Title: Values in tension. Clinical quality and civic participation in umbilical cord blood

banking in Italy

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arrangements regarding the logistics of UCB donation and collection. Adopting the notion of registers of

valuing (Heuts and Mol 2013) and analysing the case of the Italian network of public UCB banks and

collection sites, this paper shows how conflicting registers of valuing concerning UCB can shape different

organizational models of UCB donation and collection, in which social values and clinical value are not

unproblematically conflated. The paper aims to demonstrate that the functioning of biobanking arrangements

is dependent on how different values are accomplished and aligned in concrete practices of tissue donation

and collection.

Keywords: umbilical cord blood; biobanking; participation; values; Italy

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Abstract

In the dominant narrative of bioethics and biomedical discourse on public Umbilical Cord Blood (UCB) banking, the ethical value of donating UCB is unproblematically associated with the clinical quality of collected UCB. This paper shows that this view is analytically untenable as it overlooks tensions and conflicts between the social values of donation and the clinical value of banked UCB in concrete arrangements regarding the logistics of UCB donation and collection. Adopting the notion of registers of valuing (Heuts and Mol 2013) and analysing the case of the Italian network of public UCB banks and collection sites, this paper shows how conflicting registers of valuing concerning UCB can shape different organizational models of UCB donation and collection, in which social values and clinical value are not unproblematically conflated. The paper aims to demonstrate that the functioning of biobanking arrangements is dependent on how different values are accomplished and aligned in concrete practices of tissue donation and collection.

1. Introduction

Haematopoietic stem cells (HSCs) contained in the Umbilical Cord Blood (UCB) are largely used for restoring haematopoiesis in patients affected by haematological malignancies, bone marrow failures, and inherited metabolic disorders. UCB is collected after childbirth, and once it has been processed is cryopreserved in biobanks and typed for the human leucocyte antigens (HLA) system

which regulates the histocompatibility between donor and recipient. UCB is considered an alternative to bone marrow (BM) transplantation as it can be performed even in the case of a partial HLA mismatch (Gluckman 2009). Finally, UCB is considered an important source of HSCs for many patients belonging to ethnic minorities, for whom it is more difficult to find adult BM donors (Gragert et al. 2014).

Due to these aforementioned features, after the first successful UCB transplantation performed in 1988 (Gluckman et al. 1989), several public UCB biobanks were established worldwide. These banks store UCB voluntarily donated by women, and their repositories are connected in international registries of available sources of HSCs. According to the World Marrow Donor Association (WMDA 2019), which manages the worldwide registry of HSC sources, more than 730,000 UCB units are available in the international network of public UCB banks and participating registries, and around 35,000 UCB transplants have been performed to date.

In the dominant discourse of bioethics committees and medical professional bodies, the public UCB banking and donation system is described as connecting the provision of quality UCB units for transplantation with the fulfilment of values of social solidarity. For example, in its document on UCB banking, the European Group on Ethics in Science and New Technologies (2004, 18) stressed that voluntary donation, "by the fact that it implies an *act of solidarity* or generosity, contributes to *social cohesion*" (emphasis added). This discourse has been developed within the so-called public-private debate, where bioethics committees and medical professional bodies criticize the commercial UCB banks sector which sell a service of private UCB storage to mothers and parents. As noted by some scholars in Science and Technology Studies (STS), the dominant discourse in bioethics and biomedical literature promotes public UCB banking as a form of a "solidaristic moral economy of gift and altruistic participation in imagined community and nationhood" (Brown 2013, 98), and the public UCB bank is seen as "a site for the constitution of both collective health and the best values of citizenship" (Waldby 2006, 57).

This paper will show that this link between the provision of quality UCB for transplantation and the constitution of social cohesion through donation is more complex and sometimes more controversial than represented in the dominant discourse of bioethics and biomedical literature. In particular, the present paper will challenge the underlying view that the social value of donation coincides unproblematically with the clinical value of the collected UCB. The criticism against the dominant discourse put forward in this paper is framed in terms of a theory of valuation. While the dominant discourse is based on a rigid regime of valuation, this paper, by analysing the practical logistics and organizational arrangements of UCB donation and collection in the public sector in Italy, will demonstrate how there are diverging "registers of valuing" in place (Heuts and Mol 2013) regarding clinical quality as well as the act of donation. This paper aims to demonstrate that the fulfilment of the values of civic participation and clinical quality is not a prerequisite of any public banking system, but the outcome of how registers of valuing are enacted and arranged in concrete organizational settings of UCB donation and collection.

2. Valuing and the biopolitics of UCB collection

The underlying theory of value of the dominant bioethics and biomedical discourse is extremely simple. Donated UCB, as a social gift, circulates through a system inspired by the redistributive logic of the welfare state by embedding and reproducing the social values of reciprocity, mutuality, and solidarity. At the same time, it provides clinically useful tissues for medical needs. It is outside the aim of the present paper to discuss how STS scholars have called into question the public UCB banking "tissue economy" (Waldby and Mitchell 2006) as a pure redistributive economy that instead shows spaces and practices of overlap and hybridization with market forms of circulation (see Brown et al. 2011; Hauskeller and Beltrame 2016a; 2016b). The aim of this paper is to highlight how social values can instigate tension with clinical values in the context of concrete logistical and organizational arrangements of UCB donation and collection in the public sector.

