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Abstract

In China, under the heading of "private-for-public" banking, hybrid UCB banking has been politically supported by the government and is based on regulation developed since the 1990s. Although hybrid UCB banking was regarded as an 'ethical' alternative to private UCB banking due to its accessibility to 'the people', this study, based on archival research and interviews with bankers, medical professionals, scientists and pregnant women contends that the practice of this ideal needs to be closely scrutinized. Analysing UCB bank networks in China in terms of 'public biovalue' and 'ethical biocapital', we illustrate, first, how the synergy of public and private storage of UCB in hybrid models benefit private storage, and how transparency and oversight may increase donation and the uptake of UCB. Second, we describe the problems associated with this hybrid model. Finally, we show how the biovalue of public storage is used as ethical biocapital to buttress UCB networks.

Keywords：China, hybrid UCB banking, ethical biocapital, bionetworks, cord blood

Introduction

In this article on Umbilical Cord Blood (UCB) banking in China, we argue that ethics of public donation is used discursively as biocapital by so-called 'private-for-Public' UCB banks. Our research indicates that the ethics of public donation has been used discursively and practically to embellish private banking without actually increasing the volume of public storage and without making the expected improvement in the quality of the hybrid banks. We show how discursive strategies of public services make for lucrative private banking practices, and we illustrate how unclear regulatory provisions are confusing both bankers and regulators.

UCB is a rich source of haematopoietic progenitor cells which can be used to treat a range of malignant, genetic, metabolic and immune disorders. For the purpose of transplantation, haematopoietic progenitor cells sourced from UCB have several advantages over those sourced from bone marrow or peripheral blood. UCB stem cells have a strong and efficient ability for self-renewal. Compared with bone marrow, UCB has several advantages: it is easily collected, with little physical risk to the mother or new-born baby, unless collected early (Machin et al 2016; Dickenson 2013); UCB stem cell transplants result in fewer immunological rejections so that its success rate is higher than that of bone marrow stem cell transplants; and, the chance of finding a human leukocyte antigen (HLA) match from a UCB bank is greater than using the bone marrow registry (Beatty et al. 2000).

The development of the 'tissue economy' (Waldby and Robert 2006) over the past forty years has been driven by advances in technology that rapidly reversed our perception of human tissue as a useless by-product of treatment, to being a valuable and powerful source of wealth. UCB banking is a good example of how what was perceived as waste is now turned into a highly valued tissue product, collected, stored and traded in private and public markets (Stewart and Kerridge 2012). In the tissue economy, UCB has become a 'promissory matter' (Thompson 2000), which can be frozen in cord-blood banks to preserve the hematopoietic potential of stem cells for future use in treatments both real and imagined (Brown and Kraft 2006; Brown, Kraft, and Martin 2006). UCB now is recognized as a clinically valuable biological material

and is used as a substitute for bone marrow in the treatment of blood diseases (Waldby & Mitchell 2006).

Since the first UCB stem cell transplantation was successfully performed in France in 1988, the construction of UCB banks has developed rapidly. The first public cord-blood bank was set up in the New York Blood Center in 1992, after which many countries followed suit. By the end of 2010 more than 20,000 UCB transplant operations have been performed worldwide (Solves, Mirabet, and Roig 2010). As of June 2017, there were approximately 700,000 donated UCB units stored in 98 UCB registries in 54 countries for public access (BMDW 2017). These banks are listed on national and international registries and networks that can be searched by clinicians who are looking for a donor for a child or adult requiring a transplant. Soon after public UCB banks were established, a parallel commercial industry emerged, as private banks began offering to store UCB on a fee-for-service basis for personal and family use. In 1993, the first private cord-blood bank, Biocyte Corporation, was set up in Connecticut (Holden 1993), and by 2012, there were already approximately 225 private UCB banks worldwide (as of 7 February 2012, Parents' Guide to UCB Foundation, Find a Family Bank, http://www.parentsguidecordblood.org/findabank). In 2016, it is estimated that 65% of the UCB is privately stored, and the UCB banking market is expected to reach US$8,178.1 million by 2025 (HPS 2017).

Since the early 1990s, there have been fierce disputes on the ethics of 'private' and 'public' models of UCB banking worldwide (e.g., Screnci et al. 2012; Gunning, 2007; Martin et al 2008; Dickenson, 2013; O'Connor et al 2008), globally reflecting concerns about the public accessibility of UCB and the ability to finance the establishment and running of public banks (Chang 2016). In north-eastern Italy, regulation has prevented the establishment of private fee-based banks, and most pregnant women support the public collection system, as it is regarded the best way of guaranteeing maximum public access. Research showed that 'of the 772 pregnant women who agreed to UCB harvesting, 648 accessed the public collection system, and 124 accessed the private fee-based system' (Parco, Vascotto, and Visconti 2013). In South Africa, an inquiry completed in a large public hospital, which involved 217

expectant mothers attending an antenatal clinic, showed that 85% of the participants favored the establishment of a public UCB bank (Meissner-Roloff and Pepper 2013), which is very close to the result of research in Turkey (Dinc and Şahin 2009). These findings suggest a general inclination in support of public UCB banks.

