

# The Future of Cord Blood Banking in Canada

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## **Abstract**

The potential clinical utility of umbilical cord blood (UCB) as a source of stem cells has led to the emergence of several public and private cord blood banks across Canada (see Table 1). Although UCB banking in Canada remains in its early stages there are many regulatory and policy issues that need to be addressed. The purpose of the Stem Cell Network Catalyst project entitled “The Future of Cord Blood Banking in Canada” is to examine the socio-ethical and legal issues surrounding UCB banking and to develop an ethical framework to guide policy makers in mapping out the future of cord blood banking in Canada. As a first step in this process, a discussion paper was drafted in preparation for a workshop on point. The discussion paper provides a selective overview of key socio-ethical and legal issues implicated in UCB banking. The issues addressed include: 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 potential of developing a national UCB banking and transplant program. Relevant literature is synthesized and points for discussion are raised. This poster presentation provides a concise summary of the main issues identified in the discussion paper and will serve to raise awareness and provoke reflection on these important socio-ethical and legal issues amongst Stem Cell Network researchers and participants at the Annual General Meeting.

## ***The Current State of Cord Blood Banking in Canada: Public v. Private***

At present Canadians can potentially access both public and private cord blood banks. Public UCB banks in Alberta, Quebec and Ontario accept donations of UCB samples that are processed and stored for future use - either autologous, related or unrelated. No fee is associated with UCB donation to a public bank. The samples are processed, stored and are accessible through an international registry to any appropriately matched individual who might need them. Alternatively, for a fee, private UCB banks process and store UCB samples for autologous or related transplantations.

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**Table 1: Public and Private Cord Blood Banks in Canada**

Public Banks	Private Banks	
	AABB Accredited	Non-Accredited
Alberta Cord Blood Bank		
Hema-Quebec	Lifebank Cryogenics Corp.	Baby Chord Securacell
Victoria Angel Registry of Hope	Cells for Life	Cord Blood Bank of Canada
		Create
		Healthcord
		HemaStem Therapeutics
		Inseption Biosciences Inc.
		Stem Sciences Cord Blood Bank
		Progenics

***Public Awareness and Perceptions of UCB Banking***

There are few published reports of public opinion on the topic of UCB banking and transplantation. The following table provides a summary of the main findings from identified published works.

**Table 2: Summary of Public Opinion Data on UCB Banking and Transplantation**

<p><b>C.V. Fernandez <i>et al</i>, “Knowledge and Attitudes of Pregnant Women with Regard to Collection, Testing and Banking of Cord Blood Stem Cells” (2003) 168(6) CMAJ 695.</b></p> <ul style="list-style-type: none"> <li>• 143 survey instruments completed by pregnant women attending antenatal clinics in Halifax.</li> <li>• 70% rated their knowledge about UCB banking as poor or very poor.</li> <li>• 86% of women would opt to donate to a public bank; 14% to a private bank.68% of women feel that their physicians should discuss the option with them.</li> </ul>
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**Table 2: Summary of Public Opinion Data on UCB Banking and Transplantation (cont'd)**

**E. Danzer *et al*, “Attitudes of Swiss Mothers Toward Unrelated Umbilical Cord Blood Banking 6 Months After Donation” (2003) 43(5) *Transfusion* 604.**

- There is a high degree of satisfaction concerning UCB donation among women 6 months after donation.
- Accurate and detailed counseling should maximize willingness to donate UCB and alleviate concerns about improper use of donated UCB.

**D.V. Surbek *et al*, “Umbilical Cord Blood Transplantation: Acceptance of Umbilical Cord Blood Donation by Pregnant Patients” (1998) 128 *Schweiz Med Wochenschr* 689 [German].**

- 245 pregnant women identified at a Swiss pregnancy outpatient clinic completed a survey instrument.
- 95% were supportive of UCB donation for future transplantation.
- 93% expressed a willingness to donate the UCB from their own child.
- Ethnicity did not affect the expressed willingness to donate UCB.

**J. Sugarman *et al*, “Pregnant Women’s Perspectives on Umbilical Cord Blood Banking” (1998) 7(6) *J of Women’s Health* 747.**

- Pregnant women lacked knowledge about UCB banking and expressed a desire to know more.
- Concerns about confidentiality and the safety of sample collection were raised.
- Given that UCB would otherwise go to waste and in the spirit of altruism all 19 participants expressed a willingness to donate UCB to a public bank.

**Edna F. Einsiedel *et al*, “First Impressions: Understanding Public Views on Emerging Technologies”,  
online: *BioStrategy* <[www.biostrategy.gc.ca/english/View.asp?pmiid=744&x=747](http://www.biostrategy.gc.ca/english/View.asp?pmiid=744&x=747)>.**

- People are generally supportive of stem cell research but there are concerns about how stem cells are obtained.
- Most people who are opposed to embryonic stem cell research approve of stem cell research using cells derived from UBC.
- Regardless of the sources of stem cells, there is a desire for tighter controls and regulations over stem cell research and product licensing.