This paper builds on some STS work on biobanks (e.g. Tupasela 2006; Romero-Bachiller and Santoro 2018; Wyatt et al. 2018), genomic databases (e.g. Singh 2018), and biomedical data platforms (Tempini 2017) that have demonstrated how these infrastructures are sites of multiple processes of valuation and valourization – including economic, epistemic, and social values (e.g. related to identity-building and shared sociality). This literature has shown the existence, and the relevance, of different values and practices of valuation enacted by involved actors. As Beltrame and Hauskeller (2018, 25) have pointed out, the production of multiple values is "the outcome of both the entanglement of a very specific banking configuration and the practices of participation and valuing enacted by biobanks staffs, researchers and participants". This implies the reorientation of the focus on the enactment of practices of valuing and the interactions between involved actors, and the conception of biobanking configurations as the outcome of negotiations amongst them.

The notion of *registers of valuing* proposed by Heuts and Mol (2013) is particularly apt for this kind of analysis, as this concept better incorporates the novel approaches in the sociology of valuation, looking at the practices enacted by actors in assessing the value of things (Muniesa 2011; Helgesson and Muniesa 2013). Firstly, the term *register* indicates only a shared relevance (Heuts and Mol 2013, 129) that does not define the process of valuation, but merely enables it. A shared relevance means that there is a common focus of attention on some problems or objects, that allows the social process of valuation to start. Secondly, the term *valuing* indicates concrete and situated practices, or as Heuts and Mol (2013, 128, note 6) put it, valuing as something people do, rather than something caught in or framed by a culture. In this way, it is possible to study the different registers of valuing that orient the practices of actors involved in UCB banking and how they are enacted and arranged in concrete banking arrangements.

In the case of UCB banking, a first register of valuing is that which confers worth to the quantity of HSCs contained in the UCB units. The quantity of stem cells is tested by counting the vital CD34+ cells, namely cells expressing the CD34 antigen – a biomarker for HSCs. The quantity of HSCs is

estimated using the proxy of the total volume of UCB collected and the assay of the Total Nucleated Cell (TNC) count. Only UCB units reaching the threshold of 15 × 108 TNC are considered of value, as they can circulate as engrafting tissues. Those which do not reach this threshold are discarded. Indeed, transplant data established a correlation between the number of CD34+ cells, and the speed of engraftment and long-term survival (Wagner et al. 2002). Moreover, and more importantly, with the evolution of the knowledge on transplant outcomes, the threshold has been progressively set higher, involving a continuous restructuring of the infrastructure of UCB biobanks and registries (Williams 2018).

A second register of valuing related to intercorporeal circulation has to do with the histocompatibility between the donor and the recipient, which is regulated by another population of antigens – the Human Leucocyte Antigen system or HLA complex. HLA types are highly variable, and an efficient UCB unit repository should contain a wide range of HLA types. HLA alleles are related to population dynamics (Middleton et al. 2000; Pédron et al. 2006), and racial and ethnic categorizations are used as a proxy of HLA variability. In order to cover HLA variability, UCB banks adopt strategies addressed to recruit donors from different ethnic groups. This generates what Williams (2015, 325) has defined as "messy relationships" between social classifications and race and ethnicity, classifications that often overlap with inheritance, origin, and also nationality (Williams 2017). In her view, race and ethnicity are largely enacted by strategies of addressing potential donors amongst immigrants and ethnic minorities. According to this register of valuing, what is of worth is ensuring that rare HLA types are covered.

A third register is that referring to the ethical sphere, where relevance is put on the promotion of donation as an act of solidarity. In this register, what is of worth is the act of altruistic giving. The generosity of donating transforms what in the field of UCB banking is defined an otherwise clinical waste into a potentially life-saving tissue, considered as a gift of life. As discussed by Brown (2013, 98), "this system of valuing succeeds only if the discursive framework of waste is accepted by

donors" and if all the involved actors agree that "[U]CB has limited value outside its clinical usefulness in [U]CB banking". This register of valuing is thus in sharp contrast with other forms of valuing UCB, such as transferring it to the newborn. As studied by Brown (2013) and Machin (Machin 2016), this diverging valuation of UCB is at the core of conflict and negotiations amongst expectant parents, UCB bankers, midwives, and neonatologists.

