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SPECIAL ISSUE:

Biobanking Practices: Participation, Identities and Biovalues in the Making

NoArk (2007) by The Tissue Culture & Art Project (Oron Catts & Ionat Zurr) in collaboration with Marcus Canning.

NoArk is a research project exploring the taxonomical crisis that is presented by life forms created through biotechnology. *NoArk* takes form as an experimental vessel designed to maintain and grow a mass of living cells and tissues that originated from a number of different organisms. This vessel serves as a surrogate body to the collection of living fragments, and is a tangible as well as symbolic 'craft' for observing and understanding a biology that combines the familiar with the other.
As opposed to classical methodologies of collection, categorization and display that are seen in Natural History museums, contemporary biological research is focused around manipulation and hybridization, and rarely takes a public form.
To create *NoArk* we used cellular stock taken from tissue banks, laboratories, museums and other collections. *NoArk* contains a chimerical 'blob' made out of modified living fragments of a number of different organisms, living, in a techno-scientific body. In a sense, we are making a unified collection of unclassifiable sub-organisms.
Like the cabinets of curiosity that preceded the natural history museum's refined taxonomy so we hope that *NoArk* will be a symbolic precursor to a new way of approaching the made nature.

https://tcaproject.net/
http://www.symbiotica.uwa.edu.au/

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Cover *NoArk* (2007)

Special Issue

Biobanking Practices: Participation, Identities and Biovalues in the Making

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Assets, Commodities and Biosocialities
Multiple Bio*value*s in Hybrid Biobanking Practices

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Abstract: Biobanks are crucial institutions in the infrastructure of contemporary life sciences. They depend on the participation of donors who give tissues and data. Through their participation, donors can build identities and form biosociality. Biobanks are key sites in the current bioeconomy, that enable the generation of value from those tissues and bioinformation, transformed into assets or commodities. We define biobanks as hybrid zones of heterogeneous practices that blur the boundaries between institutional sectors and ways of producing economic values. On that basis we introduce a novel empirical, realist approach to the analysis of biobanking economies, explaining the different economic and social bio*value*s that emerge from the practices of valuing and interacting between the researchers, biobank staff and donor participants in specific banking activities. We discuss why STS studies on biobanking should explore the concrete practices through which multiple bio*value*s as well as biosocialities are produced simultaneously and in configurations of mutual interdependence.

Keywords: biobank; biovalues; bioeconomy; biosociality; participants' identity; practices of valuing.

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1. Introduction

In 2010 Robert Mitchell and Catherine Waldby published an article in which they explored national population-based biobanks as sites of biovalue production. Waldby had previously defined biovalue as the yield of vitality produced by the biotechnical reformulation of living processes (Waldby 2002, 310). In contrast to existing bioethical analyses of biobanks and citizens' participation and issues of informed consent, ownership, or confidentiality, Mitchell and Waldby (2010) emphasized the role of biobanks in the global bioeconomy. They placed the role of participant

involvement as the first ring in a value chain, which transforms donated tissues and the related bioinformation into commodities that generate "surpluses of both profit and health" (Mitchell and Waldby 2010, 333). Participation in biobanking was redefined as a form of clinical labour: i.e. "regularized, embodied work that members of the national population are expected to perform in their role as biobank participants" (Mitchell and Waldby 2010, 334). From this angle, the article discussed the emerging relationships between the biopolitics of donor involvement and the generation of biocapital, asking how "genetic information, biological samples, and patient experience" (Mitchell and Waldby 2010, 333) are mobilized through public sector research institutions, medical charities, small and medium biotech enterprises and big pharmaceutical companies. The focus lay on the resulting relationships of production in this area of the modern bioeconomy. Other perspectives on donor involvement in biobanking enterprises were put to one side, since for Mitchell and Waldby (2010, 336): "characterizing population involvement in biobanks primarily in civil terms makes it difficult to analyze the economic role played by populations".

The aim of this Special Issue is to re-integrate the analysis of economic biovalue production and reflections on biobanks as sites of identity and sociality production in Science and Technology Studies (STS). The need for this integration arises from the current landscape of biobanks itself and how participants relate to them. Our enquires into the bioeconomy of umbilical cord blood banking (Hauskeller and Beltrame 2016a; 2016b) have shown that multiplex and often hybrid zones of biovalue production emerge from peculiar banking configurations. Such configurations are the outcome of several interlocking elements – they include the biomaterials, technologies, laboratory practices, and regulations involved, but also economic interests, ethical values, as well as participants' social and personal identities and understandings of community. Participation in biobanking is central to the complex emerging bioeconomies and the related heterogeneous processes of valuation. Ethical, social and identity practices cannot be separated from the processes of economic biovalue creation. They are entangled in and take multifaceted shapes in the diverse banking models and configurations that have been created. Our notion of hybridity is consistent with some novel approaches in valuation studies (Muniesa 2011; Helgesson and Muniesa 2013), where rigid categories of institutional regimes of value production have been substituted by the notion of practices of valuing – i.e. valuing as something people do (Heuts and Mol 2013) – related to multiple systems of worth and moral justification (Boltanski and Thévenot 2006). Hybrid biobanking configurations blur the boundaries between institutional sectors and economic forms of production and circulation. Therefore analytical focus should be on the heterogeneous practices enacted by actors operating in biobanks configurations.

This Special Issue arose from our invitation to STS colleagues to engage in the endeavour to decipher this entanglement of citizens' participation and value creation in different biobank configurations. First in a special track during the 2016 4S/EASST joint conference in Barcelona – "Biobanks: the interdependence between forms of biovalue creation and donor participation" - and in this Special Issue of *Tecnoscienza*. We asked to address the following questions: a) How do different forms of involvements of patients, citizens and other non-expert actors shape biobank configurations? b) How are subjectivities and collective identities shaped by the involvement in biobanking activities? c) How are these varying forms of biosocial participation linked to the production of biovalue, and which kinds of bio*values* are generated?

The articles collated engage with these questions by exploring diverse biobanking configurations and situations. They show that individuals' decisions to participate and how are influenced by, and in turn affect, the ways in which different kinds of biobanks are set up and function. Banking arrangements and forms of participation are mutually constitutive, and they have to be studied as generative of the condition of possibility and development for the constitution of identities and biosociality and for the production of economic biovalue.

