

A Counterpoint Perspective:
American Academy of Pediatrics Policy Recommendations
on Cord Blood Banking

Revised 2/23/07 by C Sims

In January 2007, the *American Academy of Pediatrics (AAP)* published revised policy recommendations on cord blood banking. While the recommendations recognize the therapeutic value of cord blood stem cells, they fail to provide current, accurate information on several key issues, including:

- (1) well-established scientific evidence that proves better survival rates with genetically-related cord blood stem cell transplants;
- (2) the importance of providing fair and balanced information so that expectant parents can make an informed decision about cord blood banking;
- (3) odds of cord blood stem cell use;
- (4) the role of industry in providing patient education; and,
- (5) the expanded, later-life utility of cord blood stem cells.

Following are important facts that offer a counter-perspective for each of these issues.

Issue	AAP Recommendations	Counterpoint: Important Facts
AAP does not incorporate important scientific evidence that underscores the importance of genetically-related cord blood stem cells as the preferred choice for transplantation.	<i>“Because there are no scientific data at the present time to support autologous (related) cord blood banking...private storage of cord blood as ‘biological insurance’ should be discouraged.”</i>	<p>√ Strong scientific evidence proves that genetically related stem cells provide the best clinical outcomes. Stem cell transplants from genetically-related sources result in significantly better survival rates (63%) than transplants from an unrelated donor (29%), and are associated with less frequent and less severe graft-vs.-host disease. ¹⁻²</p> <p>√ Family (private) banking of cord blood allows quick access to a genetically related sample for that child and immediate family members, which if needed for transplant, generally results in significantly increased survival rates compared to using stem cells from an unrelated source.¹</p> <p>√ Ten to fifteen thousand Americans each year need a (bone marrow) transplant and are unable to find suitable donors.³</p>

		<p>√ The scientific evidence supporting the potential of autologous stem cell transplantation is growing everyday. There are clinical trials evaluating potential treatments for heart disease, liver disease and diabetes.^{4, 5, 6} Current pre-clinical studies are also examining the use of cord blood stem cells to treat the same indications, as well as stroke, Parkinson's disease, spinal cord injuries, ALS and muscular dystrophy.^{7, 8, 9, 10, 11, 12, 13, 14}</p> <p>√ In the past two years, one family bank released six cord blood stem cell units for autologous transplants.¹⁵ Other family cord blood banks have also released cord blood units for transplantation.</p> <p>√ While it is not standard treatment for leukemia, there are studies that have demonstrated success in the treatment of leukemia with autologous transplants. One study found that 67 percent of those treated with an autologous transplant remained disease-free after five years, compared to less than 43 percent provided with conventional treatment.¹⁶</p>
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Issue	AAP Recommendations	Counterpoint: Important Facts
<p>AAP contradicts the fundamental tenet of fair and balanced education so that parents can make an informed decision on cord blood banking.</p>	<p><i>“Cord blood donation should be encouraged when the cord blood is stored in a bank for public use...Parents should also be informed that cord blood banked in a public program may not be accessible for future private use.”</i></p>	<p>√ Both public and family (private) banking are important. Genetically related cord blood stem cells are preferred, since they increase patient survival rates and result in lower incidence of graft-vs.-host disease.¹⁻²</p> <p>√ The Institute of Medicine conducted a yearlong study on cord blood banking and provided the following recommendation regarding cord blood education and informed choice in 2005: “The information provided to a donor must include a balanced perspective on the different options for banking. The information disclosed for allogeneic (unrelated) donation should not include language that gives the donor an impression that the unit will be available to the family after donation.”¹⁷</p>
<p>The AAP recommendations cite statistics on the odds of cord blood stem cell use that are inaccurate, and outdated.</p>	<p><i>“Accurate information about the potential benefits and limitations of allogeneic and autologous cord blood banking and transplantation should be provided.”</i></p> <p><i>“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 1,000 to more than 1 in 200,000.”</i></p>	<p>√ The AAP-cited estimates are not current nor are they accurate in the opinion of some knowledgeable experts. They were published almost 10 years ago.¹⁸ More recently presented data estimate the odds of use for an individual who banks cord blood today to be 1 in 400 over the course of a lifetime and 1 in 200 for the individual’s family.¹⁹</p> <p>√ An additional study states that out of 200,000 patients, the odds of needing cord blood stem cells by age 21 are about 1 in 2,700.²⁰</p>

Issue	AAP Recommendations	Counterpoint: Important Facts
<p>AAP makes judgments about the role of patient education that are not in line with current public policy initiatives across the country.</p>	<p><i>“Cord blood banking recruitment practices should be developed with an awareness of the possible emotional vulnerability of pregnant women and their families and friends.”</i></p>	<p>√ Physician-patient discussion to ensure an informed choice about cord blood banking is far from “recruitment.” In fact, some states mandate physicians to discuss all cord blood banking options with their patients. To date, 10 states have passed cord blood education legislation; many more are expected to pass bills this legislative session.¹⁵</p> <p>√ Further, “vulnerability” is a subjective term that serves to imply a lack of ability to make an informed choice. In fact, many thought-leading pediatricians have chosen to family bank their own children’s cord blood.¹⁵</p> <p>√ The family banking industry recognizes the need for adherence to healthcare compliance guidelines. The Association of Family Cord Blood Banks strongly supports full compliance with all established laws, regulatory guidelines and marketing standards in all aspects of interactions and communications with healthcare professionals and the public.</p>

