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## **Following the banking cycle of umbilical cord blood in India: the disparity between pre-banking persuasion and post-banking utilization**

Prasanna Patra and Margaret Sleeboom-Faulkner\*

### **Abstract**

To address critique of the rare uptake of umbilical cord blood (UCB) in private banks, hybrid-banking models would combine the advantages of ‘public UCB banking’ and private UCB banking by responding to both market forces and public needs. We question both by following the cycle of UCB banking in India: the circulation and stagnation of UCB as waste, gift, biological insurance, enclaved good, source of saving lives, and commodity through various practices of public, private and hybrid UCB banking. Making the journey from ‘recruitment’, ‘collection’ and ‘banking’ to ‘research’ and ‘therapy’ allowed us to identify concerns about the transparency of this cycle. Drawing on archival research and fieldwork interviews with different stakeholders in UCB banks in India, this article shows how private/hybrid cord blood banks are competing for their market share and its implication for the circulation of UCB: speculation, stagnation and opacity.

Key words: (3) India; umbilical cord blood banking; stem cell therapy

## Introduction

Umbilical cord banks store umbilical cord blood (UCB) for future use. Both private and public cord blood banks have been established to treat diseases of immunological systems and blood disorders, such as leukemia. The aim of a public UCB bank is to treat anyone whose treatment requires UCB, while private banks store blood for potential use by paying customers and their families. As explained below, controversy exists between those that support private and those that support public UCB banks: the former claim that private banks are underused and store blood that would be more effectively and fairly used by public banks (see Hauskeller & Beltrame in this special issue); the latter argue that public banks are too expensive for small and developing countries, as private banks make use of higher numbers of stored blood units and can be cheaper compared to public banks, which tend to ask for high release fees (see Chang in this special issue). As is explained in this article, an evaluation of the degree of public-spiritedness and efficacy of different forms of UCB banking requires us to move beyond a simple taxonomy, and requires an overview of the process of UCB banking as a whole, the socio-economic context in which it occurs, and insight into the attitudes that are being cultivated among the public towards risk and science. Our contribution is to take an initial step towards such evaluation.

The last few decades have witnessed the emergence of newly globalized tissue economies (Waldby and Mitchell 2006) with innovative life science and medical biotechnology industries established around the sourcing and circulation (Brown et al. 2011) of human tissues. The transformation of UCB from a waste by-product to a source of stem cell interventions, ranging from leukemia to sickle cell disease, has given rise to a globalized commercial sector in cord blood banking, a sector based largely on promises of future therapies (Santoro 2009; Brown 2013). In 2013, there were over 500 UCB banks worldwide (Sharma 2013), and in India, in 2015, five out of fourteen UCB banks claimed to have “public” cord blood facilities (hybrid banks), the remainder being private (Parents Guide 2015).<sup>1</sup>

Private stem cell banks were established in India prior to any systematic public stem cell banking initiative in other countries, the high expenses involved of which were unaffordable to India. Private banks rapidly spread throughout the country, but the contesting claims about their sample size, recruitment strategies, banking methods, and transplantation possibilities renders clear insight into India’s UCB banking scene impossible. Reliance Life

Sciences (RLS) established the first public cord blood bank in 2002, followed by Relicord, Cryo Stemcell, Jeevan, and StemCyte. Although they collectively have over 60,000 units, as we shall see, their public banks are mainly extended programs of their private, main banks and are extremely small. Relicord and StemCyte are the two leading private stem cell banks that have both private and public banking facilities. Jeevan Bank is a not-for-profit community blood bank located in Chennai, and provides both private and public UCB banking facilities to its clients and donors (Jeevan Bank 2014). Other private banks include LifeCell, CryoBank, CryoSave, Cord Life, Baby Cell, Stem One, ISCSL and TranScell Biologics. Apart from some hospital-based repositories made for small-scale research studies and applications and the All India Institute of Medical Sciences (AIIMS) in New Delhi (Agarwal 2006; McKenna and Sheth 2011), there are no public UCB banks established, funded, or promoted by the state. With over 150,000 cord blood units in 2013, the private stem cell banking industry in India was valued at Rs. 200 crore (US\$32m) and estimated to reach Rs. 2700 crore (US\$430m) by 2020, accounting for 17% of the world market (Pharmabiz 2013).

With India's booming birth rate of 27 million births per year (Pharmabiz 2013), the country is poised to be the largest collector of UCB in the world (McKenna and Sheth 2011). UCB banking is an expanding biotech sector in India, where leading enterprises are competing with each other to capture the market. The 'hyping' tactics (Brown and Kraft 2006; Sunder Rajan 2006) of these enterprises promise cures through the application of new biomedical technologies. Such promises are accompanied by a general trend of responsabilization of the population (Rose 2007), whereby populations are made aware of the "risk" associated with giving birth to a child with inherited and late-onset diseases, and are encouraged to take responsibility to address those risks (Beck 1992; Alaszewski 2003; Gupta 2010; Sleeboom-Faulkner 2010). Citing statistics from the science literature to point out the disease risks for children at birth and presenting parents-to-be with UCB as "biological security" has led to the normalization of commercial UCB storage among the middle classes, transforming the valuation of umbilical cords as waste (Hodges 2013) to a precious and life-saving resource.