Concrete configurations of public UCB banking are the outcome of institutional arrangements and the logistical setting of collection and donation, in which the different registers of valuing are enacted and negotiated by the involved actors. In particular, the pursuance of ethical values of solidarity and the establishment of a functional repository of quality UCB units for clinical use is something that has to be arranged in order to avoid tensions among the different registers. An important constraint on concrete arrangements, that can complicate the effective pursuing of the different values, is what Heuts and Mol (2013, 130) call the *monetary register*, which concerns financial costs. UCB collection and banking is costly. The personnel performing collection must be trained; collected UCB has to be shipped to a biobank; testing and processing involve costly procedures, machineries, and reagents; and, finally, cryopreservation is highly energy-consuming as it requires freezers, liquid nitrogen, cryoprotectants, freezing bags, metal canisters, and "a validated system to monitor and record the temperature continuously" (NetCord-FACT 2016, 68). Under a regime of austerity and financial cuts to healthcare expenditures, UCB bankers are pressed to optimize the costs of banking, and this can create tensions amongst the previously mentioned registers of valuing with regard to how UCB donation and collection are logistically organized.

In order to explore these tensions and how they are managed in concrete arrangements within the public sector, I propose two ideal types of the logistics of UCB donation and collection. These are not descriptions of reality, but heuristic tools in which some aspects are accentuated in order to explore how, in concrete logistical arrangements, tensions are dealt with and the pursuance of the relevant values is accomplished. In particular, these ideal types accentuate respectively the

fulfilment of clinical qualities and the pursuance of the social values of solidarity and cohesion in donation, in order to better explore the existing tensions between these values in the logistics of UCB donation and collection. I define these ideal types as the biopolitics of UCB donation and collection, following Gottweis (2008), who defined biobanks in general as biopolitical technologies, forms of governing life.

I propose naming the first ideal type a biopolitics of antigens, since it is aimed at maximizing cord blood with a high content of cells expressing the CD34 antigen and with a high variability of human leucocyte antigens. I define it as biopolitics because, following Foucault, it is "no longer ... dealing simply with legal subjects ... but with living beings" (Foucault 1978, 142–3). In particular, donors are conceived mainly as carriers of those antigens that facilitate, in due quantity and in the right HLA profile, the efficient protection of the population from a range of conditions and malignancies. The relevance is put on the clinical quality, and under financial constraints a biopolitics of antigens results in a concentration of collection in few sites. These sites are where there are dedicated professional collectors, and where the locale has a high genetic and ethnic variability. This is because the quality of collection is related to the experience and ability of collectors, and having fewer sites with dedicated staff results in a reduction of the number of discarded units, the optimization of the collection of quality UCB units, and thus the limiting of costs. Similarly, choosing areas with high genetic and ethnic variability means better coverage of the wide spectrum of HLA types, which reduces the import of UCB with rare HLA by paying an expensive fee (Brown et al. 2011; Brown and Williams 2015). Moreover, the concentration of sites also involves a reduction in the costs of interpreters and cultural mediators required for obtaining consent from immigrants and non-native-speaking minorities. Regulations indeed prescribe that "all aspects of participation in [U]CB donation shall be discussed with the mother in a language and with terms that she understands" (NetCord-FACT 2016, 50). Therefore, a biopolitics of antigens in its pursuance of the optimization of quality UCB collection compresses the opportunities of donation,

and thus can enter into tensions with the register of valuing that sees in extending donation a way to pursue the ethical values of solidarity, altruism, and mutuality.

The second ideal-typical biopolitics is what I propose to name the (bio)politics of participation.

Here collection is thought of as enabling the largest participation in donation as possible. I bracket the prefix bio- because in this biopolitics what is of worth is the act of donation conceived as a form of civic engagement – that is, donation as participation in the common good for realizing values of solidarity and mutuality and as contribution to "social cohesion" (EGE 2004, 18). The donor is considered explicitly as a "legal subject" exerting a civic duty, and the value is set by the circulation of a gift as a social fact, embedding and reproducing these principles of obligation to the larger community of fellow citizens. A model inspired by this register of valuing tends to maximize the flow of this circulating gift by involving as many mothers as possible in realizing a system of extended donation. While this gift is always a life-saving tissue, the emphasis is placed on the act of giving. Under the constraints of the monetary register, it is necessary to sacrifice expensive strategies aimed at maximizing the quality of collected UCB. The system indeed relies on the willingness of trained midwives and obstetricians (and not on dedicated professional collectors), and so it seeks to increase the quantity collected, accepting high rates of discarded units to reach a set target of clinically useful UCB units.

Concrete arrangements in the logistical organization of UCB donation and collection can only approximate these two ideal types, but in solving tensions among different registers of valuing they combine different values. The combination of ethical values with clinical quality is, in other words, the outcome of the enactment of different registers of valuing in concrete banking arrangements.

And this combination is necessary, as without promoting participation any UCB collection would be impossible. Williams (2015) has enlighteningly shown how the UK public UCB banking system – despite being based on a biopolitics of antigens – also pursues ethical values. In the UK, indeed, UCB collection is concentrated in only nine hospitals, with dedicated collection staff, and with

locations in areas of great ethnic variability. But UCB donation is promoted with reference to notions of f public good and fairer access to HSC sources to ethnic minorities. However, in the work of Williams (2015;2017) it seems that the combination of a biopolitics of antigens and the pursuance of social values has been obtained without triggering tensions.

