

## Informed Consent in Umbilical Cord Blood Collection, Storage and Donation: A Bloody Mess

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Over the past decade, umbilical cord blood has gone from being discarded as medical waste to being frozen and preserved as an important source of hematopoietic stem cells, the precursor cells that populate the bone marrow and produce the blood and immune cells needed by the human body to function and survive. The hematopoietic stem cells retrieved via umbilical cord blood collection may be used in lieu of bone marrow transplantation to treat a panoply of disease<sup>1</sup> with several advantages over traditional bone marrow transplantation.<sup>2</sup> To date, more than 5,500 transplants have been performed using hematopoietic stem cells isolated from cord blood.<sup>3</sup>

Umbilical cord blood has also been found to be a potentially significant source of pluripotent mesenchymal cells, commonly referred to as fetal stem cells. These fetal stem cells have the ability to form a variety of different tissues when grown in culture, including neural tissue, cardiac muscle, bone and cartilage.<sup>4</sup> Massive research efforts in the area of regenerative medicine are underway to determine future potential uses of these fetal stem cells in the treatment of a variety of devastating disease including spinal cord injury, amyotrophic lateral sclerosis<sup>5</sup>, Parkinson's disease, and Alzheimer's disease. Prior to the isolation of these cells from umbilical cord blood they were obtained directly from fetal tissue, either abortuses or donated embryos, engendering heated debate regarding the propriety of fetal stem cell research. With the isolation of pluripotent mesenchymal cells from fetal umbilical cord blood, regenerative medicine research may continue unfettered by the ethical issues which have hindered fetal stem cell research in the past.

Given the importance of current and future research in the area of fetal stem cells derived from umbilical cord blood, it is not surprising that issues of umbilical cord collection have taken on increased significance over the past several years. Current debate over umbilical cord blood collection and storage has focused primarily on issues of public donation versus private storage and the potential future uses of cord blood in the realm of

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<sup>1</sup>Categories of treatable disease include, but are not limited to, leukemias and lymphomas, multiple myeloma, severe aplastic anemia and other marrow failure states, inherited immune system disorders, hemoglobinopathies, inherited metabolic disorders, and myelodysplastic and myeloproliferative disorders. National Marrow Donor Program, *available at* [http://www.marrow.org/PATIENT/Understnd\\_Disease\\_Treat/Lrn\\_about\\_Disease/index.html](http://www.marrow.org/PATIENT/Understnd_Disease_Treat/Lrn_about_Disease/index.html) (last visited March 21, 2007).

<sup>2</sup>Advantages of cord blood transplantation include a wide variety of racial and ethnic donors, decreased time to transplantation, greater tolerance of HLA mismatch, and decreased severity of graft-versus-host disease. Kenneth Moise, Jr., M.D., *Umbilical Cord Stem Cells*, 106 OBSTET. & GYNECOL. 1393, 1394 (2005).

<sup>3</sup>American Academy of Pediatrics, *Cord Blood Banking for Potential Future Transplantation*, 119 PEDIATRICS 166 (2007) [hereinafter AAP].

<sup>4</sup>Moise, *supra* note 2, at 1397.

<sup>5</sup> Amyotrophic lateral sclerosis is more commonly known as Lou Gehrig's disease.

tissue transplantation for regenerative purposes. Little attention has been paid to the informed consent process in the collection, donation, storage, and ultimate transplantation of umbilical cord blood. When issues of informed consent are discussed, it is almost exclusively in reference to the collection procedures followed by public banks or collection performed solely for research purposes.<sup>6</sup>

Increased focus on the issues surrounding umbilical cord blood storage has come from the pediatric arena. In a recent policy statement which has received attention in both the lay press<sup>7</sup> and the medical literature<sup>8</sup> the American Academy of Pediatrics (AAP) proffered recommendations regarding *Cord Blood Banking for Potential Future Transplantation*.<sup>9</sup> The document provides two sets of recommendations: the first aimed at “physicians who are consulted by prospective parents about cord blood banking”, and the second designed to provide guidance for “institutions or organizations (private or public) involved in cord blood banking.”<sup>10</sup>

