



UMBILICAL CORD BLOOD BANKING IN INDIA: CURRENT LANDSCAPE

Clinical Science

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ABSTRACT

Once regarded and discarded as medical waste, umbilical cord blood today is treasured as a source of precious hematopoietic stem cells. After the initial success of UCB in transplantations, private and public banks were established all over the world and also In India. The present paper is an attempt to overview the current landscape related to UCB banking in India.

KEYWORDS

UCB banking, private banks, public banks, hybrid model, accreditations

INTRODUCTION:

There has been an increased attention on the use of stem cells and cord blood banking in India in the past decade (Vaidya and Singhania, 2013). Umbilical cord blood is the blood left over in the umbilical cord and placenta post delivery. Once regarded and discarded as medical waste, umbilical cord blood today is treasured as a source of precious hematopoietic stem cells. Owing to many advantages UCB has over bone marrow and peripheral stem cell transplants, several umbilical cord blood banks were established all over the world and in India (Waller-wise, 2011). The aim of the current paper is to explore the current landscape related to UCB banking in India.

METHODOLOGY:

Methodologically, the findings of the study are based on the analysis of secondary as well as primary data. The secondary data was collected from various reports, websites of the UCB banks, and other data sources. The primary data was collected by field visits, and telephonic interviews.

RESULTS:

A. The cord blood banks landscape in India

There are 14 UCB banks in India that are certified by CDSCO and mentioned on its website. However, in our study we found that this list has not been updated. Three of the banks have closed operations. They are represented in our study as Firm E, which was the only purely public bank in India, Firm G, based in Hyderabad and Firm A, based in Vadodara. Some of the banks have changed names, for example: Firm K and Firm L and Firm M. Firm D has been taken over by Firm F in 2017.

Table 1 : Cord blood banks in India

S. No.	Location	Functionality
1	Firm A	Collection closed in 2020 (personal talk)
2	Firm B	Operational
3	Firm C	Operational
4	Firm D	Taken over by Firm F in 2017
5	Firm E	Closed collection in 2018
6	Firm F	Operational
7	Firm G	Closed Operations
8	Firm H	Operational
9	Firm I	Operational
10	Firm J	Operational,
11	Firm K	Operational , Name changed
12	Firm L	Name changed ,Operational
13	Firm M	Name changed ,Operational
14	Firm N	Operations Closed
15	Firm O	Operational
16	Firm P	Operational
17	AIIMS	Operational
18	School of Tropical Medicine	Operational

Source: Author's own construction

In addition, in our study we found two banks that were not listed on CDSCO website. These two banks are: The School of Tropical

Medicine's Cord blood bank (STM) and the Firm N. Interestingly, STM located in Kolkata, is the only government run cord blood bank in India. We also found the website of Firm N which shows that the bank is involved in cord blood banking. However, on contacting the director, we were informed that the bank has closed operations due to COVID pandemic.

Table 2 : UCB Banks Not Listed In CDSCO Website

Heading	Heading	Heading
The School of Tropical Medicine's Cord Blood Bank	Government owned	Kolkata
Firm N	Private	Bangalore
Cord blood storage facility at AIIMS	Government owned In house facility	Delhi

Source: Author's own construction

The cord blood storage facility at AIIMS is also not listed on the CDSCO website (as on July 2021). The industry related details below are only provided for operational UCB banks, apart from Firm E, which was the only purely public bank in India. As of July, 2021, there are thirteen operational UCB banks in India.

B. Type of Organisation and location of Storage:

Firm B, which is based at Kolkata, is a Subsidiary of a company listed on the Singapore Stock Exchange, which holds the majority interest in the bank through its wholly owned subsidiary. Incorporated in 2001, it is Asia's largest network of Private Cord Blood Bank and is headquartered in Singapore.

