



CORD BLOOD BANKING: SWOT ANALYSIS

“Strengths, Weaknesses, Opportunities, Threats”

(Market data provided courtesy of BioInformant.com)

Partnered with BioInformant Cord Blood World Europe is Proud to bring you an SWOT analysis report of the Cord Blood Banking market.

A SWOT analysis is a well-established method of evaluating strengths, weaknesses, opportunities, and threats involved in a project, business, or related venture. The process involves specifying the objective of the business venture. For purposes of this analysis, the objective is defined as sustainable, long-term growth within the global cord blood banking marketplace.

At Cord Blood World Europe we are looking to tackle the weaknesses and threats involved in the cord blood banking industry head-on and explore and improve the strengths and opportunities available to banks.

[Find out more about next week's conference here.](#)

A SWOT analysis is a well-established method of evaluating strengths, weaknesses, opportunities, and threats involved in a project, business, or related venture. The process involves specifying the objective of the business venture. For purposes of this analysis, the objective is defined as sustainable, long-term growth within the global cord blood banking marketplace.

The next step of the SWOT process is to identify “internal” and “external” factors that are desirable and undesirable for accomplishing the defined objective, as defined below:

1. **Internal Factors:** Strengths and weaknesses internal to the cord blood marketplace
2. **External Factors:** Opportunities and threats presented by the external environment (outside the cord blood marketplace)

The matrix which is then overlaid on top of internal and external factors are whether or not each is “helpful” or “harmful,” as defined below:

1. **Helpful:** Attributes which assist in the success of the objective
2. **Harmful:** Attributes which threaten the success of the objective

Thus, when these two sets of factors are overlaid on top of each other, a four-part matrix is created with the following categories (see descriptions and image below):

- **Strengths:** Characteristics of the cord blood marketplace that give it an advantage over other markets.
- **Weaknesses:** Characteristics that position the cord blood marketplace at a disadvantage relative to other markets.
- **Opportunities:** Elements that the cord blood marketplace could exploit to its advantage.
- **Threats:** Elements in the environment that could cause difficulty within the cord blood marketplace.



Created by Xhienne, "SWOT pt.svg" (File Source:[SWOT_pt.svg](#))

Note that internal and external factors can be identified as either strengths or as weaknesses, depending upon their effect on the organization's objectives. In summary, a SWOT analysis is a valuable method of assessing current market conditions within the global cord blood banking marketplace.

A. Strengths

As mentioned above, strengths are characteristics of the cord blood marketplace that give it an advantage over other markets. There are certain elements of the global cord blood banking marketplace that position it at an advantage relative to other markets. These include:

| TABLE. STRENGTHS OF THE GLOBAL CORD BLOOD BANKING MARKET |
|--|
| Cord blood stem cells are completely non-controversial because they are derived from living newborns. This is a major advantage over other stem cell types, such as human embryonic stem cells. |
| The effectiveness of cord blood transplant has been widely validated, with 30,000 transplants performed worldwide to date. |
| Cord blood is a very versatile biological material, as it can be used to treat a wide range of blood diseases, genetic and metabolic disorders, immunodeficiencies, and forms of cancer. . |
| Cord blood is a naturally occurring resource available during the birthing process. |
| Collecting cord blood for transplant use is a safe, easy, and pain-free process. Thus, cord blood transplant has a distinct advantage over directly competing alternatives, such bone marrow transplant. Bone marrow transplant involves a painful extraction process, use of local anesthesia, and higher risks of latent viral infection to the donor. |
| The cord blood industry is not restricted from offering financial incentives to doctors (obstetricians) for their support, despite the fact that the pharmaceutical industry is highly regulated in this regard. |
| The industry serves expectant parents, and broadly speaking, expectant parents are open-minded about options that could provide protection to their families. |
| Public perception toward cellular therapy is becoming increasingly favorable. 2014 saw frequent news coverage about stem cell transplants being used to treat serious medical conditions, as well as to heal traumatic injuries for sports icons. |
| While the cord blood market in the U.S. is reasonably mature (cord blood banks emerged in the U.S. in the 1990's), it is an early-stage market in other areas of the world where cord blood banks were not well established until the 2000's. This allows ample room for growth and expansion within these regions. |
| The cord blood industry naturally lends itself to diversification. While the market was initially centered around the service of cord blood banking, many cord blood banks now offer cord tissue storage and some cord blood banks have diversified further into related stem cell storage services (e.g., bone marrow stem cells, adipose stem cells, dental stem cells). |