In the first section of the policy statement, the AAP asserts that physicians should discourage prospective parents from donating cord blood privately as “biologic insurance” for their child.<sup>11</sup> Hematopoietic stem cell transplant is most commonly used in the setting of allogenic donation, where the cord blood donor and recipient are different individuals who may or may not be related but who are HLA-matched.<sup>12</sup> In contrast, autologous transplantation occurs where the cord blood donor and recipient is the same individual. In many diseases that are responsive to stem cell transplantation, such as leukemia, the predisposition to manufacture the aberrant cells may already exist in that child’s cord blood, and thus, would be an unwise choice for transplantation. And while regenerative medicine holds promise for the future, the potential therapies are too remote to justify private cord blood banking at this time. Parents should be encouraged by their physician to pursue directed donation when an affected sibling or family member may benefit from transplantation or as an alternative, bank the umbilical cord blood publicly for future transplantation to any potential HLA-matched recipient.<sup>13</sup> Physicians are also charged with providing information to families regarding the testing that will be performed on the cord blood specimen. Testing for infectious diseases and genetic

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<sup>6</sup> Jeremy Sugarman, M.D., M.P.H., et al, *Optimization of Informed Consent for Umbilical Cord Blood Banking*, 187 AM. J. OBSTET. GYNECOL. 1642 (2002).

<sup>7</sup> Lauren NeerGaard, *Parents Encouraged to Donate Babies’ Cord Blood*, HOUSTON CHRONICLE, Feb. 19, 2007, at A1.

<sup>8</sup> Bridget M. Kuehn, *Pediatrics Group Recommends Public Cord Blood Banking*, 297 JAMA 576, 576 (2007).

<sup>9</sup> AAP, *supra* note 3, at 165.

<sup>10</sup> *Id.* at 167.

<sup>11</sup> It has been estimated that the likelihood of an umbilical cord blood donor needing to use their own cord blood in the future is approximately 1 in 2,700. F. Leonard Johnson, *Placental blood transplantation and autologous banking: caveat emptor*, 19 J PEDIATR. HEMATOL. ONCOL. 185, 183.

<sup>12</sup> Human leukocyte antigen typing (HLA-typing) is performed to determine if there is a “match” for hemapoetic stem cell transplantation. There are 6 genes which encode HLA type and are located on chromosome 6 in the major histocompatibility complex, thus allowing for a potential 4-out-of-6, 5-out-of-6, or 6-out-of-6 transplantation match. Moise, *supra* note 1, at 1395.

<sup>13</sup> AAP, *supra* note 3, at 165.

anomalies<sup>14</sup> are routinely performed.<sup>15</sup> Based on these recommendations, the AAP places the onus of parental education squarely with the physician, presumably the prospective parents' obstetrician, though that is not explicitly stated.

While the physician is responsible for patient education, the AAP seems to take a different view as to who is responsible for the formal informed consent procedures involved in cord blood collection and storage. Here, in the second section of recommendations, the AAP shifts the burden to "institutions or organizations (private or public) involved in cord blood banking" to obtain written permission for cord blood collection and to provide accurate information regarding the "potential benefits and limitations of allogenic and autologous cord blood banking and transplantation" with an awareness of the potential "emotional vulnerability" of prospective parents who are considering cord blood banking.<sup>16</sup>

Though these AAP recommendations have attempted to fill a void, this haphazard approach to patient education and informed consent highlights the problems which currently exist in the cord blood collection, storage and donation process. There is no one individual or entity with sole responsibility for ensuring that the informed consent process is honored with regard to cord blood collection and storage/donation. In general, obstetricians who are collecting the cord blood for private banking are handed a cord blood collection kit by the expectant parents prior to delivery. The parents have usually arranged this service with the private storage company without any prior conversation with their obstetrician. Once the infant is delivered and the umbilical cord clamped and cut, the cord blood is collected. The physician may then choose to complete a survey included in the kit regarding the ease or difficulty of the cord blood collection process. There may be some discussion as to the perceived adequacy of the specimen at the time of collection<sup>17</sup>, but in general, there is unlikely to be an in-depth discussion regarding the merits of cord blood banking, much less a true informed consent process. Thus, parents may choose to undergo costly private banking of cord blood without the necessary facts to make an informed decision.

Criticism of this disorganized approach to informed consent may be premature, as many obstetricians may not even realize that the informed consent process differs dramatically depending on whether a parent chooses public or private cord blood banking. If a family chooses to store their child's cord blood with a private company, there is a service agreement which must be read and signed by the parent or legal guardian of the unborn

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<sup>14</sup> Human immunodeficiency virus (HIV), human T-lymptrophic virus types (HTLV) 1 and 2, hepatitis B and C, syphilis, sickle cell disease and other hemoglobinopathies. National Cord Blood Program New York Blood Center, available at <http://www.nationalcordbloodprogram.org/work/collections.html> (last visited Feb. 24, 2007).