Italy is a particularly interesting case study for exploring how the accommodation of diverging registers of valuing can generate tensions and how these tensions might be mediated. The Italian logistical system of UCB donation has been structured following a (bio)politics of participation, resulting in a very expensive enterprise with high rates of discarded units. This has triggered tensions with UCB bank operators, for whom what is of worth is the clinical quality of banked UCB. In fact, under the pressure of the network of UCB banks and other medical authorities, the Italian system is under restructuration towards a model approximating the biopolitics of antigens, which further shows tensions in registers of valuing and their management. This paper thus contributes to the STS debate on UCB banking by avoiding any straightforward association between solidarity and clinical quality and shifting study upon the ways in which these values are practically accomplished exclusively within the public sector when the decision to donate has already been taken.

3. Methods and data

The data presented in this paper come from a three-year study (2015–2018) of UCB banking in Italy, with an adoption of various methods. Firstly, in order to describe the functioning of the Italian system, I have undertaken a documentary analysis of regulations and reports, policy documents, statements, guidelines, and standards published by the relevant medical authorities. Due to the regional organization of the Italian healthcare system, the governance of the Italian network of cord blood banks involves regional governments, the National Blood Service (CNS, Centro Nazionale

Sangue), the National Transplant Service (CNT, Centro Nazionale Trapianti), the Italian Bone Marrow Donor Registry (IBMDR, which manages the Italian register of available HSC sources) and local health units.

Secondly, in order to study the politics of participation inspiring the setting of the Italian network of public banks and collection sites, discourse analysis was performed on several documents produced by different institutions. Position statements, published documents, and the webpages of donors and other associations directly involved in promoting UCB donation were considered. In addition, using the CNS website (2019) as a starting point, as it contains a list of the eighteen Italian public biobanks and their associated collection sites, a database of 325 websites (eighteen UCB banks and 307 hospitals that act as collection sites) was created and each website was searched for information about UCB donation. The webpages offering explanations and the attached informative material (a corpus of 186 documents) have been analysed using the software Atlas.ti for coding relevant parts of the texts. A particular approach to critical discourse analysis was adopted by looking at how the discourse is constitutive of social identities, social relations, and systems of knowledge and belief (Fairclough 1992).

Finally, in order to study the registers of valuing adopted by practitioners and tensions emerging between quality requirements and the promotion of donation, documentary and discourse analysis were complemented with ten semi-structured interviews with seven biobank operators, one biobank inspector, and two members of regulatory bodies (regulators). Semi-structured interviews, lasting between fifty and ninety minutes, were recorded and transcribed in full. Each transcript was coded for themes using the software Atlas.ti and read three times, focussing on the views of practitioners concerning how UCB donation is organized. The seven public UCB banks were chosen by using both a geographical criterion and a distinction about the size of the biobanks (according to the classification of the Italian CNS on the basis of their repositories and the number of connected collection sites [CNS, 2017]). Operators of three banks in the north of Italy were interviewed as

well as three operators in the centre of Italy, and one operator in the south of Italy. Two are considered large banks, two are of medium size, and three are small.

Ethical approval was granted by the Ethics Committee at the University of Exeter, College of Social Sciences and International Studies. Interviewees signed a consent form to participate in the interviews. In order to grant anonymity to the interviewees and to avoid identification, any geographical or institutional references have been removed from the reports of the interviews.

4. The Italian Cord Blood Network and the (bio)politics of participation

The constitution of what is now called Italian Cord Blood Network (ITCBN) – i.e. the network of eighteen public UCB banks and related collection sites – dates back to the second half of the 1990s when the first UCB banks and other research groups organized the first forms of cooperation and the definition of guidelines and protocols (Lazzari et al. 1996, 199). The first promising clinical results in UCB transplantation (Gluckman et al. 1989), the laboratory-based confirmation that UCB contains a sufficient number of HSCs to allow transplantations (Broxmeyer et al. 1989), and the establishment of the first UCB biobanks in New York in 1993 (Rubinstein et al. 1994), prompted the establishment of the first network of UCB biobanks. The constitution of a network of public UCB banks received strong political support from the then Minister of Health, Girolamo Sirchia, who in 2003 signed an agreement with the regional governments (Conferenza Stato Regioni 2003). The establishment of public UCB banks and donation/collection of UCB were thus recognized within the so-called Essential Levels of Care, that is, healthcare services provided by the Italian National Health Service at no charge for patients.

After several renewals, in 2009 the agreement was converted into a ministerial ordinance (Repubblica Italiana 2009) that defines the Italian regulatory framework on UCB banking. It prohibits the establishment of private UCB banks and private banking on national territory, sets the

governance of the ITCBN – which involves regional governments, the CNS, CNT, and IBMDR – and moreover, legitimizes the role of donors' and patients' associations. Indeed, Article 2, section g, states that amongst the aims of the ITCBN there is "the promotion, in collaboration with interested voluntary associations, of initiatives aimed at promoting solidaristic donation of umbilical cord blood to the population and in particular to donor mothers" (Repubblica Italiana 2009, 26).