B. Weaknesses

As mentioned above, weaknesses are characteristics that position the cord blood marketplace at a disadvantage relative to other markets. There are certain elements of the global cord blood banking market that position it a disadvantage relative to other markets. These include:

| TABLE. WEAKNESSES OF THE GLOBAL CORD BLOOD BANKING MARKET |
|---|
| Participation in the cord blood industry can involve costly accreditation requirements, including AABB accreditation, FACT accreditation, ISO certifications, and more. |
| There is a diverse range of people involved within the cord blood marketplace, including parents, obstetricians, cord blood banks, laboratory technicians, governmental regulatory bodies, and more. As such, having uniform opinions shared across the marketplace is unlikely. |
| There is a degree of inherent competition within the industry because private and public banks offer the same service to parents (cord blood storage) under different conditions (private storage vs. public donation). Most other markets do not have this conflicting public/private dichotomy. |
| While cord blood transplants provide a valuable alternative to bone marrow transplant, most obstetricians receive little education about cellular therapy applications during medical school. As such, many obstetricians are not well positioned to discuss the value and metrics of cord blood banking with their patients. |
| Cord blood banks must implement a range of protective measures and strategies to protect themselves against unexpected emergencies and weather related disasters, which substantially increases operating costs. |
| There are many conditions for which autologous ("self") cord blood transplant cannot be used, including for conditions in which there is a genetic origin. For example, autologous cord blood stem cells cannot be used to treat malignant cancers like leukemia, because the genetic mutations for the cancer are present within the cord blood. In these cases, patients must rely on the availability of genetically matched cord blood units from other donors (allogeneic transplants), which are not always available. |
| The industry is inherently subject to biological realities, which cannot always be controlled. . For instance: <ol style="list-style-type: none">1) Research indicates that cord blood stem cells can be maintained up to 15 years, but it is unknown if the cells can be preserved over the entire lifespan of a person.2) Similarly, even with optimal collection and storage of a high quality cord blood unit, success of transplant is not necessarily guaranteed. Sample quality can be variable, despite standardized collection protocols.3) Finally, nearly 70% of public cord blood donations do not satisfy public cord blood standards for storage and are discarded, which negatively affects public cord blood inventory levels. Many privately stored samples do not meet these thresholds either, but for private banking, parents have the option to pay the storage fees regardless of these thresholds. This can affect the quality of cord blood units stored at private banks as well. |

C. Opportunities

As mentioned above, opportunities are elements that the global cord blood market could exploit for its advantage. This is an interesting area of analysis because the global cord blood banking industry has matured substantially over the past few years, creating new opportunities within the market. Key opportunities within the industry include:

TABLE. OPPORTUNITIES WITHIN THE GLOBAL CORD BLOOD BANKING MARKET

Cord blood has several key advantages over direct alternatives, such as bone marrow. These advantages include:

- 1) HLA-mismatched cord blood transplants are possible, making it easier to find a genetically compatible match.
- 2) Graft-versus-host-disease (GVHD) is less frequent and can be easier to treat.
- 3) Latent viral infection in cord blood donors is rare, as compared to bone marrow donation.

Globally, there is room for growth and expansion within the area of cord tissue services. Indeed, cord tissue banking was only introduced into the cord blood market in 2008 (in Asia) and in 2010 (in the United States). While many leading cord blood banks now offer the service, across the total market it is offered by less than half of all cord blood banks.

Because rates of parental awareness about cord blood banking are low in most countries, increasing awareness rates has the potential to grow the market exponentially.

Creation of cord blood industry associations will allow cord blood banks to utilize collective resources, thereby being able to more powerfully influence public relations efforts, press budgets, and more. In 2014, cord blood industry associations were formed within both the United States (Cord Blood Association) and Brazil (Associação Brasileira de Bancos de Células Tronco).

In the United States, the federal government is beginning to give tax support to private cord blood banking. If approved, the "Family Cord Blood Banking Act" that was introduced to the House Committee on Ways and Means in December 2013 will amend the Internal Revenue Code to treat the cost of private umbilical cord blood banking services as a medical care expense for purposes of the tax deduction for medical expenses.¹

Several automation technologies have recently entered the cord blood banking marketplace. The current market leaders in automated processing are the Sepax system by BioSafe SA and the AutoXpress® (AXP®) system produced by Cesca Therapeutics (a company created by the merger of Thermogenesis and TotipotentRX Corporation in February 2014). Automation of cord blood processing has improved cell processing yields, including total nucleated cell (TNC) counts and CD34+ cells. It has also introduced improved efficiency and reduced costs in many cases.

Cord tissue derived mesenchymal stem cells do not yet have any FDA approved uses, but there are a number of ongoing preclinical and clinical trials currently underway. Having a cord tissue derived mesenchymal stem cell therapy receive FDA approval will likely create a substantial increase in cord tissue storage demand.

¹ Beta.congress.gov, (2014). *H.R.3673 - 113th Congress (2013-2014): Family Cord Blood Banking Act* | Congress.gov | Library of Congress. [online] Available at: <https://beta.congress.gov/bill/113th-congress/house-bill/3673> [Accessed 4 Nov. 2014].

