Original Article

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# The hybrid bioeconomy of umbilical cord blood banking: Re-examining the narrative of opposition between public and private services

**Christine Hauskeller* and Lorenzo Beltrame**

University of Exeter, Byrne House, St Germans Road, Exeter, Devon, EX4 4PJ, UK.
E-mails: c.hauskeller@exeter.ac.uk; l.beltrame@exeter.ac.uk

*Corresponding author.

**Abstract** Umbilical cord blood (UCB) is an important source for stem cells used in clinical treatments. For this purpose, UCB has to be collected at birth and stored in biobanks. The discourse about UCB biobanking practices commonly holds that it occurs in two opposite economies, the public sector and a competing private one. They correspond with moral economies of gift-giving in a redistributive economy versus private ownership of cord blood in a market economy. Our analysis of UCB banking in Europe shows that this opposition narrative is both empirically and analytically unsatisfactory. Using the analytic concepts of entanglement (Callon) and biomedical platforms (Keating and Cambrosio), we demonstrate how the network of actors, objects, interests and practices in biobanking creates different kinds of value and shared issues across public and private services. Our case study illustrates how the interrelation between technical, ethical, economic and logistical considerations plays out and generates a field of practices where redistributive and market economies coexist, are co-dependent and hybridize each other. The narrative of opposition therefore can inform STS studies regarding the normative values written into the public facing side of biobanking, but bioeconomic analyses benefit from building on concepts that enable the examination of the complex interrelations between the wider network of heterogeneous elements on which UCB banking relies.

*BioSocieties* advance online publication, 11 January 2016; doi:10.1057/biosoc.2015.45

**Keywords:** stem cells; umbilical cord blood; biobanks; bioeconomy; biomedical platforms



## Introduction

Umbilical cord blood (UCB) contains stem and progenitor cells used in haematology and oncology for treating haematological malignancies, bone marrow failures and inherited metabolic disorders since the 1990s (Navarrete and Contreras, 2009). In order to be used

therapeutically, UCB must be collected, processed and then stored in biobanks. UCB can only be collected during the birth of a child, after the newborn has been delivered and before the afterbirth. Specific equipment and staff skilled in collecting the cord blood have to be present and the mother or parents have to have decided and signed off the collection of cord blood. At this point already, the opposition between the two systems of the cord blood storage and use is decided. When discussing the UCB banking systems, the bioethical perspective takes into view the parents who decide whether, and in many countries for which system, they want the UCB collected and the professionals who support them in their decision.

Currently there are hundreds of UCB banks worldwide. They are connected internationally to manage a global exchange of UCB units for transplantation. According to Bone Marrow Donor Worldwide, more than 600 000 units of UCB are stored in these repositories (Bone Marrow Donor Worldwide, 2015). In the wake of stem cell science and its promise of a future regenerative medicine for degenerative diseases, a private sector industry for storing UCB has evolved. It offers pregnant women/couples storage of the cord blood or the stem cells within it, in case that the child or a tissue-compatible family member develops a disease treatable with UCB.

Bioethics and medical professional bodies have discussed the ethical and political implications of what is framed as two mutually exclusive modalities of UCB banking in which the UCB is given different status as private property or communal therapeutic good. Correspondingly, public UCB banking is defined as a form of redistributive economy, while the private sector follows the logic of a market economy. This division between the public and private banking services presents an ethical choice that parents have to make.

This framing, which we call the narrative of opposition, has been dominant in the literature on UCB tissue banking. It underpins not only official opinions of bioethics and medical-professional bodies (American Academy of Pediatrics, 1999; European Group on Ethics in Science and New Technologies, 2004; Royal College of Obstetricians and Gynaecologists, 2006; ACOG Committee on Obstetric Practice, 2008), but also biomedicine's discussions on UCB banking (for example Brand *et al*, 2008; Sullivan, 2008; Ballen, 2010) and bioethics and medical ethics literature (for example Sugarman *et al*, 1995; Annas, 1999; Ecker and Green, 2005; Samuel *et al*, 2008). In the biomedical and bioethical discourses, this narrative is mobilized against a private economy that might undermine public banking and future redistributive practices in health and care provision. If understood in this binary modality, the two UCB bioeconomic regimes of public and private are directly embedded in different institutional arrangements, inspired by ethical choices and values, and thus tied to seemingly opposite models of socio-economic organization.

In this article we argue that the opposition narrative is untenable at the descriptive level from a Science and Technology Studies (STS) perspective. STS scholars have explored social, cultural and biopolitical implications of biobanking. Closely engaging with this literature, we argue that there is no clear-cut division but a growing hybridization between the public and the private model if we analyse the UCB banking system as a biotechnological platform. Consequently, the distinction between redistributive and market economies in UCB banking does not do justice to the way in which banks are institutionally organized. The network of actors, objects and practices involved in biobanking creates shared organizational interdependencies that foster the coexistence and hybridization of both redistributive public and private market bioeconomies of UCB. We replace the simplistic

notion of embeddedness backgrounding the bioethics and biomedical narrative with two STS concepts, namely Callon's (1998) 'entanglement', and Keating and Cambrosio's (2000) 'biomedical platforms'. This is the methodological approach and perspective by which we analyse our empirical and text-based findings on UCB banking and the literature on UCB bioeconomies between donation, redistribution and market logic (Waldby, 2002; Sunder Rajan, 2003, 2006).

This article is based on longer term field observations and interviews, and the analysis of various documentary materials, including bioethics and biomedical literature, documents of medical professional organizations and advisory bodies, web pages of biobanks and of organizations governing UCB biobanking (Bone Marrow Donor Worldwide, Eurocord, NetCord).[1] Searching for 'placenta/cord blood banking' in PubMed, we selected articles on the public versus private banking debate and on ethical aspects of UCB storage. Then we collected documents produced by bioethics and expert advisory bodies (American Academy of Pediatrics, 1999; European Group on Ethics in Science and New Technologies, 2004; Royal College of Obstetricians and Gynaecologists, 2006; ACOG Committee on Obstetric Practice, 2008). On this basis we wrote the next two sections of this article: first a brief description of how UCB banking is organized and the institutions governing it, an account of the opposition narrative dominating the bioethics and biomedical literature. In the section 'UCB banking as an entangled biomedical practice' we introduce the analytical concepts we use and in the two sections following it we present our research findings. The section 'Hybrid zones blurring the boundaries' gives examples of hybrid zones, alliances and sharing of infrastructure between the public system of UCB banks and the sector of private banking companies. In the section 'Thinking across redistribution versus market economy', we explore in more detail the interlocking of practices and platforms in UCB banking and how it enables simultaneously the redistributive and the market economy in UCB "biovalue"[2] exploitation.