The concept we propose here expands the pioneering work of Mitchell and Waldby on the political economy of biobanks and the related ntions of biovalue and clinical labour as well as on the sociological and STS works on biosociality and citizenship. The aim is to apply these concepts to reflect the contemporary variety of biobanking practices and enlarge the conceptual scope through the problematization of biovalue generation. We do so along three interconnected lines of argument outlined below and supported empirically and from diverse angles in the individual articles. In section two of this introduction we clarify first the importance of the distinctions between tissues biobanks and bioinformation biobanks and between clinical and research biobanks. While these distinctions are often used for analytic reasons, the concrete forms they take in practice have important consequences for the dynamics investigated in the articles in the Special Issue. In section three we discuss how the several configurations and organizational arrangements of biobanks raise questions of ethical and regulatory governance. In doing so they become socially relevant, affecting practices of subjectivity and identity formation and, consequently, the creation of economic and commercial value as well. In section four we examine the formation processes of identities and subjectivities, discussing some operative notions deployed in STS that analytically underpin the analysis of these processes. These concepts and analyses insert the multiplicity of values (ethical, social and identitary) involved in participation into the debate on the political economy of biobanking. In section five, we critically discuss the political economy of biovalue production in biobanking, arguing that the focus on actual practices of valuing in hybrid economic spaces shows that the diverse forms of generating

economic value confound the rigid oppositions often used in the STS literature. The oppositions between commodification versus assetization as well as between exploitation of clinical labour versus accumulation by dispossession don't hold in view of contemporary practices of biobanking. Finally, in section six, we articulate a theory of the interdependence and co-constitution of diverse bio*values* that can inform STS study designs to investigate practices and institutions in the contemporary bioeconomy.

The analytical framework we have developed and the relevance of which is supported by the articles below, does not avoid the theories in political economy or sociology of identity, but begins with open concepts of biovalue(s), biosociality and bioeconomy. This provides scope for an empirical realist approach to adjust what these notions refer to and their conceptual role in the study of local biobanking practices.

2. Tissues and Bioinformation in Clinical and Research Biobanking

Biobanks are crucial infrastructures in contemporary biomedicine. They are collections of biological materials combined with information (personal medical, genealogical, environmental etc.) attached to the samples (Gottweis and Petersen 2008, 5). However, they are not as unified a kind of infrastructure as this definition might suggest. They vary in size, purpose, methodology and institutional arrangements. Biobanks are heterogenous objects (Corrigan and Tutton 2009, 303). One way to bring some order to this heterogeneity is by distinguishing between *tissues biobanks* and *bioinformation biobanks* and then further differentiate these groups into *clinical* and *research* biobanks. We use these analytic clusters to provide a brief overview on types of biobanking, they do not represent a register into which the multiple kinds of existing biobanks fit neatly and without overlap.

Tissue biobanks are fundamentally repositories of biological materials that are designed to enable their usability for clinical or for research purposes. But many banks operate in both domains: some umbilical cord blood banks, for example, provide samples for both transplantation or stem cell research (Hauskeller and Beltrame 2016a). There is also a class of tissues biobanks that offer a service of personal banking: that is tissues storage for future self- or family use, as do private cord blood banks (Waldby 2006; Santoro 2011) or banks that offer the conservation of endometrial stem cells found in menstrual blood (Fannin 2013). Finally, the tissues stored can be sold for commercial purposes and for profit (Almeling 2017; Waldby 2015), or can be release for clinical needs following a logic of public redistribution. Between those types of use several itersection zones have emerged, which we call hybrid bioeconomies (Hauskeller

and Beltrame 2016a). Compared to bioinformation biobanks, these different banking models are characterized by material interests in the tissue as such, be they clinical, scientific, and/or commercial interests. Medical information about donors and other bioinformation (e.g. medical history) are collected to determine the properties of the tissue to realize its future use-value.

In bioinformation biobanks the focus lies on the information provided. Tissues are collected to extract bioinformation that is then correlated with other information; value (again: scientific, clinical and/or commercial) is generated from the size, the richness and the usability of that information. Scholars often call these biobanks genetic (or genomic or DNA) databases, databanks or biolibraries (Hoeyer 2008, 429; Corrigan and Tutton 2009, 303).

Gottweis and Petersen (2008, 6) called such banks "population-based research biobanks", highlighting that samples and data are taken from "(parts of) the general population with or without disease". This denominator stresses other characteristics of these enterprises: a) they are mainly oriented toward research; b) they work on populations and, more importantly, c) populations can mean either or both, the general population and a specific population that carries a specific trait or condition. The explanatory power of these initiatives is taken to rest in combining genomic data (extracted from the blood samples collected from a population, for instance) with the medical records, genealogical, environmental and lifestyle information. Also, the research-oriented focus does not exclude future concrete and commercial applications of the findings. The data are analyzed both for a better scientific understanding of the etiology of diseases and conditions, and to develop new diagnostic tools (e.g. genetic tests), therapeutics and pharmaceutical products (Tutton 2004; Lewis 2004; Corrigan and William-Jones 2006).

The size of dataset collected is often less important than the detail and quality. Valuable are, depending on the research questions, the genetic homogeneity of a unique population (the Icelandic case, see e.g. Rose 2001; Pálsson and Rabinow 1999); or a relatively large population about which exhaustive medical records can be accessed (the Swedish LifeGene initiative, see Cool 2016); or, finally, a large sample of a multi-ethnic population (as in UK Biobank, see Tutton 2008). The aim of the research affects how homogeneity versus variability can be valued (Tupasela 2016). Respectively, the notion of "population" varies including so-called genetic isolates or people affected by a specific health condition – in disease-specific biobanks (see the case Singh presents in this Special Issue).

In bioinformation biobanks any distinctions between commercially-oriented activities and research initiatives are even more difficult to draw out than in tissue biobanks. While the for-profit aim is the reason for the existence of "direct to consumer genetic testing" companies (Tutton and Prainsack 2011; Harris et al. 2013), STS scholars have also discussed the potential commercial implications of population-based biobanking pro-

jects (Mitchell and Waldby 2010; Tupasela 2016). Recently, population-based biobanks have been investigated also as sites for the construction of collective identities intertwined with the generation of both scientific and economic value (Tupasela and Snell 2012; Tupasela and Tamminen 2015; Tupasela et al. 2015; Cañada et al. 2015).

The scope of biobanking initiatives, the target of their collection strategies, their research or clinical aims shape the processes of identity construction and value generation. The contributions to this special issue discuss different kinds of biobanking activity. Romero-Bachiller and Santoro explore different banking practices around a human fluid, human breast milk, and show how it is differently bio-objectified in different banking configurations engendering kin-like relations and identities built on narratives of donation, altruism and gift-giving. Singh discusses a disease-specific genomic database in which tissues are also used to derive immortalized cell lines and induced Pluripotent Stem Cells (iPSCs) that can be exchanged and used as disease models for research. Wyatt, Cook and McKevitt analyze a biobanking activity which depends on continuous long-term engagement of volunteer participants. Bühler, Barazzetti and Kaufmann explore two different bioinformation biobanks a city-cohort study oriented toward specific diseases and a general biobank aimed at the development of personalized medicine. Whereas French, Miller and Axler discuss the engagement hospitals have in different kinds of biobanking activity.

The range of different configurations and orientations to tissues and/or bioinformation addressed highlights the diversity of processes of biovalue production on the ground. In order to better understand these processes, the tissue/bioinformation distinction is insufficient. We also need an explanatory articulation of the contemporary institutional configurations in biobanking.