Based at Gurugram, Firm C is a private limited company, founded by an Indian corporation in 2006. It is the only Cord Blood bank in India available in International Market., with branches in over 15 countries and laboratories in India, Thailand and Singapore. In India the laboratory and the storage facilities are based at Gurugram, Haryana. The laboratory is spaced in an area Over 28000 sq ft dedicated laboratory. The labs are cGMP, cGTP, cGLP compliant, and Class 10,000 & class 100 clean rooms. The cell culture & expansion facility with patented technology in collaboration with DA Vinci Biosciences, USA.

Firm E, funded by a tie-up with the state of Tamil Nadu, was the first purely public cord blood bank. A public cord blood bank is a not-for-profit which will supply matching cord blood for people in need. Established in 1995, Firm E was a pioneer in setting up safe and international standard practices in blood donation, processes and distribution. Unfortunately, in 2018 Firm E shut down their blood bank due to rising competition from multiple low-cost banks.

Established in 2004, Firm F is India's first stem cell bank, which has presence across 175 centres in India. The bank's laboratory and storage facilities are located at Chennai. In October 2017, Firm F formally acquired Firm D's 18000 cryopreserved umbilical cord blood units and their corresponding customer agreements.

Firm H based in Mumbai was established in 2010. It started out only collecting samples from in and around Mumbai. They now provide services across all of India.

Firm I was established as the first cord blood repository in South East Asia in 2002 and offers both public donation and family storage. It offers a combined storage service to parents-to-be that comprises cord blood banking along with umbilical cord and cord tissue-derived mesenchymal stem cells banking. The laboratory and storage facility is located at in Navi Mumbai.

Firm J, began operations in 2009. The laboratories and processing facility are located in Lonavala, and are certified with GMP, GLP and GCP. Through its cell therapy division, Regrow, which was launched in 2009, RMS claims to offer patient-specific regenerative medicine, with over 500 successful implantations. In 2017, RMS Regrow tied up with Apollo hospital groups to offer cell based therapy of OSSGROW and CARTIGROW.

Firm K is collaboration between a U.S. based cellular therapy company and a multi-super specialty hospital in Gurgaon. The parent company is a China-based industry research alliance of research institutions for stem cell and regenerative medicine. The GMP facility of the UCB bank is located the hospital, and has expertise available for both stem cell banking and treating patients using advanced cellular therapies.

Firm L was initiated as a sister concern by a private limited stem cell research organisation based in Gurgaon. It offers pool banking for UCB storage. The laboratory and storage facility are based in Gurgaon. Firm M was established in May 2003 to offer medical services in the field of regenerative medicine. Its laboratory is based in Bangalore. The UCB bank provides various cell and tissue based banking services for therapeutic application as well as stem cell expansion service to various hospitals that provide stem cell therapy. The primary focus of the bank is to provide umbilical cord blood and cryopreservation services to expectant parents. In addition to this core service, the UCB bank offers processing and cryopreservation of stem cells from various sources like bone marrow, peripheral blood and adipose tissue.

Firm O is a joint venture between a Cord Blood and Tissue Preservation company based in the USA, a multi speciality hospital based in Gujarat and a pharmaceutical company based in Ahmedabad. The bank was founded in 1997 via a Mou signed with the government of Gujarat at the vibrant summit. It is one of the earliest public/private "hybrid" cord blood banks. The buildings and the laboratory were constructed in 2009. The processing and storage facility of the UCB bank is located at the hospital Campus in Gandhinagar, Gujarat. Firm P commenced its operations in October 2009 and is India's first hospital-based mixed cord blood banking facility. The cord blood banking facility has been established in collaboration with Rotary International, and functions both as a public and private cord blood facility. It is a part of the Bone Marrow Transplant (BMT) unit of the Mazumdar Shaw Cancer Centre. The bank aims to provide evidence based medicine with cord blood stem cells to patients who do not have HLA matching sibling donors. Cord blood tissues are sourced from across the country and stored at the Rotary Bangalore Health City Narayana Tissue Bank. Any hospital in the country can have access to it.

