

# Umbilical Cord Blood Banking in Canada: Socio-Ethical and Legal Issues

*Margo Plant & Bartha Maria Knoppers\**

Promising discoveries about the lifesaving attributes of umbilical cord blood (UCB) stem cells have led to the emergence of public and private cord blood banks throughout Canada. UCB cells are currently used in the treatment of a variety of malignant and non-malignant diseases and for research purposes.<sup>1</sup> There is also much talk of their potential use for the treatment of a broad range of degenerative, hereditary, post-traumatic and central nervous system related conditions.<sup>2</sup>

The primary purpose of public UCB banks is to create an inventory of UCB units for unrelated allogeneic hematopoietic stem cell transplants. The UCB is donated to the bank and the units are made available to suitably matched recipients regionally, nationally or internationally. In contrast, private banks allow parents to store their newborn's cord blood for autologous (use by donor) or familial use. Thus, for a fee, the UCB is stored as a form of 'insurance' in case the child or a matched family member should have a need for it in the future. In Canada, two public banks and at least nine private banks have been established to date.<sup>3</sup>

At present, the role that Canada should play in UCB banking remains unclear. Because Canada has a universally accessible healthcare system, public policy makers will soon be confronted with the difficult task of deliberating the merits and economics of establishing a national network of public cord blood banks, as well as deciding on the place of private banking of UCB for autologous use. A policy framework is necessary to guide this decision making.

---

\* Margo Plant is a Research Assistant at the Centre de recherche en droit public (CRDP) and Bartha Maria Knoppers (Canada Research Chair in Law and Medicine) is a Professor at the Université de Montréal Faculty of Law and Faculty of Medicine and Senior Researcher at the CRDP. This research was made possible through a Catalyst Grant from the Stem Cell Network of Canada.

<sup>1</sup> Karen Ballen *et al.*, "Current status of cord blood banking and transplantation in the United States and Europe" (2001) 7:12 *Biology of Blood and Marrow Transplantation* 635 at 636.

<sup>2</sup> See e.g. Today's Stem Cell Research, Stem Cell Research Medical and Health News, "Cord Blood News", online: <<http://www.stemnews.com/archives/cord-blood-stem-cells.html>>; BioMark International, Stem Cell Therapy, "Cord Blood Stem Cells", online:

<[http://biomark-intl.com/frontdoor/stem\\_cell.cfm](http://biomark-intl.com/frontdoor/stem_cell.cfm)>; Cells for Life, "The Future", online: <<http://www.cellsforlife.com/thefuture.htm>>; Inception Biosciences, "What Are Stem Cells", online: <[http://www.inception.com/what\\_stem\\_cells.html](http://www.inception.com/what_stem_cells.html)>.

<sup>3</sup> The two public banks include Héma-Québec and the Alberta Cord Blood Bank. The number of private banks is increasing more rapidly. There are eight located in Ontario, mostly in the Toronto area (Baby Chord Securacell, Cells for Life, Cord Blood Bank of Canada, Create Cord Blood Bank, HemaStem Therapeutics, Inception Biosciences, Progenics Cryobank, and Stem Sciences Inc.), and one in Vancouver (Lifebank Cryogenics). The following website provides a list of private banks around the world: <<http://www.parentsguidecordblood.com>>.

On a regulatory level, the Canadian Standards Association has published standards which are applicable to UCB banking for transplantation: *Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements*, and *Lymphohematopoietic Cells for Transplantation*.<sup>4</sup> These national standards will be incorporated into Health Canada's new regulations regarding the safety of cells, tissues, and organs for transplantation which are currently being elaborated.<sup>5</sup> In the meantime, Health Canada has released a Directive and a Guidance Document to encourage adherence to basic safety standards.<sup>6</sup> The standards set by accreditation bodies also help to promote the safety of UCB banking practices, although the accreditation process remains voluntary and therefore cannot be relied upon to protect the public.<sup>7</sup>

UCB banking in Canada is still in its early stages, and there are many regulatory and policy issues that have yet to be addressed. It is during this period of development that it is crucial to prospectively address the socio-ethical and legal issues surrounding cord blood banking. In this manner, an ethical framework can be elaborated to provide guidance to policy makers seeking to effectively regulate cord blood banking in Canada. This paper aims to provide a selective overview of some of the key socio-ethical and legal issues involved. Four main topics will be broached: 1) public awareness and perceptions relating to UCB banking, 2) the process of informed consent for the collection, donation, processing, storage, and future use of UCB, 3) issues related to ethnic diversity, and 4) the possibility of a national UCB program in Canada.

The discussion would be incomplete however, without a brief review of the ethics of private cord blood banking for autologous use. Policymakers cannot chart the future of UCB banking in Canada without taking into account the existence of private banks and their potential role in meeting future clinical needs, as well as their actual and potential contribution to research in this domain.

---

<sup>4</sup> CSA Standard Z900.1-03 and CSA Standard Z900.2.5-03, respectively.

<sup>5</sup> These regulations will fall under the Food and Drugs Act. The purpose of this regulatory framework is to ensure the safety and quality of cells, tissues and organs available for therapeutic purposes. See Canada, Health Canada, Biologics and Genetic Therapies Directorate, "Technical Requirements to Address the Safety of Cells, Tissues and Organs for Transplantation (Directive)" and "Guidance Document: Basic Safety Requirements for Human Cells, Tissues and Organs for Transplantation" (July 2005), online: Health Canada <[http://www.hc-sc.gc.ca/dhp-mps/brgtherap/reg-init/cell/cto\\_directive\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/brgtherap/reg-init/cell/cto_directive_e.html)>. The regulations should be posted for consultation in October, 2005 (As per conversation with Cathy Parker, Manager, Policy and Promotion Division, Biologics and Genetic Therapies Directorate, Health Canada, August, 2005).

<sup>6</sup> These were released in January 2003. *Ibid.* Note that the directive and the new regulations do not apply to cells, tissues or organs for autologous use. This means that private banks are only required to comply with these safety standards to the extent that they engage in the banking of UCB for allogeneic use.

<sup>7</sup> E.g. Foundation for Accreditation of Cellular Therapy, *International standards for cord blood collection, processing, testing, banking, selection and release*, 2<sup>nd</sup> ed. (Omaha, NE: NETCORD Foundation for the Accreditation of Hematopoietic Cell Therapy, July 2001).

A number of organizations have taken the position that UCB banking for autologous use should be discouraged.<sup>8</sup> The Society of Obstetricians and Gynaecologists of Canada Clinical Practice Guidelines, for example, state that “[c]ollection and long-term storage of umbilical cord blood for autologous donation is not recommended because of the limited indications and lack of scientific evidence to support the practice.”<sup>9</sup> The clinical utility of autologous storage is said to be limited because of the very low probability that an autologous hematopoietic stem cell transplant will be required by the individual in his/her lifetime, the uncertain shelf life of stored UCB, and the fact that autologous transplants are not recommended for inherited disorders or blood cancers.<sup>10</sup> Furthermore, should the need for a hematopoietic stem cell transplant arise, allogeneic UCB or bone marrow and, in some cases, autologous peripheral blood might provide an alternative source of stem cells, depending on the circumstances.<sup>11</sup> It is hoped that autologous UCB stem cells will prove to be of particular value for cellular therapy and regenerative medicine, but at present these uses remain speculative.<sup>12</sup>

Aside from the limited clinical utility of autologous UCB, private banking also raises concerns about social inequities. If UCB does ultimately prove to be useful for cellular therapy and regenerative medicine, then issues of equitable access to health care arise since the costs of private storage may be prohibitive for many parents.<sup>13</sup> In cases where there is a family member suffering from a condition which is treatable by hematopoietic stem cell transplant, it has been suggested that storage should be done by public banks.<sup>14</sup> Directed donations are in fact possible in a many public banks to address this identifiable need.<sup>15</sup> It has also been suggested that private storage of cord blood may be supplanting donations to public banks. This idea has been refuted by some on the grounds that the collection of UCB for public banks is usually restricted to a limited network of hospitals and that women

---

<sup>8</sup>E.g. American Academy of Pediatrics, Work Group on Cord Blood Banking, “Cord blood banking for potential future transplantation: subject review” (1999) 104:1 *Pediatrics* 116, online: American Academy of Pediatrics <<http://www.pediatrics.org/cgi/content/full/104/1/116>> [AAP Work Group]; The European Group on Ethics in Science and New Technologies, “Opinion no. 19: Ethical Aspects of Umbilical Cord Blood Banking” (16 March 2004), online: European Commission <[http://europa.eu.int/comm/european\\_group\\_ethics/docs/avis19\\_en.pdf](http://europa.eu.int/comm/european_group_ethics/docs/avis19_en.pdf)> [European Group]; Royal College of Obstetricians and Gynaecologists, Scientific Advisory Committee, “Opinion paper 2: Umbilical cord blood banking” (October 2001), online: Royal College <<http://www.rcog.org.uk/index.asp?PageID=545>>.

