

# Transformation of Bio-medical Waste into Bio-medical Insurance through Stem Cell Banking : An Indian Market perspective

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## Abstract

Stem cell therapy – the emerging therapy area that is drawing the attention of the pharmaceutical players worldwide – refers to the therapy wherein a damaged tissue that cannot heal itself is repaired by the use of stem cell. The market for stem cells is constantly evolving, with researches going on to exploit the true potential of the market worldwide. The prevalence of the major diseases among people with no permanent cure available and the dependency on medicines for sustainability and well-being provides the ready market for the stem cell companies to tap.

Banking of “Cord Blood” – a rich source of stem cells & a critical input for such surgical treatments-is also undergoing a boom. Further, stem cell research indicates the potential use of Cord Blood for the treatment of widespread diseases like diabetes, hypertension, Spinal Cord Injury, Parkinson's Disease, Cardiac Disease, Alzheimer's Disease etc.

The paper gives an insight of the current and the future outlook of stem cells market along with an overview of stem cell market in India including the private and public sector players in the field. The paper also describes the role of stem cell research in reducing the cost of pharmaceutical R&D significantly. It provides a vision of a potent biological health insurance market in local as well as global perspective.

## Keywords

Stem Cells, Cord Blood, Biological Health insurance, Cord Blood Bank.

## I. Introduction

The stem cells are the unspecialized blood cell that has the capacity to replicate and produce its own blood cells, Platelets, red and white blood cells. These cells are the master cells responsible for producing all the mature cells in our blood and immune system. The cord blood is a rich source of stem cells. Stem Cell Banking is a concept of preserving the Cord blood from newborn. Cord blood collection procedure takes about 10 to 15 minutes and it can be done both in normal and caesarean section deliveries. There are no risks or pain involved in the procedure. The cells can be cryo-frozen and kept stored for decades. The collected cells are preserved by freezing them in liquid nitrogen at a temperature of -196 degrees Celsius. Cord blood is more like a ‘biological future health insurance’ for the newborn baby and its future offspring’s and siblings. Stem cells from cord blood are discarded everyday in all maternity hospitals as a bio-medical waste; however this precious source can give a renewed hope to many and prove to be a life saver [1].

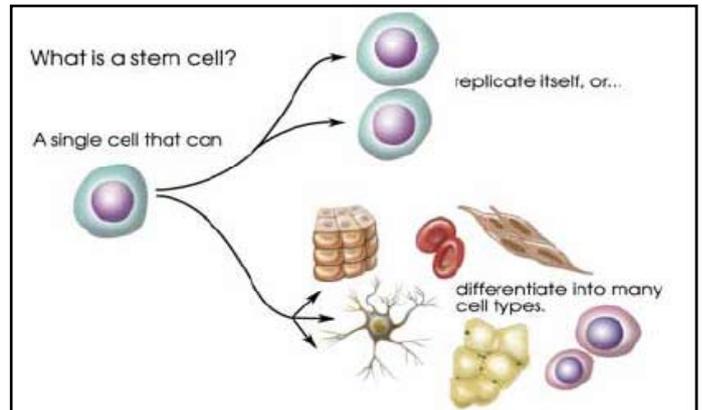


Fig. 1: Stem Cell [8]

There are basically three sources of stem cells; bone marrow, embryonic cells and cord blood. A bone marrow based surgical treatment is mostly stringent and is a difficult process as it requires accurate and correct match which is often too tedious. On the other hand the treatment based on embryonic cells involves a lot of controversies as it requires the culture of embryo or waste fetus. The third and the richest source of stem cells is the cord blood. Umbilical cord blood contains inexhaustible, non-controversial sources of stem cells for therapy [10].

Stem cells offer opportunities for scientific advances that go far beyond regenerative medicine. They offer a window for addressing many of biology’s most fundamental questions. Stem cell research may help clarify the role genes play in human development and how genetic mutations affect normal processes. They can be used to study how infectious agents invade and attack human cells, to investigate the genetic and environmental factors that are involved in cancer and other diseases, and to decipher what happens during aging. Stem cells may also revolutionize traditional chemical medicine. In the future, thousands of compounds could be quickly tested on a wide assortment of cell types derived from stem cells, making drug discovery more efficient and cost effective. Stem cells may also help scientists calculate the effects of toxic substances in drugs, food, and the environment [8].

