and one offers it at one of two collection sites. Of these 15, one also offers a mail-in option that requires women to register by the 34th week of gestation. The remaining bank requires women to register by the 36th week.

Participants were also asked what percentage of women who are approached to donate either before or at the time of hospital admission consent to do so. Most reported a high percentage of women willing to donate. While several participants knew precise percentages, most provided estimates. Two participants reported 96 and 92% and three responded, “a

majority,” “the great majority,” or “many more want to donate than can.” One participant reported “100% because the donors are self-selected.” The remaining estimates of the percentage of women who consented to donate ranged from 75% to “approximately 90 percent,” except for some programs that had more than one site. In terms of the latter, the responses were “almost 100 percent at the program site where donors are self-selected and 60 percent at the program’s fixed site” and 75–80 % at one site and no estimate for the other. Three interviewees were unable to provide an estimate. Another participant estimated that approximately 55 to 60 percent of women who delivered at the bank’s collection sites donated. This estimate is of the percentage of deliveries that result in donation rather than the percentage of eligible women who choose to donate. While that bank does not track this data, the number of women who decline to donate is reported to be “a very small percentage.”

The question of what percentage of women consent to donate proved complicated for some participants to answer. In order to know the percentage of eligible women who deliver at collection sites, are asked about donation, and consent to donate, cord blood banks need to track the percentage of women who deliver at their collection sites and are eligible to donate—women who 1) deliver a single, full-term infant with a non-complicated labor and delivery, who (depending on the policies in place at the bank) 2) have already registered to donate or who arrive on the labor and delivery floor in early labor and/or pass a nurse’s assessment that they are in a physical and emotional condition to discuss donation, and 3) who give birth while there are staff available to educate potential donors, obtain informed consent, and collect cord blood. Not all banks are able to track each of these data points. To obtain this information, banks need to allocate money and staff to track data, but not all have the resources to do so. Moreover, some banks have more than one site or method of donating; percentages of women who donate vary accordingly.

The timing and process of informed consent

In an early influential analysis of ethical issues pertaining to cord blood banking, Sugarman and colleagues recommended that written informed consent for public cord blood collection be obtained before labor and delivery, preferably during the last trimester in pregnancy. Citing evidence that women’s capacity to make decisions fluctuates during labor, they noted, “the antepartum period accords decision makers sufficient time to deliberate about their decision.”³² While most commentators agreed that the optimum time to seek informed consent is during the prenatal period, the timing of obtaining maternal consent remained controversial and practices varied at cord blood banks.^{23, 33, 34} Notably, the two banks participating in the Institute of Medicine study that did not require prenatal consent, but rather obtained consent either after hospital admission or following the collection of viable units, had marked success in banking units from minority donors.²⁴ In “A Phased Consent Policy for Cord Blood Donation” (2002) Vawter and colleagues reviewed the advantages and disadvantages from the perspectives of cord blood donors and bankers of obtaining consent at varying times: during the prenatal period, the early stages of labor for women who met established criteria, and after collection. Noting that programs that allowed women to consent to donate on the day of hospital admission had the potential to be the most inclusive, they proposed a “phased consent policy” that separated “... the decision to collect cord blood from the other decisions in cord blood donation, including consent to transmissible disease testing, mothers’ health history interview, medical record review, and long-term storage in a community bank for therapeutic and research purposes.”²²

The authors of the IOM study in 2005 similarly recognized that in order to provide equal access to stem cell therapies the “ideal” approach of obtaining informed consent before labor and delivery might not always be feasible. Pointing out that informed consent procedures

might "... need to take into account practicality and demographic realities of the donor communities without compromising donor autonomy" they stated:

At a minimum, the donor's consent for the collection of cord blood should be given prior to delivery, and the donor should be informed that no steps other than the collection of the cord blood and samples for testing of the mother will be taken until the mother (and, if present, the father) can participate in a full informed consent.²⁴