<sup>9</sup>B.A. Armson & Maternal/Fetal Medicine Committee, Society of Obstetricians and Gynaecologists of Canada, “Umbilical cord blood banking: implications for perinatal care providers” (2005) 27:3 *Journal of Obstetrics and Gynaecology Canada* 263 at 264 (recommendation 6).

<sup>10</sup>See M. Saginur, L. Kharaboyan & B.M. Knoppers, “Umbilical cord blood stem cells: issues with private and public banks” (2004) 12 *Health L. J.* 17 at 23.

<sup>11</sup>See European Group, *supra* note 8 at 6.

<sup>12</sup>See *ibid.* at 7.

<sup>13</sup>*Ibid.* at 19.

<sup>14</sup>E.g. *ibid.* at 22 (opinion 2.9).

<sup>15</sup>See *Supra* note 10 at 32.

outside these areas would generally be precluded from making a donation even if they were so inclined.<sup>16</sup>

While these concerns need to be kept in mind, it is important to recognize the contribution that private banks could potentially make in this area.<sup>17</sup> As will be discussed in the section on 'the possibility of a national UCB program', private banks may be able to assist in meeting the UCB needs of Canadians while decreasing the strain on the public purse. They may be instrumental in progressing research in this area as well. Indeed, many private banks accept donations of UCB for research purposes and have a vested interest in developing therapeutic applications for privately banked units.<sup>18</sup>

Having set out the context for UCB banking in Canada, let us now turn to an in depth analysis of the key socio-ethical and legal issues: public awareness and perceptions relating to UCB banking (A); the process of informed consent for the collection, donation, processing, storage, and future use of UCB (B); issues related to ethnic diversity (C); and the possibility of a national UCB program (D).

## A. Public Awareness

### The Data Available

Very little research has been done on the knowledge and attitudes of the public with respect to UCB banking. But there are a small number of studies that have sought to address this issue and which begin to give us an indication of public perceptions of the purpose and need for UCB banks for clinical and research use, and the distinction between public and private banks. All but one of these studies were conducted outside of Canada, and a couple of them may be outdated since attitudes concerning UCB banking are likely to change over time and with scientific progress. Nevertheless, they will be reviewed here for lack of more relevant and recent data.

The one Canadian study involved a survey of pregnant women attending antenatal clinics at a regional hospital in Halifax.<sup>19</sup> Of the four hundred and

---

<sup>16</sup>Jennifer Gunning, "Umbilical cord cell banking – implications for the future" (2005) 207:2 Supp.1 Toxicology and Applied Pharmacology 538, online: <<http://www.sciencedirect.com> at 3>. In Canada at present, Héma-Québec limits its collection to two hospitals in the Montreal area. See online: <<http://www.hema-quebec.qc.ca>>. The Alberta Cord Blood Bank, on the other hand, accepts donations from across the country. See online: <<http://www.acbb.ca>>.

<sup>17</sup>See e.g. J.J. Nietfeld & Frances Verter, "Statistics on Autologous Cord Blood Storage and Use" (Presentation at the 6<sup>th</sup> Annual Cord Blood Society Congress, Tufts University School of Medicine, October 2004), online: International Cord Blood Society <<http://www.cordblood.org/main/pdf/Verter.pdf>>.

<sup>18</sup>Kris Hundley "Mining medical waste" *St. Petersburg Times* (12 May 2003), online: *St. Petersburg Times* <[http://www.sptimes.com/2003/05/12/Business/Mining\\_medical\\_waste.shtml](http://www.sptimes.com/2003/05/12/Business/Mining_medical_waste.shtml)>.

<sup>19</sup>Conrad V. Fernandez *et al.*, "Knowledge and attitudes of pregnant women with regard to collection, testing and banking of cord blood stem cells" (2003) 168:6 CMAJ 695.

forty-three women who completed the questionnaire, 70% rated their knowledge about cord blood banking as poor or very poor. Despite this lack of knowledge, 86% of women indicated that they would chose to donate to a public bank, whereas 14% of women would opt for private banking. The most common reasons cited by those who preferred public banks were altruism and the costs of private banking. Most women who gave preference to private banks felt that it would be a good investment to protect their child's health and wished to avoid feelings of guilt should the child eventually require the cord blood. Interestingly, level of knowledge was not associated with the choice between public and private banking. In terms of future use of the donated cord blood, 30% felt that it should only be used for transplantation whereas 67% supported use for research purposes, 39% for gene therapy, and 33% for drug manufacturing. Other interesting findings were that 68% of the women indicated that physicians should talk to pregnant women about the collection of cord blood. Many wished to receive information on the subject directly from a health care professional (66%) or in a prenatal class (70%). Finally, 25% of respondents overestimated the risk of a child needing a bone marrow transplant by his or her 10<sup>th</sup> birthday.

Although this survey was conducted amongst Canadian women, the results of this study cannot be generalized to the Canadian population as a whole since the sample was not representative of this population. Specifically, the women surveyed had above average education (72% had a university or college degree) and were not very ethnically diverse (85% were white). The region also had no established private or public cord blood banks, which is a factor that would likely affect knowledge and attitudes. Surveys conducted in different geographic regions of Canada would likely yield differing results.

Two other studies may assist in deciphering public perceptions of cord blood banks even though they were not conducted within Canada. A 1998 Swiss study looked at the acceptance of umbilical cord blood donation by pregnant patients.<sup>20</sup> The questionnaire provided concise information on the use of cord blood for transplantation and was distributed to women of different ethnic backgrounds attending the University of Basel Women's Hospital pregnancy outpatient clinic. Of the 245 responses analysed, 95% were in support of umbilical cord blood banking for future transplantation. Along similar lines, 93% of respondents stated that they would be willing to donate cord blood from their own child. Previous knowledge and ethnic background were not significant predictors of willingness to donate. The authors speculated that the absence of significant differences between women of different ethnic backgrounds was an indication that a high degree of HLA diversity could be expected for donated cord blood.

---

<sup>20</sup>D.V. Surbek *et al.*, "Umbilical cord blood transplantation: acceptance of umbilical cord blood donation by pregnant patients" (1998) 128:18 *Schweiz Med Wochenschr* 689 (article in German).

Another, more recent, Swiss study investigated the attitudes of Swiss mothers toward unrelated cord blood banking 6 months after donation.<sup>21</sup> The questionnaire was distributed to 131 women who had donated cord blood for unrelated banking. Of the 78 women who responded, 96.1% stated that they would donate UCB again, 100% continued to believe that their decision to donate was ethical and 74.8% were emotionally satisfied about UCB donation. Only 5.6% of respondents had slightly negative feelings toward CB donation which included fear, worry and doubt. The reasons why these negative feelings developed were not clear. Many women (63%) indicated that they were concerned about improper use of donated UCB for genetic testing or experimentation. The authors conclude that there is a high degree of satisfaction concerning unrelated umbilical CB donation among women six months after delivery, and, in light of concerns about improper use of donated CB, specify that accurate and detailed counselling should maximize willingness to donate.

Finally, a 1998 article documents pregnant women's perspectives on umbilical cord blood banking based on three focus group discussions conducted in the south-eastern United States.<sup>22</sup> A total of 19 women with diverse socio-demographic characteristics participated. The authors reported that the women approached the subject of UCB with hesitancy and that this hesitancy was primarily attributable to a lack of knowledge. During the discussions, the women expressed a clear desire to know more about UCB banking and the collection, storage and use of UCB. They articulated concerns about confidentiality and whether the collection of cord blood posed any threat to the safety of the mother or child. There was also some indication that women's beliefs about the placenta might influence the willingness to donate cord blood. At the end of the discussion, all of the women involved indicated that they would be willing to donate UCB to a public bank. Reasons supporting this decision included altruism and the fact that the UCB would otherwise go to waste.

