



## POLICY STATEMENT

# Cord Blood Banking for Potential Future Transplantation

Section on Hematology/Oncology and Section on Allergy/Immunology

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

## 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.<sup>1-16</sup> 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.<sup>1,3,11</sup> 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.<sup>17,18</sup>

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

[www.pediatrics.org/cgi/doi/10.1542/peds.2006-2901](http://www.pediatrics.org/cgi/doi/10.1542/peds.2006-2901)

doi:10.1542/peds.2006-2901

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

### Key Words

cord blood, stem cells, hematology, oncology

### Abbreviations

FACT—Foundation for the Accreditation of Cellular Therapy

FDA—US Food and Drug Administration

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275). Copyright © 2007 by the American Academy of Pediatrics

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.<sup>19–23</sup> 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,<sup>22,24–31</sup> hematologic,<sup>22,24,25,29,32</sup> immunologic,<sup>28</sup> metabolic,<sup>26,27,30</sup> and oncologic<sup>19,20,33–36</sup> 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<sup>21,24,29</sup> and 40% to 80% after unrelated cord blood stem cell transplantation.<sup>19,20,26,27,33,35,36</sup> 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.<sup>21,34,35,37</sup> Autologous stem cells<sup>38,39</sup> 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,<sup>40</sup> 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.<sup>41–49</sup> 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 pro-

grams 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.<sup>50</sup>

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.<sup>51</sup> The potential for children needing their own cord blood stem cells for future autologous use is controversial presently.<sup>51</sup> There also is no evidence of the safety or effectiveness of autologous cord blood stem cell transplantation for the treatment of malignant neoplasms.<sup>51</sup> Indeed, there is evidence demonstrating the presence of DNA mutations in cord blood obtained from children who subsequently develop leukemia.<sup>52</sup> 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*.<sup>53,54</sup> 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.<sup>19,20</sup> However, older children, adolescents, and adults have benefited from unrelated allogeneic umbilical cord blood transplantation.<sup>34,55–61</sup> Because of the relationship between cell dose

**TABLE 1 Diseases Treatable With Umbilical Cord Blood Transplantation**

Malignancies
Bone marrow failure
Hemoglobinopathies
Immunodeficiencies
Inborn errors of metabolism

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.<sup>62</sup> Cord blood is collected in observance of good obstetric and pediatric practice.<sup>45</sup>

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.<sup>42,43</sup> 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<sup>45</sup>**

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.

#### WRITING PANEL

Mitchell S. Cairo, MD  
Joanne Kurtzberg, MD  
\*Bertram H. Lubin, MD  
\*William T. Shearer, MD, PhD

#### SECTION ON HEMATOLOGY/ONCOLOGY, 2005–2006

Stephen A. Feig, MD, Chairperson  
James J. Corrigan, MD  
Alan S. Gamis, MD  
Eric D. Kodish, MD  
Peter A. Lane, MD  
John J. Hutter, MD  
Roger L. Berkow, MD  
Immediate Past Chairperson  
Mitchell S. Cairo, MD  
Past Executive Committee Member

#### LIAISONS

Naomi L. Lubin, MD  
American Association of Blood Banks  
Edwin N. Forman, MD  
Childhood Cancer Alliance

#### STAFF

Laura Laskosz, MPH

#### SECTION ON ALLERGY AND IMMUNOLOGY, 2005–2006

Paul V. Williams, MD, Chairperson  
Bradley E. Chipps, MD  
Mary B. Fasano, MD  
Mitchell R. Lester, MD  
Scott H. Sicherer, MD  
Frank S. Virant, MD  
Sami L. Bahna, MD  
Michael J. Welch, MD  
Immediate Past Chairperson

#### LIAISONS

Gary S. Rachelefsky, MD  
American Academy of Allergy, Asthma, and Immunology  
Todd A. Mahr, MD  
American College of Allergy, Asthma, and Immunology

#### STAFF

Pamela T. Kanda, MPH

\*Lead authors

#### REFERENCES

1. Ravindranath Y, Chang M, Steuber CP, et al. Pediatric Oncology Group (POG) studies of acute myeloid leukemia (AML): a review of four consecutive childhood AML trials conducted between 1981 and 2000. *Leukemia*. 2005;19:2101–2116
2. Yumura-Yagi K, Inoue M, Sakata N, et al. Unrelated donor bone marrow transplantation for 100 pediatric patients: a sin-