<sup>15</sup> AAP, *supra* note 3, at 167.

<sup>16</sup> AAP, *supra* note 3, at 167.

<sup>17</sup> The adequacy of the specimen is another contentious area with private cord blood banking. If the specimen is of insufficient cellularity, the company contacts the family to ask if they wish to continue with storage. The parents are not educated as to how the cell count of the specimen may affect future use of the specimen, and as a result, many parents will continue to pay for storage of a specimen that would be inadequate for transplantation. Moise, *supra* note 2, at 1404.

child.<sup>18</sup> These enrollment or service agreements contain sections which are designed to serve as informed consent and differ from company to company in both format and content. There are general provisions which seem to cover the educational aspects of cord blood banking, such as an acknowledgement that the cord blood may never be needed<sup>19</sup> and a listing of the tests to be performed on the specimen.<sup>20</sup>

There are also attempts to protect physicians from liability for failure to collect cord blood if that is deemed to be in the best interest of the mother and infant at the time of delivery.<sup>21</sup> There may even be a general indemnity clause for the physician, hospital, or birthing center in the body of the informed consent portion of the document.<sup>22</sup> This fusion of contract and informed consent concepts can only further serve to confuse the prospective parents.

These issues of informed consent in the private arena are not present with regard to public banking as recruitment and education of potential donors on the part of public banks is more standardized. Public banks have representatives on the labor and delivery units of participating hospitals to identify potential donors as they arrive on the unit. They then speak with the expectant parents and obtain informed consent for the collection and donation of their infant's cord blood. As these informed consent forms have usually been reviewed by the participating hospital's institutional review board, they tend to have language written at a 7<sup>th</sup> grade level to ensure understandability. In addition, rather than being left to their own devices to read and sign the informed consent form, the collection personnel are available to go over the details of the process and answer any questions the prospective parents may have. In essence, an informed consent dialogue is accomplished rather than the illusory signing of a form. However, even here, the physician charged with the procurement of the cord blood is not charged with carrying out the informed consent process.

Though the private cord banks obtain informed consent for the collection and donation of cord blood, they do so in violation of one of the tenets of the AAP policy statement: written permission for obtaining cord blood should be obtained in the third trimester prior to the onset of labor.<sup>23</sup> Though the decision to collect and store umbilical cord blood is an important one, it is no more or less significant than other issues for which consent is routinely obtained during labor, such as delivery of the infant (both vaginal delivery and cesarean section), tubal ligation, or HIV testing. The only distinction that may be made with regard to the collection of cord blood is the fact that the patient may feel that they are "giving away" their infant's cord blood, a decision which made lead to later regret

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<sup>18</sup> The cord blood would technically be the property of the infant child with the parent consenting to storage on behalf of that child with property rights in the specimen inuring to the child at age 18. This is, of course, assuming that there is a property interest in cord blood—a discussion which is outside the scope of this article. See *Moore v. Regents of the Univ. of Cal.*, 499 U.S. 936 (1991). See also Courtney Witte, *Cord Blood Storage: Property and Liability Issues*, 26 J. LEG. MED. 275 (2005).

<sup>19</sup> AlphaCord, <http://www.alphacord.com/registrationpacket.pdf> (last visited Feb. 24, 2007).

<sup>20</sup> ViaCord, available at <http://www.viacord.com/enroll.htm> (last visited Feb. 24, 2007).

<sup>21</sup> *Id.*

<sup>22</sup> AlphaCord, *supra* note 19.

<sup>23</sup> AAP, *supra* note 3, at 168.

should the child or a family member develop a disease for which cord blood stem cell transplantation might be utilized.

Given the potential for financial and emotional manipulation of prospective parents, it seems prudent for obstetricians and pediatricians to begin taking a more active role in their patient's decisions with regard to cord blood banking. Admittedly, this seems to be much less of a concern, and less practical, with public donation as opposed to private storage. The biggest concern is the complexity of the issues surrounding umbilical cord blood collection and will certainly make the informed consent process a difficult one, and pursuit of a formalized informed consent process for umbilical cord blood banking will undoubtedly cut into what precious little clinical time busy physicians currently have for their patients. However, in the interest of safeguarding both the parent's futures and that of their unborn child, it will be time well-spent.

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