American Academy of Pediatrics
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POLICY STATEMENT

Cord Blood Banking for Potential Future Transplantation

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children

Section on Hematology/Oncology and Section on Allergy/Immunology

ABSTRACT

In recent years, umbilical cord blood, which contains a rich source of hematopoietic stem and progenitor cells, has been used successfully as an alternative allogeneic donor source to treat a variety of pediatric genetic, hematologic, immunologic, and oncologic disorders. Because there is diminished risk of graft-versus-host disease after transplantation of cord stem cells using matched related donors, the use of less-than-completely matched HLA cord blood stem cells may incur less risk of graft-versus-host disease than mismatched cells from either a related or unrelated "walking" donor, although this remains to be proven. Gene-therapy research involving modification of autologous cord blood stem cells for the treatment of childhood genetic disorders, although experimental at the present time, may prove to be of value. These scientific advances have resulted in the establishment of not-for-profit and for-profit cord blood–banking programs for allogeneic and autologous cord blood transplantation. Many issues confront institutions that wish to establish or participate in such programs. Parents often seek information from their physicians about this new biotechnology option. This document is intended to provide information to guide physicians in responding to parents' questions about cord blood donation and banking and the types and quality of cord blood banks. Provided also are recommendations about appropriate ethical and operational standards, including informed consent policies, financial disclosures, and conflict-of-interest policies for physicians, institutions, and organizations that operate or have a relationship with cord blood–banking programs.

INTRODUCTION

In a number of genetic, hematologic, immunologic, metabolic, and oncologic disorders, reconstitution of bone marrow (transplantation) can be a potentially life-saving procedure.[1–16] Allogeneic (related or unrelated) or autologous (self) bone marrow or peripheral blood stem cells are the usual sources of hematopoietic progenitor cells to achieve this goal. If autologous stem cells are not available or cannot be used, the best option for successful reconstitution therapy is to secure stem cells from an HLA-matched sibling.[1,3,11] Close matching confers a higher probability of successful engraftment and minimizes the risk of potentially fatal graft-versus-host disease. Unfortunately, there is only a 25% chance for identifying a full HLA match in a sibling donor.[17,18]

An alternative to a related donor involves seeking unrelated HLA-matched adult allogeneic donors outside of the family.[2,6,11] There are more than 7 million potential unrelated volunteer adult donors registered in the National Marrow Donor Program registry.[17] Although the number of patients who receive unrelated

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Key Words
cord blood, stem cells, hematology, oncology

Abbreviations
FACT—Foundation for the Accreditation of Cellular Therapy
FDA—US Food and Drug Administration

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adult allogeneic donor stem cell transplants continues to increase each year, many patients are unable to find a fully matched donor, which diminishes access to transplantation therapy. Nonwhite patients have a lower chance of identifying a fully matched unrelated adult donor because of genetic heterogeneity and lack of nonwhite donors. Over the past decade, unrelated-donor, banked umbilical cord blood has been shown to contain sufficient numbers of stem cells for successful transplantation between unrelated, partially HLA-mismatched individuals.[19–23] With advances in the clinical practice of cord blood transplantation, most patients unable to find a fully matched adult donor can identify a partially matched cord blood donor.

Recently, it was shown that umbilical cord blood contains a sufficient number of hematopoietic stem cells to be used for transplantation. More than 5500 unrelated-donor cord blood stem cell transplants for a variety of pediatric genetic,[22,24–31] hematologic,[22,24,25,29,32] immunologic,[28] metabolic,[26,27,30] and oncologic[19,20,33–36] disorders have been performed to date (Table 1). The 1-year survival may be as high as 75% to 90% after sibling HLA-matched cord blood donor stem cell transplantation[21,24,29] and 40% to 80% after unrelated cord blood stem cell transplantation.[19,20,26,27,33,35,36] Advantages of the use of cord blood include the fact that it is readily available, carries less risk of transmission of blood-borne infectious diseases, and is transplantable across HLA barriers with diminished risk of graft-versus-host disease compared with similarly mismatched stem cells from the peripheral blood or bone marrow of related or unrelated donors.[21,34,35,37] Autologous stem cells[38,39] have been used for gene therapy in infants with severe combined immunodeficiency, but the appearance of T-lymphocyte leukemia in some patients has indicated the need for more basic research before additional clinical trials of gene therapy can be undertaken.