But private UCB banking has been at the core of international controversy, which pitches solidaristic donation – making UCB publicly available for use - against private storage, whereby estimations of the odds that a person will need their own (autologous) UCB ranges from 1 in 10,000 to 1: 250,000 (Rosenthal 2011). Private banking has been criticized

for threatening the supply of cord blood to the public system, and causing a stagnation in the circulation of potentially life-saving UCB. Furthermore, it has been accused of displacing proven therapeutic uses of cord blood in the public sector with uses whose benefits are largely speculative (O'Connor et al 2012: 513). It has been argued that hybrid models of public and private UCB banking are a viable alternative for countries that cannot afford to run a public UCB bank. Hybrid banks would provide both private and public storage options (O'Connor et al 2012; Chang 2014) and facilitate a higher uptake of UCB units compared to public banks. This is because they can both respond to market demand and fulfill the needs of the community (O'Connor et al 2012; Brown et al 2011; Chang 2014). Even though hybrid banking can, in principle, resolve some of the problems associated with UCB banking, in this article we identify some major challenges. First, the responsabilization of families that normalizes UCB banking requires that families can make an informed decision as to whether and where to bank UCB. This in turn requires that families have full insight into the process of UCB banking and a realistic idea of the medical application of UCB to realize the 'biological security' promised. We argue that this is not the case. Second, the critique of private banking is not resolved by hybrid banking. The UCB stock in private banks is released back into circulation, but diverted in ways that are unclear and questionable.

#### *Following the life cycle of UCB banking*

In India, the creation of private and hybrid cord blood banking has been an obvious choice, considering the unavailability of funding for public UCB banks. But it is difficult to find balanced information about private and hybrid UCB banks in India: although data about recruitment, collection and payment are readily available in documentation provided by bankers, information about the handling and uptake of banked units cannot be found on websites and are often unclear when provided by UCB bank managers. As statistics on the collection and use of UCB blood are unreliable, and as it is beyond our ability to investigate UCB stored in all UCB companies in India, it was impossible for us to gain insight into a core question: Can potential clients of UCB banks in India make informed decisions about UCB storage regarding the cost, uptake and the use of UCB? To find out, we opted to follow the life cycle of UCB banks from recruitment, collection and banking to its utilization in research and medical interventions, surmising that it might give us insight into the process of UCB banking as an interconnected whole. The triangulation of information from parents, bank managers, technicians, sales people and scientists, we hoped, would enable us to

identify discrepancies between the quantity and quality of information provided to potential clients and the fate of the stored UCB units in the banking process.

We capture these weak links in reference to Appadurai's work on the social life of things (1986), whereby some objects are exchanged through barter, the market and gifts, while others are taken out of circulation by being discarded as 'waste' or enclaved as 'relics'. Similar to Appadurai, we treat demand (consumption) as an aspect of the overall political economy of societies: a function of a variety of social practices and classification, rather than a mysterious emanation of human needs, a mechanical response to social manipulation or the desire for available objects. We thus show how the upsurge in UCB banking is not so much a result of the need of the Indian population for stem cell therapy (Tiwari and Raman 2014) or a response to social manipulation (Bharadwaj and Glasner 2009; Patra and Sleeboom-Faulkner 2013), but part of the health-industry boom driven by the promissory bioeconomy and the introduction of biomedical risk categories into society (Sunder Rajan 2006).

We suggest that, in theoretical terms, although private UCB banking belongs to the 'luxury register' of consumption (Appadurai 1986: 38) among the middle- and higher income classes, what is consumed is the suggested sense of safety sold with the storage. In the process, the banking causes stagnation by diverting objects from circulation -- enclavement in Appadurai's terms, while at the same time earning profit through the storage of the enclaved blood. The use of the notion of 'enclavement' here differs from that of Appadurai: although consumption of UCB is contractually reserved, the customer pays for the object to be kept out of circulation. Thus, although UCB sets off a financial flow, the minimalisation of its physical consumption here means maximal efficacy. Thus, unlike religious relics, which are enclaved for their sacred value, and unlike "money in banks", which invest capital, in private UCB banking UCB units are largely stocked as a commercial solution to hyped risk and for high payments. For this solution to be relevant and for high payments to materialise, however, companies invest in groundwork to the effect that parents learn about the vulnerability of children to diseases, and persuading them that UCB storage renders optimal security. In this sense, storage results from an ideology that enclaves UCB blood as a form of perceived security. The cases in which UCB units are dispensed, this happens in ways unclearly related to medical interventions and experimental research, and for this reason remains hidden. This has the effect that little is known among clients about the use of UCB blood other than for therapy. We argue that it is the potential use of the UCB units that clients pay for, and that transparency around its dispensation is crucial.

## *Method*

This article is based on data gathered through both primary and secondary sources. It draws on research that explores the institutional, socio-economic and managerial aspects of UCB banking entrepreneurship in India, conducted over five months, between August and December 2013. During this period, we explored the lifecycle of UCB banking from recruitment, collection and banking to research and therapy. Gaining an overall view, we intended to shed light on the conditions under which UCB circulates between different spheres (private, public, state, science, health) and in various guises (waste, gift, good, insurance, source, etc.), which we hoped would provide us with insight into the entire cycle. With this aim in mind, we collected data about UCB banks of various size and origin, and with various aims.