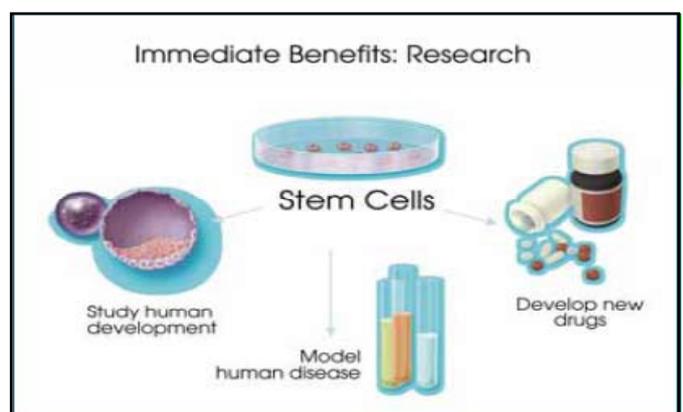


Fig. 2: The Role of Stem Cells in Basic Research [8]

First time the umbilical cord blood stem cells were used in 1988 in France to help a child suffering from Fanconi's anemia. The child was cured and since that time then similar treatment method have been applied to cure blood cancers (leukemia), sickle cell anemia, spinal cord injuries and some genetic. Today even patients with a badly damaged heart due to heart attacks have a new ray of hope when new blood vessels can be grown on the diseased heart and the dead muscles can be regenerated. Conditions such as diabetes, kidney cancer, liver diseases, coronary diseases, autoimmune and inflammatory diseases can be treated using stem cells [1].

The statistics on umbilical cord transplant reveals an upward trend and this is due to the success of research in cord blood, tests and transplant procedures. This reiterates the fact that umbilical cord transplant has been useful in providing treatments to many diseases and many people are opting for this treatment [2].

## II. Umbilical Cord Blood (UCB) Banks

A cord blood bank is place that stores umbilical cord blood for future use. Cord blood banking basically involves three steps: collection, processing and storage. Cord blood collection is a simple, safe and painless procedure that usually takes less than 5 minutes and can be performed just after child birth in which the cord is clamped and cut and the blood is drawn from the umbilical cord in a specialized bar coded bag. These collections are further harvested for stem cells, which are then stored in cryo-vials at -196 degrees celsius in liquid nitrogen [10].

Researchers now urge parents to store or donate the Umbilical Cord Blood to specialized "Cord Blood Banks". These can be either public or private institutions.

### A. Private Cord Blood Banks

This system is run by individuals or private organizations. The organization will store the Cord Blood irrespective of medical reasons. There are charges for collection and storage. The arguments against private cord blood banking are –

1. If the child has inherited blood disease, the Cord Blood would be affected too. It would be useless to have it stored in that case.
2. Doctors also prefer, in cases of children with leukemia, to have the Cord Blood of a healthy donor.
3. Private banking does not allow for choosing from an array of donors. It can only hold an individual's Cord Blood for their personal or immediate family's needs.

The advantage of this system is that blood from a healthy child with no inherited diseases can be maintained as insurance, in case a family member or the child itself should need it in the future.

### B. Public Cord Blood Banks

This system is usually government run. There are generally no charges for collection and storage. Parents are encouraged to donate Cord Blood to Public Banks.

The reasons are -

1. The chances of needing the Cord Blood are rare for a child in a family without history of disease.
2. By donating the Cord Blood, parents contribute to an already growing reserve. This way, another person from anywhere in the world may find a match in the donated blood.
3. Often, a person may not find a match among relatives for a marrow transplant. With a stem cell transplant being a viable option, a Public Cord Blood Bank would ensure

a chance for the most appropriate cord blood unit even from several unrelated donors.