Since the first unrelated cord blood–banking program was started at the New York Blood Center in 1991,[40] a number of public cord blood–banking programs have been established throughout the world to collect, type, screen for infection, and cryogenically store cord blood for potential transplantation to unrelated and related recipients.[41–49] Some of these programs had been funded by the National Heart, Lung, and Blood Institute (National Institutes of Health), the National Marrow Donor Program, the American Red Cross, or academic programs based in not-for-profit organizations. One cord blood program initiated by the National Institutes of Health exists solely for sibling donor collection for families who are likely to consider cord blood transplantation because a first-degree relative has been diagnosed with a disease that is treatable with allogeneic transplantation. In this bank, families own the cord blood, and it is shipped to a designated transplant center in the event a medical decision to proceed with cord blood transplantation is made.[50]

TABLE 1 Diseases Treatable With Umbilical Cord Blood Transplantation

Malignancies
Bone marrow failure
Hemoglobinopathies
Immunodeficiencies
Inborn errors of metabolism

A number of private for-profit companies have been established that encourage parents to bank their children's cord blood for their own autologous use or for directed donor allogeneic use for a family member should the need arise. Parents have been encouraged to bank their infants' cord blood as a form of "biological insurance." Physicians, employees, and/or consultants of such companies may have potential conflicts of interest in recruiting patients because of their own financial gain. Annual disclosure of the financial interest and potential conflicts of interest must be made to institutional review boards that are charged with the responsibility of mitigation of these disclosures and risks. Families may be vulnerable to the emotional effects of marketing for cord blood banking at the time of birth of a child and may look to their physicians for advice. No accurate estimates exist of the likelihood of children to need their own stored cord blood stem cells in the future. The range of available estimates is from 1 in 1000 to more than 1 in 200 000.[51] The potential for children needing their own cord blood stem cells for future autologous use is controversial presently.[51] There also is no evidence of the safety or effectiveness of autologous cord blood stem cell transplantation for the treatment of malignant neoplasms.[51] Indeed, there is evidence demonstrating the presence of DNA mutations in cord blood obtained from children who subsequently develop leukemia.[52] Thus, an autologous cord blood transplantation might even be contraindicated in the treatment of a child who develops leukemia.

Cord blood has been shown to contain pluripotent stem cells that have the potential to differentiate into nonhematopoietic tissue, such as cardiac, neurologic, pancreatic, and skin tissue, in vitro.[53,54] Extensive laboratory research is taking place to explore the potential therapeutic benefit of cord blood under these circumstances. The results of this research will be necessary to formulate future recommendations regarding autologous cord blood banking.

Initially, cord blood stem cell transplantation using allogeneic umbilical cord blood was performed in relatively small children, because the cell dose per weight of recipient was shown to be important.[19,20] However, older children, adolescents, and adults have benefited from unrelated allogeneic umbilical cord blood transplantation.[34,55–61] Because of the relationship between cell dose

per recipient weight and transplant outcome, the number of cord blood cells needed for marrow reconstitution in older children or young adults is much larger than that needed when cord blood is used for transplantation in small children. Cord blood transplants using multiple cryopreserved units from separate donors have been performed successfully in adults, and the approach is currently under investigation as a strategy to increase the dose of cells for transplantation in a single recipient.[62] Cord blood is collected in observance of good obstetric and pediatric practice.[45]

Although cord blood is currently considered discarded human material, it should only be collected for banking with an institutional review board–approved protocol and with signed informed consent from a parent.[42,43] Pertinent donor information communicated to the cord blood bank should be kept confidential by the cord blood bank and used only to report important medical information obtained during the cord blood collection, processing, and screening process that is relevant to the safety of the donor and family. If cord blood was collected from a newborn who subsequently developed a genetic, immunologic, or malignant neoplastic disorder, parents should notify the cord blood bank so that the unit is not used for transplantation. All cord blood units banked for potential use should be tested for infectious diseases, similar to those tested in a blood bank, and for hereditary hematologic diseases. The informed consent must contain information pertaining to what tests are to be performed on the cord blood and how the parents will be informed if test results are abnormal. Pediatricians should be aware that legal cases relating to the duty of a physician to warn parents about the risks of inheriting a genetic disease are new and untested. Pediatricians should remain vigilant, because future cases may define who has a legal duty to notify parents about genetic abnormalities identified during cord blood testing. Informed consent should be obtained before the onset of active labor and before cord blood collection.