We conclude that each circuit in which UCB biovalue is produced and circulates, is not fixed in pre-given institutional arrangements, but is the outcome of configurations of heterogeneous elements enabling the functioning of UCB biobanking. These configurations do not fit with a static conceptual separation of public and private, redistributive and market economy. On the contrary, they should be studied in how they shape the redistributive economy of public UCB banks, the market of private storage services and hybrid articulations of both. If the private–public distinction, and its socio-cultural implications, has meaning outside the parent-directed bioethics and the professional-directed biomedical discourse for STS, it must be rethought in light of the concrete functioning of these configurations.

1 Beltrame has conducted extensive systematic document analysis for this article since 2013. Hauskeller lead a research project "Ethische Fragen der Gewinnung von Nabelschnurblut für die Krebstherapie und mögliche andere Therapie" in Germany in 2001–2002 funded by the Berghof Foundation, Vita 34 and the Jose Carreras Foundation, with Wolfgang Bender and Alexandra Manzei. This research included document analysis and observation and interviews with women and professionals at obstetric and child leukaemia clinics, and staff at private and public umbilical cord blood banks, mostly in Germany. Hauskeller has worked on different aspects of stem cell research for the past 15 years.

2 Catherine Waldby defines biovalue as "the yield of vitality produced by the biotechnical reformulation of living processes" (Waldby, 2002, p. 310).

## The Organization of UCB Biobanks

That the umbilical cord is a site of haematopoiesis was discovered in the 1970s by Søren Knudtzon (1974), who detected colony-forming cells in human UCB. This discovery was confirmed and in 1988 the first successful transplant of UCB derived stem cells was performed (Gluckman *et al*, 1989). In order to manage the supply of this life-saving tissue, public UCB banks were established in the early 1990s in New York, Paris, London, Milan, Barcelona and Düsseldorf (Gluckman, 1996). Their repositories are connected through computer databases in international registries that permit the search for UCB units compatible with the patient's immune system for allogeneic transplantation (for example, the European Marrow Donor Information System and Bone Marrow Donor Worldwide). Public UCB banks are supported by national governments as part of their commitment to public health. Yet, they are organized internationally and exchange UCB units, a logistic managed by medical organizations.

A range of different organizations govern the global field of UCB banking and transplantation. We introduce the three most prominent in the management of UCB in Europe: Eurocord, Netcord/FACT and JACIE. The Eurocord group was created in 1995 within the European Group for Blood and Marrow Transplantation (EBMT) and connects biologists and clinicians working on UCB derived stem cells. It aims to promote national and international collaboration in this field for both the advancement of scientific research and clinical application (Eurocord, 2015). The International NetCord Foundation is a non-profit association of UCB banks, which aims to promote the highest quality in cord blood products and to balance global supply and demand for UCB (NetCord, 2015). NetCord, in collaboration with the US Foundation for the Accreditation of Cellular Therapy (FACT), has established a set of standards in UCB banking (NetCord-FACT, 2013). The International Society for Cellular Therapy (ISCT) and European Group for Blood and Marrow Transplantation (EBMT) have created the Joint Accreditation Committee ISCT & EBMT (JACIE), which controls and regulates biobanks and transplant centres working in the wider field of haematopoietic stem cell therapies (JACIE, 2015). Netcord/FACT and JACIE have developed accreditation standards and UCB banks can choose either NetCord-FACT or JACIE accreditation. These standards are neither mandatory nor limited to public UCB banks and have become recognized universally by stem cell transplantation programmes.

The search for UCB units for transplantation is managed by a wide range of institutions and usually starts in countries' national registries and then expands to the European Marrow Donor Information System (EMDIS) that connects several UCB banks' registries. In the United States the National Marrow Donor Program (NMDP) manages Be The Match®, a program connecting US cord blood banks with other international registries (Be The Match, 2015). All public UCB banks' registries are connected through Bone Marrow Donor Worldwide that permits the search of units globally.

Parallel to this praised public enterprise a competing model of using UCB emerged in the 1990s, namely private or family banks. Among the first were the Cord Blood Registry in San Bruno (California), ViaCord in Boston (Massachusetts) and in Europe Vita 34 in Leipzig (Germany). These commercial companies sell to parents-to-be the opportunity to store the UCB of their newborn child for future family use. Private banks are conventional enterprises in a market economy selling UCB storage as a service. In this economy, UCB is not a public resource but a privately owned asset of the family. Private banks highlight that family storage

is for related allogeneic transplantation – because the probability of finding a perfect human leucocyte antigen (HLA) match among biological kin is about 25 per cent (Perlow, 2006). Also, if a member of the family needed a transplant, the cells would be available immediately, which would lessen morbidity and mortality (Hollands and Mccauley, 2009). The private banking industry also benefits from the public belief in the potential future uses of privately stored HLA compatible stem cells when regenerative medicine can make use of UCB derived stem cells. Treatments for orthopaedic, cardiological and neurological applications might arise (Bardelli, 2010). In their advertising, private UCB banks define their service offer as an investment or a 'biological insurance'.