AIIMS set up the first cord blood bank in the government sector in 2007. The processing and storage facilities are located at AIIMS premises, New Delhi. It is used only for treatment of in house patients. The School of Tropical Medicine (STM) in Kolkata has launched the first public cord blood bank in India that is state run. The cord blood bank is operated by the school's Department of Regenerative Medicine and Translational Science. The bank was announced in early 2014 and launched at the end of 2015. The state had invested Rs 89 lakhs in the first phase.

The aim of establishment of STM was to provide stem cells to people at nominal costs, and to carry out extensive research on regenerative medicine to invent the cure for a host of ailments. As of 2015, there was no inventory in the bank.

Table 3 : UCB banks in India-Headquarters and Location

	Location	Headquarter	Laboratory
1	Firm B	Singapore	Kolkata
2	Firm C	Gurugram	Gurugram
3	Firm E	Chennai	Chennai , Closed collections of UCB in 2018

4	Firm F	Chennai	Chennai and Gurugram
5	Firm H	Mumbai	Mumbai
6	Firm I	Mumbai	Mumbai
7	Firm J	Mumbai	Lonavala
8	Firm K	Gurgaon	Fortis hospital, Gurgaon
9	Firm L	Gurgaon	Gurgaon
10	Firm M	Bangalore	Bangalore
11	Firm O	Ahmedabad	Apollo Hospital
12	Firm P	Bangalore	Mazumdar Shaw Cancer Centre
13	School of Tropical Medicine	Kolkata	Dept. of Regenerative Medicine and Translational Science
14	AIIMS	Delhi	Stem Cell Facility, AIIMS

C. Accreditations and Validation:

According to studies (Querol, 2010), NETCORD-FACT standards are the most comprehensive of all UCB governance standards, and should be an important requirement for quality assurance of CB units available for international public use. National Guidelines for Hematopoietic Cell Transplantation (NGHCT)-2021 have stipulated that the collection, banking and release for administration of the UCB should be done as per the NetCord-FACT International Standards. However, only one of the operational banks, Firm O, is NetCord-FACT certified. Five of the banks have AABB accreditation. These are Firm A, Firm B, Firm F, Firm I, and Firm O. Four of the banks have FDA accreditation.

Table 4 : UCB banks in India accreditations

	Location	Headquarter
1	Firm B	DCGI, AABB,
2	Firm C	DCGI, AABB
3	Firm E	DCGI
4	Firm F	DCGI, AABB
5	Firm H	DCGI, AABB
6	Firm I	DCGI, AABB
7	Firm J	DCGI
8	Firm K	DCGI
9	Firm L	DCGI
10	Firm M	DCGI
11	Firm O	DCGI, AABB
12	Firm P	DCGI, FACT
13	School of Tropical Medicine	DCGI

Source: Author's own construction

DCGI: Drug Controller General of India; AABB: American Association of Blood Banks; FACT: Foundation for the accreditation of cellular therapy

Validation is the process of providing documented evidence that a specific process will consistently produce a product meeting its predetermined specifications and quality (WMDA, 2020). In our study, we found that majority of the cord blood banks in India have limited validation, that is, the banks do not have transplantation data on engraftment and follow-up, many do not have integrated quality management systems and common international standards. There is a requirement for the UCB units preserved in UCB banks of India need to be assessed and judged 'fit for purpose' on the basis of current recommended practice, thereby defining the actual number of reliable quality units.

D. Banking model:

The cord blood banks in India are found to have three types of banking models. There are purely private banks. They are banks offering both private and public storage and, banks offering hybrid models. There are no purely public UCB Banks in India.

There are six UCB banks offering only private banking of UCB in India. There was only one purely public bank, Firm E that closed collection of new cord blood units in 2018. Firm E now just maintains preservation of already collected units. There are two banks that have a hybrid business model. That is they have private banking, and pool banking. These are Firm F Community Banking and Firm L having Pool banking, Firm C having Social banking.

Three banks offer Mixed (Both Private and Public) private and public banking. They are: Firm I, Firm O and Firm P.

