No. 328, September 2015 (Replaces #156, March 2005)

Umbilical Cord Blood: Counselling, Collection, and Banking

This clinical practice guideline has been prepared by the Cord Blood Banking Working Group, reviewed by the Clinical Practice – Obstetrics, Maternal Fetal Medicine, Family Physician Advisory, and Aboriginal Health Initiative Committees, and approved by the Executive and Board of the Society of Obstetricians and Gynaecologists of Canada.

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Disclosure statements have been received from all contributors.

Abstract

Objective: To review current evidence regarding umbilical cord blood counselling, collection, and banking and to provide guidelines for Canadian health care professionals regarding patient education, informed consent, procedural aspects, and options for cord blood banking in Canada.

Options: Selective or routine collection and banking of umbilical cord blood for future stem cell transplantation for autologous (self) or allogeneic (related or unrelated) treatment of malignant and non-malignant disorders in children and adults. Cord blood can be collected using in utero or ex utero techniques.

Outcomes: Umbilical cord blood counselling, collection, and banking, education of health care professionals, indications for cord blood collection, short- and long-term risk and benefits, maternal and perinatal morbidity, parental satisfaction, and health care costs.

Evidence: Published literature was retrieved through searches of Medline and PubMed beginning in September 2013 using appropriate controlled MeSH vocabulary (fetal blood, pregnancy, transplantation, ethics) and key words (umbilical cord blood, banking, collection, pregnancy, transplantation, ethics, public, private). Results were restricted to systematic reviews, randomized control trials/controlled clinical trials, and observational studies. There were no date limits, but results were limited to English or French language materials. Searches were updated on a regular basis and incorporated in the guideline to September 2014. Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology-related agencies, clinical practice guideline collections, and national and international medical specialty societies.

Values: The quality of evidence in this document was rated using the criteria described in the Report of the Canadian Task Force on Preventive Health Care (Table 1).

Benefits, Harms, and Costs: Umbilical cord blood is a readily available source of hematopoetic stem cells used with increasing frequency as an alternative to bone marrow or peripheral stem cell transplantation to treat malignant and non-malignant conditions in children and adults. There is minimal harm to the mother or newborn provided that priority is given to maternal/newborn safety during childbirth management. Recipients of umbilical cord stem cells may experience graft-versus-host disease, transfer of infection or genetic abnormalities, or therapeutic failure. The financial burden on the health system for public cord blood banking and on families for private cord blood banking is considerable.

Recommendations

1. Health care professionals should be well-informed about cord blood collection and storage and about factors that influence the volume, quality, and ability to collect a cord blood unit. (III-A)
2. Health care professionals caring for women and families who choose private umbilical cord blood banking must disclose any financial interests or potential conflicts of interest. (III-A)
3. Pregnant women should be provided with unbiased information about umbilical cord blood banking options, including the benefits and limitations of public and private banks. (III-A)
4. Health care professionals should obtain consent from mothers for the collection of umbilical cord blood prior to the onset of active labour, ideally during the third trimester, with ample time to address any questions. (III-A)

Key Words: pregnancy, umbilical cord blood, informed consent, counselling, collection, storage, banking, stem cell transplantation, ethics, public, private, Canada.

J Obstet Gynaecol Can 2015;37(9):832–844

Table 1. Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventive Health Care

Quality of evidence assessment*	Classification of recommendations†
I: Evidence obtained from at least one properly randomized controlled trial	A. There is good evidence to recommend the clinical preventive action
II-1: Evidence from well-designed controlled trials without randomization	B. There is fair evidence to recommend the clinical preventive action
II-2: Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group	C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category	D. There is fair evidence to recommend against the clinical preventive action
	E. There is good evidence to recommend against the clinical preventive action
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees	L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

*The quality of evidence reported in these guidelines has been adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.[78]

†Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.[78]

5. Health care professionals must be trained in standardized procedures (ex utero and in utero techniques) for cord blood collection to ensure the sterility and quality of the collected unit. (II-2A)
6. Umbilical cord blood should be collected with the goal of maximizing the content of hematopoietic progenitors through the volume collected. The decision to bank the unit will depend upon specific measures of graft potency. (II-2A)
7. Umbilical cord blood collection must not adversely affect the health of the mother or newborn. Cord blood collection should not interfere with delayed cord clamping. (III-E)
8. Health care professionals should inform pregnant women and their partners of the benefits of delayed cord clamping and of its impact on cord blood collection and banking. (II-2A)
9. Cord blood units collected for public or private banking can be used for biomedical research, provided consent is obtained, when units cannot be banked or when consent for banking is withdrawn. (II-3B)
10. Mothers may be approached to donate cells for biomedical research. Informed consent for research using cord blood should ideally be obtained prior to the onset of active labour or elective Caesarean section following established research ethics guidelines. (II-2A)

INTRODUCTION

Since the first umbilical cord blood transplant in 1988, cord blood has been established as an alternative source of HSC for bone marrow reconstitution.[1] Cord blood has several advantages over bone marrow and mobilized peripheral blood HSC for transplantation, including its availability, negligible risk to the donor, less stringent HLA matching requirements, and less chance of GVHD. Limitations of UCB include insufficient quantity and quality of a single CBU to engraft adults, slow engraftment rates, and the potential for transfer of genetically abnormal or premalignant cells. The establishment of cord blood banks has allowed rapid access to well-characterized CBU by transplant centres around the world, and to date, cord blood has been used in over 30 000 transplants.[2]

Hematopoietic Stem Cell Transplantation

Transplantation of blood-forming stem cells to regenerate the blood and immune system following dose-intensive radiation treatment remains a potentially life-saving procedure for patients with malignant and non-malignant blood and immune disorders such as leukemia, lymphoma, aplastic anemia, and inherited metabolic diseases.[3] Blood-forming progenitors can be harvested from patients (autologous) or from healthy HLA-compatible (allogeneic) donors who are related or unrelated. Blood stem cells can be procured from bone marrow harvests, via apheresis of peripheral blood following cytokine stimulation or from umbilical cord blood.[4–6] Health care professionals should understand that UCB contains blood-forming stem cells that can be used in HSC transplantation and also contains other progenitor cells that are involved in tissue repair and in the modulation of immune responses.

Immune compatibility is determined by the HLA genes and is a dominant factor in the selection of an allogeneic donor or CBU. HLA-matched sibling donors are typically preferred but are available for only a minority of patients. With declining fertility rates in Canada over the past 50 years, patients will have diminishing odds of having an HLA-matched sibling donor[7] and transplant recipients will rely more heavily on unrelated donors and umbilical cord