Enactment of a Law for Governmental Support of the Use of Cord Blood, and Ethical Issues

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In Korea, cord blood banking projects have been developed since 1996, and the 1st successful cord blood transplant was performed in 1998. Recently, "Cord Blood Management and Research Act" was legislated in 2010, and has been come into effect on July 1st, 2011. This review focuses the backgrounds, aims, and legislation process as well as principal articles in this act.

Keywords: Cord blood, Act

Introduction

Public cord blood banks (CBBs) have been established in order to use cord blood (CB) that was once discarded, and these banks have been operated using funds from university hospitals, public organizations, and sponsorship organizations worldwide. Countries that support such CBBs with national budgets are the United States (US) and Japan. The US government officially recognized a CBB project along with a bone marrow bank project based on the "Stem Cell Act - C.W. Bill Young Cell Transplantation Program" in 2005 (1). They devised an independent budget for the new CBB project, and secured 60 million dollars from the national budget for the preservation of 150,000 units of CB. In addition to operating a hematopoietic stem cell-related program that includes CB, in association with the National Marrow Donor Program, the US Health Resources & Services Administration in the Department of Health and Human Services supports

budgets for CBBs by direct arrangements based on the Stem Cell Act 2005. In Japan, more than three times the budget for organ transplantation is being provided for managing bone marrow and CB projects. The budget for public CB banking projects is used, in part, for laboratory testing and processing of CBs for banking, as well as for the networking activities of the Japan Cord Blood Bank Network via the Japanese Red Cross (2).

In Korea, CB banking projects have been developed since 1996, and the 1st successful cord blood transplant (CBT) was performed in 1998 (3). We had performed about 500 CBTs by the end of 2010 and banked about 25,000 units of CB for public purposes, as well as more than 300,000 units for private use. Several commercial CBBs have been established and have operated both private and public banking programs. Although a few CBBs have been established solely for public purposes, with the financial support of regional governments, more than half the public CBs are stored in commercial banks. Furthermore, since CBBs were established in Korea, many criticisms have been voiced by the public regarding the safety of long-term cryopreservation of CB as well as regarding unfair competition between CB banks, particularly in the private banking business. This was the reason why we decided to enact the "Cord Blood Management and Research Act (CB Act)" consisting mainly of budgets for donated CB pools, a quality management system for cryopreserved

Accepted for publication February 2, 2012

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CBs, a CB donor searching system, and information concerning the use of CBBs as resources for various cell therapies.

Aims of the CB Act

The aims of our CB Act were to establish a management system for the quality and safety of public & private CBs, and a governmental support system for public CBBs, as well as to stimulate activities relating to CB in research institutes and bio-industry.

Legislation process

As a first step we organized a CB committee in the Korean Society of Blood & Marrow Transplantation (KSBMT) in March, 2002 and drafted a standard for CB banks. Based on the political research reports of our committee, the Ministry of Health and Welfare officially acknowledged “The National Guideline for CB banking” on August, 2005. As the next step I developed a governmental paper on the “Legal Management for Cord Blood” between May 2004 to July 2004 (4). I also produced a governmental paper on the “Establishment of Networking & Management System for Public CBBs” from December 2005 to March 2006 (5). Finally, the draft bill was submitted to a member of the National Assembly for legislation in 2005. However, unfortunately it could not be passed to the Assembly Plenary Session. A revised bill was submitted to another member of the National Assembly, and this was finally passed by the Assembly Plenary Session on February, 2010. I also prepared enforced ordinances and enforcement regulations to come into effect on July 1st, 2011. To produce the enforced ordinances and enforcement regulations, we, the CB committee members, revised the standards for CBBs in Korea with the reference of the 4th edition of the Foundation for the Accreditation of Cellular Therapy (FACT), and also reviewed the various related acts in Korea, such as the “Blood Management Act”, “Organ Transplantation Act”, “Life Ethics and Safety Act”, and “National Health Insurance Act”.

Principal articles of the CB Act in Korea

Article 4.

National and regional governments should make efforts to establish supporting systems for activating CB donation as well as CBT.

Article 5.

The purchase and sale of CB is prohibited.

Article 6.