Recent medical research has demonstrated promising results for double cord blood transplantation, which could allow the procedure to become available to larger sized patients. As standards of care are optimized for double cord blood transplantation, cord blood transplantation will be available to a wider audience of patients.

While cord blood stem cells have generally been difficult to expand in culture (*ex vivo*), a September 2014 paper published in the journal *Science* by Canadian and American researchers indicated that a small molecule called “UM171” successfully expands cord blood stem cells, including enriching by 13-fold a subpopulation of cells known as long-term-repopulating hematopoietic stem cells (LT-HSCs).² LT-HSCs have the ability to produce all mature cells of the blood system, which means this discovery could substantially increase the usability of cord blood.

The cord blood industry is increasingly putting forth efforts to improve the representation of minorities within the public donor pool, which will make cord blood transplantation available to a wider range of patients. Recent progress in this area includes:

- 1) The Harlem Hospital in New York, USA, is encouraging its diverse patient population to donate cord blood during childbirth through a partnership with a not-for-profit group called “Preserve Our Legacy.”³
- 2) The Chinese stem-cell initiative "OtherHalf" and Canadian Blood Services (CBS) are expanding their partnership to encourage mothers of Chinese descent to donate their infants' cord blood to help people with diseases like leukemia and lymphoma.⁴

² Science 19 Sep 2014: Vol. 345 no. 6203 DOI: 10.1126/science.1256337.

³ Usa.chinadaily.com.cn, (2014). *Stem cell donors sought[Canada]chinadaily.com.cn*. [online] Available at: http://usa.chinadaily.com.cn/world/2014-10/14/content_18732938.htm [Accessed 4 Nov. 2014].

⁴ Ny1.com, (2014). *Harlem Hospital Leads Way in Effort to Increase Cord Blood Donations*. [online] Available at: http://www.ny1.com/content/lifestyles/healthy_living/218301/harlem-hospital-leads-way-in-effort-to-increase-cord-blood-donations/ [Accessed 4 Nov. 2014].

D. Threats

As mentioned above, threats are elements in the environment that could cause difficulty within the cord blood marketplace. . This is an interesting area of analysis because the global cord blood banking industry has matured substantially over the past few years, creating new threats within the market. Serious threats to the industry include:

TABLE. THREATS TO THE GLOBAL CORD BLOOD BANKING MARKET

Accreditation requirements create high cost structures for cord blood banks. Existing accreditations affecting cord blood banks include: FDA, FACT, AABB, AATB, CLIA, JACIE (Europe), NetCord (International), HTA (UK), TGA (Australia), etc. Obtaining industry accreditation involves a huge amount of upfront expense, as well as ongoing spending to maintain accreditation.

In addition to the costs imposed by these accreditation standards, the cord blood industry is also subject to continually evolving accreditation requirements.

2013 saw a decrease in the number of cord blood used for transplant in the United States, as reflected in transplant metrics published by the National Marrow Donor Program ("Be the Match"). In 2012, the "Be the Match" Registry facilitated close to 1,200 transplants; in 2013, it facilitated approximately 1,100, a substantial year-over-year decline.⁵

Public stem cell banks have had low rates of turnover for stored cord blood units, which questions the sustainability of the business model for the public sector.

Marketing pressures are substantially impacting the industry. The term "cord blood" is now one of the 20 most expensive search terms on Google. Winning U.S. based search traffic for the phrase "Cord Blood" costs \$38.38.⁶ The cost for winning worldwide search for this phrase is \$22.60.⁷

There has been recent negative press surrounding the cord blood banking industry. For instance, in April 2014, the Wall Street Journal published a piece about the cord blood industry, discussing "dirty storage, leaky blood samples, and firms going under." Similar press has emerged across Brazilian news outlets, and appeared in other regions of the world as well.

Historically, it has been difficult to expand cord blood stem cells ex vivo, which has been a factor limiting the usability of cord blood, especially for the treatment of larger patients. Protocols for expansion are still being explored, but none are commonly performed. (Note: There is some evidence of this changing, as a group of Canadian and American researchers recently showed positive results for cord blood expansion using a small molecule "UM171."⁸)

⁵ Bethematchclinical.org, (2014). *HCT Presentation Slides*. [online] Available at: <https://bethematchclinical.org/Resources-and-Education/HCT-Presentation-Slides/#902/> [Accessed 5 Nov. 2014].

⁶ Adwords.google.com, (2014). *Google AdWords: Keyword Planner*. [online] Available at: <https://adwords.google.com/ko/KeywordPlanner/Home> ("Cord Blood"; Geography: USA Only) [Accessed 5 Nov. 2014].