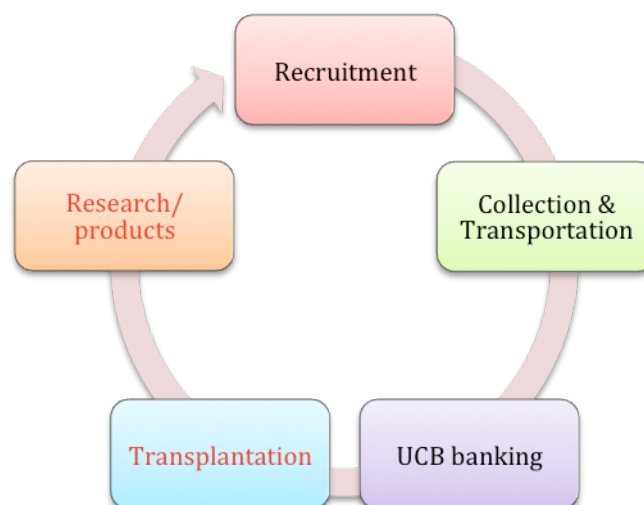
We have visited multiple sites across India that include five stem cell banks, four stem cell companies, five stem cell research institutes, and four clinics where we interviewed donors/clients (four), sales executives (five), gynecologists (three), stem cell researchers (eleven), scientists (seven), therapy providers (six), bioethicists (five), venture capitalists (one) and patients/caregivers (eight). The institutes/centers/stem cell banks and hospitals visited include the Stempeutics Research Pvt. Ltd., International Stemcell Services Limited (ISSL) and Manipal Institute of Regenerative Medicine in Bangalore, Jeevan Stem Cell Bank, Lifeline Institute of Regenerative Medicine (LIRM) and Nichi-In Centre for Regenerative Medicine (NCRM) in Chennai, StemCyte in Ahmedabad, ReeLabs and NeuroGen in Mumbai, Chaitanya Stem Cell Centre and LifeCell in Pune, CryoBank in Gurgaon, Indian Institute of Medical Science & Research, Udaan Centre and AIIMS, TranScell Biologics Ltd. in Hyderabad, and Kalinga Institute of Industrial Technology (KIIT) in Bhubaneswar. Secondary source materials such as webpages of the above institutes/centers, newspaper articles, and conference materials are referenced. We have anonymised the names of interviewees by using pseudonyms. Although CEOs of companies were happy to be mentioned by name, we still preferred to use pseudonyms for all individual interviewed, as our aim is to clarify the lifecycle of UCB, rather than to attract attention to individual persons.

Although UCB banks use different methods and have multiple purposes in practice, we initially aimed to follow the lifecycle of UCB processing as commonly advertised by UCB banks: recruitment, banking, and utilization. Doing this helped us realize that important

parts of the life cycle of UCB banking, methods of transportation, monopolization and the use of UCB in research are underexposed and transplantation is overexposed. Subsequently, we added “transportation” and “research using UCB” to the lifecycle. It also helped us compare statements of people involved in different parts of the lifecycle of UCB banking, which in this article comprises recruitment, transportation/collection, UCB banking, transplantation and research. As we will show, UCB banking as a life-saving tool or biological security is rarely materialized; in private banks, it usually stagnates as stock, and to the extent that UCB is mobilized, it is diverted into biomedical pathways that have remained unclear to us. The relevance of the notions of stagnation/circulation in the context of the life cycle of UCB units is that these concepts force us to focus on the issue of application: whether it sits in a bank as stock, or whether it returns to circulation. Following the life cycle of UCB can yield socio-economic and ethical insights into the UCB banking cycle (recruitment, collection, storage, life saving therapy). Thus, a view of the entire life cycle of UCB banking helps us address two issues: Whether prospective parents have sufficient information before deciding whether to store UCB, and whether the hybrid model of UCB banking can help solve the problems associated with private UCB banking, as explained above.

### **The lifecycle of UCB banking**

In this part we follow the lifecycle of UCB banking, comprised of recruitment, collection and transportation of UCB, banking, research and transplantation (see figure).



*Figure:* The life cycle of UCB banking



### *Recruitment*

This section shows the groundwork done to facilitate recruitment and marketing among prospective parents to persuade them of the privilege of storing UCB privately. This groundwork entails persuading prospective parents of the high risk of inherited disease in India, the safety and security of UCB banking, the use of additional insurance, and its affordability.

In India, UCB was previously discarded as medical “waste,” but has increasingly become a source for stem cell transplantation and research. This increase in value has required substantial groundwork. As sales executive, Mr Reddy, of LifeCell narrated:

Some four to five years back we really had to work hard to convince the expectant parents, and even obstetricians and other health-care providers, about the regenerative benefits of UCB. It was a worthless thing to them. But now, thanks to developments in science and increasing awareness among people, they value it (Mr. Reddy, Sales Executive-4, Pune, dated 24-Oct-2013).

A father who has stored his child’s UCB and tissue in one of the big private banks said:

I never imagined that something like a flesh tube or a cord that connect the mother with the child can have so much medical potential. I have stored it, but I am still amazed about its possibilities. It used to be buried under the soil so that animals cannot eat it. That would bring ill health for the child. It was nothing but garbage. But now, the same waste can be used to treat diseases; it is magic. Only science can do it (Mr. Daar, father, 39 years, interviewed in Hyderabad, on 24-Oct-2013).

The costs associated with storing UCB, however, are high considering the low chance of its use, especially in the case of private banking. The uptake of the units by clients and the internationally acknowledged success of transplantation are rare. Nevertheless, private banks market their services to parents and health-care providers as a leading-edge medical technology (Sullivan 2008).

The decision of parents to bank the UCB of their child with a private banking company is primarily based on ‘facts’ presented to them by experts employed by banking companies, including references to articles about consanguineous marriage, the numbers of

infants born with chromosomal and genetic disorders, and malformation. Expert views and the presentation of such “facts,” coupled with a trend of parent preference for a limited number of children in rapidly growing urban middleclass society, have raised people’s concern about their future health status and biological destiny. As one mother, who has stored her child’s UCB with TranScell Biologics, a Hyderabad-based private CB bank, says:

Every day you hear about a new disease. Sometimes they are scary; you always think that might happen to my child. Money is nothing before that helplessness. So, that made us to think of this banking (Interview, Mrs. Komra, Aged 38 years, Mother of four, dated 28-Oct-2013, Hyderabad).

Private UCB banks target specific populations that are “at risk.” According to Mr Rohan, a sales representative of a large bank operating throughout India, these include “the rich, upper-middle-class, small-sized, nuclear-family-oriented couples in urban India, high-salaried IT professionals, parents belonging to ethnic and religious groups that practice consanguineous marriage, people with family history of members with some kind of genetic disorder” (Rakesh, Bhubaneswar, 12-Nov-2013). As one pregnant mother said when asked why she was planning to bank the umbilical cord of her child:

In my aunt-in-law’s family there is a 12-year-old girl with thalassemia. I have seen how they struggle to arrange for blood transfusions. I am sure that we do not need to worry, as both I and my husband have been tested. But, you never know: some disease might express in a later stage. Since both I and my husband are working, we cannot afford to have more than one child. We came to know about UCB banking through our gynecologist. It is an once-in-a-lifetime chance, so we have decided to bank the umbilical cord of the child. We have already registered with LifeCell (Interview, Mrs. Gupta, expectant mother, 31 years, Bhubaneswar, 16-Nov-2013).