## The Narrative of Opposition in STS Models of the UCB bioeconomy

> Tissue banks were up till now relying on free donation for treatment to the benefit of other persons or for research, and by the fact that it implies an *act of solidarity or generosity* it *contributes to the social cohesion*, while the *commercial cord blood banks are running for profit*. This reflects a more general shift to a *privately funded health care system* from a *health system based on solidarity* and motivated by public health considerations, which has characterised Europe in the last decades.
>
> (European Group on Ethics in Science and New Technologies, 2004, p. 18; emphasis added)

This excerpt of the Opinion of the European Group on Ethics in Science and New Technologies (EGE) on *Ethical aspects of umbilical cord blood biobanking* expresses the widely shared narrative in the bioethics and biomedical literature for describing UCB biobanking. It is built on a rigid divide of two opposing models which are seen as embedded in and fostering different economic logics and ethical models of health care with diverging societal implications. This opposition narrative distinguishes between a redistributive economy of public resources managed by the public system, and a market economy in which biomedical services are managed by commercial companies. It is underwritten by an ethical narrative that sees social solidarity and its principal values as conflicting with private ownership in tissues and health care driven by considerations of market value.

Public UCB biobanking is described as "a matter of good public health" where "those who [donate] will value real public benefits" (Ecker and Green, 2005, p. 1283) and donation is "a rare and praiseworthy example of altruism" (Annas, 1999, p. 1522) of UCB that "has gained new status as a natural resource" (ibid, p. 1521). While public banking is seen as producing social solidarity and cohesion (EGE, 2004), bioethical and medical professional bodies have criticized private banking practice (The American Academy of Pediatrics, 1999; EGE, 2004; The Royal College of Obstetrician and Gynaecologist, 2006; ACOG Committee on Obstetric Practice, 2008). The expression "biological insurance" seems "unwise" (American Academy of Pediatrics, 1999, p. 117), because the probability that one may be able to use personal UCB for haematopoietic disorders ranges from 1/20 000 to 1/2700 (Royal College of Obstetrician and Gynaecologist, 2006, p. 7). In cases of leukaemia and malignancies related to genetic conditions autologous transplants are ineffective (Gluckman, 2000). By working on "exaggerated claims of individual benefit", private UCB banks exploit

the emotional vulnerability of parent with misleading advertising, overstating the possible utility of UCB derived stem cells in a future regenerative medicine, with speculative or "at worst, exaggerated claims designed to attract business" (Ecker and Green, 2005, p. 1283). Finally, private banking damages public health because resources are diverted from the circuit of supply of this life-saving tissue from the public sector (Institute of Medicine, 2005) and new inequalities are created concerning access to a biomedical service (EGE, 2004). Critics call for strict regulation of the activity and advertising practices of private UCB banks (for example The American Academy of Pediatrics, 1999; EGE, 2004; The Royal College of Obstetrician and Gynaecologist, 2006).

By contrast, supporters of private banking claim the value of 'patient autonomy' (Perlow, 2006) and see patients as "rational agents with the rights to be informed and to make choices which affect themselves and their offspring" (Hollands and Mccauley, 2009, p. 201).

This narrative about UCB banking builds on ideals of altruism that have shaped public policies about blood services since the establishment of the first blood banks in the 1940s (Healy, 2006). The central notion of voluntary and unpaid donation was systematized by Richard Titmuss' famous book *The Gift Relationship* (1970). Following Titmuss, the gift economy of blood – the combination of altruistic donation and public redistribution – is not only ethically and politically justified but engenders social bonds and cohesion. The public service based on donation is an important factor in securing safety and quality. Busby *et al* have noted that today, policies on blood sourcing and supply are still associated with "citizenship, solidarity and imagined national communities" (2014, p. 83), framed in terms of ethical and political ideals. Yet, the technical reformulation and division of blood into components (that is, blood components and plasma derivate products) has led to new ways of blood circulation that cannot be aligned comfortably with this ideal. Today, public blood services and supply are entangled with commodification and commercial value creation (Waldby and Mitchell, 2006; Busby *et al*, 2014).

The narrative of opposition is built on a simplistic notion of embeddedness, in which the redistributive economy of public UCB banks is not only inspired and informed by solidarity and social cohesion but it "contributes" (EGE, 2004, p. 18) to them. By contrast, the commercial for-profit sector replaces social relations with economic transactions. This line of reasoning conflates the two main institutional arrangements of UCB banking into proper socio-political orders with their values and norms. The communitarian values of solidarity would create an institutional arrangement producing public resources for the public good. Economic interests involved in the private sector would develop an institutional arrangement promoting commercialization and private good.

In this article we argue that this account is untenable from an STS perspective, because it is both descriptively inadequate and of little analytic use when studying current UCB biobanking practices and the arrangement and actions of their contributing elements. Firstly, early ethical and sociological studies on UCB collection, storage and exchange have already criticized the oppositional narrative as a simplistic logic of public versus private, solidarity versus profit. The bioethical discourse facing donors-to-be does not capture the crossovers between public and private UCB uses and facilities (Hauskeller, 2002; Manzei, 2005). As we discuss below, STS scholars have increasingly problematized this idea of two opposed forms of bioeconomy – one inspired by ethical and moral commitments and the other driven by competitive market values – showing that any UCB bioeconomy is embedded into complex social relations that

support and enable its functioning. Secondly, the narrative of opposition, with its simplistic view of embeddedness, is also untenable because it does not consider the heterogeneous network of practices, technologies, objects, materialities, regulations and institutions that shape any economy (Callon, 1998) and thus also UCB bioeconomies. We hold that are the configurations of this network that define the circuit in which UCB biovalue is produced and circulates – more than the fixed and pre-given institutional arrangements in biobanking. In the next section, we introduce the analytical notions with which we analyse how these configurations create complex UCB bioeconomies that cannot be easily encapsulated into binary distinction such as public–private and redistributive-market economy. We argue, thus, that an STS approach can better describe the functioning of UCB bioeconomies and consequently the ethical and societal implications of different biobanking regimes. Before introducing this analytical approach, we illustrate STS problematization of the narrative of opposition that have examined both the public and the private side of the UCB economy.

On the one hand, Waldby and Mitchell (2006) have elaborated how the definition of a tissue as medical waste implies that its use in biomedical practices will instead generate commercial and epistemic value and that this notion of waste is problematic, because placenta and UCB tissues were used in epidemiological research and in cosmetics before stem cell research emerged as a potential use. The transformation of UCB into a source of stem cells enrolled it among the new types of "separable, exchangeable and re-incorporable body parts" (Rabinow, 1999, p. 95). In the STS literature practices of UCB use have become relevant sites of capitalization (Waldby and Mitchell, 2006; Cooper, 2008) and terms such as bioeconomy or biocapital highlight how biological materials (organs, tissues, cells, and gene sequences) "are increasingly inserted into projects of product-making and profit-seeking" (Helmreich, 2008, p. 464).