### **Is There a Need for an Information Campaign or Regulation of Advertising?**

Although more research is needed, the data discussed in the previous section provides some indication that there may be a lack of information amongst the general population concerning UCB banking. In addition, it has been noted that private banks may exaggerate the potential clinical applications of stem cells derived from cord blood, over-represent the probable need for autologous or familial transplant, and overstate the speed of progress in the area of stem cell research.<sup>23</sup> Private banks may also be disinclined to reveal some of the limitations of autologous transplant, including the fact that genetic diseases cannot be cured by this method.<sup>24</sup>

---

<sup>21</sup> Enrico Danzer *et al.*, "Attitudes of Swiss mothers toward unrelated umbilical cord blood banking 6 months after donation" (2003) 43:5 *Transfusion* 604.

<sup>22</sup> Jeremy Sugarman *et al.*, "Pregnant women's perspectives on umbilical cord blood banking" (1998) 7:6 *Journal of Women's Health* 747.

<sup>23</sup> *Supra* note 10 at 30 (these observations were based on a review of various private UCB bank websites).

<sup>24</sup> *Ibid.*

In order to improve knowledge around the issue of UCB banking, an information campaign could be considered. In addition, given the vulnerability of new parents, regulation of advertising in this area may be desirable. Similarly, the recruitment strategies used by both private and public banks may require supervision to ensure, for example, that parents are being adequately informed. Public banks must also be careful to avoid the use of coercive measures in their attempts to increase minority recruitment.

A number of issues arising from the foregoing discussion merit further investigation and reflection. For example, how well informed is the Canadian public on issues relating to UCB banking? What are the opinions of the Canadian public with respect to UCB banks, the use of UCB for clinical and research purposes, and the relative merits of public and private banks? Do attitudes differ across the country or among racial or ethnic minorities? Is there a need for an information campaign to increase public knowledge? Are UCB banks preying on the vulnerabilities of new parents and misleading potential donors? Should advertising in this area be regulated? And finally, is there a need for supervision of the recruitment practices used by private and public banks?

## **B. Informed Consent**

Since the discovery that umbilical cord blood could be useful for clinical and research purposes, the general position is that consent should be required for its collection and use.<sup>25</sup> Treating UCB as abandoned waste material or presuming consent for its collection and use would be difficult to justify in this day and age, especially given the sensitive nature of the medical information that needs to be collected in order to protect the safety of potential recipients.<sup>26</sup>

Even though the need to obtain consent is well accepted, there are a number of issues relating to consent which remain unresolved. For example, a consensus has not yet been reached on questions such as when consent should be obtained and from whom, as well as what information should be provided and in what manner. Accordingly, cord blood banking consent policies and practices may vary from bank to bank. This variability stems from various factors, including whether the bank is public or private, the collection procedure used, the use to which the collected cord blood will be put, whether the cord blood will be stored identified or not, and public policy priorities.<sup>27</sup>

---

<sup>25</sup> See e.g. Dorothy E. Vawter *et al.*, "A phased consent policy for cord blood donation" (2002) 42:10 *Transfusion* 1268 at 1269.

<sup>26</sup> See e.g. *supra* note 9 at 272.

<sup>27</sup> *Supra* note 25 at 1268-69.

## Timing

The timing of consent for the collection, storage and use of cord blood is an issue that has been frequently addressed in the ethical literature. It is generally agreed that consent should ideally be sought prior to labour and delivery. The IOM Report, for example, recommends that “[i]nformed consent for the collection, storage and use of cord blood should be obtained before labour and delivery, and after adequate disclosure of information.”<sup>28</sup> Similarly, the American Academy of Pediatrics recommends as follows: “[w]ritten permission should be obtained during prenatal care, and before the onset of labour. The practice of collecting cord blood first and obtaining permission afterward is considered unethical and should be discouraged.”<sup>29</sup> The Society of Obstetricians and Gynaecologists of Canada recommends that “[i]nformed consent for umbilical cord blood collection and banking should be obtained during prenatal care, before the onset of labour, with confirmation of consent after delivery.”<sup>30</sup> These recommendations are in line with the attitudes of women who have been involved in focus group discussions or have been surveyed on the matter.<sup>31</sup> Obtaining consent prior to labour and delivery with affirmation following delivery is considered by some to be an ideal approach.<sup>32</sup>

There is, however, some support for a more flexible approach to consent. The IOM Report concedes that in some cases it will not be feasible to obtain consent before the onset of labour.<sup>33</sup> In such circumstances, it may be acceptable to obtain the donor’s consent for the collection of cord blood after the onset of labour but prior to delivery, as long as the donor is assured that no further steps will be taken until the mother (and father, if present) have had the benefit of full informed consent. The Report remarks that two of the banks visited by the committee took a flexible approach to consent and that this approach seemed to translate into greater representation of otherwise under-represented populations. The New York Blood Center, for example, seeks consent from donors only after the cord blood has been collected – consent to collection is either presumed or thought to be unnecessary. This is done for logistical reasons and because it is believed that explicit consent to collection is not ethically required.<sup>34</sup> Consent to donation is fully informed, but is obtained after collection.

---

<sup>28</sup> Institute of Medicine of the National Academies, Committee on Establishing a National Cord Blood Stem Cell Bank Program, Board on Health Sciences Policy, Emily Ann Meyer, Kathi Hanna, & Kristine Gebbie, eds., *Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program* (Washington, D.C.: The National Academies Press, April 14, 2005) at 111 (recommendation 5.2), online: National Academies Press <<http://www.nap.edu/books/0309095867/html>> [IOM Report].

<sup>29</sup> AAP Work Group, *supra* note 8 at 118.

<sup>30</sup> *Supra* note 9 at 273 (recommendation 13).

<sup>31</sup> See *supra* note 22 at 751 (but note that the focus groups only comprised 19 women – it cannot be assumed that all women would feel this way); see also *supra* note 19 (83% of respondents felt that women should be asked about cord blood banking before 30 weeks of pregnancy).

<sup>32</sup> See L. Kharaboyan *et al.*, “Umbilical cord blood banking: implications for women, children and obstetrical-care providers” *Women’s Health Issues* (submitted) at 6.

<sup>33</sup> *Supra* note 28.

<sup>34</sup> *Supra* note 25 at 1270.

Since improving the ethnic diversity of banked units has been identified as a priority, an argument can be made in favour of this more flexible approach. However, not obtaining consent to the collection of cord blood may be offensive to the public and may undermine public support for such programs. Vawter *et al.* explain:

To presume consent to cord blood collection in a nonemergency situation, for a nontherapeutic activity that may cause the parents psychological, spiritual, or social discomfort in the interests of a possible stranger, raises important concerns about respect for donors and family members. After-collection consent policies prioritize concern for efficiency and pursue it at the expense of respect for donors and their family members, which may undermine trust in community cord blood banking and possibly other types of organ and tissue donations as well.<sup>35</sup>

It is therefore important to ensure that a flexible approach to consent does not compromise respect for donors. Vawter *et al.* propose a 'phased consent policy' for cord blood donation which separates consent to blood collection from consent to donation, including consent to testing, health history interview, medical record review, and storage and future use of the cord blood.<sup>36</sup> This approach requires explicit consent to the collection and donation of cord blood, but consent to ex utero collection may be obtained during the early stages of labour in women who meet established criteria. In those cases, consent for donation is postponed until after the mother has recovered from delivery when she is better disposed to consider this relatively more complex decision. While general information about cord blood banking may be provided to women during pregnancy, this is not required for a woman to be eligible to donate cord blood. In this way, women who have not had the benefit of prenatal care, or who received this care from a clinic which did not provide the opportunity for consent to donation prior to labour, are not precluded from donating. The authors claim that this consent policy "attends to the unique characteristics of cord blood collection and donation, respects donors and their families, maximizes the number and diversity of cord blood units collected, preserves the relationship between providers and patients, and preserves public trust in cord blood and other types of tissue banking."<sup>37</sup>

The guidelines of various agencies currently involved with the accreditation of cord blood banks, or the standardization of relevant policies and practices, allow for some flexibility in the timing of the consent process. The Foundation for Accreditation of Cellular Therapy (FACT) / NetCord International Standards for Cord Blood Collection, Processing, Testing, Banking and Release, for example, allow for consent to be obtained before or within 7 days of delivery, unless the cord

---

<sup>35</sup> *Ibid.* [footnotes omitted].