Expert knowledge has normalized new risk cultures that can be hedged by banking. The UCB banking industry further creates concerns about banking security and safety measures in the race to acquire customers. Thus, the company LifeCell provides dual-storage facilities at Chennai in south India and Gurgaon in north India as a security measure against natural

calamity in one of the locations. Mr Ravi, a sales executive of LifeCell, believes it improves the scope for recruitment:

Dual-storage facilities make the sample secured. You never know: something like a tsunami that affected the Chennai coast a few years back, or an earthquake like that happened in Gujarat. Though our facilities are earthquake proof. It is better to divide your sample and keep it at two places, to be on the safe side (Interview, Sales Executive-3, Chennai, 14-Octo-2013).

Some clients are influenced by the good infrastructure of a bank's facilities, but others feel that accreditation by competent national and international agencies is more important. Still others feel contact with the sales executive or regional manager is crucial, and there are those who bank if a friend or relative has previously stored cord blood in a bank. As a couple working as IT professionals in a multinational company, Mr. and Mrs. Manohar have decided to store their child's UCB with a private bank:

What we did is, we checked their website. They have the necessary ISO certificates, the facilities are absolutely shielded and equipped to handle calamities of any sort. The buildings are earthquake proof, the cylinders for cell storage are waterproof and can withstand any kind of calamity including tsunami (Mr. and Mrs. Manohar, interview of parents in LifeCell, 2014).

Cord blood banks such as StemCyte and LifeCell display their licenses, registrations and accreditations wherever possible, including ISO, American Association of Blood Banks (AABB), the National Accreditation Board for Testing and Calibration Laboratories (NABL), and the Drug Controller General of India (DCGI). Interviewed customers generally show awareness of accreditation.

At a private bank, the UCB unit belongs to the client: a family storing a unit with a private bank is said to have a degree of "biological insurance." Banks are also providing life insurance coverage to their clients through private-sector insurance companies. For example, LifeCell has an arrangement with Max New York Life Insurance (MNYL). But most attention is given to UCB storage as biological insurance. One parent explained:

For me there are three main reasons why I decided to bank with LifeCell. First, they are India's largest stem cell bank, second would be they store samples in two places that is safe. The third reason is that they provide a 10 lakh rupees insurance promising to arrange stem cells from other banks in case they fail. So, that is reducing my burden in future and ensuring the future health of my child. That I appreciate (Mrs. and Mr. Gandhi, interview available in LifeCell webpage 2014).

The arrangement between cord blood banks and life insurance companies is designed to influence the decision-making of clients in the recruitment process.

Even though UCB banking is still viewed as elitist (Hodges 2013), novel methods to make it affordable through innovative payment methods enabled the expansion of private banks, such as LifeCell and CryoBank, to small cities and towns in India. The recent announcement by the Union government of India in February 2014 to withdraw the 12.36% service tax on cord blood banking will create financial leeway for promoting the concept of "biological insurance' among the middle classes" (The Telegraph 2014; IMT 2014). The CEO of LifeCell, the largest Indian cord blood bank with over 80,000 customers, said:

We understand the importance of educating expectant parents on the value of UCB banking and our effort is to offer an affordable UCB banking to reach out to maximum number of families ... (Pharmabiz, 8-Oct-2013).

LifeCell has several payment plans towards the storage fee. It charges Rs. 19,900 (approximately US\$350) as an enrolment and cord blood and tissue processing-fee. Then it charges Rs. 4,000 (approximately US\$70) as an annual storage fee. There are options for storing cord blood at single or dual-storage facilities with different fee structures. Similar attempts to slash the stem cell processing and storage fees have been made by other banks, such as StemCyte and CryoBank. TranScell, a small-scale private bank based in Hyderabad, charges a one-time Rs. 75,000-100,000 for collection, processing, and storage for 21 years.

This section has tried to illustrate how prospective parents are educated as to how UCB banking can abet the Indian population's major risk of developing disease by commercially enclaving UCB in biobanks. Considering the rapid increase of UCB banking and support by the state, companies have succeeded in normalizing the practice, but it is also clear that smaller companies engaged in UCB banking do this in combination with other biomedical activities.

### *Collection and Transportation*

Commercial cord blood banking is characterized by strong competition, involving the ability to deal with complex logistics, large connection networks with hospitals covering increasingly large areas, and the flexibility and speed needed to collect and transport the UCB to banks.

Private UCB companies generally collect UCB at the birth hospital and ship it to the private bank. The collection takes place after and before the delivery of the placenta. To date, little data is available to suggest which of the two collection methods is safest and which allows for the optimal collection of UCB (Smith and Thomson 2000). However, our research has noted frequent complaints regarding the inexperienced nature of the collecting go-betweens and mediating company representatives. Collection involves complex networks where stakeholders such as doctors, nurses, and other health-care providers, sales executives of the UCB bank, the pregnant mother, expectant parents, and family closely interact. In the process clients are compelled to use the hospitals that collaborate with the UCB banks they have a contract with.