The public system of UCB banks could be seen as an epitomizing case of state-led biopolitics of the population (Santoro, 2011; Beltrame, 2014) that identifies "the supply of blood, organs and other bodily fragments and the body politic" (Santoro, 2009, p. 18). Brown noted that public UCB biobanking "is promoted with reference to a solidaristic moral economy of gift and altruistic participation in imagined community and nationhood" (2013, p. 98). The logic of public UCB biobanking would produce "a subjecthood that is, simultaneously, biological and national" (Santoro, 2009, p. 18). This is explained by the fact that, historically, public UCB banks were built on the previously established bureaucratic networks of donation and storage of blood and thus joined to the discourse and the ideology of Titmuss's *The Gift Relationship*, where the act of donation is a socio-political symbol of social integration (Santoro, 2011). Accordingly, population-based biobanks partake in the construction of national and polity identities (Busby and Martin, 2006). STS studies have stressed how tissues and other body parts are involved in complex economic systems of exchange and circulation, and ideals of gift, donation and solidaristic public system are embroiled in processes of capitalization and biovalue production (Waldby, 2002; Mitchell and Waldby, 2010).

Because of the considerable commercial value of UCB, channelling this value has been part of public banking practices. An example for this are findings from Hauskeller and Manzei's interview study from 2001. Then some public banks in Germany protracted the collection of donated UCBs from the delivery ward for up to 3 days, thus risking a decline in cell number to sub-transplant requirement levels. Between 45 and 60 per cent of the donated UCBs did not fulfil the volume criteria for transplants (Manzei, 2005, p. 58). Hauskeller (2005, pp. 15–16)

noted that public UCB biobanks discard samples with an insufficient volume – the minimum recommended volume ranges from 70 ml to 100 ml in order to have sufficient stem cells for a successful engraftment (Gluckman, 2009, p. 623). The discarded UCBs can be sold to research groups and biotech companies for a surplus. A proceeding that has not been included in the consent procedure when women were asked to donate UCB to public banks. Manzei concludes, "private companies have been criticized for exploiting the fears of parents to make profits and the practices of public banks have been praised as morally commendable. This image alters when public banks also place the marketability of stem cell preparations at the centre of their activity" (Manzei, 2005, p. 58, translation by Christine Hauskeller). The opposition narrative of altruistic donation for the public good versus a profit-oriented tissue industry veils the actual market economy operating in the public sector and excuses lax standards of UCB collection with financial shortfalls (Hauskeller, 2005; Manzei, 2005).

We complete this brief summary of STS criticism of the public redistribute narrative with recent evidence on international trade of UCB between public banks. Brown *et al* (2011) have shown that UCB units are traded between public biobanks and transplant centres at a price exceeding the cost of storage – thus generating an income. Klaus Hoeyer looked at the opposition narrative and profit generation arguing that the expression 'compensation of expenses' arises because the exchange of body parts does not follow either market logic or a gift exchange but is underwritten by the moral idea that body parts must be non-tradable commodities in an exchange system where price are set without generating profit (Hoeyer, 2009).

On the other hand, STS studies have problematized the dominant narrative of bioethics and biomedical discourse on the side of private UCB banking. While the dominant narrative depicts private banking as completely running through market transactions substituting social relations, scholars have explored the co-construction of "new promissory technologies, novel therapeutic applications, and new types of consumers motivated by changing moral imperatives" (Martin *et al*, 2008b, p. 142). Private storage of UCB represents a form of possession that "severs questions of property from the questions of commodification" (Waldby and Mitchell, 2006, p. 124). The value of privately stored UCB resides in retaining the biological material instead of attaching to it an exchange value (Brown, 2013). In other words, UCB is neither alienated nor commodified, but transformed into an investment, a form of a corporeal indemnity (for example Brown *et al*, 2006) against future possible risks and illnesses. Other scholars, instead, compare personal UCB banking to the 'economy of hoarding' rather than of investment (Fannin, 2013). Private UCB banking is structured according to a "neoliberal privatised market" of biomedical services where individuals-as-consumers negotiate the possession of a biological asset (Brown *et al*, 2011, p. 1115). Other studies have highlighted how new family duties and responsibilities are implied in private banking. It prefigures a particular kind of (neoliberal) subject: the calculative and self-managing agent (Rose, 1993), who cares for his/her own health and for his/her family and kin (Brown and Kraft, 2006; Santoro, 2011; Beltrame, 2014). The market does not reshape these relations according to commercial transactions, but mediates new family duties and kinship responsibilities (Brown and Kraft, 2006).

In sum, STS work on the regimes of UCB banking and biovalue exploitation calls into question the main points of the narrative of opposition. Scholars recognize that the biotechnological development creates increasingly complex bioeconomies in which tissues circulate, and that the act of donation does not serve as an unambiguous identifier for the kind

of public health economy at play, but is one element in a network of social and economic relations where communal functions and financial interests coexist and interlock (Waldby, 2002). At the same time, private UCB storage has been rethought as inserted in moral commitments to family duties and ties.

## UCB Banking as an Entangled Biomedical Practice

In this article we want to move a step further in the problematization of the private–public distinction and its ethical and societal foundations. We show that a critical analysis of present UCB biobanking practices does not support this dual logic of two economies. The simple opposition postulated in bioethics and biomedical literature is mainly prescriptive and normative. However, if we take into account public–private interactions and the overlaps and hybridization between redistributive and market economy, how can we explain the different biopolitical pacts (Santoro, 2011) related to biobanking models without sacrificing distinction between the 'regime of truth' ascribed to current haematological applications and the 'regime of hope' (Martin *et al*, 2008b) in future-oriented promises of regenerative medicine[3]? In other words, how can we explain the different cultural, social and biopolitical implications of UCB bioeconomies, when the narrative of opposition is untenable?