Issue	AAP Recommendations	Counterpoint: Important Facts
<p>AAP policy does not recognize the potential for expanded, later-life cord blood stem cell utility.</p>	<p><i>“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 (i.e. premalignant changes in stem cells).”</i></p>	<p>√ Researchers have found cord blood used later in life would be free of malignancies and preferable for use in the treatment of many health conditions, such as aplastic anemia and non-genetically linked cancers.²¹</p> <p>√ In leukemia and genetic diseases where autologous stem cells are not used, cord blood stem cells from a sibling will generally be superior to those from an unrelated donor. This forms one of the central reasons for family cord blood banking. Based upon current research there is every reason to believe that successful methods of stem cell expansion will become a reality in the near future. Cord blood contains a small population of pluripotent stem cells that in laboratory conditions can differentiate into lung, pancreas skin and other cell types. This demonstrated plasticity is one of the reasons why many people believe that cord blood stem cells may at some time in the future offer hope for the repair of failing organs and tissues. When, if ever, this will happen is highly speculative but there is enough evidence to support this as a reasonable possibility.</p>

¹ Gluckman E, Rocha V, Boyer-Chammard A, et al. Outcome of cord blood transplantation from related and unrelated donors. *New England Journal of Medicine*. 1997;337:373-381.

² Wagner J, Kernan N, Steinbuch M, Broxmyer H, Gluckman E. Allogeneic sibling umbilical-cord blood transplantation in children with malignant and non-malignant disease. *The Lancet*. 1995;346:214-219.

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- ³ National Marrow Donor Program. Available at: http://www.nationalcordbloodprogram.org/qa/why_do_we_need_it.html. Accessed February 2007.
- ⁴ Assmus B, et al. Transplantation of Progenitor Cells and Regeneration Enhancement in Acute Myocardial Infarction. *Circulation*. 2002; 106: r53-r61.
- ⁵ National Institutes of Health. Safety Study of Autologous Stem Cell in Liver Cirrhosis. <http://www.clinicaltrials.gov/ct/show/NCT00382278?order=2>. Retrieved November 2006.
- ⁶ National Institutes of Health. Umbilical Cord Blood Infusion to Treat Type 1 Diabetes. <http://www.clinicaltrials.gov/ct/show/NCT00305344?order=1>. Accessed November 2006.
- ⁷ Hu Cheng-heng, et al. Transplanted Human Umbilical Cord Blood Mononuclear Cells Improve Left Ventricular Function Through Angiogenesis in Myocardial Infarction. *Chinese Medical Journal*. 2006; 119 (18): 1499-1506.
- ⁸ Tang XP. Differentiation of Human Umbilical Cord Blood Stem Cells into Hepatocytes In Vivo and In Vitro. *World Journal of Gastroenterology*. 2006; (25): 4014-4019.
- ⁹ Ende N. Effect of Human Umbilical Cord Blood Cells on Glycemia and Insulinitis in Type 1 Diabetic Mice. *Biochemical and Biophysical Research Communications*. 2004; 325: 665-669.
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- ¹² Kuh SU. Functional Recovery After Human Umbilical Cord Blood Cells Transplantation with Brain-Derived Neutrophic Factor into the Spinal Cord Injured Rat. *Aeta Neurochirurgica*. 2005.
- ¹³ Chen R, Ende N. The Potential For the Use of Mononuclear Cells From Human Umbilical Cord Blood in the Treatment of Amyotrophic Lateral Sclerosis in Sod1 Mice. *Journal of Medicine*. 2000; 31 (1 & 2): 21-30.
- ¹⁴ Kong K. et al, Human Umbilical Cord Blood Cells Differentiate into Muscle in sjl Muscular Dystrophy Mice. *Stem Cells*. 2004; 22: 981-993.
- ¹⁵ CBR data on file.
- ¹⁶ Marco F, et al. High survival rate in infant acute leukemia treated with early high-dose chemotherapy and stem-cell support. *Journal of Clinical Oncology*. 2000; 18:3256-3261.
- ¹⁷ Institute of Medicine. Cord blood: Establishing a National Hematopoietic Stem Cell Bank Program. Available at <http://www.iom.edu/report.asp?id=26386>. Accessed November 2006.
- ¹⁸ Work Group on Cord Blood Banking. Cord Blood Banking for Potential Future Transplantation: Subject Review. *Pediatrics*. 1999; 104 (1): 116-118.
- ¹⁹ Pasquini MC, Logan BR, Verter F, et al. The Likelihood of Hematopoietic Stem Cell Transplantation (HCT) in the United States: Implications for Umbilical Cord Blood Storage. *Blood*. 2005; 106(11).
- ²⁰ Johnson FL. Placental Blood Transplantation and Autologous Banking – Caveat Emptor. *J Pediatric Hematol Oncol*. 1997;19(3): 183-186.
- ²¹ Wiley JM, Kuller JA. Storage of Newborn Stem Cells for Future Use. *Obstetrics & Gynecology*. 1997;89(2): 300-303.