3. Institutional Configurations

Gottweis (2008, 24) concluded that biobanks are technologies of governing life through "collecting, storing, interpreting, and assembling life in the form of human materials, such as tissue or DNA". As such, they involve a continuous re-definition of the boundaries between "the scientific/technological, the social, the cultural, and the political" as well as the "relationships between patients and doctors, between genes and diseases, scientists and the public, the pharmaceutical industry and medical sciences" (Gottweis 2008, 22). Biobanks are also key sites in the current bioeconomy. They enable the transformation of tissues and bioinformation into exchangeable commodities, or assets producing rents through patenting or other financial strategies. We argue that the examination of biobanking should be wider than focusing primarily in a logic of "corpo-

ratization and commodification of healthcare and medicine" that results from the active intervention of private companies in the field of contemporary biomedicine (Gottweis 2008, 28).

One key element of the analytical framework we propose is the hybrid nature of biobanking economies. Hybrid bioeconomies criss-cross and overstep distinctions drawn between public and private institutions, redistribution and market economy, or commodification and assetization (Hauskeller and Beltrame 2016a). Hybridity means firstly that organizational configurations and institutional arrangements cannot be used as fixed explanatory categories for economic value production. The analytical focus should be put on the practices of valuation enacted by the involved actors within the peculiar configurations in which they operate. Secondly, hybridity implies that these practices encompass a complex of different non-economic values (e.g. scientific reputation, international collaborations, healthcare benefits, individual and collective identities). Therefore, the exploration of different organizational and institutional configurations of biobanking enterprises is not merely a classifying task, it is a step toward the explanation of the production of multiple bio*values* by enacted valuing practices within these configurations.

Our perspective contrasts with the three ideal types of institutional models proposed by Gottweis and Lauss (2011) to capture the range of bioeconomic configurations:

1) The *entrepreneurial biobank,* founded by a commercial company often in partnership with state institutions;
2) the *biosocial* biobank, an enterprise promoted, funded and sometimes managed by patient activists' groups;
3) the *public biobank,* established, funded and ruled by state authorities or by charities and the not-for-profit sector.

These ideal types of banking arrangement overlook cases of public-private partnership in biobanking and public biobanking enterprises established through licensing agreements with a commercial pharmaceutical or biomedical company (see Pálsson 2008; Lewis 2004 for a typology of forms of pharmaceutical companies' engagement in biobanking activities). Similarly, the biosocial model forms a hybrid through partnership with commercial companies. The well-researched cases of PXE International (Novas 2006) or the Association Française contre les Myopathies (AFM) (Callon and Rabeharisoa 2008; Mayrhofer 2008; 2015) exemplify biobanking activities that have been initiated, funded and managed by patient organizations yet have licensing agreements with commercial biotech companies.

Corrigan and Tutton (2009) offer a more exhaustive list of possible configurations, organized according to the sources of the biomaterial and information, the research foci, the actors initiating biobanking activities and the expectations of these endeavours (see Table 1). However, this classification excludes both most of the existing tissue biobanks (that provide or sell tissues for research or clinical treatments) as well as those

commercial enterprises that sell genetic tests directly to the consumer. Moreover, Corrigan and Tutton (2009, 304) add that:

> many biobanks have been initiated, funded or undertaken by alliances of actors, ranging from collaborations between (1) publicly funded universities and hospitals; (2) public-private partnerships comprising commercial companies; (3) the academic sector and/or medical charities in cooperation with national and regional governments; (4) pharmaceutical, biotechnology and genomic companies in collaboration with clinical research organizations; and (5) disease advocacy organizations in collaboration with universities or even pharmaceutical companies.

It has been observed in recent years that many of these alliances were not established at the beginning of a biobanking initiative. Collaborations as well as commercial agreements and deals can be stipulated during the course of the collection and storage activity. This suggests that the types proposed by Gottweis and Lauss (2011) do not exist in a pure form, instead complex configurations have been emerging. Mayrhofer and Prainsack (2009) have argued that the network structure of collaborating biobanks is increasingly diffuse, and involves more and more partnerships across the public and private sectors, the domestic and international dimension, and the healthcare, research and commercial clusters (see also Tupasela and Snell 2012).

Sources	*Research Foci*	*Actors*	*Expectations*
Population-based prospective (volounteers from the general population)	Common, complex diseases	National or regional governments	Prevention and treatment of disease
Hospital patients	Personalized medicine	Medical charities	Reduction of healthcare costs
Patients or other volunteers participating in clinical trials	Cancer research	Pharmaceutical sector	Speed up drug development and approval
	Orphan and rare diseases	Teaching hospitals	Generate new income stream for pharmaceutical sector
		Diseases advocacy groups	Produce 'personalized' drugs for subgroups or individuals
		Biospecimen industry sector	

Table 1 – Varieties of biobanks and their scientific and institutional settings (Corrigan and Tutton 2009, 304).

Studying banking configuration is more than an exercise in arranging elements according to characteristics for the sake of it and, like all classification exercises, neither objective nor exhaustive. Yet, given that policies and ethical discourses on biobanking have mobilized and often rest their rules and judgments on such classifications, it is necessary to discuss them and contrast them with developments in the field. Only then can one observe and analyze the increasing *hybridity* of biobanking practices and its implications for the production and social appreciation of the implicit and manifest bio*values*.

Firstly, configurations affect biobanking governance. According to Gottweis and Petersen (2008, 8), we witness "multi-directional forms of governance", where the traditional top-down approach coexists and intersects with bottom-up patterns (biosocial banking model) and with "horizontal exchanges" between market actors. Mayrhofer and Prainsack (2009, 75) argue that network configurations involve a form of "governance emerging out of the field itself": effective collaboration requires reliable standards of data collection and management as well as harmonization practices and ethical conduct. These elements produce materially binding (even if formally non-legal) protocols and guidelines of practice. Mayrhofer and Prainsack (2009, 70) also note that governmental regulation is not as fast as the progress of scientific activity, instead it is the research activity itself that generates forms of governance, enforcing also ethical conduct in procuring, processing and using samples and information. This implies a shift in the focus from formal institutional arrangements to the concrete social practices and interactions that make biobanking configurations work. Cooperation and the sharing of tissues and bioinformation require work to embed the activity in the social context (Hoeyer et al. 2017; see also Tupasela and Snell 2012).