Some banking companies have arrangements with doctors and obstetricians, whom they appoint to panels, which link the banks with a range of hospitals. Such “syndicate of doctors” is paid by the bank to allocate prospective patients to the hospitals they have deals with. To maximize the number of clients, a bank needs to have links with a large number of fertility clinics, hospitals, obstetricians, and midwives to bring prospective parents into contact with the sales executive appointed to a particular area. In this exercise, larger banks are in an advantageous position compared to smaller banks, such as TranScell. As the CEO of LifeCell said:

We have tie-ups [agreements] with 300 hospitals at 110 locations. So any mother delivering in these hospitals can donate her umbilical cord to us ... There are no hurdles as far as the hospitals and doctors are concerned (Mr. Chandramauli, CEO, LifeCell, Pharmabiz, 12-Nov-2013).

The companies that have large hospital networks have an advantage over others. As the CEO of TranScell said:

LifeCell or StemCyte have more money, trained executives, and wider network with hospitals and clinics. They give better salaries to their executives, and better perks to doctors and people who help them with recruitment of clients. In my company, sales executives leave after about four-to-six months. I am unable to pay competitive incentives to our panel doctors. So, that affects your business (Interview, Dr. S. Kumar, CEO-1, TranScell, in Bhubaneswar, 14-Nov-2013).

Apart from wide networks, robust infrastructural facilities, and funding to incentivize syndicate agents, the speed and safety of collection are crucial to both clients and bankers. Thus, TranScell provides its services mainly to clients living in the city of Hyderabad, where the company is based. Many prospective parents and pregnant mothers visit the TranScell lab and storage facility center, where scientists and trained staff reassure them that their sample is stored in a timely manner and in a safe place. Most banks have one, or at best two, centralized storage facilities, but their collection centers are spread throughout the country or concentrated in the area of operation. Banks advertise the robustness of their logistics and the efficacy of their collection and transport ability. LifeCell has partnered with Sequel Logistics, a logistics company, to offer “Personalized Shipment Service.” Efficacious collection and transport are projected as something that would enhance the quality and viability of the stem cells.

This section showed the importance of UCB networks to the growth and survival of the enterprise. In this competitive arena, the smaller banks with limited networks, such as TranScell and International Stem Cell Services Limited (ISCSL), find it difficult to compete. This has implications for the number of clinics they can reach and the number of samples they can collect. As we shall see, it also affects the way UCB banking companies diversify.

### *UCB banking*

This point of the cycle was complicated: the banking itself, which is part of the cycle of UCB banking, can only be understood in terms of the kind of banking concerned. The diversity of UCB banking we came across make us realize that without clear information on the kinds of activity involved of UCB banks, potential donors cannot make appropriate decisions about donation. We have tried to depict the great variety of UCB banking in India in terms of the taxonomy below. The taxonomy is only of heuristic value, and serves to show the difficulties involved in potential parents’ decision-making around UCB banking. The taxonomy,

comprising public (not-for-profit) cord blood banks, local banks, global banks, charitable banks and academic/research banks, shows that UCB banking is far more complex than the simple division between private, public and hybrid banking would suggest.

**Public (not-for-profit) cord blood banks** may collect and use the donated cord blood (gift to the public) for transplantation into a suitable match (e.g., unrelated allogeneic transplantation), while *private banks* collect and store the units for potential use by the newborn infant (autologous transplantation). In case of *hybrid banking*, the private bank adds a public part, which is financially supported by the private part; in the case of *family banking*, which can be an option in a private bank, a family member in need of a stem cell transplant procedure can also use the stored units. Depending on the kind of contract, the UCB can be collected and used for laboratory-based research studies and in clinical trials as well. The separation between these various activities, we will show, is unclear, largely due to the increased entwinement between competition and collaboration, and therapy and research. In this section, we classify UCB banks in India according to size, institutional embedding, collaborative network, service provision, and research. As will become clear, some banks are maintained as part of other activities organized around clinical stem cell applications and research.

**Local banks** have limited scope and their area of operation is restricted to a city or province. For instance, TranScell Biologics Private Ltd., a private UCB bank, stem cell service and research center based in Hyderabad, was initiated in 2008 by a scientist-cum-entrepreneur. The scope of operation of this bank is limited to the city of Hyderabad and surrounding areas in the state of Andhra Pradesh in south India. Because of its limited infrastructural facilities and resources (small numbers of sales executives, health counselors, gynecologists in the service panel, logistical support for transportation of collected samples from distant areas, and lack of adequate storage facilities and research staff), the bank struggles to expand. As it aspires to become a national-level bank, it tries to create partnerships with private venture capital companies. The bank has about 4,100 UCB units stored at its facility, including 4,000 UCB units in private and 100 units in its public storage modes. Only five units of UCB have been used for stem cell transplantation purposes (both autologous and allogeneic) within India and abroad (the Middle East) (Interview Kumar, 14 November 2013). To increase its revenue, TranScell has combined banking facilities with research activities, as its CEO states:

Ours is a different kind of company that focuses on UCB banking, stem cell processing facilities and research on stem cell science. We have around 4,000 units under private or family banking, which is for the purpose of generating revenue. We charge around Rs. 75,000 to 100,000 (US\$1,300–1,700) per unit towards a one-time preservation fee for 21 years. We also have around 100 units of UCB collected from voluntary donors that will be used for research purposes (Interview, Dr. S. Kumar, CEO-1, TranScell, in Bhubaneswar, 14-Nov-2013).

Local banks consider the expansion of collaborations with therapeutic or transplantation services as the logical next step towards increasing the scope of the enterprise. The same CEO explained company strategy:

My focus now is to increase the storage capacity, to explore collaborating opportunities, negotiate with investment communities, and to emphasize end-user collaboration (Interview, Dr. S. Kumar, CEO-1, TranScell, Bhubaneswar, 14-Nov-2013).

For this stem cell scientist, UCB banking served multiple purposes, including the financing of research, the provision of research materials and participation in clinical applications.