<sup>36</sup> *Ibid.*

<sup>37</sup> *Ibid.* at abstract.

blood is collected from the placenta in utero, in which case consent must be obtained before collection.<sup>38</sup> In neither case may consent be obtained during active labour. The Canadian Standards Association's standards for *Lymphohematopoietic Cells for Transplantation* are silent on the timing of consent for cord blood collection, specifying only that "[i]n the event of cord blood donation, informed consent in accordance with applicable laws and regulations shall be obtained from the mother."<sup>39</sup> The general requirements applicable to all cells, tissues and organs for transplantation add only that consent procedures should conform with medical standards of practice.<sup>40</sup>

Currently, the two public cord blood banks operating in Canada, the Alberta Cord Blood Bank and Héma-Québec, require advance registration for the collection of cord blood.<sup>41</sup> Private banks presumably also require advance registration. This requirement implies that the prospect of intra-partum or post-collection consent is not a reality currently faced by Canadian women. It may, however, become an issue as cord blood banking becomes more common in this country. Even if a more flexible consent policy is adopted, there should be a concerted effort to ensure that women receive information on cord blood banking during the prenatal period so that they will have the opportunity to make an informed choice between public and private banking and to contemplate what they consider to be acceptable uses of their infant's cord blood.

### Who must consent?

Another issue that needs to be addressed is that of whose consent is required for the collection, donation, testing, storage and long-term use of cord blood. The necessity of obtaining the woman's consent is not generally questioned since she will be required to provide personal medical information as well as a blood sample which will be tested for various genetic or infectious diseases. But it is not entirely clear if the consent of the father should also be required, or if the child should be asked to renew the consent once he/she attains the age of majority.

The Canadian Standards Association requires that consent be obtained from the mother.<sup>42</sup> FACT/NetCord is a bit more explicit in specifying that informed consent shall be obtained from the biologic mother and that where there is a

---

<sup>38</sup> *Supra* note 7 at C2.100, C2.120.

<sup>39</sup> CSA Standard Z900.2.5-03 at 10.1.2.5.

<sup>40</sup> CSA Standard Z900.1-03, "Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements" at 10.1.

<sup>41</sup> The Alberta Cord Blood Bank accepts registrations up until the 34th week of pregnancy. See online: <<http://www.acbb.ca>>. Héma-Québec accepts registrations up until 36 weeks of pregnancy. "Establishing a National Cord Blood Bank System for Canada" (Presentation at the Canadian Hematology Society and the Canadian Blood and Marrow Transplantation Group Symposium, Toronto, Ontario, June 24th, 2005) [attended personally by both authors] [*Symposium*].

<sup>42</sup> See *supra* note 39.

surrogate mother, her consent is also required.<sup>43</sup> Neither mentions the necessity for consent from the father. Theoretically, if the cord blood is collected in utero, the mother's consent should be sufficient since the placenta is an extension of her body.<sup>44</sup> But where the cord blood is collected ex utero, it could be argued that the decision to donate is one that concerns both parents, as do decisions about a child's medical care.<sup>45</sup>

When focus groups were asked about the role that fathers should play in consenting to CB donation, some women were in favour of having the fathers more involved in the decision, while others were reluctant to include the father in this process.<sup>46</sup> A survey of pregnant women revealed a similar division of opinion with approximately two-thirds of respondents indicating that the father should have a choice about the collection of cord blood and whether to donate to a public or private bank.<sup>47</sup> In case of disagreement, however, 77% felt that the final decision should be left to the mother.<sup>48</sup>

It also remains to be determined whether the child him/herself should be required to provide consent to ongoing storage and use if their donated cord blood has been stored in a traceable manner and is still in existence at the time the child attains the legal age of majority.

### What Information Should be Provided?

A quick reading of the informed consent forms currently used by various public and private banks reveals wide variability in content and detail. The content varies between public and private banks, but also amongst banks of the same type. Furthermore, the language used in many of the documents is often not very intelligible from the perspective of the average person.

Kharaboyan *et al.* suggest that informed consent for UCB banking should address the following key issues: that banking for autologous use is of questionable value given the current state of scientific knowledge, that UCB donated to a public bank may not be available to the donor or a family member if the units in question have already been used, information about testing of UCB units for infectious and genetic diseases, information on alternatives to UCB, and information about possible future use of UCB for research purposes.<sup>49</sup>

---

<sup>43</sup> *Supra* note 7 at C2.100, C.2.110.

<sup>44</sup> IOM Report, *supra* note 28 at 110.

<sup>45</sup> *Ibid.*

<sup>46</sup> *Supra* note 22 at 753.

<sup>47</sup> See *supra* note 19 at 696.

<sup>48</sup> *Ibid.*

<sup>49</sup> *Supra* note 32 at 13.

The FACT/Netcord International Standards add that donors should be informed that a personal and family history will be required, that medical records of the mother and infant will be reviewed, and that a maternal blood sample will be required for genetic and infectious disease testing.<sup>50</sup> The cord collection procedure must be described, and policies on the maintenance of linkages for notification purposes and the disposal of cord blood units not suitable for transplant must be disclosed.<sup>51</sup> Other relevant information includes the procedure concerning notification of abnormal results, and questions of confidentiality and ownership.<sup>52</sup>

All of this information should be provided in a manner that makes it accessible to potential donors or clients – this means that the use of technical jargon should be avoided and that the information should, if possible, be made available in a language understood by that person. In order to address the variability in information provided, the desirability and feasibility of creating a universal informed consent form for all Canadian UCB banks should be considered.

### Re-Evaluating Informed Consent

The efficacy of the informed consent process for umbilical cord blood banking was evaluated in a recent study conducted in the United States.<sup>53</sup> The study involved telephone interviews with 170 women who had donated their newborn's umbilical cord blood to a public cord bank. Although 98.8% of the women indicated that all their questions had been answered and 96.5% were satisfied with how they were informed about donation, there was evidence of notable shortcomings in the process. For example, only 32.9% of women understood that they had the option of not having UCB collected at all, 55% realized that they could opt for private banking instead, 78.8% mistakenly believed that they could donate UCB to a specific recipient, and many appeared to be unclear on the potential risks and benefits of donating UCB (e.g. 48% thought that one reason to donate was to protect the baby). This study illustrates that, even where an 'optimal' informed consent procedure is in place, those making a decision about whether to donate may not be as well informed as one would hope.

In response to the difficulties of attaining an optimal informed consent, some authors have questioned people's desire for autonomy in medical decision making and called for a dose of realism with respect to what can be expected of the process of informed consent.<sup>54</sup> Other authors, while acknowledging that informed consent is an imperfect process, have re-affirmed the value of informed consent in protecting autonomy but conceded that many individuals may wish to exercise their

---

<sup>50</sup> See *supra* note 7 at C2.300.

<sup>51</sup> *Ibid.*

<sup>52</sup> See *American Association of Blood Banks guidelines* cited in IOM Report, *supra* note 28 at 109.

<sup>53</sup> Jeremy Sugarman *et al.*, "Optimization of informed consent for umbilical cord blood banking" (2002) 187:6 *American Journal of Obstetrics and Gynecology* 1642.

<sup>54</sup> E.g. Carl E. Schneider, "Some realism about informed consent" (2005) 145:6 *Journal of Laboratory and Clinical Medicine* 289.

autonomy through a less rigorous mechanism, such as by deferring to a physician in the case of clinical decision making, or a research ethics board in the case of research.<sup>55</sup> In the context of umbilical cord blood banking, this argument could potentially find application in the level of consent required for future research uses of banked cord blood.

Two recent Swedish studies on research using biobanks provide some support for this notion, although the results obviously cannot be generalized to the Canadian population. While UCB banks differ from biobanks in terms of their purpose, parallels can be drawn to the extent that stored tissues may be used for future research and accompanying personal medical information may be retained in a linked or coded fashion. Both studies were conducted by the same investigators and appear to have involved a substantially similar questionnaire. One study investigated the attitudes of the Swedish public towards the use of tissue for research,<sup>56</sup> the other looked at the perceptions of individuals who had donated blood to a Swedish biobank.<sup>57</sup> In the former study, only 4.2% of respondents considered informing donors about the research objectives as the most important ethical issue in relation to biobanks, although 30.5% felt that this issue was important. Similar results were obtained in the second study: 3.9% considered informing donors about the research objectives as the most important ethical issue, while 31.5% felt the issue was important. Both studies revealed that a majority of respondents, 85.9% and 66.8% respectively, would accept surrogate decision making by research ethics committees for determining the research uses of donated blood. Of those respondents who would accept surrogate decision making in the second study, approximately 60% were nevertheless interested in receiving information about projects involving their samples. The researchers arrive at similar conclusions in both studies. In the former, they conclude that “[t]he current emphasis on the question of informed consent in policy making for biobank-based research does not seem to be reflected unambiguously in the concerns of the general public.”<sup>58</sup> In the latter, they state that “[t]his study calls for reconsideration of the importance attributed to informed consent in debates about ethics of biobanks and genomics companies and for in-depth exploration about what is at stake for donors in various contexts.”<sup>59</sup>

Hoeyer *et al.* suggest that the donating public may consider information about research objectives as more of a service than a safeguard.<sup>60</sup> They call for more research to determine whether the apparently higher level of interest in informed consent reported in research conducted in the United States is a reflection of a

---

<sup>55</sup> E.g. David J. Satin, “More realism about informed consent” (2005) 145:6 *Journal of Laboratory and Clinical Medicine* 292 at 293.