- gle institute's experience. *Bone Marrow Transplant.* 2005;36:307–313
3. Anak S, Saribeyoglu ET, Bilgen H, et al. Allogeneic versus autologous versus peripheral stem cell transplantation in CR1 pediatric AML patients: a single center experience. *Pediatr Blood Cancer.* 2005;44:654–659
  4. Kasamon YL, Jones RJ, Piantadosi S, et al. High-dose therapy and blood or marrow transplantation for non-Hodgkin lymphoma with central nervous system involvement. *Biol Blood Marrow Transplant.* 2005;11:93–100
  5. Korthof ET, Snijder PP, de Graaff AA, et al. Allogeneic bone marrow transplantation for juvenile myelomonocytic leukemia: a single center experience of 23 patients. *Bone Marrow Transplant.* 2005;35:455–461
  6. Bunin N, Aplenc R, Iannone R, et al. Unrelated donor bone marrow transplantation for children with severe aplastic anemia: minimal GVHD and durable engraftment with partial T cell depletion. *Bone Marrow Transplant.* 2005;35:369–373
  7. Ozkaynak MF, Sandoval C, Levendoglu-Tugal O, Jayabose S. A pilot trial of tandem autologous peripheral blood progenitor cell transplantation following high-dose thiotepa and carboplatin in children with poor-risk central nervous system tumors. *Pediatr Hematol Oncol.* 2004;21:635–645
  8. Nagatoshi Y, Kawano Y, Okamura J. Comparison of the outcomes of allogeneic bone marrow transplantation from partially mismatched related donors, matched sibling donors, and matched unrelated donors in Japanese pediatric patients: a single center result. *Pediatr Transplant.* 2004;8:260–266
  9. Maschan AA, Trakhtman PE, Balashov DN, et al. Fludarabine, low-dose busulfan and antithymocyte globulin as conditioning for Fanconi anemia patients receiving bone marrow transplantation from HLA-compatible related donors. *Bone Marrow Transplant.* 2004;34:305–307
  10. Bielora B, Trakhtenbrot L, Amariglio N, et al. Multilineage hematopoietic engraftment after allogeneic peripheral blood stem cell transplantation without conditioning in SCID patients. *Bone Marrow Transplant.* 2004;34:317–320
  11. Bunin N, Aplenc R, Leahey A, et al. Outcomes of transplantation with partial T-cell depletion of matched or mismatched unrelated or partially matched related donor bone marrow in children and adolescents with leukemias. *Bone Marrow Transplant.* 2005;35:151–158
  12. Eapen M, Horowitz MM, Klein JP, et al. Higher mortality after allogeneic peripheral-blood transplantation compared with bone marrow in children and adolescents: the Histocompatibility and Alternate Stem Cell Source Working Committee of the International Bone Marrow Transplant Registry. *J Clin Oncol.* 2004;22:4872–4780
  13. Chandy M, Balasubramanian P, Ramachandran SV, et al. Randomized trial of two different conditioning regimens for bone marrow transplantation in thalassemia: the role of busulfan pharmacokinetics in determining outcome. *Bone Marrow Transplant.* 2005;36:839–845
  14. de Buys P, Khanna D, Furst DE. Hemopoietic stem cell transplantation in rheumatic diseases: an update. *Autoimmun Rev.* 2005;4:442–449
  15. Entz-Werle N, Suci S, van der Werff Ten Bosch J, et al. Results of 58872 and 58921 trials in acute myeloblastic leukemia and relative value of chemotherapy vs allogeneic bone marrow transplantation in first complete remission: the EORTC Children Leukemia Group report. *Leukemia.* 2005;19:2072–2081
  16. Roy V, Perez WS, Eapen M, et al. Bone marrow transplantation for diamond-blackfan anemia. *Biol Blood Marrow Transplant.* 2005;11:600–608
  17. Karanes C, Confer D, Walker T, Askren A, Keller C. Unrelated donor stem cell transplantation: the role of the National Marrow Donor Program. *Oncology (Williston Park).* 2003;17:1036–1068, 1043–104, 1164–1167