We dislocate the social, cultural and biopolitical implications of biobanking beyond fixed institutional arrangements carrying different ethics and economic paradigms and instead analyse the co-evolving configurations, networks of practices, technologies, objects, regulations and institutions that shape UCB biobanking. The implications of biobanking should be rethought in the light of bioeconomic regimes of circulation in which redistributive and market logic coexist and hybridize each other. We adopt a different analytical framework from embeddedness in order to explain both the persistence of redistributive and market UCB bioeconomies and their hybridization.

We draw on the concept of 'entanglement' developed by Callon (1998). Callon points out that an entity can circulate only if entangled in a network of relations. His notion of network is neither static nor limited to human actors: it encompasses objects, technologies, metrological instruments and standards, regulations, professional associations, forms of organizations, currencies and other elements. The circulation of a good in a regime of redistribution or in a pure market transaction relies on the 'formatting' of this network of relations. It is the effect of the configuration of relationships within a collective of entangled elements. These configurations "modify and transform the entities concerned and make new ones appear" (Callon, 1994, p. 413). They also define the economic status of goods: any entity is intrinsically neither a public nor a private good, but is "the strategic configuration of the relevant actors" (p. 407) that enables the circulation of a good as public rather than private. The analytic approach underlying the concept of entanglement can explain the emergence of redistributive, market and hybrids UCB bioeconomies, because we look at the configurations of the network of objects, technologies, practices, standards and institutions in which UCB circulates and its

3 It must be added for accuracy that the whole development of haematopoietic stem cells clinical applications emerged, in its beginning, from a "regime of hope" (Martin *et al*, 2008a, p. 32; see also Brown *et al*, 2006). This illustrates that what is at one point 'just hope' can appear as a rather practical therapeutic option a decade later in this field.

biovalue produced and exploited. We thus avoid the static categories and bring out a different side of the complex bioeconomies of UCB in which redistribution and market logic are interdependent.

A second concept relevant for our analytical approach is that of biomedical platforms (Keating and Cambrosio, 2000). It is used to identify configurations of different scientific and clinical practices with their techniques, instruments, biomaterials, norms, conventions, regulations, protocols, standards, guidelines and accreditation criteria. A biomedical platform produces new entities and new knowledge. This concept is recursive: regulations, norms and conventions generate practices and entities that are at the same time both the subject of regulation and elements feeding back into regulations. Biomedical platforms is a concept useful for investigating the dynamics of interaction among the heterogeneous elements constituting a field, and how these configurations produce regulations, practices and entities (Cambrosio *et al*, 2006). Therefore, we can investigate UCB bioeconomies not by looking at ethical imperatives embedded in economic models, but as the outcome of configurations of biomedical and organizational platforms in which banking and the use of UCB take place.

## Hybrid Zones Blurring the Boundaries

The intersections between the institutions and practices in which donated and privately stored cord bloods are managed create hybrid zones that increasingly blur the boundary between redistributive and market economy.

An important hybrid zone arising from special medical needs is created around dedicated allogeneic UCB transplantation from a relative: expecting the need for a transplant for one child, the UCB of a sibling is stored and thus families with a known history of haematological or genetic disorders that can be treated with a stem cell transplant are encouraged to store UCB. Dedicated UCB storage (which could be family related allogeneic or autologous) is performed both by national public banks. Many private UCB banks also offer this service at no charge (Wolf, 1998). Medical professional associations, while criticizing private banking in general, have suggested this option for families at risk (for example ACOG Committee on Obstetric Practices, 2008). Dedicated UCB storage is not part of the redistribution model. It is a case of family banking. In countries where private banking is forbidden – for example in Italy[4] – the public banking system provides this kind of family banking. In countries where the private sector is developed, dedicated UCB storage is often offered by private banks for free (that is, apart from their typical market offer). Reimbursement follows if and when the UCB is used therapeutically through the health-care providers. Consequently, in this case the equation private = market economy and public = redistributive economy does not apply.

4 In Italy, Ministerial Decree 18 November 2009 prohibits the establishment of private UCB banks and forbid family and autologous storage. However, dedicated autologous and related allogeneic storage are allowed in case of existing pathologies treatable with UCB transplants or for family with a history of immunological or haematological malignancies (the list of pathologies is defined and upgraded by successive decrees). This kind of autologous and family banking is carried out by public UCB banks within the public health-care system.

  

For another example for blurred boundaries are hybrids banks, we refer to mixed banking models or public–private partnerships in UCB biobanking. For example, the US private biobank Cord Blood Registry (San Bruno, CA) established a programme of UCB donation (Wolf, 1998). Manzei reports in 2005 that some public banks in Germany are run by private companies, for example the public UCB bank Freiburg is run by the private company Metreon Bioproducts GmbH, a daughter company of CellGenix Technologies Transfer GmbH and Schering AG. Some are closely connected with University spin-offs, as in the case of the Düsseldorf public bank, whose Director founded a private company in 2003, Kourion Therapeutics AG, which "aims to develop path-breaking medical innovations from umbilical cord blood" (Manzei, 2005, p. 55, translation by Christine Hauskeller). In Austria, the public UCB bank of Linz did stop participating in the registries of the Bone Marrow Donor Worldwide and is now the private company Vivocell Biosolutions GmbH that, with its donation programme, covers this public function. As reported by Martin *et al* (2008b), Canadian Cord Blood Registry offers three different programmes: public donation, private storage and family-directed banking for families with a history of haematological and genetic disease. The most discussed hybrid banking models is the United Kingdom's Virgin Health Bank, where UCB samples are split: 20 per cent of the samples are stored for private use and 80 per cent for public use (Lancet, 2007; Fisk and Atun, 2008). However, as O'Connor *et al* (2012) demonstrated in their review of hybrid banks, public banks also adopt mixed programs: for example, Alberta Cord Blood Bank in Canada is a public institution offering a private storage option to generate income.