International experts have identified some ethical controversies related to public and private UCB banking. Although UCB stem cells have been studied for decades and the first UCB stem cell transplantation was already performed in 1988, clinical translation was not widely used. Therefore, this translational technology is still quite new and, in many respects, remains controversial (Patra & Sleeboom-Faulkner 2016; Hauskeller & Beltrane 2016). For example, there are disputes about the range of applicable clinical indications, the number of units needed in relation to the weight of potential patients, and the storage life of UCB stem cells (Dickenson 2013). Despite these issues, developments in stem cell research may yield new opportunities for therapy, which could make UCB a more important target for both private and public banking. Some argue that, considering the low probability of using UCB for autologous transplantation, public storage is to be preferred over private banking, as this is believed to lead to a higher uptake and use in research (Chang 2016; Machin, Brown & McLeod 2012).

In the case of private storage, the purpose of saving UCB is exclusively for donors and their relatives, and its medical application benefit is comparatively small: the stored units, it was argued, cannot be used for the general public and can not be used in research, producing few or no public benefits (Aznar 2012). For this reason, private UCB banks have enjoyed limited support among researchers, scientific groups, and other public institutions. Thus, some scholars argue that governments should build and develop public rather than private UCB banks (Gassas 2011; Ikuta 1998). Over the last decade, however, this viewpoint has been disputed, at first, by those observing the development of private UCB banks, and later, by those that argue in favour of adopting hybrid models (Waldby and Mitchell 2006; O'Connor et al., 2012; Dickenson 2013; Chang 2016).

Those in favour of private UCB banking have called attention to the

unaffordability of establishing large-scale UCB banks to many governments, and to the flexibility of private banks in responding to the demands of the market. The opposition to portrayal of public UCB banking as 'altruistic' and 'distributive justice' in contrast with 'profit-driven' private biobanks was strengthened with the appearance of 'hybrid UCB banks', which have blurred the boundaries between the two (Hauskeller & Beltrane 2016; Chang 2016). Hybrid banks comprise both private UCB storage, for which customers pay, and 'free' public storage. The idea is that fees for private storage can be used to waive that for public storage. However, the precise financial conditions and benefits of banking with hybrid UCB banks vary. Thus, the release fee, the conditions of usage, insurance of the stored units, and yielding of the units makes it well-nigh impossible to provide a simple definition for 'hybrid UCB banking'.

Realizing the complexity of hybrid models, Hung-Chieh Chang (2016) has argued against the tendency to use traditional classifications of UCB banks to characterize hybrid UCB banking; instead, she argues that they should be defined according to their use. Taiwan for instance, has UCB banks with varying aims, ranging from research and medical use, to charitable work and business development (Chang 2016), while Patra & Sleeboom-Faulkner (2016) have suggested that a taxonomy of UCB banking categorized 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. It is important, then, to pay attention to how hybrid UCB banking models are embedded in society, as their practices are largely conditioned by regulatory, economic and social conditions.

The case of hybrid UCB banking in India shows that there is a large disparity between pre-banking persuasion strategies employed by UCB banking activities and post-banking utilization. It has been argued that the UCB banks there, who actually seem to present themselves as hybrid, due to a lack of regulation have been able to recruit donors under false pretences and fail to account for the storage and utilization of UCB (Patra and Sleeboom-Faulkner 2016). In the case of hybrid UCB banking in China, however, the integration of private and public storage is politically supported

and regulation using the ‘private-for-profit model’. As in many countries, the Chinese government was unable to shoulder the financial burden of running UCB banks. Instead, it formulated policies in support of the hybrid UCB banking model described below.

According to Michelle et al (2012), research on models of UCB banking worldwide, the emergence of public banks is an expression of social values such as cooperation, altruism, social solidarity, collective social responsibility and ethical citizenship, while the emergence of private banks is an expression of commercial values such as competition, speculation, innovation and profit (Michelle AC et al 2012). The Chinese model was envisaged politically as based on the principle of ‘using banks to pay for banks’: the profits made from private cord-blood banks are used to support the development of public banks. For this reason, UCB banks in China are believed to have a clear dual identity (Zhao and Li 2008).

Although similar principles have been described by others (Hauskeller & Beltrane 2016; Chang 2016), in the case of China, policy-makers have made the hybrid UCB banking model their political and regulatory concern. A case study of the regulatory policies behind UCB banking and the realization of their intended aims, therefore, is important to explore the political possibilities of the hybrid model, and can serve to examine some of the pitfalls of the model in general and points of friction inherent to the Chinese situation. Although hybrid UCB banking has been seen as an ‘ethical’ alternative to private UCB banking, we argue that the implementation of the regulation and the political intention behind it, depend on the way in which the relation between private and public storage is managed. The ethical dimension of UCB-banking, as we shall see in this case study, extends far beyond the bioethical notions of voluntary informed consent provided by the individual and the public access to UCB blood storage; we also need to pay attention to the discursive ways in which ‘public storage’ has been used in the sale of hybrid UCB banking.