The role of associations has been paramount in lobbying for the extension of the network of collection sites, which reached its peak in 2014 with 320 collection sites accounting for 66.5% of all childbirths in 2014 (CNS 2014, 18). The role of ADISCO, the Association of Women UCB Donors, in particular has been key. Its mission is to "promote donation and conservation of umbilical cord blood through activities aimed at creating a culture of allogeneic and solidaristic donation" (ADISCO 2019, emphasis added) and "to promote initiatives aimed at incrementing cord blood donation by creating and educating groups of volunteers active throughout the country" (Sciomer 2010, 317). ADISCO, through the years, has indeed exerted lobby activities in order to enrol local health units in the ITCBN as collection sites, often by raising funds and by promoting seminars, workshops, and other informative campaigns (ADISCO 2019). Similarly, ADOCES (the Association of HSC Donors) is also active in pushing for an increase of UCB donation, which is seen as a way of raising the chances of finding a donor for patients waiting for a transplant (ADOCES 2011). The aims of these associations converge in that they promote the enlargement of donation. According to another association involved – MASCOD (an association of physicians promoting UCB donation) – the aim is to "assure all women who want it, the concrete opportunity to donate the umbilical cord" (MASCOD 2019).

The enlargement of donation opportunities has been linked with moral discourses related to a register of valuing about the solidaristic nature of the act of donation (Beltrame 2019). On the 186 webpages and in the informative material retrieved from the websites of public UCB banks and collection sites, UCB donation is defined as *solidaristic* 101 times, and described as an act of

solidarity (43 times), of generosity (18), and as an act of love (18). What I named a (bio)politics of participation is clearly stated in a 2011 position statement signed by eight medical professional associations, the CNS, the CNT, and supported by IBMDR, ADISCO, ADOCES, and other patients' and obstetricians' associations:

The network of maternity units/collection sites must be *incremented* and qualified, through adequate staff endowment and training as well as an improvement of the facilities, in order to respond optimally to the *increasing demand of UCB collection*

Institutions, scientific societies, voluntary associations commit themselves to supporting the *ethical* value of donation as an *inalienable collective capital* for the health of citizens.

Solidaristic donation of HSCs from UCB should be supported in order to *triple the current* repository to reach 75,000 UCB units available for transplantation ...

(AEIOP et al. 2011, 3–4, emphasis added)

This excerpt is particularly representative of the (bio)politics of participation. Firstly, it points to the increase in the network of collection sites to promote donation. Secondly, it frames donation in an ethical discourse in which the value resides in the solidaristic act that nourishes the collective good. Finally, issues of the quality of UCB banked is merely mentioned, but the focus is on the quantity of UCB collected. In the (bio)politics of participation, indeed, enlarging the pool of available UCB units is the main objective, as quantity is thought to realize both healthcare needs and the social values of reciprocity, solidarity, and obligation that are exercised and reinforced through donation.

Inspired by this logic, Italy now operates eighteen public UCB banks that are connected with 274 collection sites that cover 62.8% of the total childbirths in Italy (CNS 2018, 16). The rate of donation amounts to 3.8% of the childbirths at the collection sites. However, the rate of banking is 6.3%, implying that 93.7% of donated UCB units are discarded (CNS 2018, 11). This is due to the fact that collected UCB units not reaching the TNC thresholds for banking established by CNS and IMBDR (according to the standards set by WMDA and other international medical associations) are

discarded. These thresholds are continuously modified because, with the development of clinical application, the biomedical literature suggests increasing the TNC – as a proxy for the number of vital CD34+ cells that are associated with successful engraftment and long-term survival. This introduces the issue of temporality, as discussed by Williams (2018), which constantly modifies the usability of the repositories.

The whole field of UCB transplantation has been characterized by continuous changes, that have affected standards in biobanking (see Beltrame 2014, 75–76). As reported by Gluckman (2009), initially UCB transplantation was believed to work only between HLA-identical siblings in paediatric patients. The successful use in non-related and with HLA-mismatched settings was demonstrated only at the end of 1990s (Rubinstein et al. 1998; Wagner *et al.* 1996), and was established by reviews of follow-up studies (Navarrete and Contreras 2009). The same relationships between the amount of CD34+ and engraftment and survival was still contested in 2002 (Wagner et al. 2002). In 2010 Querol and colleagues (2010, 972) reported "big discrepancies in CD34 enumeration" – therefore using the proxy of TNC was suggested. Due to the changes in the TNC threshold, only 30% of the current Italian UCB inventory of around 42,000 units banked is considered suitable for being released for transplantations. As stated by an Italian regulator, the remaining 70% constitutes "a completely *immobilized inventory*" of units "with scarce cellularity that are not selected by transplant centres but occupy freezer space, and uselessly consume liquid nitrogen" (Regulator 1). A UCB banker puts it thus: "the problem is that it is useless to continue to freeze things that are not needed" (Biobank operator 7).