**Global banks** start either with support from a multinational company or as a branch of a foreign UCB bank with national presence, as in the case of LifeCell and StemCyte. LifeCell was launched in 2005 with technology licensed from Cryo-Cell USA. It is spread over more than 100 medical centers in India and, in 2014 it has over 80,000 UCB units preserved at its dual-storage facilities at Chennai in south India and Gurgaon in north India. The use of cord blood units from this largest UCB bank in India is, however, low: in 2013, LifeCell had released only 23 cord blood units for therapy out of an inventory of 70,000 units (Krishnan 2013).

StemCyte India Therapeutics Pvt. Ltd., established in 2008, is a joint venture between StemCyte Inc. (USA), Apollo Hospital Enterprises Ltd., and Cadila Pharmaceuticals Ltd. StemCyte India's headquarters are located in Ahmedabad, with the processing and storage facility at Apollo Hospital Campus in Gandhinagar, both in the state of Gujarat. StemCyte engages in the collection, processing, testing, and storage of both private and public UCB units and their therapeutic applications. The bank claims to have dual-banking facilities



(private and public) in India and more than 35,000 “racially diverse” UCB units in its public repositories in all its centers (StemCyte 2015). Its main objective is to build an inventory of “racially diverse” (Indian) UCB units. StemCyte’s CEO argues that there is less chance of immune rejection if cells of the same “race” are used (Hiddleston 2011), and the scarcity of some “racial units” is one of the most lucrative forms of UCB banking (Brown et al. 2011). It has a wide network of hospitals and contacts established all over India. StemCyte has provided more than 1,850 UCB units to over 200 transplant centers across six continents worldwide, and it has provided 27 cord blood transplants in India for hematopoietic diseases.

“**Total**” or “**holistic**” banks claim to provide “complete” stem cell services covering cell collection, processing, storage, and therapy provision. Examples are ReeLabs, Mumbai, and ISSSL, Bangalore. ReeLab was formed in 2009 as a stem cell therapy center, and it later added stem cell banking facilities for UCB, tissue, menstrual blood, and dental pulp. It also provides storage facilities to smaller companies that wish to store their samples for a fee. ReeLab claims to have 2,000 UCB units stored at its facility that has a 10,000 UCB storage capacity, and is planning to expand (Sudhendranath 2013). ReeLabs introduces itself as “a one-stop shop in stem cell medicine” with products such as “ReeCord for stem cell banking and ReeCure for stem cell treatments for various congenital, developmental, degenerative, and malignant disorders.” ISSSL, in Bangalore, provides “complete” stem cell services, such as stem cell expansion, differentiation, cord blood banking, and treatments for diseases such as peripheral vascular disease, Buerger’s disease, osteoarthritis, diabetes, and renal failure. ISSSL provides stem cell banking for UCB and tissues, and is engaged in stem cell research and therapy provisions.

A **charitable bank** is run by either a charitable trust or small private bodies, where amassing profit is not the major drive. Jeevan Stem Cell Bank (JSCB) based in Chennai is one example. JSCB is a unit of Jeevan Blood Bank and Research Centre, and collects both private and public cord blood units. Its public cord blood bank was set up in 2008, and at present it has an inventory of 700 UCB units. The Tamil Nadu government announced a grant of rupees 9 crore (US\$150,000) to Jeevan’s public UCB bank in April 2013 to help the bank host a collection of 3,000 cord blood donations (Kumar 2013). The objective of JSCB’s public cord blood bank is to make available umbilical cord derived stem cells to patients in India, either free of charge for the poor or on a cost recovery basis for those who can afford it, and at a prescribed fee for those Indians living abroad. It also offers cord blood units to advance medical research. JSCB has also signed a memorandum of understanding (MoU)

with IIT (Indian Institute of Technology), Madras, in March 2013 for research and development in stem cell biology.

An *academic or research bank* is attached to or run by government-funded academic research institutions or hospitals. The primary aim is to promote basic research on stem cells with or without translating it into therapeutic application, which we discuss in the next section.

Considering the variety of UCB banks, it should be clear that categorizing the UCB banks in India in terms of private/public/hybrid is unhelpful, as most banks are commercial hybrids. Of the banks discussed, only the charitable and academic/research banks are not-for-profit, even though all charge fees for the uptake of UCB. For the purpose of examining the circulation of UCB, the banks are better classified according to size, institutional embedding, collaborative network, kind of service provision, and research, as these tell us something about the advertised functions of the UCB.

#### *UCB transplantation*

This section discusses the sourcing of UCB units, and involves the disentanglement of commercially stored UCB units as transplants from private storage into clinical therapies. As therapies for diseases other than blood disorders are not recognized as evidence-based and require permission from the National Apex Committee (CDSCO 2013; Tiwari and Raman 2014), many of the applications mentioned below are controversial.

Most UCB banks in India have been established in the last few years, and UCB transplantation is in its infancy (McKenna and Sheth 2011). Only one cord blood bank, StemCyte India, has published a detailed list of its UCB transplantations on its official website, claiming that it is the “only company having clinical experience of treating 52 hematopoietic diseases and the record of providing more than 2,000 cord blood units for transplantation across 235 centres worldwide.” It further claims to have facilitated 27 cord blood transplants in India, for which it provides a list of 25 disease conditions, including thalassemia major (13), aplastic anemia (2), relapsed bilineage leukemia (1), spinal cord injury (2), AML (1), Hurler’s syndrome (1), CGD (1), infantile ALL (1), relapsed ALL (1), HLH (1) and Fanconi’s anemia (1) (StemCyte 2015). Some of these transplantations are experimental, so effectiveness is by no means guaranteed.