The discourses around UCB banking show remarkable diversity. As part of a bioeconomy, capital is being conceptualised and organised vis-à-vis life itself (Mills 2015). Thus, as ‘biocapital’ (Rajan 2006; Rose 2007), it has become part of systems of

exchange and circulation involved in a regime of knowledge pertaining to the life sciences. UCB banks have close connections across the private and public sectors, forming networks that include the processing industry, a user network (laboratories, hospitals, industry) and government (licensing, permissions and state-run research, industry and hospitals). Here, UCB forms an important source of promissory capital (Thompson 2005), based on discourses oriented to future scientific discovery and therapeutic applications that can yield financial assets and enrich reputations. UCB storage advertises tissue donation in terms of life insurance, therapeutic application and saving lives. Produced by the biotechnological reformulation of living processes, such 'biovalue' (Waldby 2002) promises to be both lucrative and therapeutic. But in the case of UCB banking, although UCB is needed for more than therapeutic purposes, donor recruitment of this former waste product is required in the name of therapeutic utility. Therapeutic success is largely determined by the availability of a broad range of UCB to increase the chances of finding a suitable match. Maintaining a public bank, however, does not cater to the desired multiple usages of UCB and is expensive. Private banking, however, while more lucrative and more flexible in catering to market demands, lacks the numbers of people willing or able to pay for storage.

In understanding the significance of the hybrid model for UCB banking we need to examine UCB as both asset (Birch & Tyfield 2012**)** within the bioeconomy and as biovalue in the sphere of donor recruitment. The UCB 'bionetworks' (Sleeboom-Faulkner & Patra 2011) are collaborative entrepreneurial networks that use these pro-life ideologies and the hyping of life science applications to attract investment from the state and industry, and from clients. The UCB networks, which combine different aspects of the life science industry in order to extend their UCB pool, do not actually need to enlarge the public storage of UCB. Just by advertising their hybrid banking, the bionetworks can increase their contacts with private and state institutions, gain trust through the state licensing system, and acquire a reputation for distributive justice by including 'free' public storage. This in itself, including a now strengthened belief in future therapeutic success, means that the hybrid model is augmented by its, what Sarah Franklin called, 'ethical biocapital

(Franklin 2013) in terms of reliability, quality and justice. Franklin showed how an ethically sensitive bio-tech enterprise incorporated public opinion in its decision-making and contained public anxiety by appropriately reacting to public unease about scientific innovation (Franklin 2013). In a similar vein, 'profit-for-public' UCB banks invoke the ethical claims of redistributive justice and of public biocapital in arguments regarding the management of UCB banking. As we shall argue, although the hybrid model may thrive economically, its public benefits are yet to be achieved.

In order to improve our understanding of the construction and business operation model of UCB banking in China, the authors conducted fieldwork and archival research on UCB banking and its construction and operation in China between 2012 and 2015. Based on website searches of cord blood banks in China (including those of Beijing, Tianjin, Guangdong and Shanghai)[1] and interviews with over a dozen people working for UCB banks, thirty pregnant women, nine doctors and scientists, we present controversies around the public and private UCB banks and issues related to the 'private- for -public' business model.

UCB banking in China

In China, UCB banking sector has rapidly grown over the last decades, and UCB stem cells have been used in clinical interventions and research of at least 36 diseases, including leukemia, lymphoma, and aplastic anemia (Chen 2013). In 1996, the Chinese government initiated a program to set up ten UCB banks throughout the country. By the end of 2007, the Ministry of Health approved the establishment of ten UCB banks. According to MOH regulation, only MOH qualified UCB banks with a blood bank practice license issued by provincial medical department can collect and store UCB. Therefore, UCB banking is organised on a provincial level, and the

[1] Beijing Cord Blood Bank (http://www.chinacord.org/indexweb.jsp), Tianjin Cord Blood Bank (http://www.cnlifebank.com/shengmingyinxing/44.html), Union Stem Cell & Gene Engineering Limited Company(http://www.chinastemcell.com/index.html), Guangdong Cord Blood Bank (http://www.gdcordblood.org/zjqxk/index_51.html), Shanghai Cord Blood Bank (http://www.shanghaicordblood.org/).

collection of UCB is supposed to be exclusive to one province. This limitation is intended to constrain the monopolisation of the market and to keep the UCB banks under provincial regulatory control. There is a strict access system of operating cord blood banks and by now eight UCB banks have been awarded licenses by the Chinese Ministry of Health and provincial health departments. From their initial establishment, it took on average seven years for the banks to obtain a license (http://www.chinacord.org/ccweb2/hydt/hydt01-20170802-1.jsp). Some of the banks also have been accredited by the American Association of Blood Banks (AABB) and the Asia UCB Bank Organization. The storage capacity of the blood banks in China ranges from 0.3 to 1.5 million units. Most UCB banks have joined the China Marrow Donor Program (CMDP) query system, and have provided international matching services for medical institutions.

