Use of Umbilical Cord Blood for Stem Cell Research

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Abstract

Umbilical cord blood (UCB), long treated as waste material, is today considered a valuable source of hematopoietic stem cells. UCB is used, mostly in children, for the treatment of blood malignancies and inherited blood and metabolic disorders. In addition to blood precursor cells, UCB also contains stem cells that can differentiate into other types, such as cartilage, fat, hepatic, cardiac, and neural cells, fuelling speculation about the use of cord blood stem cells for regenerative medicine. Further research is therefore needed to investigate the expanded potential of UCB and its therapeutic use in cell and tissue therapies. According to a recent survey, practices for the procurement of UCB for research vary widely across Canada, so this area may not yet be ready for uniform regulation. However, some harmonization of practices to increase the availability of UCB for research would be useful for Canadian investigators. In this article, we address several important ethical and legal issues relating to the use of UCB in research and recommend guidelines to serve as a source of useful information for researchers. While their legal acceptability may vary across Canada, it is hoped that these recommendations foster more harmonized UCB research practices.

Résumé

Le sang de cordon ombilical (SCO), longtemps considéré comme un déchet, constitue aujourd'hui une source précieuse de cellules souches hématopoïétiques. Le SCO est utilisé, principalement chez les enfants, pour la prise en charge des affections malignes sanguines et des troubles métaboliques et sanguins héréditaires. En plus des cellules précurseurs du sang, le SCO contient également des cellules souches qui peuvent se différencier en d'autres types (cellules du cartilage, du tissu adipeux, du foie, du cœur, du système nerveux, etc.), ce qui alimente les spéculations quant à leur utilisation aux fins de la médecine régénérative. De plus amples recherches s'avèrent donc requises pour explorer le potentiel élargi du SCO et son utilisation thérapeutique dans les thérapies cellulaires et tissulaires. Selon un récent sondage, les pratiques utilisées pour l'obtention du SCO à des fins de recherche varient grandement au Canada; ainsi, ce domaine pourrait ne pas être prêt à se voir imposer une réglementation uniforme. Cependant, une certaine harmonisation des pratiques visant à accroître la disponibilité du SCO à des fins de recherche s'avérerait utile pour les chercheurs canadiens. Dans cet article, nous traitons de plusieurs des importantes questions éthiques et juridiques liées à l'utilisation du SCO à des fins de recherche, et nous recommandons des lignes directrices qui constitueraient une source de renseignements utiles pour les chercheurs. Bien que leur acceptabilité sur le plan juridique puisse varier d'une province et d'un territoire à l'autre, nous espérons que ces recommandations pourront favoriser l'harmonisation des pratiques de recherche en ce qui concerne le SCO.

Key Words: Umbilical cord blood, research, ethical issues, legal issues

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INTRODUCTION

Umbilical cord blood, long treated as waste material, is today considered a valuable source of hematopoietic stem cells. UCB is used, mostly in children, for the treatment of blood malignancies and inherited blood and metabolic disorders. In addition to blood precursor cells, UCB also contains stem cells that can differentiate into other types, such as cartilage, fat, hepatic, cardiac, and neural cells,[1] fuelling speculation about the use of cord blood stem cells for regenerative medicine.[2] For example, recent studies have led to speculation that UCB may be useful to treat autoimmune type 1 diabetes in children.[3] In addition, it seems that particular HLA mismatches are more successful with UCB than with bone marrow transplants,[4] although HLA mismatches do seem to have an impact on efficacy.[5] UCB can be collected at birth, without pain to the mother or child, and can be quickly typed, tested, and frozen after collection, making it rapidly available to any recipient.

These advantages are offset by certain disadvantages, such as a longer time to engraftment, during which the recipient is vulnerable to infections, and the risk of transmission of yet-undiagnosed hereditary diseases. The most important disadvantage, however, is the comparatively low stem cell count in UCB, which has made it difficult to use in treating adults weighing more than 110 pounds.[6]

Although initially seen as research, UCB transplantation is now viewed as an accepted therapy for the treatment of various diseases; in the United States it is near to attaining the

status of standard therapy.[7] Because of the potential of UCB, clinical research has focused on techniques that can expand the utility of cord blood transplantation, such as cell expansion and transplantation of cells from multiple cords. Various clinical trials of such techniques are under way.[6] Further research is therefore needed to investigate the expanded potential of UCB and its therapeutic use in cell and tissue therapies.

A recent survey (Survey Report) was conducted to assess the current needs and state of UCB research practices in Canada.[8] It concluded that future demands for human UCB research will likely remain stable or continue to increase. The Survey Report also revealed that practices for the procurement of UCB for research vary widely across Canada, so this area may not yet be ready for uniform regulation. Yet, some harmonization of practices to increase the availability of UCB for research would be useful for Canadian investigators.

In this article, we address several important ethical and legal issues relating to the use of UCB in research and recommend guidelines to serve as a source of useful information for researchers. While their legal acceptability may vary across Canada,[9,10] it is hoped that these recommendations foster more harmonized UCB research practices.

INFORMATION FOR PARENTS AND PHYSICIANS

Parents' lack of knowledge concerning the utility of UCB has been documented.[11] Ideally, parents should have access to a neutral source of information on the utility of UCB for both treatment and research to further develop its potential. This neutral source should also provide information about their various options: discarding UCB, banking it in a private bank, or donating it to a public bank.[12] Many obstetricians and physicians involved in the care of pregnant women do not provide much or any information on UCB collection and use, and future parents are sometimes left with documentation from private banks and what information they can find independently as their only sources of information on these topics.

The Survey Report revealed a lack of information concerning the fate of cord blood in Canada, with the only practical sources of such information being the public and private banks themselves. The concern is that information provided by private banks may not be objective. The Survey Report therefore suggests providing information about the possible uses of UCB through prenatal health care programs and identifying a national hub responsible for the production and dissemination of such information for physicians, future parents, and the general public.[8]

Recommendation 1

Due to the lack of awareness of the potential utility of UCB for both treatment and research, mechanisms should be made widely available for disseminating information about UCB to physicians, the public, and prospective parents. National professional associations and researchers should be encouraged to develop more educational materials on the clinical and research uses of UCB and to promote their use.

UCB FOR RESEARCH: SOURCES AND CONSENT

The Survey Report revealed that most responders obtained UCB for research from hospital labour and delivery departments (over one third), from obstetrician-gynaecologists (one fifth), or by direct solicitation of samples from parents (almost a quarter of investigators). Only one investigator obtained UCB samples from a local private cord blood bank, and the remainder obtained their samples from public banks.[8]

Like all tissue, UCB can reveal important information about not only the child, but also the mother and the father. The practice of collecting UCB without the parents' consent undermines respect for tissue donors' autonomy and should therefore be discouraged. For that reason, research ethics boards should inquire into the collection process of any tissue if they authorize its use without consent of the patient.

The Survey Report mentioned that many investigators would support a move towards national guidelines for the systematic collection and storage of cord blood across the country to ensure quality control for epidemiological research.[8] In the current ethical and legal environment, such an approach would require that parents be notified of the default collection of UCB and its anonymized use in such research and be allowed to opt out. Parents should also be adequately informed of other possible uses of cord blood, such as public and private banking, and asked explicitly for their consent to other types of research.[13]

Recommendation 2

Hospital admission consents could provide for the routine collection of anonymized UCB for quality control or for research of an epidemiological or public health nature. Hospitals could also notify parents of the general nature of such research and provide for the possibility to opt out. For

ABBREVIATIONS

HLA	human leukocyte antigen
REB	research ethics board
UCB	umbilical cord blood

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