<sup>56</sup> Klaus Hoeyer *et al.*, “Informed consent and biobanks: a population-based study of attitudes towards tissue donation for genetic research” (2004) 32:3 *Scandinavian Journal of Public Health* 224.

<sup>57</sup> Klaus Hoeyer *et al.*, “The ethics of research using biobanks: reasons to question the importance attributed to informed consent” (2005) 165:1 *Archives of Internal Medicine* 97.

<sup>58</sup> *Supra* note 56 at abstract.

<sup>59</sup> *Supra* note 55 at 100.

<sup>60</sup> *Ibid* at 99.

culture which accords greater value to autonomy, or whether this finding is merely a by-product of the manner in which the surveys were designed – specifically that they rest on certain assumptions about donors’ interests in information as a means for enhancing their autonomy. The authors emphasize that other concerns, including societal interests, fairness, equality and transparency, also underlie public trust and are perhaps not given the attention they deserve.<sup>61</sup> If cultural differences are at issue, then data specific to the Canadian population will be important, especially given our socialized medical system which may reflect a greater degree of concern for the common good.

Despite the apparent importance that Americans accord to the notion of informed consent, there is evidence that a lesser form of consent may be acceptable to them for future research use of banked samples in certain circumstances. In a 2002 study conducted in the United States, two out of three respondents felt that consent should be necessary for research using clinically derived identified samples, whereas only one in eight believed consent should be required for additional research on research-derived anonymized samples.<sup>62</sup> The study results suggested that once donors consented to research use of their clinically derived samples, consent for further research on these samples may not be required. Their data also seemed to indicate that it may not be necessary to specify which kind of research will be conducted on the sample at the time of original consent. Despite this finding, the authors were careful to point out that consent for future research would be valid only so long as there was no increase in the risks to which donors might be exposed.

In the Canadian context, the Tri-Council Policy Statement on *Ethical Conduct for Research Involving Humans* provides guidelines for the use of human tissues in research.<sup>63</sup> The guidelines specify that informed consent should be obtained for the collection and use of human tissues in research.<sup>64</sup> Article 10.3 relates to the use of previously collected tissues:

- (a) When identification is possible, researchers shall seek to obtain free and informed consent from individuals, or from their authorized third parties, for the use of their previously collected tissue...
- (b) When collected tissue has been provided by persons who are not individually identifiable (anonymous and anonymized tissue), and when there are no personal harms to them, there is no need to seek

---

<sup>61</sup> *Supra* note 56 at 228.

<sup>62</sup> Dave Wendler & Ezekiel Emanuel, “The debate over research on stored biological samples: what do sources think?” (2002) 162:13 *Archives of Internal Medicine* 1457.

<sup>63</sup> Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans* 1998. (with 2000, 2002 and 2005 amendments), online: <<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>>.

<sup>64</sup> *Ibid* at article 10.1.

donor's permission to use their tissue for research purposes, unless the applicable law so requires.<sup>65</sup>

Thus, if the UCB is collected for transplant purposes but found to be unsuitable, researchers are expected to obtain free and informed consent unless the unit has been rendered anonymous. Informed consent includes providing information about the purpose of the research, how the use of the tissue could affect privacy, etc.<sup>66</sup> The guidelines do not indicate how detailed this information should be, so it may be possible to accommodate a more general form of consent within this framework. It remains to be determined, however, whether this would be acceptable to the Canadian public.

In summary, there are many questions relating to informed consent which require further consideration. Specifically, what level of consent is required for the collection, donation, processing, storage, and clinical or research use of UCB? Is a lesser form of consent acceptable for some aspects of UCB banking e.g. specific consent for collection, donation and storage, but general consent for future research use? What if some types of research offend the sensibilities of potential donors? Would it be feasible to have a checklist of acceptable 'types' of research for which the donor could grant or deny consent? Whose consent is required? When should consent be obtained? Is a flexible approach to consent permissible in light of the need to increase the representation of otherwise under-represented populations? What information should be provided in the process of informed consent? Is it possible or desirable to develop a universal informed consent form for all UCB collected in Canada? With progress in the field of genetic diagnosis, is there pressure to subject donated units to extensive genetic testing? What are the implications of extensive genetic testing of UCB in terms of informed consent? Should donors be informed of genetic test results and, if so, should this be limited to conditions for which a treatment exists? Would genetic counselling become a legal obligation for UCB banks if genetic test results are to be revealed to donors?

### C. Issues Related to Ethnic Diversity

An important goal of cord blood banks is to increase the ethnic and racial diversity of banked cord blood in order to ensure equitable access to transplantation. It is believed that cord blood banking programs are likely to be more successful than marrow donor programs at recruiting donations from ethnic minorities.<sup>67</sup> However, according to a 2002 study, initial efforts in the United States did not appear to be effective in achieving this goal. The study results indicated that minority recruitment was in fact worse in cord blood programs than in marrow

---

<sup>65</sup> *Ibid.*

<sup>66</sup> *Ibid* at article 10.2.

<sup>67</sup> E.g. *supra* note 20.

donor programs for four of the five areas surveyed.<sup>68</sup> Furthermore, the overall percentage of minority donors for both programs was low compared with the percentage of minority women in the baseline delivery population.

The London Cord Blood Bank reported having more immediate success with minority recruitment for cord blood donation – specifically, 41.5% of the first 1000 collections were obtained from non-European minorities.<sup>69</sup> This was achieved by selecting collection hospitals with an ethnically diverse maternal population. More recently, this strategy appears to have been effective in the United States as well: a 2004 study indicated that a racially diverse inventory can be achieved in a national network of cord blood banks.<sup>70</sup> The reported cord blood donor population was 64% white, 16% black, 12% Hispanic, 4% Asian, 1% Native American, and 3% other. There is evidence that cord blood units from African American donors may contain lower cell counts per volume than other ethnicities.<sup>71</sup> This finding may imply that even more emphasis needs to be placed on recruitment of black donors in order to bank an acceptable number of units with sufficiently high CD34 counts.<sup>72</sup>

Increasing the ethnic and racial diversity of banked cord blood remains a priority, both on a national and international level. In order to attain this goal, potential barriers to cord blood donation will need to be explored and appropriate strategies to increase minority recruitment will need to be implemented.

### **Barriers to Cord Blood Donation in Ethnic and Racial Minorities**

A recent study evaluated barriers and motivators to blood and cord blood donations in young African-American women.<sup>73</sup> One hundred and sixty-two African-American women between the ages of 18-30, living in the St. Louis metropolitan area, were interviewed by telephone. The primary barrier to cord blood donation identified by the survey was a lack of awareness that cord blood donation has the potential to save lives.

In terms of motivators for donation, the majority of respondents (78%) did not believe that any recognition was necessary for the donation of cord blood, although a few indicated that they would appreciate some form of recognition such as a thank you, a letter of recognition, a monetary reward, or information on how

---

<sup>68</sup> Karen K. Ballen *et al.*, “Racial and ethnic composition of volunteer cord blood donors: comparison with volunteer unrelated marrow donors” (2002) 42:10 *Transfusion* 1279.

<sup>69</sup> S. Armitage *et al.*, “Cord blood banking in London: the first 1000 collections” (1999) 24:2 *Bone Marrow Transplantation* 139.

<sup>70</sup> Karen K. Ballen *et al.*, “Racial diversity with high nucleated cell counts and CD34 counts achieved in a national network of cord blood banks” (2004) 10:4 *Biology of Blood and Marrow Transplantation* 269.

<sup>71</sup> *Ibid.*; Joanne Kurtzberg *et al.*, “Results of the cord blood transplantation (COBLT) study unrelated donor banking program” 45:6 *Transfusion* 2005 842.