During the development of UCB banking, governmental policy and regulation are crucial in guaranteeing the safety of UCB (McKenna and Sheth 2011). In 1999, the Ministry of Health (MOH) issued *The Administrative Measures for UCB Stem Cell Banks* (MOH 2013), and in 2001, it issued *The Management Standards for Establishment of UCB Banks* (MOH 2008). These regulations regulate the qualifications and administrative requirements for UCB banks in China, including the funding requirements for the establishment of banks, their capacity to raise funding, and standards for UCB registration and qualification. Regulations also clarify the responsibilities of banks for UCB collection, preservation and clinical application.

Additionally, in order to protect human genetic resources and to strengthen the safety and management of the clinical application of cord blood, in 2017, the MOH[2] enacted *The Notification on the Cancellation of Approval Right for the Entry and Exit Permit of Human Blood & Tissues and Organs.* According to this notification, all medical institutions are prohibited to use human blood (including plasma and other

[2] From March 17, 2013, officially the National Ministry of Health had changed official name to National Health and Family Planning Commission, and from March 27, 2018, officially National Health and Family Planning Commission had changed official name to National Health Committee. For the convenience of understanding internationally, the paper still uses 'MOH' here.

blood components), tissue and organs from overseas sources for clinical medical purposes. In special cases, like for humanitarian purposes or saving lives, the medical institutions need permission to import or export blood and special blood components (such as peripheral blood hematopoietic stem cells, bone marrow hematopoietic stem cells, umbilical cord blood hematopoietic stem cells and so on). Here, the Red Cross Society of China is to manage the entry and exit procedures (MOH 2017).

The operation and governance of UCB banks in China has created an environment in which competition among industry networks could thrive. The 1999 MOH regulation required that applicants for setting up a UCB bank should have the capacity to raise funds in multiple ways for bank construction and operation, and encourages not-for-profit pubic UCB banks to raise funds to maintain this public service. In fact, it has been estimated that setting up a Chinese cord-blood bank that could store 10,000 samples would cost about RMB 100 million; the additional operating costs of storing 5,000 samples for one year would run up to RMB 2.5 million (Jiang 2004).

To cope with funding shortfalls, in China UCB banks adopted a model of public-private integration. In practice, under this model, all the licensed UCB banks have both public and private storage, combining public and private UCB storage service and using a "private-for-public" business model. This "private-for-public" business method is a typical model used by UCB banks to raise money (Chen 2011). The UCB saved in public storage derives from public donations, and are considered to contribute to the public good. Private UCB banking involves charging a storage fee from clients who store UCB in private storage, and which will be used only by clients and their relatives. Public banks accept donations and store UCB free of charge, and public UCB is mainly used for allogeneic transplants, cell therapy, and research. When the donated UCB needs to be used, there is no need to contact the donors. The only possible benefit of donation is that public donors have priority for human leukocyte antigen (HLA) matching and using UCB saved in public storage. However, they need to pay for the services and uptake as everyone else.

In the next section, we present the controversy and tensions that have arisen about the ways in which public and private interests compare in the hybrid model. The

second section discusses the business operation, including price and networking strategies of UCB banking networks in China, while the third section discusses our research findings regarding the main operational challenges of UCB banks in terms of oversight and advertising. The conclusion recaps our findings and suggests how 'public donation' and governance are used as ethical biocapital in support of hybrid UCB banking.

Controversy and tension between public and private storage

UCB banks form the foundation for developing stem cell treatment technology, and promote the practical application of the technology. In China, the main model of the UCB bank is "public-private integration". As mentioned above, the original intention of this model was to solve the challenge of funding public UCB collection in a fair and ethically acceptable manner. This section discusses controversies regarding the ration of private versus public stock and the usage in the 'private-for-public' business model.

A main criterion for validating the success of the 'private-for-profit' model is the proportion of private to public stock. Clearly, if public stocks are low compared to private stocks, the model is not fulfilling its main purpose. As we shall see, the regulation of UCB banking plays a crucial role here. In China, UCB banks are not financially supported by the government, so that they rely on alternative fund-raising. Although hybrid banks were meant to use the private part of the banks to fund the public part, it has become clear that the public stocks remain low. The stock of units of blood in private storage is larger than that of public storage in each UCB bank in China. For example, it was reported by CNTV on 9 July 2012 that so far Tianjin UCB bank had saved 150,000 units of UCB in private storage; in contrast, only 10,000 units were stored in its public storage.[3] The stock of UCB in private storage therefore

[3] China Network Television (CNTV), hosted by China Central Television (CCTV) International Network Limited, is the national network of CCTV Broadcasting agency, officially launched on December 28, 2009.

is quite low. Beijing UCB bank has preserved 120,000 units in private and 20,000 units in public storage, but there have been 387 cases of usage from public and only 7 from private storage by July 2012. (CNTV as of 9 July 2012, according to the CNTV, on its website: http://news.cntv.cn/society/20120709/117269.shtml). The situation is similar for the Guangdong UCB bank, which had around 120,000 units in private storage and 1000 in public storage by May 2012, but the usage from public storage was 148, and 16 in private storage (Lu 2012).