Martin *et al* (2008b, pp. 139–140) have described hybrid banking models as a case of entangled public and private regimes of biovalue creation. Yet, they have mainly focused on the epistemic and biomedical implications: hybrid banks combine the regime of truth of current haematological applications with the regime of hope of future development of regenerative medicine. According to O'Connor *et al* (2012), the emergence of hybrid banks reflects the influence of both market forces and public sector policies. In their view, after the adoption of restrictive regulations prohibiting private banking in countries such as Italy and France, private banks would have made privately stored UCB available to the public system in order to "weaken the warrant for legislation or regulatory controls" limiting or hampering their business (O'Connor *et al*, 2012, p. 515). In other countries hybrid models were incentivized directly through public policies imposing that privately stored blood should be available to the public system (for example in Turkey and Spain). They conclude that hybrid models "cater to both communitarian and neo-liberal values rather than forcing parents to choose between them" (ibid.). This explanation, however, still follows the initial embeddedness logic, despite institutional admixtures. In order to make a stronger case for a systematic entanglement beyond the narrative of opposition, we present another explanation of the emergence of hybrid banking models, related to the interplay of biomedical and organizational platforms with the articulation of market logics.

Hybrid bankings and the multiplex intersection zones between public and private show that a rigid distinction between opposed UCB bioeconomies does not adequately describe how the UCB banking functions in practice. We suggest that cooperation across the public and private sector produces configurations within the regimes of UCB biovalue exploitation that account and serve both institutional forms and maintain them in their differences and hybridity.

## Thinking across Redistribution Versus Market Economy

UCB can circulate and its biovalue extracted and exploited, only if 'entangled' (Callon, 1998) in a network of heterogeneous elements and within the biomedical platforms (Keating and Cambrosio, 2000) organizing UCB banking and clinical use. A UCB biobank (both public and private) is a network. Gottweis and Lauss (2011, p. 62) define biobanks as "highly complex and multiconnected networks" linking several sites of biomedical research and clinical practice. The circulation of UCB as a medical technology entails the networking of several elements, including practices, expertise, biomaterials, standards, regulations, regulatory bodies, institutions and organizations. Collecting UCB at birth intersects with birthing practices (Brown, 2013) and depends on trained midwives or obstetricians; UCB should be gathered in a blood collection bag containing an anticoagulant and it is drained using a sterilized needle and a catheter. Further, a whole range of device producers is involved providing the technical means. Banking UCB involves testing, processing and storing: this implies another articulation of expertise, practices, biomaterials and technologies. In order to reduce volume for storage, only the blood component (called 'buffy coat fraction') containing stem cells is kept. This requires cell selection, using machines and chemicals such as centrifuges and Hydroxyethyl Starch to separate stem cells from red cells and plasma. Cryopreservation uses Dimethyl Sulfoxide as cryo-protectant, freezing bags, metal canisters and freezers with a monitoring system. All these operations, technologies and biomaterials are defined and regulated by oversight agencies regarding quality and safety.

One of the main problems in haematopoietic stem cell transplantation is the difference in available HLA phenotypes.[5] The balance of different HLA phenotypes is easier to achieve with UCB than with bone marrow derived transplantation protocols (Rubinstein *et al*, 1993). UCB is HLA-typed at the time of storage, however, some HLA phenotypes are underrepresented. This problem could be solved only by enlarging the pool of donated UCB, a strategy facing several logistical problems: hospitals need trained personnel, physicians, midwives and obstetricians who undertake UCB collection and parents must be willing to donate. The currently adopted solution to alleviate this problem as much as possible is the worldwide connection UCB banks to cover the variability of HLA phenotypes across the geographical spread of banks. Regulations of quality and safety (and thus institutions), technologies for connecting UCB repositories and the definition of common standards in banking practices are basic requirements for a global UCB operation. Professional organizations, licensing authorities and regulatory bodies set standards and monitor practice for this system.

The circulation of UCB, and the extraction of its biovalue, relies on this network – or is entangled in it, to use Callon's term. And, just to give one example for the overlap, the training of obstetric teams in UCB collection is the same for public or private storage. This configuration explains both the particular kind of biovalue it assumes, as well as the several forms of hybridization between redistributive and market economy that we explore.

5 The compatibility of a transplant with the host's tissue in human allo-transplantation is regulated by the human leukocyte antigen (HLA) complex – that is, the loci of genes encoding the antigens responsible for immune reactions and thus for organ transplant rejections. Common in haematopoietic stem cell transplantation is graft-versus-host-disease (GVHD): lymphocytes of the engrafted tissue attack the host's body cells because they recognize them as antigenically foreign. To prevent this, the HLA systems of donor and recipient must be histocompatibility. UCB lymphocytes have a naive immunophenotype and therefore the rate of graft-versus-host disease in UCB transplants is low and permits transplantation between partially mismatched donors and recipients (Gluckman, 2000).

## Symbolic capital through accreditation

Practitioners have long called for regulations not only for harmonizing UCB banking practices in order to support the global circulation of UCB units, but also to intercept the proliferation of private UCB banks. The rationale can be summarized thus: if it is not possible to prohibit private banking, at least government should establish strict regulations related to quality and safety standards (EGE, 2004). The EU Tissue and Cells Directive 2004, for example, does not distinguish between public and private banking. It states that "Member States shall ensure that all tissue establishments … have been accredited, designated, authorised or licensed by a competent authority" (Directive 2004/23/EC, Art. 6). But this does not guarantee common standards and harmonization across countries and thus it does not solve the problems of international collaboration in UCB transplantation. NetCord-FACT and JACIE standards answer to these needs. Furthermore, if we look at the list of UCB biobanks accredited by these organizations, we find among them commercial banks (FACT, 2015). For instance, Biovault-family, a private UCB bank operating in the field of family banking in the United Kingdom, highlights on its websites JACIE accreditation (Biovaultfamily, 2015).

Above we have described hybrid banking models, where public and private interests merge, or where private banks manage public donation programs or dedicated UCB collection for families at risk. All banks which want to work with the public system need NetCord-FACT or JACIE accreditation. Managing donation programs and the participation in the exchange of UCB units for transplantations could be seen as what Sunder Rajan (2003) calls a form of symbolic capital that can be translated into economic capital. Sunder Rajan described this mechanism when discussing the role of pharmaceutical companies in funding large public research projects: by enabling the disclosure of biological information in the public domain, commercial enterprises display their effort to *de*commodify something which could be patented. This ethical choice of de-commodification can be turned into symbolic capital used in advertising to demonstrate that the mission of the company is ethical and not just profit-making. In UCB banking, managing donation programs or offering dedicated allogeneic or autologous storage at no charge appears as an ethical commitment and creates symbolic capital: these companies are not only for profit, but they contribute to the public good.