RECOMMENDATIONS

Cord blood transplantation has been shown to be curative in patients with a variety of serious diseases. Physicians should be familiar with the rationale for cord blood banking and with the types of cord blood–banking programs available. Physicians consulted by prospective parents about cord blood banking can provide the following information:

1. Cord blood donation should be discouraged when cord blood stored in a bank is to be directed for later personal or family use, because most conditions that might be helped by cord blood stem cells already exist in the infant's cord blood (ie, premalignant changes in stem cells). Physicians should be aware of the unsubstantiated claims of private cord blood banks made to future parents that promise to insure infants or family members against serious illnesses in the future by use of the stem cells contained in cord blood. Although not standard of care, directed cord blood banking should be encouraged when there is knowledge of a full sibling in the family with a medical condition (malignant or genetic) that could potentially benefit from cord blood transplantation.
2. Cord blood donation should be encouraged when the cord blood is stored in a bank for public use. Parents should recognize that genetic (eg, chromosomal abnormalities) and infectious disease testing is performed on the cord blood and that if abnormalities are identified, they will be notified. Parents should also be informed that the cord blood banked in a public program may not be accessible for future private use.
3. Because there are no scientific data at the present time to support autologous cord blood banking and given the difficulty of making an accurate estimate of the need for autologous transplantation and the ready availability of allogeneic transplantation, private storage of cord blood as "biological insurance" should be discouraged. Cord blood banks should comply with national accreditation standards developed by the Foundation for the Accreditation of Cellular Therapy (FACT), the US Food and Drug Administration (FDA), the Federal Trade Commission, and similar state agencies. At a minimum, physicians involved in procurement of cord blood should be aware of cord blood collection, processing, and storage procedures as shown in Table 2.

Institutions or organizations (private or public) involved in cord blood banking should consider the following recommendations:

1. Cord blood–banking recruitment practices should be developed with an awareness of the possible emotional vulnerability of pregnant women and their families and friends. Efforts should be made to min-

TABLE 2 **Recommended Procedures for Related and Unrelated Cord Blood Banking[45]**

Cord blood should be collected in a bag containing citrate-phosphate-dextrose anticoagulant
Cord blood should be processed and frozen within 48 h of collection
Standardized freezing and storage conditions should be followed (FACT)
Segments should be attached to the cord blood for testing and confirmation of identity
Extra cells and plasma should be stored for potential additional testing
FDA regulations regarding infectious disease testing should be followed
Banks should be accredited by FACT and follow FACT cord blood banking standards
Cord blood units should be stored under liquid nitrogen or at equivalent temperatures

imize the effect of this vulnerability on cord blood–banking decisions.

2. Accurate information about the potential benefits and limitations of allogeneic and autologous cord blood banking and transplantation should be provided. Parents should be informed that autologous cord blood would not be used as a stem cell source if the donor developed leukemia later in life. Parents should recognize that there are no scientific data to support the claim that autologous cord blood is a tissue source proven to be of value for regenerative medical purposes. The current standard uses of cord blood transplantation are listed in Table 1.
3. A policy should be developed by cord blood banks regarding disclosing to the parents any abnormal findings in the harvested blood.
4. Specific permission for maintaining demographic medical information should be obtained, and the potential risks of breaches of confidentiality should be disclosed.
5. Written permission for obtaining cord blood should be obtained before onset of active labor.
6. If the cord blood bank is conducting research, an institutional review board must review and approve recruitment strategies and consent forms.
7. Cord blood collection should not be performed in complicated deliveries. The cord blood stem cell–collection program should not alter routine practice for the timing of umbilical cord clamping.
8. Regulatory agencies (eg, FDA, Federal Trade Commission, and state equivalents of these federal agencies) are encouraged to have an active role in providing oversight of the cord blood program. All cord blood–banking programs should comply with FACT or equivalent accreditation standards.
9. Physicians or other professionals who recruit pregnant women and their families for for-profit placental cord blood stem cell banking should disclose any financial interest or other potential conflict of interest they have in the procedure to their patients.
10. Professionals affiliated with institutions or organizations that promote for-profit placental blood stem cell banking should make annual financial-disclosure and potential-conflicts-of-interest statements to an appropriate institutional review committee that possesses oversight authority.
11. Targeted efforts should be made to recruit underserved minorities (black, Hispanic, American Indian/Alaska Native individuals) in public cord blood–banking programs to extend to them potential treatments afforded other segments of society.

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