⁷ Adwords.google.com, (2014). *Google AdWords: Keyword Planner*. [online] Available at: <https://adwords.google.com/ko/KeywordPlanner/Home> ("Cord Blood"; Geography: All Locations) [Accessed 6 Nov. 2014].

⁸ Fares, I., Chagraoui, J., Gareau, Y., Gingras, S., Ruel, R., Mayotte, N., Csaszar, E., Knapp, D., Miller, P., Ngom, M., Imren, S., Roy, D., Watts, K., Kiem, H., Herrington, R., Iscove, N., Humphries, R., Eaves, C., Cohen, S., Marinier, A., Zandstra, P. and Sauvageau, G. (2014). Pyrimidoindole derivatives are agonists of human hematopoietic stem cell self-renewal. *Science*, 345(6203), pp.1509-1512.

New legislation and policy changes have the potential to negatively impact the cord blood industry. For example, the "one cord blood bank per region" law instituted in China has had irreversible effects on the cord blood industry in that country. Similarly, any new law controlling biological specimens, tissue collection, tissue storage, or cellular therapy standards could negatively impact the industry.

There is the potential for competitive transplant approaches (bone marrow or peripheral blood) to be shown more optimal for patient engraftment, outcome, or recovery.

Patent challenges for processing or transplant technologies can also be a substantial risk. For instance, from 2002-2006 PharmaStem Therapeutics claimed that all cord blood banks were using procedures for which they owned a patent, and tried to force private U.S. cord blood banks to pay licensing fees and royalties. The PharmaStem patent was overturned in 2006, but the possibility for similar patent challenges exists.

Changes in public perception of private versus public banking can also shift, and it is unknown at any moment in time which will be favored – leaving both sides of the industry at risk.

Shifts in policy recommendations made by influential medical organizations can also impact the industry, as key groups hold substantial influence over public opinion. Examples of such organizations include the American Medical Association, the American Academy of Pediatrics, the Royal College of Obstetricians and Gynecologists.

Cord blood transplant procedures can be very expensive, ranging in cost from \$200,000 to \$300,000. This can make the procedure cost prohibitive for individuals who have inadequate insurance coverage. For those who do have insurance coverage, it still necessitates that their provider approves coverage, and terms and conditions for "medical eligibility" can vary substantially from one insurance provider to another.

Changes in transplant reimbursement structures by medical insurance providers can also negatively affect the industry (amount paid per procedure).

In most regions, government has substantial impact over the ability of private cord blood banks to operate profitably. If there is a shift in government support, it can have a major market impact. For instance:

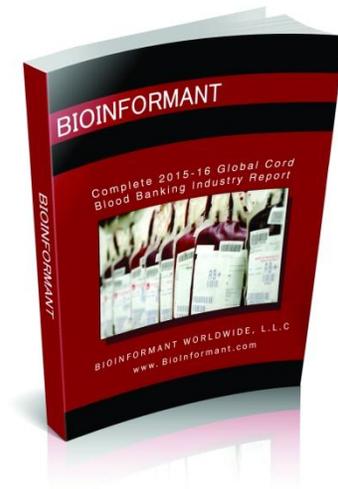
- 1) In Ecuador, the government is creating the first public cord blood bank and has instituted laws such that private cord blood banks cannot approach women about private cord blood banking options during the first six months of pregnancy. This has created a crisis for the private banks, and there are now only two remaining in Ecuador.
- 2) In China where there is a "one license per region" policy for cord blood banks, the government issues these permits.
- 3) In Canada, cord blood banks must be registered with Health Canada and they can inspect facilities at any time.

This SWOT analysis is provided courtesy of BioInformant Worldwide, LLC.

BioInformant Worldwide, LLC, is your global leader in cord blood industry data. We are the only market intelligence company that has specifically served the cord blood sector since it emerged. BioInformant has been cited by prominent news outlets that include Nature Biotechnology, the Wall Street Journal, CBS News, Yahoo Finance, Medical Ethics, MarketWatch, and more.

To learn more about the cord blood marketplace, view the “Complete 2015-16 Global Cord Blood Banking Industry Report” here:

<http://www.bioinformant.com/product/complete-2015-16-global-cord-blood-banking-industry-report/>



If you work in Cord Blood Banking and the issues raised in this report apply to you, come along to the Cord blood World Europe Congress and get up to speed on the best way to improve your business and save costs.

Come and join us and make a difference, show yourself as an industry leader, stay ahead of your competitors, network with the industry, make new collaborations and learn how to make your cord blood bank a success.

The World Cord Blood Congress is bringing together public and private banks, clinicians, researchers, and solution providers to tackle the challenges and opportunities facing this field of regenerative medicine. On 20th - 21st May in London we will do something amazing.

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