Though this is not a feature characteristic only of Italy (Williams 2018), together with the high rate of collected units that are then discarded, it is a source of tension with the registers of valuing of UCB bank practitioners.

5. Towards a biopolitics of antigens. Tensions and the restructuring of the network

Heuts and Mol (2013, 131) speak about a register of *handling*, in which the value is assessed by handling objects. Public UCB bank practitioners, by handling the unit and evaluating it for their use in the clinic, place the relevance on that register of valuing dealing with the cellularity, vitality, and also the HLA variability. Speaking against the logic of extending donation without considering the clinical quality of what is collected, this UCB bank operator stated:

We are within the field of haematology, so we've got our pulse on the situation of *what is requested in clinics* and of what the features of demanded units should be *nowadays*, and this enables you to see the situation clearly (Biobank operator 5, emphasis added).

"Nowadays" refers to the question of temporality (Williams 2018) discussed above, that of the "immobilized inventory" (Regulator 1). Changes in what is requested in clinics produce a continuous adjustment of banking strategies and make the previous logic of combining solidarity with large repositories no longer an effective way of pursuing ethical values and clinical quality at the same time. This is an effect of the peculiar evolution of this field of haematological application, characterized by "a two-way interaction between basic biological research and medicine", where "it was successes in transplantation that prompted the basic research on the features of stem cells contained in [UCB]" (Beltrame 2014, 75). Transplant outcome data have suggested a change in the logic of UCB collection: from the need of large repositories to guarantee as many available source of HSCs as possible, to the need for units with high cellularity and rare HLA types.

The shift to what Williams (2018, 476) has defined as "second-generation" UCB biobanks – where the cell dose is paramount – is not simply a question of adapting the "practices of collection management" to the "discoveries made in the course of managing such infrastructures in the past". It also signals a change in the operative logic of donation/collection that triggers tensions. Indeed, the logic of the first-generation biobanks, where "there was no minimum cellularity cut-off for

banking UCB units" (Regulator 1), was easily accommodated within a (bio)politics of participation. As the aim was that of collecting as many UCB units as possible, extending donation was the best strategy to fulfil that aim. In other words, until the clinical value was set on the quantity, there were no tensions with the pursuing of the social values attached to donation. With the focus on TNC, and the need for limiting the cost of the system by concentrating collection, providing clinical quality UCB can generate tensions with the promotion of solidarity through extended donation.

The no-longer straightforward alignment between registers of valuing also involves further tensions. It marks, for example, a divergent interpretation of the kind of circulation that is of value. In the (bio)politics of participation, what is of worth is the circulation of the gift across the web of relationships constituting the social fabric. In the registers of valuing underpinning the biopolitics of antigens, however, the valuable circulation is only that from the donor to the recipient. UCB is a biomedicalized tissue that, without sufficient cellularity, stops circulation at the more valuable moment, that is, it remains *immobilized* in a repository instead of completing its journey by engrafting in a recipient body and restoring haematopoiesis.

This also involves a divergent definition of waste. The whole discourse of UCB donation is based on the principle of not squandering a life-saving tissue, that outside the use in HSC transplantation is a valueless "medical waste" (Brown 2013, 98). Accordingly, in the discourse of the (bio)politics of participation, "waste" coincides with non-donated UCB. In the registers of valuing of UCB bankers, waste is instead freezing units (occupying spaces and consuming liquid nitrogen) which will never be released for transplant. As I have shown elsewhere (Beltrame 2019), the definition non-donated UCB as waste is still characterizing the promotion of UCB donation in websites and documents produced by Italian public healthcare institutions. Other practices of valuing UCB are not mentioned.

By adopting registers of valuing focussed on clinical qualities, biobank operators call into question the notion of gift. This is due in part to the fact that UCB banks are complex infrastructures that deal with biomedically transformed objects rather than with simple gifts (Beltrame 2014; Williams 2018) and have to comply with the standards enforced by national health authorities (e.g. the UK Human Tissue Authority, the Italian IBMDR and CNS/CNT). On this basis, operators and regulators reframe the same notion of donation. As one regulator stated, "blood donation, as well as cells, tissues, and cord blood donation are, as it were, an opportunity for the citizen" (Regulator 1); or, in more radical terms: "donating is an opportunity, not a right" (Biobank operator 7). They are not devaluing the act of donation and the related solidaristic ethos, but, in the words of a biobank operator, the meaning of UCB banking:

gravitates around the patient. And to the patient, I must provide beautiful units, with a lot of cells, with a lot of CD34 – well collected and well screened for If we move our gaze from the patient to the mothers ... then we must allow all mothers to donate anywhere, at any time in the day, and any day of the year. But then we've really missed our goal. (Biobank operator 1)