McKenna and Sheth (2011) have reported that 32 patients in India have had transplantations using related or unrelated UCB, including 13 cases of thalassemia. Of these, six cases were transplanted using fully-matched sibling-UCB at Apollo Hospitals, Chennai. UCB units were obtained from LifeCell and CordBank. Similarly, seven unrelated UCB units were utilized to treat thalassemia cases at Gujarat Cancer & Research Institute (GCRI), Ahmedabad. The unrelated UCB units were procured from private UCB banks, namely Relicord and StemCyte. Hyderabad-based TranScell has provided its UCB units for five transplantations (both autologous and allogeneic) to centers in India and one in the Middle East (personal communication with CEO, TranScell, 14 November 2013). Furthermore, it advertises that stored UCB is used for therapeutic interventions for cancers, blood based disorders, brain and neurological disorders, diabetic ulcers, eye/ocular disorders, muscular dystrophies, autoimmune diseases and bone and cartilage defects, most of which it also conducts experimental research on (Transcell 2016).

Some banks, such as ReeLab in Mumbai and ISCSL in Bangalore, have been established for the declared purpose of providing all necessary stem cell therapeutic services to patients requiring them. ReeLab's CEO said:

ReeLab claims that it is the only firm that processes and stores stem cells from all possible sources and uses it for therapy. We've had cases where the stored samples have been retrieved and used for therapy of family members. Other market players are merely storing cord and cord blood stem cells. No other company is into stem cell therapy (Abhijit Bopardika, CEO, Dental Stem Cell Division, ReeLab) (Sudhendranath 2013).

It has become clear from the examples above that applications of UCB units for both routine and controversial therapies are provided to patients. Interviewed patients said that they had not been made aware of the controversial nature of these therapies or the origin of the UCB. Nor did they realize that the advertised lists of disorders to which stem cells had been applied gave no information on whether they had been applied successfully. Discussion with patient groups for spinal cord injury and muscular dystrophy in India made clear that one of the most urgent demands is clarity around the scientific state-of-the-art of the therapies on offer (Workshop Bangalore, October 2013). Knowledge about the safety and efficacy of therapies has implications for the decisions made by expecting parents at the recruitment phase of the cycle of UCB banking.

### *Research using UCB*

This section discusses the relationship between research using UCB and its sourcing, involving the disentanglement of commercially banked UCB units from stock into research projects in private and government institutions. For decision-making purposes, prospective parents should have information about what proportion of the UCB stock is diverted into research. Provided literature and customer agreements, however, does not make this clear.

Many private and public institutions and hospitals without adequate banking or cryopreservation facilities are involved in research activities using UCB, including StemCyte India, who operates a hybrid public and private bank “to store UCB stem cells and use them to prevent and treat various diseases and health disorders,” including spinal cord injury, HIV, cardiac repair and stroke (StemCyte 2015). Apollo Hospitals has a 51-49 partnership with StemCyte with an initial investment of US \$15 million to carry out research on chronic strokes, spinal cord injury, and muscular dystrophy. A UCB bank is functional at Apollo Ahmedabad as a joint venture between Apollo Group, StemCyte Inc., and Cadila Pharmaceuticals (Anna University 2014).

TranScell Biologics Ltd. claims to have 4,000 UCB units under private banking facilities and around 100 UCB units under its public collection for research purposes. TranScell is also collaborating in international trials and allocating its resources for research purposes, by using its “good manufacturing practice” (GMP) stem cell processing units. One officer explained that the company has three stem cell products in its pipeline for the treatment of osteoarthritis, muscular dystrophy, and solid tumors (Interview, Dr. S. Dravida, CEO-1, TranScell, in Bhubaneswar, 14 November 2013). As stem cell treatment for these diseases is not evidence-based, and as the company has not had official permission for conducting clinical trials, questions of legitimacy and awareness arise.

Another leading private stem cell research institute is Nichi-In Centre for Regenerative Medicine (NCRM), an Indo-Japanese collaborative stem cell institute based in Chennai, which has entered into partnership with charity-based Jeevan Stem Cell Bank in Chennai. It manages both private and public banking facilities and reportedly has an inventory of 700 UCB units under its public banking facilities (Interview, Mrs. Sindh, Researcher at Jeevan Blood Bank, Chennai, 13 October 2014). Similar issues of the proportion used for research and the legitimacy of the research arise, with the extra complication of whether private or public UCB units are used.

There are no data available on the amount of UCB collected and stored at any government-funded research institute or hospital in India. However, there are reports that suggest stem cell research using UCB is being carried out at several centers. For example, a joint study by Dhot et al. (2003) conducted at the Department of Transfusion Medicine, Armed Forces Medical College, Pune and Armed Forces Transfusion Centre at Army Hospital Research & Referral (AHRR), New Delhi, reported that 172 samples of UCB were collected and cryopreserved. The study aimed to improve techniques for the collection of cord blood, to study the influence of cryopreservation on stem cell count, and to carry out cord blood stem cell transplantation at AHRR in New Delhi. For this study, pregnant women undergoing full term vaginal deliveries at these centers were randomly selected at the time of admission for delivery, with informed consent (Dhot et al: 2003; Wadhwa et al. 2013).

AIIMS, the premier medical hospital and research center based in New Delhi, set up India's first UCB bank in the government repository in 2006. It collects UCB from "the five to eight deliveries that happen daily in the institute" with parents' consent, for "use in treating patients of cancer and other debilitating diseases" and, as of now, this is only for "in-house" patients, but the Institute has ambitious plans for setting up a national cord blood bank (Ghosh 2006). The Stem Cell Facility at AIIMS is currently undertaking a research project on the "isolation and expansion of mesenchymal stem cells (MSCs) from human bone marrow/umbilical cord and the evaluation of its cardiomyogenic and neurogenic differentiation potential," for which it is using UCB units collected from donors that give birth there (Interview, PH-2, 30 Sept. 2013). Besides these centers, other government-funded public institutes and hospitals use UCB in their research, including the Cancer Research Institute of Tata Memorial Centre, Mumbai, and the National Centre for Cell Sciences (NCCS), Pune (cf. Wadhwa et al. 2013; Chandra et al. 2011).