<sup>72</sup> *Supra* note 70 at 274.

<sup>73</sup> Brenda Grossman *et al.*, “Barriers and motivators to blood and cord blood donations in young African-American women” (2005) 78:3 *American Journal of Hematology* 198.

their donation helped someone. The authors suggest that altruism may therefore be a sufficient motivator for donation. This inference is supported by the findings of various studies outlined above which revealed that altruism was the principal reason underlying a decision to donate.<sup>74</sup> Those studies were not targeting a specific minority population. Interestingly, both those studies and the study targeting African-American women found lack of knowledge to be a significant concern. These common findings might lead one to believe that barriers and motivators amongst the African-American population are similar to those existing in the general population. Grossman *et al.* note that “barriers to donation in African-American women do not appear to be different than barriers in the Caucasian population.”<sup>75</sup>

However, racial or cultural factors certainly cannot be overlooked as possible reasons for the lesser representation of minority populations within cord blood bank inventories. Studies looking at organ donation amongst African-Americans have identified mistrust of the medical system as a possible barrier to organ donation.<sup>76</sup> This factor may well be at play for cord blood donation as well. Siminoff and Arnold explain:

...we believe that the negative opinions of African-American persons about cadaveric organ donation reflect a deeper distrust of the medical system. These perceptions are not directed specifically at organ donation and transplantation; rather, they must be seen as part of the distrust that develops among persons who have been subjected to institution-alized racism and to a system that may unconsciously continue to reify the racism of the larger society...<sup>77</sup>

The belief that mistrust of the health care system may affect donation rates is supported by the results of a recent telephone survey designed to evaluate race and gender differences in willingness to donate blood and cadaveric organs.<sup>78</sup> The investigators found that willingness to donate blood was most influenced by concerns regarding trust in hospitals and health care professionals.<sup>79</sup> This phenomenon was more pronounced for black males than for black females, however. Furthermore, the results cannot necessarily be generalized to cord blood donation.

Religious beliefs held by certain minority groups may also be a factor influencing willingness to donate. A 1993 Gallop Organization poll found that

---

<sup>74</sup> See section on Public Awareness above.

<sup>75</sup> *Supra* note 73 at 201 [footnotes omitted].

<sup>76</sup> E.g. Laura A. Siminoff & Robert Arnold, “Increasing organ donation in the African-American community: altruism in the face of an untrustworthy system” (1999) 130:7 *Annals of Internal Medicine* 607.

<sup>77</sup> *Ibid.* at 609.

<sup>78</sup> L. Ebony Boulware *et al.*, “Understanding disparities in donor behavior: race and gender differences in willingness to donate blood and cadaveric organs” (2002) 40:2 *Medical Care* 85.

<sup>79</sup> *Ibid.* at 92.

black and Hispanic respondents were much more likely to report that organ donation was against their religion (14 and 13%, respectively) than were white respondents (4%).<sup>80</sup> These beliefs would not necessarily affect cord blood donation which differs in kind from organ donation. Indeed, in contrast to organ donation, religious beliefs were not identified as a significant barrier to blood donation among African-Americans in a recent survey.<sup>81</sup> Further research is necessary to determine what role religious or spiritual beliefs play in cord blood donation.

Along similar lines, it has been noted that some cultures may attribute special significance to the placenta.<sup>82</sup> In a multi-cultural society, it is important to recognize that members of cultural minorities may hold certain beliefs about the placenta and/or cord blood which differ from the mainstream North-American perception of these tissues as waste. Jenkins and Sugarman outline the varied and changing social meanings that have been attributed to the placenta over time and across cultures.<sup>83</sup> They emphasize that empirical research is necessary to uncover the diverse meanings attributed to human biologic material and that ethically appropriate approaches to the collection, storage and use of human biologic materials must take these meanings into account. They suggest that a failure to do so may act as a barrier to donation, if, for example, a minority culture is concerned that future research on their donated tissues may be conducted in a manner that is insensitive to their cultural beliefs.

The meanings attributed to the placenta and UCB may also have implications for the level of consent required for future research use of donated UCB. Jenkins and Sugarman explain: "where belief systems are consonant with the treatment of HBM [human biologic material] as waste, less stringent protections might be employed for research. In contrast, where there are divergent views about these materials, a more robust informed consent process might be required."<sup>84</sup> Taking such beliefs into account may be important in generating and maintaining public trust in a system of UCB banking.

### Strategies to Increase Minority Recruitment

Ballen *et al.* note how appropriate resources and societal support were able to increase minority recruitment of marrow donors for the National Marrow Donor Program.<sup>85</sup> Accordingly, they recommend various strategies to increase minority

---

<sup>80</sup>The Gallop Organization, Inc., "The American public's attitudes toward organ donation and transplantation" (Boston: The Partnership for Organ Donation, 1993), online: Transweb: All About Transplantation and Donation <[http://www.transweb.org/reference/articles/gallup\\_survey/gallup\\_index.html](http://www.transweb.org/reference/articles/gallup_survey/gallup_index.html)>.

<sup>81</sup>*Supra* note 78.

<sup>82</sup>See *supra* note 22 at 752; Gwynne L. Jenkins & Jeremy Sugarman, "The importance of cultural considerations in the promotion of ethical research with human biologic material" (2005) 145:3 Journal of Laboratory and Clinical Medicine 118 [Jenkins & Sugarman].

<sup>83</sup>*Ibid.*

<sup>84</sup>*Ibid.* at 122.

<sup>85</sup>*Supra* note 68 at 1283.

donation to cord blood programs: increase the number of minority members hired as employees for the cord blood program, allow donor recruitment during labour rather than requiring pre-natal recruitment, and form alliances with donor recruitment groups. They also recommend societal supports including public service announcements, outreach through local churches or community organizations, and increased educational materials made available in various languages.

The study by Grossman *et al.* which investigated barriers to donation in African-American women indicated that the support of clergy leadership for blood and cord blood collection programs would positively influence donation rates.<sup>86</sup> This strategy may therefore be particularly effective within the African-American community. Focusing education campaigns around diseases that disproportionately affect that community, and are treatable by hematopoietic stem cell transplantation, may also assist in rallying support. The Grossman *et al.* study, for example, specifically stressed the role of blood and cord blood donations in the treatment of sickle cell disease.

Minorities also should be made aware that there is a higher probability of matching if donors and recipients are from the same race or ethnicity. This knowledge may empower minorities to improve their own chances of benefiting equally from the health care system. A study on barriers to bone marrow donation among unrelated African-Americans revealed that individuals who knew that bone marrow transplantation is potentially life-saving and that the chances of finding a matched donor are higher within the same racial group were more than twice as likely to indicate a willingness to become a donor.<sup>87</sup>

If mistrust of the medical system is a factor limiting the willingness of minority populations to donate to cord blood programs, then public education campaigns should also address issues of trust and equity.<sup>88</sup> Discussion groups and face-to-face dialogue have been found effective in creating trust and confidence between physicians, hospitals, and potential African-American donors.<sup>89</sup> The wider context cannot be ignored either – in order to breed trust, equitable access to the health care system as a whole must be assured.<sup>90</sup>

Further research is required to elucidate minority religious, cultural or spiritual beliefs concerning UCB and the placenta. This will allow for the development of ethically appropriate procedures for UCB collection, donation, storage, and use.<sup>91</sup> In the meantime, the informed consent process could perhaps allow for greater choice in order to accommodate personal, religious, spiritual, or cultural

---

<sup>86</sup> *Supra* note 73 at 201.

<sup>87</sup> Joseph H. Laver *et al.*, "Assessment of Barriers to Bone Marrow Donation by Unrelated African-American Potential Donors" (2001) 7:1 *Biology of Blood and Marrow Transplantation* 45.

<sup>88</sup> *Supra* note 76 at 609.

<sup>89</sup> See *supra* note 87 at 47.

<sup>90</sup> *Supra* note 76 at 609.

<sup>91</sup> Jenkins & Sugarman, *supra* note 82.

beliefs. A checklist of options could be incorporated such that individual donors can limit their consent to those aspects of UCB banking which are in keeping with their values and beliefs.

If the racial and ethnic diversity of banked cord blood is to be increased, there are many issues that will need to be addressed. The foregoing discussion gives rise to a number of questions in this respect: what are the cultural, ethical and legal issues surrounding the collection and use of UCB amongst different ethnic communities in Canada? What are the barriers to donation within each of these cultural minorities? How can these barriers be overcome in order to increase minority recruitment for UCB donation? And, how can cultural beliefs be sensitively accommodated by cord blood banking programs?