In Clause 2 of the *Administrative Measures for UCB Stem Cell Banks* it is stated that institutions or individuals have no right to collect or provide UCB for profit. Additionally, Clause 8 states that applicants for a UCB banking license should have the capacity to raise funds for setting up and operating a UCB bank. The clauses can easily lead to confusion, as it is not clear from the text to what extent surplus income may be creamed from private storage activities, and to what extent they may be invested into the public part of the UCB banks. Furthermore, the capital requirement encourages the use of the ethical reputation of the hybrid model – its public biovalue - as ethical biocapital in the negotiation of collaborative constructions among UCB banks, bioindustry, private-public research networks and funding-starved hospitals to raise funding and to recruit potential donors. The collaborations in such networks, as we shall see, are extremely hard to supervise. Additionally, there is no system in place for determining justifiable private-public stock ratios, and there is no clear definition for determining what is "non-profit", necessary for both regulators and bankers to define what part of the UCB bank's capital is for-profit or not (Yue 2008). According to the existing 'private-for-public' business model, it can be seen that, although for-profit UCB banks are not approved by the government, the government is acquiescent in the use of profit from private storage to run the public storage of UCB banks. However, there is no clarity about what part of the revenue from private storage must be reinvested into the public part of the bank.

The "private-for-public" business model for UCB bank development has been debated since its inception. The focus of controversy is the conflict between public

welfare and business profit. Under the current model, the commercialization of UCB banking has resulted in the hyping of the potential use of UCB blood: private storage thrives while public storage is limited. Opinions in favour of the hybrid model believe that private storage has heavily enabled public storage. They argue that, as there are insufficient public funds, the 'private-for-public' model is consistent with China's financial conditions (Zhao and Li 2008; Xiao 2015). To prevent the further commercialization of UCB banks, it has been suggested that there should be an appropriate ratio of public to private storage for UCB banks (Wang 2009). The controversy between "public" and "private" has exacerbated. The banks, which are financially and logistically tied in large collaborative networks, and survive by advertising the 'life' insurance value of UCB, are unsure how to proceed.

The business operation of UCB banking networks in China

In recent years, the price of private storage has risen. The storage duration of UCB usually ranges from 18 to 22 years, and the price varies from approximate 20,000 to 25,000 Chinese RMB (Liu 2013). The number of pregnant women and new-born babies is relatively high in China. The number of new-born babies in 2015 was around 16.55 million nationwide according to the official data from the National Bureau of Statistics of China (Dong 2016), and in 2016 the number rose to 18.67 million, mainly due to the implementation of the two-child policy (Lü & Wang 2017). No doubt, China has a large potential market for private UCB storage, and the potential profit of private UCB storage is considerable. Since formally, no national investment is available for the operation and management of public storage, private storage to support the hybrid public-private UCB banks. According to MOH regulation, the UCB collection should be exclusive to one province or directly controlled by one municipality. Usually, the banks have cooperation agreements with some hospitals. The banks operate and collect cord blood in their networks of collaborative hospitals. If women/families decide to donate or store cord blood, they usually choose the cord blood bank cooperative with the hospital where the baby will

be born. As shown below, however, banks have pricing and networking strategies to spread their nets as wide as possible, and to increase the total stock, banks try to attract more pregnant women for the collection of UCB.

Price strategy for the private storage bank

The price of UCB storage includes a fee for blood collection and testing, and a fee for annual storage for ten or twenty years. Usually, the tests costs approximately 10,000 RMB, and the cost for one UCB unit stored in liquid nitrogen is approximately 600 RMB per year. Banks prefer payment of the total fee up front. In order to encourage families to store for longer and to pay in full, some banks offer a certain discount if the family chooses to pay at purchase. An example is the Shandong UCB bank, which offers different discounts for different payment methods. The price for ten years' storage is 19,180 RMB, which includes a technology service fee of 12,380 RMB and storage fee of 680 RMB per year. If paid in full, the price is 15,480 RMB, which is a reduction of 3,700RMB. For 20 years' storage, the total price is 25,980 RMB, and the price is 18,580 if paid in full, which is 7,400RMB off (Shandong Cord Blood Bank 2017). In addition to advertising a favorable price, some banks offer free insurance. An example is the Beijing UCB Bank, where "UCB storing insurance for medical care" is provided by Taikang Life Insurance Company Ltd. The insured amount is 425,000 RMB, including insurance liability for UCB stem cell transplantation of 300,000 RMB (BCBSCB 2017), which may be attractive as the transplantation fee, usually amounting to approximately 200,000 RMB, is high for most Chinese families.

UCB Bionetworks

UCB banks form complex business networks driven by entrepreneurial activities and make use of ideologies that offer 'health' and 'life' in pursuit of business. Since UCB banks need to raise funds, the banks try to attract a large range of investors, reaching beyond provincial boundaries: UCB bionetworks link up hospitals, medical providers, biotech companies, research laboratories and insurance companies, forming a complex and often opaque business model. There is fierce competition among the

banks, each of which has its broad collaboration network to develop in pursuit of UCB, storage, research and biomedical trade. For example, Beijing UCB Bank was jointly formed by Beijing Jia Chen Hong Bio-technology Limited Company and Beijing University Renmin Hospital. Jia Chen Hong Company was approved by the Beijing Scientific Association as an enterprise of new advanced technology, and its registered business scope is in the provision of UCB stem cell cryopreservation, technical testing, matching retrieval, technical consultation and technical service (http://www.tianyancha.com/company/5134367). Beijing UCB Bank has established collaborative relationships with 120 hospitals with delivering midwifery units, which in June 2015 covers 16 districts and counties in the entire Beijing area (BCBSCB 2017).