Secondly, institutional configurations have implications for processes of commercialization and economic value production. Commercialization is a thorny issue in the debate about ownership of the donated tissues and bioinformation given to biobanks. The question is how altruistic gift-giving of participants is transformed into or becomes part of a proprietary asset and/or commodity (see Hayden 2007). The private sector is interested in accessing the tissue and bioinformation collections stored in hospitals and public biobanking initiatives for profit-making reasons (Lewis 2004). STS scholars have investigated the reactions of donors to the transformation of their "gift" into a commodity, showing that healthy volunteers are more critical than patients and ill people, who instead tend to accept commercial agreements as a "necessary evil" in the development of treatments (Haddow et al. 2007; Tupasela and Snell 2012; Hoeyer 2013). Participants justify their willingness to donate with their trust in medical institutions such as hospitals, and this trust arises from the perception that they are oriented toward healthcare (Tutton 2004; Busby 2004; Busby and Martin 2006; Hoeyer 2008). For that reason, a commercial orientation added to such public banking enterprises can challenge their legit-

imacy and give rise to what Pálsson (2008, 47) has called the "bio-politics of the dispossessed", the strong opposition of actors who felt deprived of the control and security they had enjoyed over samples and bioinformation and the relation of trust that grounded their participation.

STS scholars, often in dialogue with bioethics, have explored the available legal and regulatory mechanism for solving such quandaries through exploring forms of consent and public oversight (see Corrigan and Tutton 2009; Hoeyer 2008). This Special Issue concentrates on the practical accomplishment of addressing potential commercial uses of tissues and bioinformation in the interactions between biobank staff and participants. French, Miller and Axler discusses especially how hospitals configure their biobanking initiatives in order to leverage the commercial potential of their privileged access to samples and health records whilst maintaining the social license that derives from their healthcare orientation. Locating their analysis at the meso-organisational level, they highlight the work that goes into aligning the "entrepreneurialization" of care with the socially legitimate healthcare obligations in biobanking configurations. Wyatt, Cook and McKevitt analyze in-depth the everyday work of biobank staff, their numerous decisions and negotiations to enlist engaged volunteers to participate in research with potential commercial applications. Romero-Bachiller and Santoro in this issue explore configurations in human milk banking focused on the situated practices of donation and on how the different regimes of bio-objectification and use of this fluid are intertwined with the construction of relationships and identities. In contrast, Singh presents a study on a form of biosocial bank – established and funded by a non-profit foundation – where donated tissues and data are also made available for potential commercial applications.

The articles have in common that the banking activities analyzed happen in what we have called hybrid zones (Hauskeller and Beltrame 2016a). The frequent hybrid organization of contemporary biobanks suggests that STS studies of this field might shift focus from analysing static institutional arrangements and banking models to examining the logics enacted, shaped and hybridized in the everyday work of participants and biobank staff. This Special Issue contributes theoretically and empirically to the study of how the specific institutional *gestalt* of contemporary biobanks is not always as designed at the outset. It is instead shaped by the engaged practices of the diverse actors involved, from which also the production of economic, social and personal bio*values* results.

4. Participation and the Construction of Identities and Forms of Biosociality

Issues related to participation are often debated in STS literature in a dialogue with bioethics that is sometimes critical, sometimes constructive.

This dialogue has produced some normative pronunciations about the *right and just* way of involving donors and to critical discussions about the practical modalities of such involvement. Our contribution complements this work by looking at participation in biobanking as a site for the construction of identities and forms of biosociality, which we consider important bio*values* in our analytical framework.

The point of departure of the analytical framework we propose in this introduction and which is supported in the original articles by, is that, as convincingly argued by Tutton and Prainsack (2011, 1082), "discursive and material practices of recruitment and conditions of participation" produce different subjectivities. Scholars have shown how the legal mechanisms of informed consent are also a technique that produces the donor subjects as neoliberal, empowered citizens, autonomous political agents who make choices based on risk-benefit calculations to improve their wellbeing; subjects with the right and the duty to participate (Corrigan 2004; Hoeyer 2004; Tutton 2007). Moving the analytical centre away from the legal mechanisms and formal engagement procedures, we focus on the practical and pragmatic management of participation enacted by involved actors (researchers, biobankers and participants). The aim is to add another dimension to the STS analyses of subjectivities, identities and forms of biosociality, to point out some of the limits of studying mostly formal mechanisms of participation, instead of human interaction and sense-making.

The integrative and complementary perspective we propose draws on Haimes and Whong-Barr's finding that participation is "a highly varied social process, with multiple meanings", involving "levels and styles of participation" as well as "variations in the meanings and processes attached to the decision-making" (2004, 57). Participation is considered as "an analytical framework" that enables researchers to explore "the multiple and complex subject-positions that people occupy" in biobanking activities (Tutton 2007, 176). This Special Issue explores the situated, contingent and context-dependent social practices of *making* participation. The specific forms of participation discussed emerge from the interactions between the researchers and biobanks' operators and the participants. This analytical angle, centered on situated practices in the contributions, allows analyzing the production of bio*values* in relation to personal as well as collective biosocial identities.

Firstly, we look at the construction of collective identities. Several STS scholars have explored how population identities are co-constructed through processes of characterization involved in biobanking initiatives (Nash 2012; Tupasela et al. 2015; Tupasela and Tamminen 2015; Tupasela 2016). In order to characterize samples and data collected from a population, ideologies and historical narratives about ancestry and ethnicity are mobilized and thus genetic traits are linked to notions of cultural heritage and nationhood. However, it is debatable whether these forms of populations characterization are sufficient in themselves to constitute a

politics of identity and contribute to the building of collective identifications. Prainsack has underlined that, rather than *producing* identities, biobanks may "play in important role in *reinforcing* collective identities" (Prainsack 2007, 97, emphasis added).

Here the creation of identities is studied not as the effect of how participants have been characterized, but as actively produced by participants through their interactions with biobank staff. Bühler, Barazzetti and Kaufmann in this issue discuss the construction of populations in two different biobanking initiatives in Switzerland, a city cohort project and a general bioinformation biobanks oriented toward personalized medicine. Their study shows that the strong engagement in the city cohort is based on a shared identity and sense of belonging not engendered by formal mechanism of participation, nor exclusively by the local setting. It is the outcome of the long-term everyday interactions between biobank staff and participants. The former provide regular medical feedback to the latter, transforming participation in a strong care relationships. In contrast, the general bioinformation biobank, even if it deploys formal mechanisms of participation, is not able to activate similar processes of identification. Bühler, Barazzetti and Kaufmann's article demonstrates that characterizing populations through the combination of genetic relatedness and a rhetoric of common heritage is not enough to mobilize engaged collective participant identities. These emerge from the resonance between a specific biobank research orientation (the city cohort), the identifiable local setting (the city) and the socially embedded practices of interaction with participants.

The role of situated practices of interaction and participation is also thematic in the articles that draw on the concept of biosociality, a key (social) biovalue constitutive for ethically and socially, and hence scientifically, successful biobanking activities.