#### **D. The Possibility of a National UCB Program**

There appears to be considerable impetus in Canada for the creation of a national UCB program. This sentiment may be fuelled by the United States Congress' decision to earmark a significant sum for the creation of a National Cord Blood Stem Cell Program, as well as the Institute of Medicine's recommendations on the matter.<sup>92</sup> The creation of a national cord blood bank system for Canada was in fact the topic of a recent symposium held by the Canadian Hematology Society and the Canadian Blood and Marrow Transplantation Group.<sup>93</sup> The symposium included a panel discussion on 'Critical Issues in Establishing a Canadian Cord Blood Bank System' which, among other things, brought to light several reasons why a national cord bank would be preferable to continued reliance on existing Canadian and international banks. Some of the reasons mentioned include that Canada has a minority population that is not adequately served by existing banks, the need to increase the availability of units with larger cell doses and better HLA matches, and the importance of contributing to research which, in turn, will ultimately translate into better clinical practice. Regulatory issues were cited as a possible barrier to the international availability of UCB units for transplantation. One panel member noted that until there is greater harmonization internationally, it may become more and more difficult to import the necessary units from banks outside of Canada.

There does appear to be a need for greater availability of transplantable UCB units in Canada. Keating & Huebsch estimate that approximately 400 patients a year (for whom no sibling or unrelated donor are available) could benefit from an alternate stem cell source such as UCB.<sup>94</sup> Nevertheless, it remains to be determined whether UCB banking should be considered a high priority in Canada.<sup>95</sup> It is

---

<sup>92</sup> See IOM Report, *supra* note 28.

<sup>93</sup> Symposium, *supra* note 41.

<sup>94</sup> A. Keating & L. Huebsch, "Umbilical cord blood transplantation in Canada: a companion background document", *ibid.* at 3.

<sup>95</sup> *Ibid.* at 6.

necessary to look not only at the opportunity costs of establishing a national cord blood bank, but also at alternative models that might, in whole or in part, achieve the same goals.

### Opportunity Costs of Establishing a National Cord Blood Program in Canada

The funding of a national system of cord blood banks is a major hurdle and must figure heavily in any decision regarding its implementation.<sup>96</sup> It is difficult to estimate the magnitude of the costs required to set up and run a national network of cord blood banks, but some figures are available. The New York Blood Centre National Cord Blood Program website states that the costs of collection, processing, testing and storage of cord blood amount to about US \$1,800 per unit.<sup>97</sup> Since most stored units will never be used, the costs per unit released for transplantation are considerably higher. The New York Blood Centre National Cord Blood Program apparently charged US \$15,300 per UCB unit in 1996.<sup>98</sup> Similar figures were reported in a 1999 Italian study which sought to determine the fee per UCB unit released for transplantation that would permit cost recovery within 10 years.<sup>99</sup> They generated estimates for three separate organizational models: model A (7 UCB banks with an inventory of 1,500 units each), model B (two multi-regional banks with an inventory of 5,000 units each), and model C (one national bank with an inventory of 10,000 units). It was determined that fees of US \$15,061, \$12,666, and \$11,602 per unit, respectively, would allow full cost recovery, assuming that 3% of the inventory could be released per year.

Although the exact costs will vary from country to country and according to the organizational model adopted, it is clear that UCB banking is an expensive endeavour – particularly when the health care system is assuming the costs of purchasing UCB units for transplants to be performed within the country. While the costs of an UCB transplant may be similar to the costs of a bone marrow transplant, transplants involving UCB may end up being considerably more expensive if double or sequential cord blood transplants become common practice.<sup>100</sup> In light of the significant drain that the establishment of a national system of cord blood banking could represent for Canadian tax dollars, it is necessary to evaluate whether cord blood banking should take precedence over other measures designed to promote or maintain the health of Canadians. If Canada were to become autonomous in supplying its own cord blood, would this decrease costs as compared

---

<sup>96</sup>In Canada, the funding of a public network of banks is further complicated by Constitutional issues related to the division of powers between the Federal and Provincial Governments. See e.g. *ibid.*

<sup>97</sup>New York Blood Centre National Cord Blood Program, online: <[http://www.nationalcordbloodprogram.org/donation/prospective\\_donor\\_faq.html](http://www.nationalcordbloodprogram.org/donation/prospective_donor_faq.html)> (This is a public bank).

<sup>98</sup>Written communication from P. Rubinstein (June, 1996), cited in G. Sirchia *et al.*, “Cost of umbilical cord blood units released for transplantation” (1999) 39:6 *Transfusion* 645 at 649.

<sup>99</sup>*Ibid.* at 645-650.

<sup>100</sup>*Supra* note 94 at 5-6.

to obtaining the necessary units from international banks? What competing concerns are vying for the limited pool of public funds? Where can an investment of funds produce the greatest good for Canadians? Can we justify the expense of a national cord blood program in light of current scientific knowledge concerning the clinical applications of UCB?

Although funds for public banks may be derived from a variety of sources, including charitable contributions, research grants, and the release of cord blood units for transplantation, the costs of establishing a national system of cord blood banking would fall primarily to the federal and provincial governments. Given this reality, it becomes ethically necessary to consider if there are other ways of meeting the hematopoietic transplant needs of Canadians which would put less of a strain on the public purse. These alternatives should be fully explored before any decisions are taken regarding the future of cord blood banking in Canada.

### Alternatives to a National Program

A potentially cost effective alternative to a national program might be achieved by means of public-private partnerships. Some form of mutually beneficial collaboration between public and private banks may increase the availability of appropriately matched UCB units for transplantation. Possible models for such public-private partnerships should be explored. The differing standards adhered to by public and private banks is an issue that would need to be addressed if a closer relationship between the two is to be established.<sup>101</sup> To the extent that private banks are engaged in supplying UCB for allogeneic use (as opposed to personal/autologous use), these differing standards will be addressed in part by the Health Canada Regulations regarding the safety of cells, tissues, and organs for transplantation which are expected to come out in the near future.<sup>102</sup>

It may also be possible to finance public banks based on revenue from private banking. Another option is to encourage private banks to make units available for public use. For example, some private banks currently run parallel programs which accept donations of UCB and make them publicly available on the international market.<sup>103</sup> In the future, there may be other ways for private banks to increase the number of publicly available units. In a recent report to the Netherlands Organisation for Health Research and Development, Nietfeld suggested that cell expansion may progress to the point where part of the stem cells stored for autologous use could be donated for allogeneic use.<sup>104</sup> This prospect is very much dependent on

---

<sup>101</sup> Symposium, *supra* note 42.

<sup>102</sup> *Supra* note 5.

<sup>103</sup> E.g. The Victoria Angel Registry of Hope is a philanthropic division of Cells for Life Ltd. (a Canadian Bank) which accepts donations of umbilical cord blood and makes the samples available to people throughout the world (it is unclear from the website whether there is a fee charged for the release of these units), online: <<http://www.cellsforlife.com/angel.htm>>. Another example is Cryobanks International, see "Public Cord Blood Donation", online: <<http://www.cryo-intl.com/cordblooddonation.html>>.

<sup>104</sup> Personal communication with J.J. Nietfeld, cited in Gunning, *supra* note 16 at 5.

the advancement of cell expansion techniques, however, since, without expansion, the cell dose that can be derived from the majority of single UCB units is inadequate for transplant recipients weighing over 50 kilograms.<sup>105</sup>

Partnerships between public cord blood banks and biotechnology companies are another possibility. Kourion Therapeutics AG, established in parallel with the non-profit Dusseldorf Cord Blood Bank, was an example, although it has now been taken over by an American company which operates a private cord blood bank.<sup>106</sup> The patenting of procedures relating to the processing and storage of cord blood may be inevitable, but it must be kept in mind that this has important implications in terms of accessibility.

Even if the idea of a national cord blood program is rejected, it may be possible to develop a more limited form of cord blood banking that would nevertheless require coordination on a national scale. Canada could engage in banking which focuses specifically on needs which are not being met by international UCB banks. Rather than trying to become largely self-sufficient in meeting the cord blood needs of our entire population, public Canadian banks could, for example, specialize in minority UCB banking. Since there are world-wide shortages of minority units, Canada may stand to release more units on an international market which could make the banking process more financially feasible. Of course this approach would not overcome the problem of regulatory discrepancies, which will have to be dealt with through some form of international consensus. It also assumes that minority recruitment can be increased sufficiently to sustain such a program. Furthermore, it may be unfair to the majority population if international inventories are not sufficient to meet their UCB needs.