The UCB bionetwork models of other banks are quite similar. Guangdong Cord Blood Bank was co-founded by the Maternal and Child Health Care Hospital of Guangdong Province and Guangzhou Tianhe Nuo Ya Limited Bio-company. The UCB bank is a branch of this hospital, and the director of the Bank is also the CEO of Maternal and Child Health Care Hospital of Guangdong Province in this business set up. The hospital is in charge of quality and technical control, and the Tianhe Nuo Ya Company is responsible for investment and sales. They both take charge of UCB collection, preparation, testing, and cryopreservation. During its business development, Guangdong UCB Bank built a collection network, which in July 2015 covers 177 hospitals in 19 cities in Guangdong province (GCBSCB 2017).

The cooperation between UCB banks and their collaborative hospitals takes the shape of a UCB collection network. The networks are driven by ideologies that purport to ensure life on the basis of the life-generating capacity of UCB. To accumulate such biovalue, UCB banks hold events for pregnant mothers, such as a “salons for pregnant mothers” and “schools of pregnant mothers.” At such venues, they conduct lectures advertising the life-saving value of UCB, and arrange site-visits to UCB banks for the pregnant women and their families (BCBSCB 2017). Usually, UCB banks set up an “information desk for UCB” in the clinic of the obstetrics department in its collaborative hospitals. The company provides the hospitals with

collection equipment. Based on the content of the public donation or private storage contract signed by pregnant women and the UCB bank, a doctor collects UCB when the baby is delivered and forwards the UCB to the bank for testing and storage.

Although according to MOH regulation the UCB collection should be exclusive to one province or directly controlled by one municipality, in practice, there are many 'unapproved' banks that claim that they store hematopoietic stem cells and collaborate with hospitals to collect UCB. For example, in early 2007, in Fushan city, the Guangdong UCB Bank and the Maternal and Child Health Care Hospital of Fushan City signed a UCB collection agreement. They built a collaborative relationship, whereby the hospital became one of the collection sites of the bank. Every month approximately 80 UCB units were collected in this hospital for the bank. However, in April 2015, the hospital refused to continue (Zhang 2015). This unexpected change resulted in dissatisfaction among many pregnant women who had signed UCB storage contracts with Guangdong UCB Bank, and had already paid the storage fee (Zhang 2015). It was reported that two other institutions also offered UCB storage services in this hospital, which had replaced the "information desk for UCB storage" belonging to the Guangdong UCB Bank. The two institutions were Han-Shi Union Stem Cell Bank and Guangdong Xi-Rui Stem Cell Technology Limited Company. They had displayed leaflets with the storage items and the 'attractive' prices of their own services. In addition to UCB storage, there were also higly-priced storage items for placenta mesenchymal stem cells (Zeng 2015). This story discloses that profit-seeking stem cell enterprises do their business in cord blood collection and storage without authoritative approval and qualification. Such irregularities reflect the weakness of oversight and unauthorised application of stem cells in China (Miu 2015).

Under current market conditions these 'alternative' stem cell enterprises attract many companies to the UCB business, including industries involved in the processing, distribution and application of tissue and stem cell products. The fact that both formally authorised UCB banks face many issues in the application of the hybrid model illustrates that the state has lost control over the UCB banks, which no longer subscribe to the principles underlying the original 'private-for-public' model.

Issues concerning the operation of UCB storage in China

In this section we summarize the issues faced by the Chinese private-for-public model. The identification and description of the issues are based on the views of stakeholders in UCB banking, including the views from mothers, pregnant women, doctors, managers and scientists. Details of the anonymised informants referred to in this section are listed in the Appendix.

Oversight

Currently cord blood banks take responsibility for quality monitoring of the cord blood saved in their storages. For example, Beijing cord blood bank monthly take random samples of four units cord blood from the public storage to tests the number, activity and differentiation of cord blood stem cells.[4] Additionally, cord blood banks currently are responsible for monitoring the quality of the cord blood they store. Not all collected UCB is suitable for storage. If the UCB does not pass the appropriate tests, it does not qualify for banking. In that case, the UCB banks usually only charge half or less of the testing fee. But currently the standards for UCB testing, quality control and accountability of the institutions in charge of UCB testing are not clear. The UCB banks themselves test the UCB and offer a testing result report to the families that pay for the private storage service. In fact, the current lack of monitoring of the use of standards for storage may result in unqualified samples being stored. Usually, all UCB samples are accepted as qualified and enter storage whether they pass the bacteria test or not so that the full storage fee can be charged by UCB banks. This practice has led to several scandals reported by the media. For example, in January 2008, the Shanghai UCB Bank was accused of being involved in storing unqualified UCB by *Southern Weekend*, a newspaper in China well-known for its critical reporting. The *Southern Weekend* disclosed their investigation of the falsely qualified testing results for UCB in its report. In 2006, it was revealed that the

[4] Beijing Cord Blood bank: http://www.chinacord.org/ccweb2/qxcc/qxcc01.jsp.