The origin and conditions for UCB units used for stem cell research in the cases above are mostly unclear. CEOs of the banks usually do not provide clear information about UCB pathways, which indicates that clients and donors are not informed about them. Some companies, such as StemCyte India, reassure their clients that:

If StemCyte India fails to provide viable stem cells during retrieval, StemCyte will try to provide a matching sample from its international public inventory or would pay up

to 20 Lakh rupees, whichever is less, to the parents. (Varies according to plan chosen) (Stemcyte India 2016).

Publications do not usually mention the source of UCB units used, let alone the circumstances and arrangements made for their use. Although much of the UCB derives from commercially banked UCB units, it is not clear whether it is bought, bartered, or discarded material.

## **Conclusion**

Making use of Appadurai's work on the circulation of objects, we identified issues concerning the stagnation of UCB through UCB storage and the opaque way in which it is diverted into use. It became clear that informational disparity exists between information provided during the recruitment and collection phases of UCB banking and their utilization after. In other words, by following the life cycle of UCB banking, we found a disparity between pre-banking persuasion and post-banking utilization of UCB. We conclude that for patients to decide whether to bank UCB with private and hybrid UCB banking models in a more balanced manner, potential clients need more clarity about the proportions of UCB and the pathways along which they return to circulation.

The medical utility of privately banked UCB is of a potential rather than actual nature, and the uptake rate of UCB is low and its recognition for the purpose in regenerative medicine is limited. Due to the limited uptake of UCB by clients, then, cord blood either stagnates in private banks or is diverted into unclear pathways. In India, private UCB banking has thrived over the last decade, and the introduction of 'hybrid' models, which appeal to public values and have broadened the scope for UCB exchange, has added to its commercial success. Examining the life cycle of UCB banking allowed us to identify various issues related to UCB banking in India, including hybrid banking, summarized in Table 1.

We conclude that prospective clients of UCB banks do not receive balanced information about the benefits of banking UCB and its utilization. The introduction of discourses using unclear scientific jargon such as 'risk' has made potential parents sensitive to speculation about the possibility that their child would be born with genetic and other disorders. Pseudo-scientific information and disinformation about the use, storage and safety of application have been instrumental in persuading parents, anxious to provide security for

their potential offspring, to store UCB. In short, it is not made clear to clients what happens to the units after the contract ends and under what conditions the units can be used in clinical trials and in medical interventions, or sold as part of medical products, such as platelet gel and platelet rich plasma (Cryo Stemcell 2015).

Hybrid banking, due to support for the public part by the private part, has been portrayed as representing communitarian values (O’Connor et al 2012) and stimulating the cell flow and research collaboration (Chang 2014). Although in India hybrid banking has enabled the increase and diversity of uptake of UCB, in our study the client was not informed about the public proportion of UCB uptake and the utilization of samples. This is important, as the public part is usually small and the utilisation of the samples can vary from evidence-based applications to save lives to experimental interventions and the creation of medical products. Furthermore, the free collection and storage of donated UCB is often counterbalanced by high release charges. As the ownership of the units lies with the bank, the clients are entirely dependent on the bank’s network linking UCB banking, research centers, and hospitals of both private and public origin, and its ability and knowhow regarding the uptake, matching and use of UCB. We also saw that the various banks have different strategies of dealing with samples. Smaller enterprises can only survive by combining banking with activities that divert UCB into the realm of experimental research applications.

On the basis of the observed data, we conclude that in many respects the nomenclature of UCB banking in terms of public/private/hybrid is misleading: a hybrid bank does not necessarily mean that the bank operates on communitarian principles or yields efficacious therapies for its costumers. An alternative taxonomy of UCB banking categorised in terms of size, institutional embedding, collaborative network, service provision, and research may be more useful to understand the commercial, public and collaborative activities of UCB banks. And as for prospective UCB-banking clients, as long as there is no transparency about the issues outlined above, the division of public/private and hybrid is misleading at worst and confusing at best.

**Table 1:** Issues related to the life cycle of UCB banking

<b>Recruitment</b>	<ul style="list-style-type: none"> <li>- Speculation on potential disorders of prospective child</li> <li>- Use of ‘scientific’ vocabulary to gain scientific authority</li> <li>- Withholding of information about the odds of UCB uptake</li> <li>- Use of misleading terms such as ‘biological security’</li> <li>- Provision of one-sided information on safety storage</li> <li>- Portrayal of UCB banking as taking responsibility for child and country</li> </ul>
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<b>Collection and Transportation</b>	<ul style="list-style-type: none"> <li>- Clients were not told about controversies around the timing of UCB collection or the need to utilize only hospitals in the bank’s network</li> <li>- The speed of collection varies with the size of the network, as banks may be located at a distance, something that clients may not realize</li> <li>- The hype around ‘safety’ and ‘personalized’ services may draw attention away from other issues mentioned above</li> </ul>
<b>UCB banking</b>	<ul style="list-style-type: none"> <li>- No transparency about the uptake of UCB units, the quality of the units stored, the numbers used for research, therapy and other purposes</li> </ul>
<b>Research</b>	<ul style="list-style-type: none"> <li>- Little clarity about the proportion of banked UCB units used/sold/bartered for research and the creation of cell products</li> <li>- Clients are not made aware of research &amp; commercial activities before signing contracts</li> </ul>
<b>Transplantation</b>	<ul style="list-style-type: none"> <li>- Conditions other than blood diseases require NAC-permission for treatment with UCB. They usually have no permission. Interviewed clients were generally not aware of this.</li> <li>- Clients are usually not aware of the (lack of) medical potential of UCB in light of evidence-based medicine</li> </ul>

## Notes

<sup>1</sup> The banks we include here are Cordlife India, Babycell, Cryo Stemcell, Cryo-Save India, Cryo Banks India, ISCSL, Jeevan, LifeCell, NovaCord, ReeLabs, Reliance, Relicord, StemCyte India and Transcell.

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