Biosociality, and the related notion of biological citizenship (Rose and Novas 2005), is often evoked in STS analyses of biobanking, and sometimes taken for granted. In our analytical framework, however, biosociality is problematized in relation to how it comes about. Biosociality was introduced by Paul Rabinow (1996, 241) to refer to "a truly new type of autoproduction" around biological features that emerge from practices that simultaneously generate knowledge, modify nature and reassemble identities and social formations (see also Gibbon and Novas 2008). Biosociality and the related notion of "biological citizenship" (Rose and Novas 2005) intend to address "modes of subjectification, through which individuals are brought to work on themselves…by means of practices of the self, in the name of their own life or health, that of their family or some other collectivity" (Rabinow and Rose 2006, 198). These notions highlight the active political involvement of individuals resulting in the construction of communities of identities and biosocialities through new ways of "forming novel relations with figures of scientific or medical authority in the process of caring for, and about, health" (Rose and Novas 2005, 446) and

in "an active role in shaping the direction of science" (Rose and Novas 2005, 452).

The articles in this Special Issue, with their focus on biobank participation, show empirically that biosociality and biological citizenship are neither an effect of formal participation mechanisms nor the outcome of participant population characterization. Biosocial banking models as defined by Gottweis and Lauss (2011), namely as sites where biosociality and biological citizenship are produced, do not do so because of peculiar organizational arrangements. Rather, the production of biosociality as well as the "partnership model" in research and decision making (Mayrhofer 2008) are the effect of the active political engagement of patient associations initiating and managing these banks (Novas 2006; Callon and Rabeharisoa 2008; Mayrhofer 2008; 2015). Furthermore, Sunder Rajan (2008) has shown that a shared biological identification is not sufficient to generate forms of biosociality. "Experimental subjects" participating in global clinical trials in developing countries are passively subjectified in modalities set by these markets. Biosociality develops only under *structural conditions* that enable participants to contribute and engage as active political subjects (Sunder Rajan 2008, 178-179).

We argue that these structural conditions for the development of biosociality include the practices of participation enacted and the interaction between biobanks staff and participants as a key factor. Jennifer Singh shows how participants in a large autism genetic database create a form of biosociality through participation and the virtual connectivity enabled by the digital network platform developed by the funder. With the donation of blood and information, the participants obtain a standardized and official clinical evaluation. This return, or "diagnostic currency", is important besides the access to dedicated educational and support services it allows. It is crucial for addressing anxieties, distress and uncertainties concerning the condition of their children. Participation is a way to confirm the medical and social legitimacy of the diagnosis. The search for a genetic cause of autism answers to parents' uncertainty about the causes and allows them to build narratives of doing something for their families and for the general autistic community that enacts a common biosociality (see also Singh 2015). Biosociality is effected by active participation, in the exchanges and relationships with researchers and with other families on the digital network platform. Finally, Singh's analysis details how the peculiar configuration of the biobank and the fact that the research includes only one specific patient family configuration channels the production of biosociality through the exclusion of other family structures and biases against ethnic minorities, single parents and other economically disadvantaged groups.

The role of interpersonal interactions in enabling biosociality is also emphasized in the analysis presented by Wyatt, Cook and McKevitt. They have studied the ongoing, every-day recruitment work of biobank staff whose job it is to sign-up and maintain the long-term engagement of vol-

unteers in biomedical research. Romero-Bachiller and Santoro elucidate how the different practices of human milk donation, sharing and technical manipulation not only enable the circulation of this human fluid and the contained bacteria and microbiota, but engender forms of intercorporeal sharing as a site for the construction of biosocialities through the development of altruistic engagement and reciprocity, imperatives to care, trust and emotional identifications.

The contribution of this Special Issue to the STS debate on biobanking is to establish an analytical framework to decipher the *scale* and *grade* of participation in relation to local biobanking configurations and the work of all participating agents. In this way, we can elucidate the structural conditions for the *differentiated emergence* of biosocialities and other bio*values* instead of positing them as a fixed feature of biobanking participation and/or institutional configurations.

5. The Production of Economic Biovalue in the Hybrid Bio-economy of Biobanking

A complex debate has unfolded in STS over the political economies and economic theories that are most plausible to explain the phenomena that can be observed empirically. The dispute concerns especially the notions of biovalue and how it is created. The focal points lie either on the contribution of material and information from patients, which has been criticized by some as a form of exploitation of clinical labour. The alternative position emphasizes that it is the labour of professionals that transforms stuff that has been donated into an asset through appropriation and the work involved in making it accessible.

This debate is important for our perspective, and that is why we present it here in some detail, to then argue that these perspectives are not separate or stand in a clear hierarchy of relevance for the creation of bio*values*. There is more to bio*values* than material and societal processes of exploitation and assetization. This Special Issue presents new theoretical and empirical work on the creation of bio*values* in biobanking and widens considerably the meaning of bioeconomy in Mitchell and Waldby's work (2010). Recent empirical findings present a rich hybrid tapestry of biobanking and related bioeconomies. Studying forms of engagement and participation in relation to research and institutional agendas highlights that bio*values* are not just financial revenues. Multiple kinds of values are involved in biomedical activities and contribute to the societal, scientific and economic performances of biobank projects.

In economic terms, biobanks are conceived as important nodes in what Waldby and Mitchell (2006, 31) have called "tissue economy", that is any "system for maximizing" the productivity of tissues "through strategies of circulation, leverage, diversification, and recuperation". Genomic sequences and digitalized health, genealogical and environmental data are

transformed into commodities that generate biovalue through the linking of "various types of pharmaceutical and diagnostic biocapital" (Mitchell and Waldby 2010, 337). In this way, biobanks are made part of a view of the so called bioeconomy that defines it as the commercial dimension of the life sciences, biomedicine and biotechnologies in a market-economy framework (Birch 2012; Petersen and Krisjansen 2015; Pavone and Goven 2017). Taking this perspective, terms such as *biocapital* and *biocapitalism* (Sunder Rajan 2006; Rose 2007) are often used to identify bioeconomic activities and to give a sense of the increasing insertion of "the substances and promises of biological materials… into projects of product-making and profit-seeking" (Helmreich 2008, 464), in modes of value creation that follow the logic of capitalist processes of production and accumulation (Franklin and Lock 2006; Sunder Rajan 2006; Cooper 2008).

As Helmreich notes, this understanding focusses the analysis and reflection on the dynamics of labour and commodification (2008, 464). Commodification is inherent to the same notion of biovalue introduced by Waldby (2002). As "the yield of vitality produced by the biotechnical reformulation of living processes" (ivi 310), capitalization of biovalue occurs through the transformation of biological matter into commodities bought and sold on the market. The category of labour is instead introduced by a reframing of the notion of participation in biomedical activities.