In addition, private banks are accused by medical professional and bioethics bodies of applying less stringent quality criteria in UCB processing and storing. Participating with donation programs in the global exchange of UCB units implies to be accredited by NetCord-FACT or JACIE, as an operator who follows best standards in UCB banking. Private companies believe that NetCord-FACT or JACIE accreditation provides a positional advantage over their non-accredited competitors. The platform of accreditation, created for guaranteeing standards of quality and safety and for hampering commercial practices, is thus used as a factor in the struggle for markets and market share by commercial companies. A second implication is that hybrid UCB banking models emerge not only to weaken the warrant for restrictive regulations, as suggested by O'Connor *et al* (2012), but also as a way to obtain competitive advantages. The result is that drawing a clear-cut distinction between market logics, redistribution and ethical motivations becomes increasingly difficult.

## The seamless flow of (public?) goods

The hybrid nature and the allied interests of the public and private sector can be illustrated also in the fight against a patent on the cryopreserved UCB. Eurocord opposed

commercialization of UCB banking and defended the use of this tissue in the framework of public health-care provision only. It insisted on defining cord blood as a tissue and not as a drug in order to avoid its patentability.

In 1993, the US biotech company Biocyte Corporation filed a patent application with the US, Japanese and European Patent Offices for a patent covering "hematopoietic stem and progenitor cells of neonatal and foetal blood, that are cryopreserved, and the therapeutic uses of such cells upon thawing" (see Butler, 1996, p. 99). In the United States the patent application was challenged by the private biotech company Cryo-Cell International, while the European Patent Office granted a patent to Biocyte in May 1996. Eurocord decided to challenge this patent, with the support of a heterogeneous network of actors including the US biotechnology company Thermogenesis and Astra Pharmaceuticals. Representatives of Eurocord declared in a letter to the journal *Nature*, that UCB transplantation "should be carried out only in an orthodox clinical setting where *commercial considerations do not apply*" and that UCB "should not be used for the *benefit of financial speculators*" (Gluckman *et al*, 1996, p. 108; emphasis added).

The Eurocord representatives based their challenge on moral and political grounds. The aim was to affirm that "cord blood should not be patented … is it not ethical to patent a human tissue" (Falkenburg as quoted in Butler, 1996, p. 99). Although the Biocyte patent was then rejected on legal basis (it did not meet the legal criteria of novelty and 'non-obviousness'), Eurocord retrospectively claimed its moral stance: "this result … is also an ethical victory as it overturns a patent on human tissues" (Gluckman, 2000, p. 69). UCB was thus defined as a non-patentable material.

The interesting phenomenon in this case is the heterogeneous network supporting this challenge. The challenge was brought forth by a public institution in coalition with private companies excluded from the market by that patent. The role of patents in the narrative of opposition between redistributive economy-public resources and market economy-private goods is complicated. Scholars have questioned the ideal of 'gift relationship' or blood donation, highlighting how the development of biotechnology has produced flows of biomaterials increasingly incorporated into complex bioeconomies (Waldby, 2002). They studied the role of tissue donation or the re-vitalization of previously wasted biomaterials in the production of a commercial biovalue according to market logic and corporate forms of conducting biomedical research and its clinical application (Waldby and Mitchell, 2006). Sunder Rajan (2003) has demonstrated how corporate actors (for example pharmaceutical companies) support the disclosure of biological information in the public domain by supporting public research consortia as a way to remove what he calls 'speed bumps' represented by the patent protection. In his view, this openness and anti-patent stance is not motivated by an ethical resistance to the commodification of human tissues. Instead it is an articulation of the market logic of biocapitalism: the seamless flow of biological information and biomaterials enables the production of profit across bioeconomic markets. In other words, decommodifying biological information and biomaterial reduces costs and increases the speed for the production of other biovalues (for example drugs and therapies).

The case of the challenge to UCB patentability could be read through this lens, but it displays some divergent features. We may say that the practitioners in public UCB banking sincerely defended the redistributive economy, but in doing so they also fostered the functioning of competing and parallel market economies. A patent on the processing and

storing of UCB would have damaged both public and private banks: it would increase the cost of storage and raise the market price for families and health insurances when UCB is used for treatment. A complementary economy of biomaterials, technologies and drugs involved in and connected with UCB banking criss-crosses public, private and clinical applications. If demand drops in any part of the system, the price of the good (UCB) increases and so does the prices of complementary goods (biomaterials, technologies and drugs involved in UCB processing, banking and clinical applications). Eurocord was supported by private UCB banks and biotech and pharmaceutical companies, because the non-patentability of UCB enables the redistributive tissue economy in the public system, and simultaneously the market economy of private biobanking and its accompanying industries and emerging biomedical technologies.

Nevertheless, rather than concluding that the whole production of biovalue and its related social relations "are always-already embedded in the logic of the market" of biocapitalism (Sunder Rajan, 2003, p. 88), this case illustrates that redistributive and market economy in the field of UCB banking emerge in symbiosis from the configuration of the elements that constitute their enabling networks and platforms.

## The market of redistribution

As discussed above, clinical application of UCB-derived stem cells needs the organization of an international network of UCB biobanks in order to enlarge the pool of HLA types and optimize the supply of UCB units for transplantation. This is best provided through a global redistributive economy. However, as Brown *et al* have shown, public UCB banks are involved in an international trade in UCB units: the banks operate in "a market model in which the costs associated with storage are offset through pricing strategies for blood products, particularly if those products can attract a premium through international exportation" (Brown *et al*, 2011, p. 1116). UCB units are not exchanged for free in the international circuit of public banks; instead the export price is higher than the cost of storage, and this is a source of income for UCB banks, supplementing support from charities and the state.