A Cord Blood Committee is to be established in the Ministry of Health and Welfare (MHW) to review general matters regarding the quality control of CB as well its safety. The items to be reviewed by the Cord Blood Committee are as follows:

- 1) Establishment of policies regarding CB management
- 2) Criteria for CB donors and recipients
- 3) Management and permission criteria for CBBs
- 4) Evaluation and appraisal of CBBs
- 5) Guidelines for CBB management
- 6) Management of the CB coordinating center and establishment of a CB database
- 7) Support and promotion of CB research

Article 7.

CBBs should obtain consent from mothers who donate or store their own CBs.

Article 10.

This article lists the exclusion criteria for the collection and cryopreservation of CBs for transplantation (Table 1). CBs that are excluded may be stored to be utilized in research and bio-industry.

Article 11.

Public and private CBB associates must obtain permission to establish CBBs from an Administrator of the MHW. They should have facilities, equipment, human resources, and quality control systems as specified in the enforced ordinances (Table 2).

Table 1. Exclusion criteria for collection and cryopreservation of CBs

1. CBs which are clotted or contaminated during collection
2. Turbid, discolored or hemolysed CBs
3. Collection bags with damaged seals
4. CBs which remain unfrozen for 36 hours or more after collection
5. CBs which weigh below 60 gram
6. CBs with below 90% viability or with less than 8×10^8 total nucleated cells before cryopreservation
7. CBs which yield positive findings for infectious markers in the CBs or maternal blood, such as HBsAg, Anti-HCV, Anti-HIV type 1/2, Anti-CMV IgM and Anti-HTLV type 1/2, or in cultures for bacteria

*Items 4-7 may not apply to private CB banks.

Article 12.

Although a person or institution has not obtained permission for a CBB, the use of CBs for research and biotechnology by them may be permitted, provided their use is approved by their institutional review board or the Korea Food and Drug Administration.

Article 17.

The Administrator of the MHW may establish or designate public CBBs to manage donated CBs. National and regional governments should support the CBB budgets for establishing and banking public CBs.

Table 2. Facilities and equipment for cord blood banks

1. Air filter system, temperature and humidity control system
2. Suitable sanitary areas for CB processing and cryopreservation
3. Facilities in case of blackouts
4. Equipments
 - Clean bench
 - Refrigerated centrifuge
 - Programmable freezer or ultra deep freezer
 - Liquid nitrogen tank with alarm and temperature monitoring system
 - PVC plastic seal
 - Syringe pump or tubing device
 - Refrigerator for storage of samples
 - Plasma extractor
 - Water bath
 - Portable liquid nitrogen tank

Article 19.

Each CBB should have a Medical Director to supervise human resources, facilities and equipment, and ensure quality control in matters relating to CB banking.

Article 22.

CBBs which terminate their activities should transfer all items including stored CBs to another CBB and/or Cord Blood Coordinating Center (CBCC).

Article 23.

A CBCC should be established to manage all data regarding donated CBs, and to coordinate and supply CBs. The principle roles of the CBCC are as follows:

- 1) Information management and supply of donated CBs
- 2) Identification, notification, and coordination of CBs for transplantation
- 3) Data management and analysis, and reporting of CBT data

Article 28.

An international exchange program for public CBs should be administered through the CBCC.

In summary, the Korean CB management system specified in the CB Act is as follows (Fig. 1). Public or private CBBs should be approved by an Administrator of the MHW. The government should establish and promote the

Fig. 1. Diagram of the cord blood management system in Korea. MHW, Ministry of Health and Welfare; CB, cord blood; CBB, cord blood bank; CBCC, cord blood coordinating center.

activities of public CBBs by means of national budgets. The CB committee should be part of the MHW, and a CBCC with an advisory committee should also be established. The CBCC will coordinate CBs between transplant centers and CBBs, and also engage in an education program for CBB associates as well as a recruitment program. The CBCC also has an important role to play in an international exchange program. Research institutes may obtain CBs from medical institutes as well as public CBBs provided they notify the CBCC, and their use of CBs is approved by their institutional review board or the Korea Food and Drug Administration.

Acknowledgments

This study was supported by a grant of the Korea Healthcare Technology R&D Project (A101712), Ministry for Health & Welfare, Republic of Korea. This work was supported by a grant from the Korea Science and Engineering Foundation (2010-0029508) through the MRC for Regulation of Stem Cell Behaviors at Hanyang University College of Medicine, Republic of Korea.

Potential conflict of interest

The authors have no conflicting financial interest.

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