In addition there is a cord blood banking unit in AIIMS that was established in 2006. The aim was to collect and store the umbilical cord blood from the deliveries happening daily, after taking due consent from parents. Initially, it was meant for only in-house patients, but there were plans to set up a national cord blood bank. AIIMS currently uses cord blood banking only in specific cases for in house patients. Four of the banks: cord blood bank at AIIMS, Firm P, Firm K and STM are hospital based.

Table 5 : Banking models of UCB banks in India

Sr. No.	Location	Banking Model
1	Firm B	Private
2	Firm C	Private/Social banking
3	Firm E	Public
4	Firm F	Private/Community banking
5	Firm H	Private
6	Firm I	Private/Public
7	Firm J	Private
8	Firm K	Private
9	Firm L	Private/Pool banking
10	Firm M	Private
11	Firm O	Private/Public
12	Firm P	Private/Public

Source: Author's own construct

Table 6 : The Hospital based Cord Blood banks in India

Hospital	UCB bank centre	UCB banking model
AIIMS	Stem Cell Facility	In house patients
School of Tropical Medicine (STM)	Department of regenerative medicine	Not Known
Firm P	Mazumdar Shaw Cancer Research Centre	Private/Public
Firm K	Fortis Hospital	Private

Source: Author's own construct

Of the hospital based UCB banks, AIIMS has UCB banking facility only for in house patients. Firm P has both private and public banking model. Firm K has only private banking model.

Firm C offers two kinds of UCB banking models-private and social banking. Social banking offers access to the society registered members to a pool of commonly shared CB units. The plan offers access to the stored stem cells entire family, viz., baby, baby's siblings, parents, maternal grandparents and paternal grandparents. Initially, the CB stem cells are stored for a period of two years for exclusive use of the family. After two years, the CB unit becomes part of the 'pool' and can be accessed by any other member of the 'social banking' plan.

Price:

The banks offer different prices for storage. Each of the private cord blood banks has different charges and paying options. Many charge a collection fee and an annual storage fee. Some of the banks offer 21 years storage, while others offer 75 years of storage.

The lowest price is Rs. 19990 (Firm F) and the highest is Rs. 390250 (Firm B). On average it take Rs. 30–40K followed by annual charges of Rs. 4-5000. Banks also offer monthly EMI plans for customers. The banks offer different package having different benefits to customers, such as insurance, expansion of mesenchymal cells, Medical coverage and so on.

CONCLUSION:

In the current paper, we overviewed the current landscape related to UCB banking in India. In India, UCB banking is permitted only under the license of CDSCO. However, we found that the list of UCB banks put up on CDSCO website is not updated. Some of the banks have closed operations, and a few have changed names. There is a need for updating the same according to the current landscape of UCB banks in India. Regarding accreditations, only one of the operational banks, Firm O, is NetCord-FACT certified. Five of the banks have AABB accreditation. These are Firm A, Firm B, Firm F, Firm I, and Firm O. Four of the banks have FDA accreditation. The cord blood banks in India are found to have three types of banking models. There are purely private banks. They are banks offering both private and public storage

and, banks offering hybrid models. There are no purely public UCB Banks in India.

REFERENCES

1. Hurley, C. K., & Raffoux, C. (2004). World Marrow Donor Association: international standards for unrelated hematopoietic stem cell donor registries. *Bone marrow transplantation*, 34(2), 103-110.
2. Querol, S., Gomez, S. G., Pagliuca, A., Torradella, M., & Madrigal, J. A. (2010). Quality rather than quantity: the cord blood bank dilemma. *Bone Marrow Transplantation*, 45(6), 970-978.
3. Umbilical Cord Blood: Information for Childbirth Educators. (n.d.). PubMed Central (PMC). Retrieved August 20, 2021, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3209739/>
4. Vaidya, A. (2013). Quality control measures in cord blood banking in India - critical appraisal and recommendations. PubMed. <https://pubmed.ncbi.nlm.nih.gov/24698987/>
5. <https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadBloodBank/Umbilical-CordBlood-Bankndia.pdf>
6. <https://parentsguidecordblood.org/en>