The disadvantage of this system is that it is not always guaranteed that the donor will receive Cord Blood should he or she need it. It may have been donated. However, matches may be found from among many other donated samples. The match referred to is required between the donor's and recipient's human leukocyte antigens (HLA). The closer the match is, the better is the body's chance of accepting the new stem cell. The first ever Cord Blood Bank in the world was started in New York's Milstein National Cord Blood Center. It is a Public Cord Blood Bank. Today, there are over 40 Cord Blood Banks worldwide, both public and private [9].

## III. STEM CELL MARKET IN INDIA – AN OVERVIEW

Almost non-existent a few years ago in the country, stem cell banking is now a flourishing business with more and more people wishing to store their baby's cord blood as a form of bio-insurance, even though it comes at a heavy price. Cord blood storage is fast gaining momentum as a less traumatic alternative to treat neurological illnesses, and as a guarantee for the family against a host of diseases. Stem cell treatment is a therapy in which new cells are injected into damaged tissues and banks generally charge anything between Rs 60,000 and Rs 80,000 to harvest the cord blood for private use. Increased awareness about the benefits of stem cell therapies has led to mushrooming of several firms providing treatment and blood storing services in less than six years.

According to Stem Cell Global Foundation (SCGF), a Delhi-based organisation promoting research, stem cell banking is a Rs100 crore business in India and at an annual growth of over 35%, it is expected to touch Rs140 crore by 2010. Globally, stem cells are used to treat over 130 diseases and it is estimated that more than 500 clinical trials are being done to develop therapies using stem cells. LifeCell, the first such organisation to bring this concept to India, claimed that about 20,000 parents have so far banked their baby's cord blood stem cells with it. Cyrobanks India, another major player, said to have gathered more 15,000 clients since it made an entry in the country four years ago [3].

### A. MAJOR PLAYERS IN CORD BLOOD BANKING IN INDIA

1. Lifecell, Chennai
2. Jeevan, India's first voluntary, public cord blood
3. Cordlife Sciences and Cryobanks International plan to establish cord blood banks in Kolkata and New Delhi respectively
4. Reliance Life Sciences, Delhi .
5. Histostem, a South Korean biotech company, plans to establish the world's largest cord blood bank is Mumbai. The Indian government is to have a 10% stake in this venture.

LifeCell is the first and the largest private cord blood stem cell bank and stem cell solutions provider in India which facilitates the cryogenic preservation of umbilical cord blood stem cells at its central facility in Chennai, India. LifeCell was incorporated in 2004 in technological collaboration with CRYO-CELL International Inc, Florida, USA – the world's largest and oldest stem cell bank. LifeCell has been granted the prestigious AABB Accreditation. AABB (American Association of Blood Banks) is an international non-profit organization dedicated to developing the highest standards in blood and cord blood banking, transfusion medicine and cellular therapy [5].

Jeevan, the first blood bank in India to introduce 100% blood

component facility, is seeking the financial and scientific resources to open India's first Public Stem Cell Bank in the "Not For Profit Sector". Jeevan is recognized as a research organization by the Department of Scientific and Industrial Research, a division of the Department of Science and Technology, Government of India. Jeevan has the clinical expertise and the organizational capability to establish India's first voluntary, public cord blood registry [6].

CordLife operates Australasia's largest network of private cord blood banks with full processing and cryo preservation storage facilities in Singapore, Hong Kong, Indonesia and India as well as marketing presence throughout the region. Since its inception in 2001, CordLife was first certified by Singapore's Ministry of Health, and subsequently accredited in 2005 by the world's most recognised quality standards in cord blood banking - American Association of Blood Banks (AABB). In 2006, CordLife was awarded the prestigious 'Technology Pioneer' status by the World Economic Forum for advancing the field of adult stem cell therapy, cord blood banking and technologies.

Cryobanks International India a JV between Cryobanks International USA and RJ Corp founded in 2006. Cryobanks International is a leader in the collection, processing and banking of umbilical cord blood stem cells. Cryobanks International provides a Private Cord Blood Storage Program for expecting families that wish to privately store their baby's precious stem cells and a Public Cord Blood Donation Program for those who prefer to donate.