Brown *et al* have illustrated the functioning of this market, where registries act as intermediaries or trading zones, and, more relevant to the context of this article, the key role of standards in enabling this market. National repositories, too, are in competition, because this trade in UCB "largely advantages those countries able to capitalize on a higher ratio of exports to imports" (ibid, p. 1119). Any positional advantage in UCB trading depends on both the scale of HLA types collected (which increases the likelihood of having useful UCB units for export) and compliance with international standards in biobanking: "the high cost premium attached to international trade is a strong incentive for the establishment of more comprehensive domestic supplies" (ibid.). But it is also an incentive to improve compliance with international standards.

An example of this dynamic is the Italian network of public biobanks. Eighteen public biobanks operate in Italy, 12 of which participate in Bone Marrow Donor Worldwide, and four are NetCord-FACT accredited. The banks are geographically well distributed and strongly connected with local public hospitals. In the analysis of Brown *et al*, Italy's balance of trade was rated positively. However, their data refer to 2008 and in 2011 the situation changed significantly. According to the director of the Italian National Transplant Centre, 17 000 out of 20 000 UCB units stored in Italian banks do not match the international standard. He stated "index of export have been decreased … we need to re-qualify the offer and to provide samples of higher quality" (De Bac, 2011, p. 23).

The global redistributive economy of public UCB banking follows a market logic. This does not mean that the articulation of a biocapitalist market logic is pervasive in the global circulation of this biomaterial. Even if the director of the Italian National Transplant Centre adopted the language of management ('index of export', 're-qualify the offer'), the search for profit is not the central engine of this market. The financial surplus from the trade in UCB is spent on covering the operating cost of biobanking. The economic principle that is dominant in public banking is one of self-preservation and sustainability, costs necessarily add value to the donated UCB. Given the current funding provisions for the public system, this is a precondition of redistribution. Quality standards in UCB processing and storage facilitate this global trade, but, at the same time, competition feeds back to improve these standards and compliance with them. The differential geographical distribution of HLA types among donors and patients and its variability formats the public UCB networks and produces the hybrid forms in which the global redistributive economy works through a market model that is not following a market logic.[6]

## Conclusions

In this article we have explored several examples that call into question the dominant narrative of opposition between the public system and the private sector of UCB biobanking that rules the bioethical debate. We have presented new research material that substantiates critique concerning the analytical usefulness of this narrative for the study and understanding of the UCB bioeconomy.

We have shown how the production and exploitation of biovalue in the field of UCB biobanking and clinical application are not simply embedded in institutional arrangements inspired by different ethics and economic logics. Instead of an opposition between the public-redistributive economy and the private-market economy, we have pointed out that UCB increasingly circulates in hybrid zones, where the established boundaries between the two traditional UCB economies are blurred. We argued that these overlaps, contaminations and hybridizations are the outcome of the configurations of the network connecting several and heterogeneous elements – including biomaterials, technologies, practices, expertise, standards, regulations and corporate, biomedical and governing institutions. It is the interplay of technical, ethical, economic and logistical considerations, together with the performative role of regulations and the agency of institutional and corporate actors involved, that produces hybrid configurations of the networks in which UCB circulates.

The public system relies on the existence of global standards, but these also provide symbolic and material competitive advantages on the private market. The public system requires UCB to be a not patentable resource, but this condition also sustains a competitive market for the commercial exploitation of UCB biovalue; the global supply and redistribution of HLA types, given its differential geographic distribution, can be served best through a market model under the current conditions of restricted public funding.

6 On the formation of exchange systems in which body parts are traded at a price, but without commodification and out of the pure market logic, see Hoeyer (2009).

We conclude that the analytical distinction between social, cultural and biopolitical implications of different regimes of UCB banking remains valid in relation to the particular concerns of those who address parents-to-be concerning a decision about what happens with the cord blood at birth. Yet, the opposition narrative applies there only in the sense that if parents do decide to donate rather than privately store, they do not invest in future use of the tissue for themselves. As a description of the field as wholesale characterized by fixed and opposed institutional arrangements and economies the private–public distinction is neither useful nor adequate. STS studies elaborate complex bioeconomies in the field of UCB banking and clinical use, which we have attributed to the configuration of the networks and platforms in which UCB biovalue circulation and exploitation happen. UCB assumes different biovalues – a life-saving tissue in current haematological applications versus a promissory object in the future development of regenerative medicine and a biological insurance against possible future diseases – according to these emerging configurations. Moreover, both in public and private banking, and in hybrid banking models as much, redistributive and market economy are constantly at risk, coexisting and hybridizing into systems of exchange that are not easily encapsulated into rigid categories. Therefore, in the place of rigid normative and economic categories – such as 'gift/redistribution' or 'the market' – the examination of local level practices across biomedical and organizational platforms provides a fuller understanding of the dynamics that shape the UCB banking sector and how its regimes of biovalue operate.

## Acknowledgements

The authors would like to thank the reviewers and editors of the journal for their supporting engagement with our article. We also thank the European Commission's Marie Skłodowska-Curie Programme for awarding us the Fellowship Grant (Horizon 2020 – MSCA-IF-2014 – 657361-REGUCB) that has enabled our collaboration and the Brocher Foundation in Hermance, Switzerland, where Christine Hauskeller stayed as a fellow in the autumn of 2014 when this article was written.

## About the Authors

Christine Hauskeller (PhD) is a philosopher and sociologist. She is Associate Professor at Exeter University, where she previously worked as research fellow and Co-Director of EGENIS, the ESRC Centre for Genomics in Society, UK. She studies how understandings and values influence policy-making and the practices of biomedical science and its applications. Critical and feminist theories inform her approach.

Lorenzo Beltrame has a PhD in Sociology and social research (University of Trento, Italy). He was post-doctoral fellow at the Italian Institute of Human Science (Florence, Italy) and collaborated with the Science, Technology and Society Program of the University of Trento (STSTN). He was research fellow at the Institute for Advanced Studies on Science, Technology and Society (IAS-STS, Graz, Austria). Currently he is Marie Skłodowska-Curie Fellow at EGENIS, University of Exeter.

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