Mitchell and Waldby (2010) indeed conceive participation in biobanking as a form of *clinical labour*: that is, embodied or bodily-embedded work, largely unrecognized, that produces economic value through "subjects giving clinics access to the productivity of their in vivo biology, the biological labor of living tissues" (Waldby and Cooper 2008, 59; see also Cooper and Waldby 2014). Clinical labour encompasses the donation of tissue for medical research as well as to more onerous forms of involvement like participation in clinical trials (Sunder Rajan 2006; Cooper 2008). The provision of oocytes for assisted conception and stem cell research, surrogate pregnancy, and the selling of organs and other bodily tissues as a means of making a living (Waldby 2008; Waldby and Cooper 2008). In the case of bioinformation biobanks, clinical labour refers to the life of the participants (their medical history, their everyday nutrition habits and exposure to environmental factors) that is accessed and valued through data mining techniques (Mitchell and Waldby 2010). Biovalue resides in data obtained, and is realized through their commercialization (as commodities) and the exclusive appropriation of the intellectual property rights on them. Thus clinical labour is associated with the notion of "free labour" introduced by Terranova (2000) to denote how the activities of Internet users constitute an unpaid labour that produces revenue. Participants are at the same time producers and the consumers of the biomedical commodities thus produced (Tutton and Prainsack 2011; Harris et al. 2012).

Recently this concept of the bioeconomy based on commodification and clinical labour has been challenged regarding the meaning of

biovalue (Birch and Tyfield 2013; Birch 2017) and this critique constitutes part of the analytical framework we present here. Our understanding of biovalue and how bio*values* are produced combines insights from Waldby and Mitchell but unfolds the multiple kinds of bio*values* that play a role in biobanking and in the related bioeconomies and biosocialities.

Birch and Tyfield (2013) argue that the notion of biovalue is misleading, there is nothing valuable in biomaterials (tissues and/or bioinformation) *per se*, but what is valuable is the health they can provide (2013, 304). This value of health, or vitality, is socially constituted through ethical and political values, it is not an economic value inherent to the biological characteristic of biomaterials (ivi 308). Secondly, if the economic value is realized in the market exchange of products providing health, value is produced by "the knowledge and knowledge labor required to transform … [biomaterials] into commodities" (ivi 308). Birch and Tyfield insist, however, that value in the bioeconomy is not mainly realized through commodity-based market exchange. The view that the biological as such has no inherent economic value has several interrelated implications.

The first is that value is generated by knowledge labour of researchers and other professionals who transform bioresources into a "commodity of some sort" (ivi 313). This implies that the procurement of biomaterials is a practice located somewhere between an appropriation of resources and the exploitation of (unwaged) "labour". Both Birch and Tyfield (2013) and Cooper and Waldby (2014) in a subsequent reformulation of the notion of clinical labour have relied on the theories of Italian post-workerist Marxists argue that in the post-Fordist mode of production the emerging biocapitalist process of accumulation is penetrating life itself. Instead of the *subsumption* of productive labour, the new logic of accumulation works through the subsumption of "subjectivity itself, in its experiential, relational, creative dimensions" (Morini and Fumagalli 2010, 240). The collapse of foundational distinctions that characterizes the concept of productive labour– such as that between the time of work and the time of life, production and reproduction and production and consumption – implies that a "theory of life-value" has to replace the classical "theory of labour-value" (ivi 236). Whereas Birch and Tyfield (2013) use these notions to argue for the inconsistency of the category of clinical labour, Cooper and Waldby use it to expand the meaning of the concept of labour:

> *the life science business model is organized around a classical (Lockean) labor theory of value* which identifies the cognitive labor of the scientist as the technical element necessary to the establishment of intellectual property in living matter. (…) In this account, *the bodily contribution of tissue providers and human research subjects appears as an already available biological resource, as* res nullius, *matter in the public domain*, even while in practice the mobilization of these providers and subjects represents a growing logistical problem for the life science industries (Cooper and Waldby 2014, 9, original emphasis)

Cooper and Waldby maintain that tissue and bioinformation provision can be defined as a form of labour as it requests the mobilization of providers and it is based on the alienation of biological resources intended as the product of clinical labour. However, defining the bodily contribution as "an already available biological resource" in the public domain, appropriated by intellectual property rights, confounds the insistence on participants' clinical labour as the crucial factor that creates biovalue. It recognizes the mechanisms of value appropriation and of *accumulation by dispossession*.

This is the second implication of Birch and Tyfield's criticism (2013). In their view, the subsumption of biological and vital aspects implies that value is generated by subjecting the knowledge necessary to that subsumption to regimes of intellectual property rights. Applying the reflections of David Harvey (2010; 2014) and Christian Zeller (2008) on the process of accumulation by dispossession, Birch and Tyfield argue that value is generated from the extraction of *rents* from appropriated resources through a regime of property and monopoly. Intellectual property rights regimes act as mechanisms of enclosure: they enclose knowledge and natural resources, dispossessing others from the property and enabling the exclusive appropriation and the monopoly over the materials to generate rents (see also Birch 2012; 2017).

Consequently, the third implication is that rent-seeking strategies are not based on the direct exploitation of labour and commodification, when natural resources and knowledge are transformed into assets. An asset is "a tangible or intangible resource that can be used to produce value and, at the same time, has value as property" (Birch and Tyfield 2013, 302), while a commodity is produced for being exchanged as its value is realized only in exchanges. Assets can generate value also through other finance-dominated strategies of accumulation. As explored also in other work by Birch (2012; 2017), patents are the objectification of the intangible value of biological and knowledge property held by a firm. Revenue streams coming from patents are realized "from the trading of shares or investments in the firm (i.e., financial assets) or intellectual property (e.g., knowledge assets) and not from trading a material commodity produced by that firm" (Birch and Tyfield 2013, 311). Financial speculations are thus based on "the more mundane political-economic" promises of the rising value of shares in firms (Birch and Tyfield 2013, 322), what Birch later called a process of capitalization (2017, 466). In other words, in their understanding the bioeconomy is not commodity-based, but is asset-based: it is an economy aimed at asseticizing natural resources and biotechnological knowledge in which value is generated through rent-seeking processes that operate financial strategies of accumulation in asset-based markets.

Our approach does not require taking sides in the debate over commodification versus assetization and clinical labour versus accumulation

by dispossession. We conceive the economy of biobanks as a hybrid bioeconomy, which means that those different processes of biovalue production can occur simultaneously and with varying dominance and overlap. The configurations analyzed in the articles, their different institutional setting with different biomaterials collected and exchanged, demonstrate that concrete biobanking activities cannot be encapsulated once for all into a rigid dichotomy between commodity-based economy and asset-based economy. We do not set a certain regime of valuation as the starting point or core of the analysis. Instead we focus the analytical gaze on the enacted practices in the situated configurations that shape the production of bio*values* according to processes of commodification or assetization.

Romero-Bachiller and Santoro explore the circulation and different forms of bio-objectification of human breast milk, including a regime of public redistribution to informal sharing economies based on interpersonal gift-giving, but also a commercial factory context in which the donated milk is used to derive potential bio-commodities (patented probiotic products that employ bacterial strains to treat mastitis in lactating women). French, Miller and Axler investigate the establishment of biobanking activities in entrepreneurial hospitals. They show that in the attempt to leverage economic benefit from their unique access to patient tissues and medical information these institutions employ a logic of assetization rather than commodification. Singh unfolds the different uses of the donated materials in the SSC autism genomic database, insofar as alongside the study to find links between copy number variants (CNVs) in the genome and autistic phenotypes, the SSC also sells lymphoblastoid cell lines and iPS cell lines derived from the donated blood samples (i.e. commodification).