## ***Informed Consent***

To date, the discussion about informed consent for UCB donation has closely paralleled the discussion about informed consent in the context of gene banks. UCB samples, like DNA samples, are collected and stored for future use. Unlike gene banking, the collection of UCB samples has a predominantly clinical purpose though samples not suitable for transplantation may have research value. The timing of eliciting informed consent is complicated by labour and delivery and by the fact that the biologic sample is directly referable to two individuals - the mother and the child - and potentially to other genetically related individuals.

**Table 3: Main Issues for Consideration in the context of Informed Consent**

<ul style="list-style-type: none"><li>• Who can give consent for the collection, storage and use of UCB? In the context of UCB research who is the “research subject”? Who, if anyone, has the legal authority to make decisions concerning research for an infant? What are the implications of the infant maturing to the status of a competent adult?</li></ul>
<ul style="list-style-type: none"><li>• Given that UCB samples may be relevant for both clinical and research purposes, what information must be conveyed to the donor/research subject?</li></ul>
<ul style="list-style-type: none"><li>• Can fully informed consent be obtained for the collection and storage of a UCB sample and a general authorization for future research uses (with or without certain defined limits) if approved by a competent research ethics board?</li></ul>
<ul style="list-style-type: none"><li>• What are the implications of genetic testing of UCB for the informed consent process? Under what circumstances should (or must) donors be informed of test results?</li></ul>
<ul style="list-style-type: none"><li>• Should genetic counseling become a legal obligation for UCB banks if genetic test results are to be revealed to donors?</li></ul>

## ***Ethnic Diversity***

An important goal of UCB banking is to increase ethnic and racial diversity of banked cord blood to ensure equitable access to transplantation. It is expected that UCB banking programs have the potential to be more successful than marrow donor programs at recruiting donations from ethnic minorities though in practice this potential has not materialized. In order to attain this goal, the potential barriers to donation must be explored and strategies to increase minority recruitment must be considered.



**Table 4: Barriers and Strategies to Overcome Barriers in the Recruitment of Minority Donors to UCB Banks**

<b>Barriers to Minority Recruitment</b>	<b>Strategies to Overcome Barriers</b>
Lack of awareness of UCB donor programs.	<ul style="list-style-type: none"> <li>• Develop comprehensive public outreach and education programs.</li> <li>• Permit informed consent process to occur during labour and delivery.</li> </ul>
Mistrust in healthcare system	<ul style="list-style-type: none"> <li>• Target education campaigns to groups that are disproportionately affected by specific diseases that are potentially treatable with UCB transplant.</li> </ul>
Religious beliefs	<ul style="list-style-type: none"> <li>• Where possible, engage religious leaders in the support of UCB programs.</li> </ul>
Cultural norms	<ul style="list-style-type: none"> <li>• Develop ethically appropriate and culturally sensitive procedures for UCB collection, donation, storage and use.</li> <li>• Ensure that the informed consent process is sufficiently flexible to accommodate personal, religious, spiritual and cultural beliefs.</li> </ul>

## ***Should Canada Invest in a National UCB Banking and Transplant Program?***

### ***Arguments in Favour of Developing a National UCB Banking Program in Canada***

- Canada has a large minority population that is not adequately served by existing Canadian or internationally accessible bone marrow or UCB banks.
- More stored units of UCB are needed to ensure better transplant matches. Keating and Huebsch\* estimate that approximately 400 patients a year could benefit from UCB transplantation.
- More research on UCB samples is needed to ensure continuing clinical advances in this area.

\* See “Umbilical Cord blood Transplantation in Canada: A Companion Background Document for the Canadian Blood and Marrow Transplantation Group and the Canadian Hematology Society”, Symposium on Establishing a National Cord Blood Bank System for Canada, June 24, 2005, Toronto, Ontario.



## ***Arguments Against a National UCB Banking and Transplant Program***

- The costs of developing a National UCB banking and transplant program are not trivial and would largely fall to the federal and provincial governments. Given this reality, it is important to carefully consider whether there are effective, fiscally responsible alternatives that would meet the hematopoietic transplant needs of Canadians.

## ***Alternative Model: Public-Private Partnerships***

Given the that the existing UCB banking capacity in Canada is divided between public and private banking facilities, it is important to consider how this capacity can best be optimized and expanded to meet the needs of Canadians.

## ***Options that Demand Further Consideration***

- Can public banking be funded from revenues obtained from private banking?
- Can mutually beneficial partnerships be created between public cord banks and biotech firms?

## ***Next Steps***

The Catalyst Grant Team is moving to develop comprehensive informed consent standards and a template document that can be used by public and private cord blood banks in Canada. The template will be designed to ensure that couples fully understand the limits, risks and potential benefits of UCB transplantation and research.

In the meantime, dialogue about the need for a national UCB program in Canada and the role that the leading public agencies, including Canadian Blood Services and Hema Quebec, together with private partners, can play in this regard is ongoing.

This poster was presented at the Stem Cell Network Annual General Meeting, Calgary, Alberta, November 22-25, 2005.

