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.


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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2. Centre de Recherche en Droit Public, Université de Montréal
### Table 1: Public and Private Cord Blood Banks in Canada

<table>
<thead>
<tr>
<th>Public Banks</th>
<th>Private Banks</th>
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<tr>
<td>Alberta Cord Blood Bank</td>
<td>AABB Accredited</td>
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<tr>
<td>Hema-Quebec</td>
<td>Lifebank Cryogenics Corp.</td>
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<tr>
<td>Victoria Angel Registry of Hope</td>
<td>Cells for Life</td>
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<td>Progenics</td>
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<tr>
<td>Stem Sciences Cord Blood Bank</td>
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<td>Healthcord</td>
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<td>HemaStem Therapeutics</td>
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<td>Inception Biosciences Inc.</td>
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### 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


- 143 survey instruments completed by pregnant women attending antenatal clinics in Halifax.
- 70% rated their knowledge about UCB banking as poor or very poor.
- 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.
Table 2: Summary of Public Opinion Data on UCB Banking and Transplantation (cont’d)


- 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.


- 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.


- 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.


- 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

<table>
<thead>
<tr>
<th>Issue</th>
<th>Description</th>
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<tr>
<td>Who can give consent for the collection, storage and use of UCB?</td>
<td>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?</td>
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<td>Given that UCB samples may be relevant for both clinical and research purposes, what information must be conveyed to the donor/research subject?</td>
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<td>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?</td>
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<td>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?</td>
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<td>Should genetic counseling become a legal obligation for UCB banks if genetic test results are to be revealed to donors?</td>
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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

<table>
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<tr>
<th>Barriers to Minority Recruitment</th>
<th>Strategies to Overcome Barriers</th>
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| Lack of awareness of UCB donor programs. | • Develop comprehensive public outreach and education programs.  
• Permit informed consent process to occur during labour and delivery. |
| Mistrust in healthcare system | • Target education campaigns to groups that are disproportionately affected by specific diseases that are potentially treatable with UCB transplant. |
| Religious beliefs | • Where possible, engage religious leaders in the support of UCB programs. |
| Cultural norms | • Develop ethically appropriate and culturally sensitive procedures for UCB collection, donation, storage and use.  
• Ensure that the informed consent process is sufficiently flexible to accommodate personal, religious, spiritual and cultural beliefs. |

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.

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 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.