  18. Wagner JE, Rosenthal J, Sweetman R, et al. Successful transplantation of HLA-matched and HLA-mismatched umbilical cord blood from unrelated donors: analysis of engraftment and acute graft-versus-host disease. *Blood.* 1996;88:795–802
  19. Kurtzberg J, Laughlin M, Graham ML, et al. Placental blood as a source of hematopoietic stem cells for transplantation into unrelated recipients. *N Engl J Med.* 1996;335:157–166
  20. Rubinstein P, Carrier C, Scaradavou A, et al. Outcomes among 562 recipients of placental-blood transplants from unrelated donors. *N Engl J Med.* 1998;339:1565–1577
  21. Rocha V, Wagner JE Jr, Sobocinski KA, et al. Graft-versus-host disease in children who have received a cord-blood or bone marrow transplant from an HLA-identical sibling. Eurocord and International Bone Marrow Transplant Registry Working Committee on Alternative Donor and Stem Cell Sources. *N Engl J Med.* 2000;342:1846–1854
  22. Gluckman E, Broxmeyer HA, Auerbach AD, et al. Hematopoietic reconstitution in a patient with Fanconi's anemia by means of umbilical-cord blood from an HLA-identical sibling. *N Engl J Med.* 1989;321:1174–1178
  23. Migliaccio AR, Adamson JW, Stevens CE, Dobrila NL, Carrier CM, Rubinstein P. Cell dose and speed of engraftment in placental/umbilical cord blood transplantation: graft progenitor cell content is a better predictor than nucleated cell quantity. *Blood.* 2000;96:2717–2722
  24. Jaing TH, Hung IJ, Yang CP, Chen SH, Sun CF, Chow R. Rapid and complete donor chimerism after unrelated mismatched cord blood transplantation in 5 children with beta-thalassemia major. *Biol Blood Marrow Transplant.* 2005;11:349–353
  25. Hall JG, Martin PL, Wood S, Kurtzberg J. Unrelated umbilical cord blood transplantation for an infant with beta-thalassemia major. *J Pediatr Hematol Oncol.* 2004;26:382–385
  26. Escolar ML, Poe MD, Provenzale JM, et al. Transplantation of umbilical-cord blood in babies with infantile Krabbe's disease. *N Engl J Med.* 2005;352:2069–2081
  27. Staba SL, Escolar ML, Poe M, et al. Cord-blood transplants from unrelated donors in patients with Hurler's syndrome. *N Engl J Med.* 2004;350:1960–1969
  28. Myers LA, Hershfield MS, Neale WT, Escolar M, Kurtzberg J. Purine nucleoside phosphorylase deficiency (PNP-def) presenting with lymphopenia and developmental delay: successful correction with umbilical cord blood transplantation. *J Pediatr.* 2004;145:710–712
  29. Locatelli F, Rocha V, Reed W, et al. Related umbilical cord blood transplantation in patients with thalassemia and sickle cell disease. *Blood.* 2003;101:2137–2143
  30. Krivit W, Shapiro EG, Peters C, et al. Hematopoietic stem-cell transplantation in globoid-cell leukodystrophy. *N Engl J Med.* 1998;338:1119–1126
  31. Kelly P, Kurtzberg J, Vichinsky E, Lubin B. Umbilical cord blood stem cells: application for the treatment of patients with hemoglobinopathies. *J Pediatr.* 1997;130:695–703
  32. Fruchtman SM, Hurlet A, Dracker R, et al. The successful treatment of severe aplastic anemia with autologous cord blood transplantation. *Biol Blood Marrow Transplant.* 2004;10:741–742
  33. Wall DA, Carter SL, Kernan NA, et al. Busulfan/melphalan/antithymocyte globulin followed by unrelated donor cord blood transplantation for treatment of infant leukemia and leukemia in young children: the Cord Blood Transplantation study (COBLT) experience. *Biol Blood Marrow Transplant.* 2005;11:637–646
  34. Rocha V, Labopin M, Sanz G, et al. Transplants of umbilical-cord blood or bone marrow from unrelated donors in adults with acute leukemia. *N Engl J Med.* 2004;351:2276–2285