Before Canadian policy makers can lay out a road map for the future of UCB banking in Canada, certain key questions must be addressed. Most notably, what are the needs of Canadians in the realm of UCB? Is there a need for a national system of UCB banking in Canada? What are the opportunity costs of establishing such a national system? What are the alternatives to a national program of UCB banking? Would these alternative models adequately meet the needs of Canadians? What are the ethical-legal-social implications of these alternative models?

## **Conclusion: Looking to the Future**

If an ethical framework for decision making around the future of cord blood banking in Canada is to have enduring validity, it must be capable of addressing both actual and anticipated socio-ethical and legal issues relating to UCB banking and use. This encompasses current and future clinical, as well as research, uses of UCB. From a clinical perspective, UCB is currently viewed primarily as a complementary source of hematopoietic stem cells for transplantation for recipients who

---

<sup>105</sup> *Supra* note 9 at 267.

<sup>106</sup> *Supra* note 16 at 5.

are unable to obtain stem cells from other sources such as sibling or unrelated donor bone marrow. As the science behind UCB banking and transplantation progresses, including the perfection of techniques for cord blood expansion, there may be an increase in the relative number of transplants involving UCB as opposed to those derived from bone marrow. UCB presents certain advantages over other stem cell sources, but it also has significant limitations.<sup>107</sup> It remains to be seen which stem cell source will prove to be the most useful for this and other clinical applications.<sup>108</sup> Following the discovery that cord blood may also contain non-hematopoietic progenitor cells, there is much talk of the potential usefulness of UCB in cellular therapies and regenerative medicine.<sup>109</sup> If these possibilities become clinical realities, then the demand for UCB may increase. Research in this area is in the very early stages, however, and any therapeutic applications remain purely speculative.

From a policy standpoint, it is important to remember that scientific discoveries about the nature and constitution of cord blood may have significant socio-ethical and legal implications. For example, a team of scientists has recently claimed that cells found in bone marrow and blood are a source of developing oocytes, although, as of yet, there is no evidence that they could be fertilized and develop into a fetus.<sup>110</sup> Nevertheless, this possibility raises ethical concerns and may have far reaching consequences for the donation of blood, bone marrow, and potentially cord blood. It would likely affect willingness to donate, informed consent procedures, and ethical objections to some forms of research to be performed on donated UCB.

There are a number of socio-ethical and legal issues relating to UCB banking and use that have not been discussed in the present paper. Some examples include the uncertain legal status of UCB (and consequences flowing from this status, e.g. ownership),<sup>111</sup> the benefits and risks of long term linkage, and issues of privacy and confidentiality related to UCB banking. Before policy makers can make an informed decision on the future of cord blood banking in Canada, all of these issues will need to be explored and further research will need to be conducted. It will also be necessary to set out concrete next steps to move this issue forward. Inaction will engender a situation in which UCB banking is left to evolve in a haphazard manner – this un-deliberated development will not necessarily serve the interests and needs of Canadians.

---

<sup>107</sup> See *supra* note 9. Advantages of UCB: more rapidly available, decreased risk of transmission of infectious disease, lesser incidence of GVHD, ease of collection, less risks involved in collection. Disadvantages: low cell dose, longer time to engraftment, risk of transfer of genetically abnormal hematopoietic stem cells. Other advantages include: large number of potential donors, perfect HLA match not required, *supra* note 16 at 1-2. Other disadvantages include: uncertain quality of current UCB inventory, difficult searches to locate HLA matched unit, *supra* note 94 at 1.

<sup>108</sup> See "Proceed with caution," Editorial, (2005) 23:7 Nature Biotechnology 763, online: <<http://www.nature.com/nbt/journal/v23/n7/pdf/nbt0705-763.pdf>>.

<sup>109</sup> *Supra* note 16 at 4-5.

<sup>110</sup> Gretchen Vogel, "Controversial study finds an unexpected source of oocytes" (2005) 309:5735 Science Magazine 678, online: <<http://www.sciencemag.org/cgi/reprint/309/5735/678.pdf>>.

<sup>111</sup> See e.g. *supra* note 10 at 25.

### Figure 1: Workshop Findings\*

This paper was prepared for the purposes of a workshop on 'The Future of Umbilical Cord Blood Banking in Canada' which was held in Montreal on August 31<sup>st</sup>, 2005. The workshop participants included representatives from various public and private UCB banks in Canada, Health Canada, Canadian Blood Services, Héma-Québec, the Canadian Blood and Marrow Transplant Group, an International Accreditation Body, and the Society of Obstetricians and Gynaecologists of Canada, as well as researchers, academics and physicians practising in the area.

Generally, the group agreed that there is a need to increase public awareness concerning UCB banking in Canada and noted the lack of understanding of the difference between embryonic as opposed to UCB stem cells amongst the general population. The lack of data on professional attitudes toward UCB banking and the need for professional continuing education on the subject were also highlighted. Overall, there appears to be a need for an information strategy on the part of public authorities.

The process of informed consent was discussed in relation to the collection, storage, and clinical or research use of UCB. The issue of who should be responsible for obtaining consent was of significant concern. In terms of what should be disclosed, there was a tendency in favour of full disclosure. In light of the wide diversity of consent forms currently in use and their variable levels of intelligibility to the average donor, it was agreed that it would be desirable to develop a template for informed consent which could be used by UCB banks across Canada.

Strategies to increase the HLA diversity of banked UCB were discussed. The need to work with minority communities and involve them in the development stage of recruitment efforts was stressed. It was noted that no one strategy will be effective for all minority communities and that the funding requirements for increasing minority recruitment should not be underestimated. Some suggestions included increasing awareness through patient advocacy groups, conducting studies to better understand cultural values and attitudes towards UCB banking, and addressing linguistic barriers to obtaining information on the subject. The use of international registries was identified as one means to increase access to ethnically diverse UCB units.

The medical need for a national public system of cord blood banking was questioned by some participants. Given the enormous expense that such a system would entail and uncertainty with respect to whether the need for UCB will increase or decrease in the future, it was felt that alternative models should be

### Figure 1: Workshop Findings\* (cont'd)

explored. If a national program is to be established, then well structured pilot programs will need to be undertaken in partnership with the scientific community. Because it is a high risk investment, public funding would be necessary for any national initiative. If there is to be greater reliance on the private sector, then the differing of standards between public and private banks will need to be addressed. It was felt that as long as there is full disclosure and good information, then private banking options should be freely available. Although the magnitude of the clinical benefits associated with a public system were questioned, it was noted that a public program would serve to stimulate research and advance knowledge in the area and that Canada could make a valuable contribution in this respect. There was a consensus that, at the very least, there is a need for a strategy for synergy or collaboration between existing facilities. It was noted that the creation of a national registry which could be linked up with the international system would allow for more efficient searches and ensure greater accessibility. An appropriate information technology infrastructure would be necessary to achieve this objective.

Overall, it was agreed that a national strategy is needed with respect to UCB banking, whatever form that strategy may take. It was further agreed that increasing public awareness and minority recruitment are important objectives. A simplified process of informed consent was seen as desirable, and to this end a template will be devised in order to provide guidance to Canadian UCB banks. Finally, before investing large amounts of public funds into a national program of UCB banking, more investigation is needed to determine actual clinical needs and to establish what the real benefits of such a system would be.

\*The workshop was organized by the Centre de recherche en droit public of the University of Montreal. The workshop and the present paper form part of a wider initiative on 'The Future of Umbilical Cord Blood Banking in Canada'. Funding for this initiative is provided by the Stem Cell Network (Catalyst Grant). The project team includes Bartha Maria Knoppers (Project leader, Canada Research Chair in Law and Medicine, Centre de recherche en droit public, University of Montreal), Tim Caulfield (Canada Research Chair in Health Law and Policy, Health Law Institute, University of Alberta), Connie Eaves (Deputy Director/Senior Scientist, Terry Fox Laboratory, B.C. Cancer Agency), and Jacques Galipeau (M.D., Associate Professor of Medicine and Oncology, Sir Mortimer B. Davis Jewish General Hospital & Lady Davis Institute for Medical Research). Lori Sheremeta (Research Associate, Health Law Institute, University of Alberta) and Margo Plant (Research Assistant, Centre de recherche en droit public, University of Montreal) are associate members of the team.