Here the tension between the register of valuing is particularly evident, as this operator places relevance on the patient and on the quality of the UCB provided. Under the pressure of donors' associations, however, local political authorities have extended the number of collection sites. Another operator reported that the government of her region "wanted to grant donation to everybody" (Biobank operator 6). This implies that, with a lack of sufficient resources, obstetrician and midwives have been burdened with the duty of collecting UCB "after receiving a general training" (Biobank operator 6) that is considered insufficient. In the view of UCB bankers, "the training of the staff doing collection is directly proportional to the quality of collection" (Biobank operator 1). In this sense, operators mention the example of other countries in which UCB collection is organized on a different basis, one where there is a concentration of collection sites and work on the training of a dedicated collection staff. Biobank operator 6 and Regulator 1 mentioned the case of France where the number of biobanks is merely five and where collection sites have

been rationed. However, other biobank operators hope for a model inspired by a biopolitics of antigens based on only one collection site:

If we could have fixed staff at the maternity ward in [this hospital] alone, we could have far more collections and they would be carried out better, rather than having [so many] collection sites dispersed across the region. There are biobanks in the world, for example in Australia, where obstetricians doing collection have a certificate because they have done many collections, because they do well, because they know how to do them. Thus, a bank like that in Sydney in very few years, with expenditure decidedly lower than ours in Italy, has banked a large number of *beautiful* units, well crafted, with a lot of cells. (Biobank operator 1, emphasis added)

The reason, once more, is that the aim of collection is that of providing quality UCB for transplantation rather than allowing donation everywhere. This is because it is here believed that the focus should be put on patients and on what is provided to them, not on donor mothers that exert a right and a civic duty. As explained by another biobanker, the altruistic and solidaristic nature of the act of donation should not be linked with extended opportunity to donate, but with the clinical quality of the collected UCB. The morality of donation is thus reframed:

Let's think that collection, if well done, leads to good transplantation, because at the end of the day the aim of the whole process is transplantation. Good transplantation starts with a good collection.

So, if you work well at the beginning, at the end of the cycle we'll have good transplantation.

(Biobank operator 4)

The monetary register is operating as a sort of *primer* allowing a rethink of the whole logistics of UCB collection in Italy. It is not the paramount concern of biobankers, but it is deployed in order to set their registers of valuing as dominant over the (bio)politics of participation. In 2018, a study based on 2012 data and promoted by the CNS and CNT (Pupella et al. 2018) demonstrated that the cost of collection is lower in large UCB banks. The difference in the cost of banking UCB units between biobanks with an inventory of more than 3,000 units and biobanks with fewer than 1,000

units is even more striking (€3,614 versus €8,158). This study concluded by advocating the concentration of "cost-consuming activities in no more than three to five [biobanks] to maintain a sustainable [biobanking] network" (Pupella et al. 2018, 320). And there is indeed currently a plan − discussed by CNS, CNT, IBMDR, and ITCBN − to restructure the network by reducing the number of UCB banks and, above all, ration collection sites. Partially the reduction of collection sites has been realized through the effect of budget cuts to healthcare expenditure: in Italy maternity units with fewer than 500 childbirths per year are progressively closing. But the reform plan is based on the idea of maintaining only five UCB banks, designated "hubs", which will cryopreserve UCB units. The remaining thirteen banks will continue to operate locally only to coordinate collection in fewer sites, selected using two criteria: performance in terms of collection/banking ratio, and capacity in the procurement of rare HLA haplotypes.

The question of identifying those sites strategically located to reach rare HLA profiles is still under debate. Contrary to the UK where the strategy of selecting maternity units has been based on a careful analysis of areas with high rates of live births from parents of different ethnicities (see Williams 2017), in Italy it seems that there is, at present, no clear plan. According to Biobank operator 6 the Italian Bone Marrow Donor Register (IBMDR), because of its possession of data on HLA profiles, should prepare a HLA map of Italy in order to identify the best collection sites. Moreover, this strategy cannot focus solely on immigrant populations as the native population also shows peculiar HLA haplotypes – "we are patchworked … we have seen that we have an extremely high variability of antigens HLA" (Biobank operator 6). Other biobankers think that it should be the banks themselves that indicate strategic collection sites – "I would maintain active that of a hospital that may not have so many births per year, but that effectively absorbs the majority of the South-American population in [this city]" (Biobank operator 3). Furthermore, peculiar immigrant settlement patterns have been documented in Italy (e.g. Benassi and Ferrara 2013). Biobank

operator 6, for example, reports that her regional bank collects more UCB from immigrants in a small hospital in a rural province than in the main hospital in the capital of the Region.

At the moment therefore, the plan to restructure the ITCBN towards a biopolitics of antigens is still dealing with organizational questions. But the pivotal question concerns how friction with the established logic, based on the register of valuing of a (bio)politics of participation, can be avoided. What regulators and biobankers are trying with the restructuring of the network is to instil a different meaning to donation according to their dominant registers of valuing, both to potential donors and to collectors.