Concentrating now on the second common debate among scholars on the labour involved in the bioeconomy, we also see not an either-or situation but a continuum of practice. Not much is gained from a blanket critique of an exploitation of the donor's clinical labour or capital value through accumulation by dispossession of donor's biological resources. Empirically the provision of tissues and bioinformation in any biobank is influenced by the interplay between biobanking configurations and the concrete practices of valuing that are enacted in and around the activity. The provision of biomaterials is shaped in concrete biobanking contexts by a complex of institutional settings, ethical and moral norms enforced by legal mechanisms and enacted by involved actors, as well as by the power relations among them.

Feminists bioethicists have shown that the procurement of oocytes and surrogacy in assisted fertilization are a form of exploitation of clinical labour (e.g. Dickenson 2001; Waldby 2008; Widdows 2009). At the same time, sociologists have characterized the appropriation of supernumerary IVF embryos for stem cell research in developing countries as accumulation by dispossession (Glasner 2005; Gupta 2011). In the most recent study we have been conducting on cord blood biobanking, it is difficult

to identify either forms of exploitation of labour or accumulation by dispossession: in public banking an otherwise discarded tissue is collected but then redistributed for public medical needs; in the private banking sector this bioresource is valued precisely because it is owned as a private biological asset (Hauskeller and Beltrame 2016b). Commodification takes different and hybrid forms in which the banking service itself is more consistently commodified than is the biomaterial (ibid.).

Wyatt, Cook and McKevitt address specifically the limits of the notion of clinical labour as applied to participating volunteers in the UK BioResource. This institution is not simply a collection of samples, genomic data and health and lifestyle information. It is designed as a living database, registering individuals willing to participate in future medical research. Clinical labour as theorized by Mitchell and Waldby (2010) and Cooper and Waldby (2014) does not envisage the ongoing labour of both participants and BioResource staff in building the basis for continuous involvement. It does not include the "numerous decisions and negotiations that are involved in the everyday work of maintaining (the value of) volunteers" (Wyatt et al. in this issue). A wider or different concept and terminology might be needed to denote what participants do in terms of labour and the source of biovalue, which does not reside in "biological fragments and/or database entries", but in and through "the ongoing biosocial participation of the willing research volunteer" (ibid.).

6. From Biovalue to Bio*values*. The Entanglement of Multiple Kinds of Value

In their critique of the notion of biovalue, Birch and Tyfield (2013, 308) argue that charging "the biological" of a value-generative capacity would imply to neglect the role of what they call "bio-values": "the social or ethical values that make biotechnology a profitable venture" because through them "vitality comes across as a preference (or social value) of individual citizen consumers rather than a new value (or capital) relation". We take this alleged conflation of social/ethical and economic values as a positive point of departure to examine the complexity of bioeconomic activities. Separating ethical and social values from labour and other political-economic processes suggests that only the latter shape and contribute to the generation of economic biovalue. Ethical and social bio*values* are thus considered exogenous factors in the economic process, whose unique role is that of providing preferences and demands to meet by the bioeconomy.

To mark what our perspective adds to the literature, we have been using bio*values* in the plural. This stresses that multiple co-constitutive values (ethical, social and economic) are mobilized in the bioeconomy of biobanking activities. Waldby and Mitchell (2006, 33) recognized that any form of circulation (i.e. tissue economy) is presupposed on and con-

stitutes certain kinds of social and power relations and involves different social values. Other STS scholars have shown how symbolic and strategic values are produced alongside monetary or financial values in biobanking activities (Tupasela 2006; 2016; Tupasela and Snell 2012). Our contribution goes further by proposing a way of accounting for the realization of different bio*values* and explaining how they are produced in co-constitutive processes. Instead of only looking at how the production of economic biovalue is premised on ethical and social bio*values*, and how the latter shape the ways in which the former are created and circulate, we argue that the concrete practices of actors involved in biobanking activities are practices of valuing based on multiplex systems of worth and, as such, they at once produce diverse kinds of values.

Recently, Niccolò Tempini introduced a helpful model of the creation of multidimensional values, analysing the online interactions of patients on the social media-based data infrastructure *PatientsLikeMe.* He argues that *business value* and *scientific value* extracted from the data generated by the interactions of patients on the digital platform are not simply accompanied by the *community value* (the creation of communities of people sharing similar conditions) and the *individual value* (medical information obtained and the building of "narratives and interpretations of the self") but also fostering the latter (Tempini 2017, 196). In his understanding patients' interactions are not a form of free, clinical labour that generates economic and epistemic values, but also a value in themselves (as producing biosociality, informational and self-identity resources). Moreover, the more economic and epistemic value is generated, the more resources and opportunities for further community and individual values arise. As Tempini points out, there is "a complex convergence of value dimensions at play", since "different data users are interested in multiple value dimensions at once" (2017, 195-196).

We propose that in biobanks also a plurality of bio*values* is produced, and that they are co-constitutive of each other. The articles in this Special Issue evidence that the production of economic biovalue does not simply rely on the generation of biosociality and other that make the provision of tissues and bioinformation more legitimate and readily available. Forms of biosocial participation are not simply instrumentalized for the appropriation of economic value, because biosocialities are generated through participation in biobanking activities. This is particularly clearly brought out in Singh's analysis of diagnostic currency: by donating tissues and bioinformation participants have access to resources to construct identities and relationships, to access services and to solve anxieties related to the respective health conditions. Romero-Bachiller and Santoro show how donating or sharing milk realizes and enforces commitments to the ethical bio*values* of altruism and solidarity (helping other mothers) and the social bio*values* in establishing kin-like relationships. Bühler, Barazzetti and Kaufmann's article also discusses the individual values re-

lated to obtaining medical information and care as well as the social bio*values* that lie in developing a sense of belonging to a community.

We have argued that multiple bio*values* are enacted and carry forth the biobanking bioeconomy, and the articles in this Special Issue unfold this conceptual position. The realization of different bio*values* is integral to biobanking practices. Several kinds of values converge in heterogeneous and hybrid practices of bioeconomic profit and value production. Hybrid economic institutions such as biobanks do not represent any kind of rigid institutional regime of value production. Hybridity, as we argued, blurs the boundary between institutional sectors and economic forms of production and circulation. The production of bio*values* has to be studied as 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. The co-constitution of social and economic bio*values* results from the fact that practices of valuing, as argued above, are always dependent on a complex of different systems of worth encompassing moral and social norms as well as economic valuations.