Shanghai UCB Bank had prepared quality storage reports before the testing results had come out. As a result, the Shanghai UCB Bank was penalised by the Shanghai Health Bureau for its procedural improprieties (Zhu, Guo, and Zhang 2008). Unfortunately, after UCB is stored, it is almost impossible to retest it, as it risks spoiling the units of UCB.

Advertising

According to MOH regulations, UCB collection should obey the principle of voluntary and informed consent. However, in practice, company salespersons exaggerate the effects of UCB and the benefit of private storage, and avoid talking about public storage. One interviewee, a mother of a new-born baby, said she had not known that UCB can be donated into public storage. The sales force (*xiaoshou renyuan*) repeatedly emphasized the benefit of private storage, and never mentioned UCB donation to her (Interviewee 1). Similarly, a pregnant woman, when she asked about donation possibilities, the salespersons were vexed, and told her that if she wanted to donate UCB into the public bank, it would no longer be hers, and if used by others, gone; so 'she had better think carefully.' (Interviewee 2).

Furthermore, the hybrid UCB banks provide selective information to attract prospective clients. On the official website and in the leaflets at information desks in hospitals, UCB banking is often claimed to be a "life bank" or "life insurance" (Wang 2009). Brochures of UCB banks overstate the qualities of private storage of UCB, claiming for instance: 'Umbilical cord blood can treat hundreds of stubborn diseases, including leukemia!', 'Natural Perfect Match type, no allograft rejection reaction!', 'Umbilical blood, the seed of life, built the bridges of life!', 'Responsible parents please buy a life insurance for the baby!'. Doctors and haematologists, however, pointed out that such kinds of propaganda exaggerate the efficacy of autologous UCB; they purposely create the misconception in the minds of mothers and their families that UCB can be used to cure almost all diseases, even though the probability of cord blood autotransplantation is very small in practice (Refer to interviewees 3, 4, 5).

In China, UCB may be used in the treatment of some blood diseases such as

leukemia, aplastic anemia, lymphoma and myeloma, for example, but not for all diseases. The incidence of blood disease in China is about 1 in 100,000 (Chen 2013). If the disease is caused by a genetic disorder, the UCB has no value for autologous use, because the UCB carries the same gene. Thus, the opportunity for a person to use his or her UCB for autologous transplantation is very low: only around 1 in 200,000 according to the data of National Institutes of Health (Yan 2013). Additionally, there are certain risks involved in UCB storage. For, the cell viability of UCB cannot be completely guaranteed in long-term storage, and the quantity of hematopoietic stem cell may decrease over time (Refer to interviewees 6, 7, 8). At the end of 2010, Guangdong UCB Bank unfroze a unit of UCB that had been stored for 11 years. Its cell viability was approximately 98.25% (Lu 2012). One study concludes that the storage of UCB for up to 76 months does not change the essential quality parameters, and HSCs qualifies for distribution (Kubiak et al 2016). However, it remains uncertain whether and under what conditions UCB is still viable after 20 or more years of storage (Querol et al 2010). Advertisements deliberately avoid these issues and prospective parents are usually not aware of them (Refer to interviewees 4, 10, 11). In fact, an exaggerated emphasis of the development of private storage and the profit it creates is not beneficial for the sound development of UCB banking. For, it is not entirely clear whether and how much of the UCB-bank's profit may be invested into the development of public banks (Yu et al 2014), as the regulation disallows profit from collecting UCB and it presumes funding to be available from other sources, profit cannot be reinvested. This situation clearly does not reflect the original intention behind the 'private-for-public' model.

The following cases show the effect of insufficient information about the storage and its uptake on donation. If facing the options of public and private storage, people who can afford the private storage charge of around 22,000 RMB, hope that they can benefit from the UCB donations into public storage. One pregnant woman explains:

> If there is only one chance for saving UCB, then, surely, I will choose to save it in a private bank. Even if the UCB saved is of no use to me, I may still be able to use

> the UCB saved in the public bank. This means that I can use the units of others, but other people cannot use mine. If UCB is donated to a public bank and it is used by others, I may not be able to find a suitable match when I need it. What would I do then? (Interviewee 9)

The woman is clearly unaware of the low rate of UCB stored in the public part of the hybrid bank. In another case, a pregnant woman does not seem to know about limited HLA-matching opportunities and frequent issues related to the quality and the quality of the UCB donated into public storage:

> It seems to be no harm to save cord blood of baby, about 20,000 yuan, but it can be kept for 18 years. If an autologous umbilical cord blood transplant is needed, the cell-matching fee is waived, and the transplant insurance is already paid. So, I will sign the contract and save cord blood for my baby. (Interviewee 10)

These cases in this section illustrate how the dual identity of the UCB banks can easily mislead donors. Potential private donors are given the impression that the hybrid UCB banks contain a public section available for free HLA-matching, not realizing that there may be issues both regarding the quality and quantity of the UCB units. At the same time, those who donate into public storage can do this for free and get priority when they need HLA-matching. But the donors do not stand much to gain compared to those who do not donate at all, as they still have to pay high uptake fees.