Although it is widely agreed that the prenatal period is the best time to educate women about cord blood donation, the practice of obtaining either full or preliminary consent to collect cord blood on the day of hospital admission for labor and delivery has gained acceptance in recent years. While the 1999 American Academy of Pediatrics (AAP) statement on cord blood banking states that "written permission should be obtained during prenatal care, and before the onset of labor," – that is, implicitly, before admission for labor and delivery --the updated 2007 AAP statement recommends, "written permission for obtaining cord blood should be obtained before the onset of active labor," thus allowing for the consent process to take place during early labor.^{35, 13}

Even personnel from banks that offer the option of donor education, registration, and consent at the time of hospital admission recognize the challenges this may present for some donors, particularly those previously unfamiliar with the uses of cord blood. Studies demonstrate that many women remain poorly informed about cord blood donation.^{26, 34,36,37} After discussing her bank's efforts to distribute informational materials to the offices of physicians who provide prenatal care, a participant from a bank that offers time of admission donor registration commented:

...we still have a lot of work to do. A lot of the women don't hear about it until they get to the delivery room, and that's not the place to present all of this information. (Interview # 15)

Thus the greater availability of donor registration on the day of hospital admission underscores the need to devote more resources for prenatal cord blood education.

Participants from banks that offer donor registration on the day of hospital admission were asked whether they complete the informed consent process at one time, or use a phased consent process and/or phased taking of medical history. Of those 15 banks that offer cord blood donor registration on the day of hospital admission at one or more sites, 7 banks obtain full informed consent and medical history during early labor.

Three banks/programs obtain a full informed consent of potential donors in early labor but a staged, two-step medical eligibility screening and history, with the full health history only completed after labor and delivery if the sample meets volume criteria. Thus, donors are consenting to cord blood collection, testing, storage, and use, but banks only take complete health histories if they know the sample is of sufficient volume to be bankable if it passes genetic and infectious disease testing. This is efficient for banks and does not require mothers to give detailed medical histories unnecessarily.

Three banks/programs use a phased two-step informed consent and a two-step medical history, with full informed consent and health screening completed only if the sample meets volume criteria.

Two banks/programs do a full consent and medical history if the patient is not in active labor. If the woman is in active labor but a nurse has told the collection specialist that she would like to hear about cord blood options, one bank obtains a preliminary consent that

gives the bank permission to collect cord blood. They do not process the blood until the woman has recovered from labor and delivery, when they return to fill out a complete consent and medical history. The second bank obtains an initial consent to collect and do a preliminary review of medical records, with full medical history and consent to further evaluate the sample completed after labor and delivery, only if a cell count determines the collected unit meets banking criteria.

The recruitment of minority donors

The search for successful strategies to recruit minority donors to meet the transplant needs of diverse patient populations has been an ongoing concern since the early days of public cord blood banking.³⁸ Minority patients are less likely to find matches for multiple reasons, including relatively low representation in volunteer registries and the increased genetic diversity with many low frequency HLA types found in patients of African ancestry.⁹ We inquired what efforts, if any, cord blood banks make to recruit minority donors. Interviewees mentioned targeted education and “marketing” by publicizing the existence of cord blood banking programs in African-American churches and at health fairs, community centers, and other locations frequented by minority populations; having brochures and FAQ about cord blood available in multiple languages, and the use of hospital translators when conversing with non-English speakers about cord blood donation. In addition, several participants mentioned that they actively screen for ethnic diversity, prioritizing and selecting minority donors from their pool of potential donors in circumstances where they are unable to collect cord blood from every potential donor. As one participant stated, “Well we approach the minority donors over approaching a Caucasian donor.” (Interview # 13)

Nine participants specifically identified the initial selection of the location of the collection site as the chief mode by which they recruited minority donors. One participant noted:

So the collection sites that we have chosen tend to be high birth collection sites with a patient population of the groups that we’re targeting. (Interview # 1)

Another commented how recruitment methods had shifted over time:

Initially we counted on the flyer in the Ob’s office and talks that we gave around town and on community-oriented TV to get people interested and give us a call... But what has happened over the last probably I’d say three or four years is that that has shifted from being a dominant mode of recruitment to having recruiting in the hospital at the time of delivery...[as the dominant mode]... So frankly we’ve been more successful with African-Americans...by going to the hospitals where they are ...[delivering]. (Interview # 6)

Participants also stated that as they expanded existing banking programs, they did so by setting up collection sites in hospitals where the demographic composition of the patients would facilitate recruitment of minority donors. One participant commented:

So every time we have grown with a new hospital, it has been with diversity in mind. We take into account...the number of births in that particular facility per year, and then we also look at the demographic makeup of the patients who come there so that we can...be more inclusive and, yes, that’s a big part of it. (Interview # 8)

Similarly, another participant explained:

We don’t particularly recruit donors... We meet people at the hospitals where we collect... Our way of recruiting donors is being at the hospital. So it’s trying to set up collection sites where we have minorities or a certain percentage of the population that we need. We have a website...and we get tons of questions about

donations, collections ...and we try to address this as much as possible, but we don't have an active recruitment program. Instead we try to plan where we collect...We're aiming different collection sites, as we're trying to expand now, so we try to get access to minority populations by going to the hospitals where they are. (Interview # 12)

DISCUSSION

All public cord blood banks studied here reported a variably high percentage of women willing to donate (with the exception of the three banks unable to provide an estimate). Clearly the willingness of potential donors to donate is not an obstacle to public cord blood donation. Instead, only a small percentage of women giving birth in the US have access to public donation opportunities in the hospitals where and when they deliver. Currently, the barriers for public cord blood banking for transplant are the ability to collect and process donations – which is dependent on the global issues of access, staffing and funding -- and issues particular to samples such as their volume and cell dose. Funding, therefore, is the most fundamental issue for public cord blood collection sites and banks as it impacts every aspect of cord blood banking, including the recruitment and education of potential donors both before and after hospital admission; the number of collection sites; the availability of staff to collect donations; routine re-contacting of donors, and efforts to track bank practices surrounding recruitment and donation.²⁰

Since the IOM study in 2005, more public banks offer women the opportunity to register to donate cord blood on the day of hospital admission. Of the cord blood banks represented by our participants, the overwhelming majority offer pregnant women this option.

Phased consents and/or phased medical eligibility screenings/taking of complete medical history are one way some banks deal with the tension between obtaining the most fully informed consent of donors and providing access to cord blood donation to the most inclusive pool of donors. The shift to greater availability of cord blood donor registration at the time of hospital admission highlights the need for further empirical work on the adequacy of the informed consent process. Future research should take into account the perspectives of all stakeholders, including representatives from public cord blood banks, individuals involved in consenting, and parents who have donated as well as those who have chosen not to donate.

The location of collection sites in hospitals with large numbers of minority births, coupled with the availability of donor registration at the time of admission for labor and delivery, are the main methods banks use to facilitate cord blood donation by minorities and increase the HLA diversity of banked units. For those banks that offer cord blood donor registration on the day of admission, selection of collection sites has become as least as important as recruitment during the prenatal period. Because recruitment relies on education and consent at the time of hospital admission rather than during prenatal care, targeted recruitment to achieve diversity of tissue types in public cord blood banks has had an impact on the timing and process of obtaining informed consent. The practice of obtaining donor consent at the time of labor and delivery highlights the need for cord blood education prior to hospital admission so women and their partners will already be familiar with the issues surrounding cord blood donation.

This survey of current practices of public cord blood banks reveals a shift in recruitment and consent practices to allow broader access to cord blood donation in an era of limited financial resources. Our data highlight the need for more prenatal cord blood education, so that expectant parents are prepared to make a more fully informed decision about cord blood

donation. A wider public dialogue about the potential and uses of cord blood that engages not only expectant parents but all Americans is also necessary to create greater public recognition and funding for collection and banking of this valuable resource.

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