Another important player is Relicord- which is Reliance Life Sciences Stem Cell Banking services has established south Asia's first most advanced and completely automated stem cell enriched umbilical cord blood repository. This is the first cord blood repository in the world to be accorded a license by an official regulatory authority, Food and Drug Administration (FDA), Government of India.

Histostem Co. Ltd., is a South Korean, US based Biotechnology Company that is developing the latest human cell based therapy. It is a pioneer in cell based therapy. The main divisions of Histostem are cell therapy research, public cord blood bank for transplantation, and family cord blood bank. It is in the process of investing \$20million to establish the world's largest cord blood bank, providing stem cells for transplant surgeons globally.

New private cord blood banks are being established all over India in an attempt to use their knowledge, research and storage facility to benefit the Indian population. What seemed like a dream few years back is now becoming a reality. The use of umbilical stem cells for therapeutic purposes can ensure lower treatment costs and longer lives.

#### IV. Future Potential

The stem cell market is growing rapidly due to increasing regulatory approval and public acceptance bodies. The benefits of stem cell therapy are attracting an increasing number of patients. The product submarket for human and embryo stem cells are expected to drive the growth of the overall market. In addition, intensive R&D efforts and the increasing investments into research on stem cells therapy are soon expected to improve the efficacy of stem cell treatment. However, the high cost of the therapy may affect market growth. Table 1 lists the current and emerging applications of stem cells [4].

Table 1: Applications of Stem Cells [10]

Current Applications of Stem Cells/Cord blood	Emerging Stem Cell /Cord blood Applications
<i>Acute Leukemias</i> <i>Chronic Leukemias</i> <i>Thalassemia</i> <i>Fanconi's Anemia</i> <i>Sickle Cell Anemia</i> <i>Hodgkin's Lymphoma</i> <i>Non-Hodgkin's Lymphoma</i> <i>Multiple Myeloma</i> <i>Others</i>	<i>Cardiac Disease</i> <i>Diabetes</i> <i>Multiple Sclerosis</i> <i>Muscular Dystrophy</i> <i>Parkinson's Disease</i> <i>Spinal Cord Injury</i> <i>Stroke</i> <i>Alzheimer's Disease</i> <i>Lupus, Rheumatoid Arthritis</i>

It is the multifaceted role of stem cells in a whole wide range of diseases that accounts for this huge potential. It takes 10–12 years for a new drug discovery, whereas it takes just 3–5 years in stem cell research; the prelaunch cost of development for a new drug is US\$ 500 million against the US \$200 million in stem cell research. And the success rate of a new drug is 5–10% against 50% or better in stem cell research [11].

The global stem cell market is estimated to be \$88.3 billion by 2014, growing at a CAGR of 14.8 % from 2009 to 2014. The U.S. currently holds a 60% share of the global stem cell market; and forms an especially lucrative market for areas such as bone marrow transplantation through stem cells [4].

India's global share in cord blood based surgical treatment is a meager 0.25% (20 out of 8000 cord blood transplants). Major breakthrough in stem cell research promising low cost treatment is attracting foreign players in India. While advancement in stem cell therapy would provide solutions to incurable and severe injuries, an established cord blood banking sector in the country would widen the compass of beneficiaries by making these affordable for the masses [10].

High birth rate and lack of any stringent government regulations are the factors favoring the development of cord blood banking in India. With approximately 72000 births daily, resulting in discarding of 72000 umbilical cords a day-the storage of stem cell rich blood derived from these umbilical cords can prove to be the best possible insurance against life threatening diseases.

#### V. Conclusion

Stem cell research is an emerging field of interdisciplinary research with clinical implications focused on repair, replacement or regeneration of cells to salvage impaired organ function. From biological insurance, repository services, autologous and allogenic transplants, assisted devices to system solutions, the tremendous potential of stem cell research can be limited only by imagination [11].

More than 45,000 people across the world are receiving adult stem cell transplant every year. Stem cell technology can reduce pharmaceutical R&D by 25% each year, with savings of up to US \$25 million in each drug market.

India is capable of leading from the front given its early success, potential and the proactive, favourable regulations of government agencies. The revenue is expected to increase manifold with new stem cell products likely to enter into the market in 2009 and onwards.

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