Conclusion

We set out this research with the aim to understand how in China political and regulatory support for hybrid UCB banking played out in practice. To our knowledge this is the first case, and we expected that regulatory caution regarding this 'profit-for-public' model would ensure the financial support and expansion of public UCB banking. The prohibition on making profit from gathering UCB and the requirement of funding availability to acquire a licence were designed to ensure this.

Furthermore, the stipulation that only provincial authorities can licence UCB banks was to ensure provincial oversight and limit the operational territory of hybrid UCB banks to provincial boundaries. The Chinese model, therefore, seemed to be an ideal case for examining the hybrid model of UCB banking.

Official reports, the media and interviewees, however, reported that China's 'private-for-profit' model of hybrid UCB banking failed to live up to the expectation of expanding the market for public UCB storage; the privately managed enterprises operated across the country, beyond their provincial operational remit; and, the quality of the UCB they stored was proven inadequate in various scandals. In this article, we have shown that causes can be found in the areas of regulation, the bionetworks and the trade in biovalue: As for the regulation, confusion exists among bankers and scientists about what constitutes legitimate profit, there is no clarity about the ration between private and public UCB volume, and there are no clear quality standards and oversight, inadequate regulation of advertising. As for the bionetworks, it is not clear where there are conflicting interests between public and private institutions, making it difficult to carry out regulatory aims according to its spirit: UCB banks continue to retain few public units, transgress their provincial remits, and thrive as private UCB banks. As for biovalue, we found that a lack of understanding exists among UCB donors about the difference between private and public storage and the possible therapeutic use of UCB.

Interviews and archival research show that only clarity on the ratio between the volumes of public and private UCB volume and capital flow between the private and public parts of the hybrid UCB banks will enable and incentivise bankers to increase the public volume of public storage, and only provincial oversight can improve the quality of storage. But while clear regulation on the public/private storage ratio is likely to enhance the hybrid UCB banking business model and enable more investment into public UCB banks, issues of regulatory oversight are bound to remain. This is especially the case where there are conflicts of interest, that is, where the UCB bionetworks straddle private and state research institutions and industry.

The Chinese case of hybrid UCB banking seemed strong because of the political

support it received, ensuring that only bona fide bankers would be licensed, facilitating control by means of provincial level organisation, and preventing profiteering by regulating UCB donation on a non-profit basis. However, some of these precautions also indicate the weakness of the hybrid model of UCB banking, notably the questions of how private storage should support public storage and how to create transparency around this in the context of bionetworks that link up private and state enterprises in interdependent industrial webs.

Under these conditions, it is ironic that the distinction between private and public storage enjoys substantial currency. Support for public storage through private storage, as illustrated by the slogan of 'private-for-profit' is widely used in the 'campaigning' of the hybrid UCB banks. Together, the ethical glow of the 'private-for-profit' slogan and the campaign to convince the public of the safety and the rapidly increasing future biovalue of UCB form the core advertising strategy of UCB banks. Frequent references to the scientific progress of regenerative therapies and the special needs of China's population due to its family planning policies further strengthen the promissory value (Thompson 2005) of investments into UCB banking. Here, the ethical biocapital borrowed from the distributive ethics associated with public UCB banking and the authority borrowed from 'stricter regulatory oversight' by provincial regulators serve the business of the 'private-for-profit model' of UCB banking well.

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Appendix: List of interviewees

1. L, a mother of a new-born baby. Beijing Huilongguan Hospital, Beijing. May 16, 2015.
2. ZH, pregnant woman. Beijing Obstetrics and Gynecology Hospital, Beijing. May 20, 2015
3. T, Doctor. Beijing Ludaopei Hospital, Beijing. October 28, 2014
4. TY, Doctor. Beijing Obstetrics and Gynecology Hospital, Beijing. May 20, 2015.
5. Q, Professor of hematology. Institute of Hematology, Chinese Academy of Medical Science. Tianjin. September 19, 2014.
6. ZQ, Doctor/Professor of hematology. 309 Army Hospital, Beijing. February 22, 2015,
7. H, Professor of hematology. National Stem Cell Engineering Technology

Research Center, Tianjin, September 20, 2014.

8. D, Staff of UCB bank. Beijing Cord Blood Bank, Beijing. January 27, 2016.
9. W, Pregnant woman. Beijing Haidian Obstetrics and Gynecology Hospital, Beijing. March 6, 2015.
10. CH, pregnant woman. Beijing Obstetrics and Gynecology Hospital, Beijing. May 20, 2015.
11. ZX，pregnant woman. Beijing Obstetrics and Gynecology Hospital, Beijing. May 20, 2015.