It is not that biobanks will close their doors to couples who want to donate... The mothers will give birth in a maternity unit where there are qualified personnel, trained by the bank in order to make a collection which is obviously qualitatively valid. (Regulator 1)

In their view, the social and ethical value of UCB does not simply lie in its being donated but in its effective ability to circulate as engrafted tissue restoring haematopoiesis. Operators are aware that this can clash with the logic underpinning the current logistics of donation. They are also aware that the existing system can demonstrate some sort of path-dependency. As one biobanker stated, "we should prepare for change", and indeed if change was not prepared for, "there would be an insurrection" (Biobank operator 6), especially from donating mothers who "obviously expect that this biological material they donated will be preserved in the event that one day it will be used" (Regulator 1). In fact, as aforementioned, in the informative materials published on the websites of public hospitals acting as collection sites, the dominant logic in promoting donation is still inspired by the (bio)politics of participation with its emphasis on "solidaristic donation" for the common good (Beltrame 2019). Moving from a (bio)politics of participation to a biopolitics of antigens does not only affect the organizational logistics of UCB collection but also and foremost a re-thinking of how participation through donation is put forward. This involves that the "culture of solidaristic donation", promoted by donor associations like ADISCO as a commitment to the national public

good, should be re-scaled as an act of altruism towards subjects in need of a transplantation. Indeed, moving from a promotion of donation as a sort of civic duty available on the whole territory to focused enrolment strategies at a local level can endanger the willingness to donate. In fact the reduction from 320 collecting sites to 274 has resulted in a drop of donation rate from 5.8% (CNS 2014, 18) to the current 3.8% (CNS 2018, 16) – and the drop in donation is higher than the relative drop in childbirths. As the case of the UK shows (Williams 2015) a reorganization of the logistics of UCB collection toward a biopolitics of antigens involves that the same notion of solidarity should be re-conceived from a generalized civic engagement to an altruistic commitment to the equity of access for particular categories of patients. In other words, a different register of valuing about donation and the related value of solidarity.

6. Conclusion

The Italian case analysed in this paper shows how, in the logistics of UCB donation and collection, the value of UCB is open to contrasting interpretations related to the main registers of valuing that orient the practices of actors involved in UCB banking. The Italian logistics of UCB donation and collection has been conceived as realizing the value of solidarity by enlarging as much as possible the opportunities of donation, but it has generated tensions with UCB bank operators whose registers of valuing put emphasis on the clinical quality of what is banked. These tensions have become more pronounced with the evolution of the clinical practice of UCB transplantation, when transplant outcome data have suggested the need to increase the cell dose of UCB units and the coverage of rare HLA types. With the shift to what Williams has called the second-generation of UCB banks, which is oriented toward a biopolitics of antigens, the straightforward alignment between clinical quality and social solidarity has become more problematic. Under the pressure of the monetary register, the need for reducing the costs of UCB banking and collection has marked an increasing tension with the logistics of donation based on a (bio)politics of participation. The latter

now appears not only as expensive, but ineffective in providing a flow of UCB units satisfying the needs of cellularity and HLA variability. In the view of biobank operators, the aim now is no more that of simply increasing the number of donated units – which at the same time fulfils the values of solidarity – but rather the focus is on providing patients with units containing a high content of CD34+ and HLA variability. In other words, there is a shift from a social gift to a medicalized bio-object. The registers of valuing are changing from evaluating participation in donation as a value in itself, to donation being of instrumental value insofar as it provides the necessary antigens. However, a biopolitics of antigens, in order to function, needs to enable participation by pursuing ethical values of solidarity. As discussed in this paper, the same notion of solidarity is shaped by different registers of valuing. While in the (bio)politics of participation solidarity is conceived as a generalized act of civic engagement, in the biopolitics of antigens it should re-thought as an altruistic commitment to the equity of access for particular categories of patients. If organizational arrangements in UCB collection are not aligned with how the social values attached to the act of donation are promoted, emerging tensions may result in a drop of participation.

The two ideal types of UCB donation/collection logistics are useful tools in exploring how tensions in valuing practices not only characterize the dilemma between donation and private banking (Porter et al. 2012), or that between donation and the transfer of UCB to the newborn (Brown 2013; Machin 2016), but also in the organization of UCB collection and donation in public UCB banking arrangements.

The Italian case is interesting as it illustrates how concrete arrangements of donation and collection are characterized by the presence of different registers of valuing that can enter into tensions. The alignment of solidarity with clinical quality is not a given in any public UCB banking system; they should be instead practically accomplished. Biobanks are complex infrastructures in which multiple values are produced and are at stake. The framework of the registers of valuing used in this study is therefore useful for scholars studying the tensions emerging in biobanking practices that deal with

different values. Instead of posting a straightforward equivalence between the socially embedded act of donation and clinical quality (as portrayed by the dominant narrative of the bioethics and biomedical discourse), this approach allows to explain that values are realized according to how biobanking activities are organized. In turn, the organization of biobanking and the logistics of donation and collection depend on the registers of valuing and the practices of valuation enacted by the involved actors and institutions. In this sense, the approach outlined in this paper can be useful also for biobank operators in order to deal with the multiple values involved in biobanking activities and so for engendering both participation and the fulfilment of clinical quality aims.

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