35. Barker JN, Davies SM, DeFor T, Ramsay NK, Weisdorf DJ, Wagner JE. Survival after transplantation of unrelated donor umbilical cord blood is comparable to that of human leukocyte antigen-matched unrelated donor bone marrow: results of a matched-pair analysis. *Blood*. 2001;97:2957-2961
36. Rocha V, Cornish J, Sievers EL, et al. Comparison of outcomes of unrelated bone marrow and umbilical cord blood transplants in children with acute leukemia. *Blood*. 2001;97:2962-2971
37. Gluckman E, O'Reilly R, Wagner J, Rubinstein P. Patents versus transplants [letter]. *Nature*. 1996;382:108
38. Chinen J, Puck JM. Successes and risks of gene therapy in primary immunodeficiencies. *J Allergy Clin Immunol*. 2004;113:595-603
39. Cavazzana-Calvo M, Lagresle C, Hacein-Bey-Abina S, Fischer A. Gene therapy for severe combined immunodeficiency. *Annu Rev Med*. 2005;56:585-602
40. Rubinstein P, Dobrila L, Rosenfield RE, et al. Processing and cryopreservation of placental/umbilical cord blood for unrelated bone marrow reconstitution. *Proc Natl Acad Sci U S A*. 1995;92:10119-10122
41. Wagner JE, Kurtzberg J. Banking and transplantation of unrelated donor umbilical cord blood: status of the National Heart, Lung, and Blood Institute-sponsored trial. *Transfusion*. 1998;38:807-809
42. Sugarman J, Reisner EG, Kurtzberg J. Ethical aspects of banking placental blood for transplantation. *JAMA*. 1995;274:1783-1785
43. Sugarman J, Kurtzberg J, Box TL, Horner RD. Optimization of informed consent for umbilical cord blood banking. *Am J Obstet Gynecol*. 2002;187:1642-1646
44. Steinbrook R. The cord-blood-bank controversies. *N Engl J Med*. 2004;351:2255-2257
45. Smith F, Kurtzberg J, Karson E, et al. Umbilical cord blood collection, storage and transplantation: issues and recommendations for expectant parents and patients. *Cancer Res Ther Control*. 1999;10:217-226
46. Kurtzberg J, Cairo MS, Fraser JK, et al. Results of the cord blood transplantation (COBLT) study unrelated donor banking program. *Transfusion*. 2005;45:842-855
47. Fraser JK, Cairo MS, Wagner EL, et al. Cord Blood Transplantation Study (COBLT): cord blood bank standard operating procedures. *J Hematother*. 1998;7:521-561
48. Cairo MS, Wagner EL, Fraser J, et al. Characterization of banked umbilical cord blood hematopoietic progenitor cells and lymphocyte subsets and correlation with ethnicity, birth weight, sex, and type of delivery: a Cord Blood Transplantation (COBLT) Study report. *Transfusion*. 2005;45:856-866
49. Ballen KK, Kurtzberg J, Lane TA, et al. Racial diversity with high nucleated cell counts and CD34 counts achieved in a national network of cord blood banks. *Biol Blood Marrow Transplant*. 2004;10:269-275
50. Reed W, Smith R, Dekovic F, et al. Comprehensive banking of sibling donor cord blood for children with malignant and non-malignant disease. *Blood*. 2003;101:351-357
51. Johnson FL. Placental blood transplantation and autologous banking: caveat emptor. *J Pediatr Hematol Oncol*. 1997;19:183-186
52. Rowley JD. Backtracking leukemia to birth. *Nat Med*. 1998;4:150-151
53. Lewis ID, Almeida-Porada G, Du J, et al. Umbilical cord blood cells capable of engrafting in primary, secondary, and tertiary xenogeneic hosts are preserved after ex vivo culture in a non-contact system. *Blood*. 2001;97:3441-3449
54. Kogler G, Sensken S, Airey JA, et al. A new human somatic stem cell from placental cord blood with intrinsic pluripotent differentiation potential. *J Exp Med*. 2004;200:123-135
55. Takahashi S, Iseki T, Ooi J, et al. Single-institute comparative analysis of unrelated bone marrow transplantation and cord blood transplantation for adult patients with hematologic malignancies. *Blood*. 2004;104:3813-3820
56. Ooi J, Iseki T, Takahashi S, et al. Unrelated cord blood transplantation for adult patients with de novo acute myeloid leukemia. *Blood*. 2004;103:489-491
57. Ooi J, Iseki T, Takahashi S, et al. Unrelated cord blood transplantation for adult patients with advanced myelodysplastic syndrome. *Blood*. 2003;101:4711-4713
58. Laughlin MJ, Rizzieri DA, Smith CA, et al. Hematologic engraftment and reconstitution of immune function post unrelated placental cord blood transplant in an adult with acute lymphocytic leukemia. *Leuk Res*. 1998;22:215-219
59. Laughlin MJ, Eapen M, Rubinstein P, et al. Outcomes after transplantation of cord blood or bone marrow from unrelated donors in adults with leukemia. *N Engl J Med*. 2004;351:2265-2275
60. Chao NJ, Koh LP, Long GD, et al. Adult recipients of umbilical cord blood transplants after nonmyeloablative preparative regimens. *Biol Blood Marrow Transplant*. 2004;10:569-575
61. Barker JN, Weisdorf DJ, DeFor TE, Blazar BR, Miller JS, Wagner JE. Rapid and complete donor chimerism in adult recipients of unrelated donor umbilical cord blood transplantation after reduced-intensity conditioning. *Blood*. 2003;102:1915-1919
62. Barker JN, Weisdorf DJ, DeFor TE, et al. Transplantation of 2 partially HLA-matched umbilical cord blood units to enhance engraftment in adults with hematologic malignancy. *Blood*. 2005;105:1343-1347