Important to add is, though, that this does not mean that the production of bio*values* can only be described as *contingent varieties*, in the sense of disallowing generalization or the analysis of what happens in terms of existing theoretical concepts in political economy, sociology and ethics. In this introduction to the empirical articles that follow, we have explained these *contingent varieties* as the outcome of concrete *conditions* for the production of multiple (economic and non-economic) bio*values*. These conditions are dependent on the particular configurations of patient participation, interactions between staff and participants, design of purpose, and bio*values* envisaged. As such, the production of bio*values* is made intelligible and accountable in the different shapes it takes.

Doing this we are not suggesting that forms of exploitation or accumulation by dispossession, driven by profit motives, are not equally important for the growing bioeconomy. We also don't stipulate that exploitative practices involved are counteracted or can be traded off against other bio*values* like health benefits and a sense of biosocial belonging or citizenship. Shifting the focus on concrete practices, while considering the theories and categories developed in political economy, STS, sociology and bioethics, enables us to explain the shapes of the production of both economic and social bio*values* in biobanking configurations. Our analytical framework is not limited to re-integrating the analysis of economic biovalue and the reflection on biosociality and identity-building in biobanks. It traces a new path in the analysis of the bioeconomy of biobanks as sites for the simultaneous and interdependent production of multiple bio*values*. The articles in the Special Issue contribute new and original research to this contemporary critical project.

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Hybrid Zones, Bio-objectification and Microbiota in Human Breast Milk Banking

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Abstract: This paper critically examines hybridity and complexity in human biobanking, focusing on current forms of human milk banking in Madrid (Spain). We present and analyze three practices where human breast milk is stored and circulated: the "12 de Octubre" human milk bank, set in a neonatology unit and based on altruistic donations; informal human milk sharing among mothers; and drug-development practices that use donated human milk as a source of probiotics. Our analysis show that these practices rely on complex socio-technical assemblages, which are also characterised by hybrid zones and points of intersection between them. By understanding bacteria as a boundary object, we analyze the entanglements, disentanglements and re-entanglements of microbiota in the mechanisms of human milk bio-objectification that each of these biobanking practices entails. The distinctions or confusions between "virtuous" and "wicked" bacteria are part of a complex choreography where political, technical and sociocultural aspects get entangled.

Keywords: human milk banks; biobanking; intercorporeality; bio-objectification; microbiota.

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1. Introduction

While a common definition of biobanks equates them with the large, population-based repositories of biosamples and health-related information that have proliferated in recent decades, there are a wide variety of other places where cells, tissues, organs, fluids, genetic data and

other types of bodily materials are collected, processed, preserved and circulated – from blood and organ banks to tissue culture collections, egg and sperm banks, diagnostic archives or genetic databases. If the development of large-scale research biobanks is somehow recent, many of these other kinds of biobanks have a longer and richer history, entangled with the evolution of biosciences since the 19th century. However, all of them have proliferated in recent years, becoming an essential cornerstone of the bioeconomy (Pavone and Goven 2017). All biobanks share one thing: they rely on the procurement of biomaterials or biodata by individuals (Cooper and Waldby 2014; Santoro and Romero-Bachiller 2017). There are different forms by which biobanks can establish this procurement – from altruistic donation to direct selling, with many intermediate arrangements – but in any case, the generation of biovalue, in any of the many senses of the concept (Birch and Tyfield 2013), is not possible without it.

Scholarly attention to biobanks started to increase from the 2000s onwards. While bioethics has focused on debates which are still far from resolved about informed consent, property of the body and privacy, social sciences and STS have studied the socio-technical arrangements where biobanking takes place. In the beginning, most approaches in one way or another pursued a classification of different types of biobanks, a clarification on "what was new" about new biobanks – an elaboration of distinctions. For instance, the literature on new forms of private biobanking showed the difference between public systems, based on altruistic donation and search for the public good, and new commercial banks, based on market logics and individual profit. The way in which cord blood banking differed in public banks versus private companies was a particularly useful example (Waldby 2002a; Brown and Kraft 2006; Santoro 2009).

But gradually STS and social science perspectives on biobanks have changed their focus of interest: STS scholars increasingly emphasize the hybrid character of the widely different forms of biobanking. Comparative studies have shown the complex entanglements of biomedical practices, economic interests, ethical values and forms of public involvement that come together, sometimes in conflicting ways, in biobanks in different sectors of the global bioeconomy (Gottweiss and Lauss 2012). Whereas cord blood banking was once used as an example of the opposition between public and private regimes, current perspectives have focused on the blurring of boundaries between public and private banks, as well as on the growth of hybrid models (Brown and Williams 2015; Hauskeller and Beltrame 2016; Sleeboom-Faulkner and Chang 2016). From a feminist STS perspective, the notion of care has put complexity and ambivalence at the forefront of studies on biomedical practices – donation to biobanks among them (Mol, Moser and Pols 2010; Santoro and Romero-Bachiller 2017). The empirical literature on biobank donors and their motivations has also increasingly noted the complexity of values and logics behind donation,

which cannot be limited to the idea of "pure" altruism versus "pure" benefit/exploitation (Lipworth et al. 2011; Locock and Boylan 2016). Even informed consent in biobank donation appears to be a much messier affair now, related to personal as well as social motivations (Hoeyer and Linöe 2006), not to mention its role in other areas of biobanking directly linked to private companies, such as egg donation (Lafuente 2017).

In this paper, we want to pursue this line of investigation and critically examine hybridity and complexity in human milk biobanking. Human milk is a peculiar biomaterial: hybrid, intercorporeal in itself (Waldby, 2002b) and, like other liminal biomaterials, difficult to categorize – is it a food? A tissue? A drug, given its immunological properties? Or all of these things at once? Nevertheless, it was one of the first biomaterials to be standardized, banked and medicalized (Swanson 2014). As is the case with other body parts (Santoro 2011), human milk brings together ancient symbolic associations related to the mother-child link and novel scientific attributes – e.g. speculations on its possible use in cancer therapies. Taking on breast milk banking as an object of research is also interesting because human milk has always been fraught with tensions and controversies, perhaps even more so nowadays given the current panorama of renewed interest in the promotion of breastfeeding from medical institutions and other social collectives. New kinds of practices involving human milk are appearing, as can be seen in digital platforms and internet services where human milk can be shared altruistically or directly bought and sold (Geraghty et al. 2013). Another layer of tension which will surface throughout this article has to do with the increase in biomedical research on human milk and the recent proliferation of human milk labs (Palmquist 2015, 28), a trend which correlates with the growing presence of bioeconomic private companies interested in developing new commercial products in this area. Human milk banking intersects with all these conflicting dimensions at once.

The aim of the article is to explore practices of human milk banking in Madrid. We look into the official human milk bank (HBM), the 12 de Octubre Milk Bank, founded in 2007 as a hospital bank, which currently provides donated milk at a regional level. But we will also show that formal human milk banks are not the only form of biobanking in Madrid, and that there are other practices related to human milk collection, preservation and circulation. In particular, we will present two other places where human milk is stored and circulated, generating different forms of biovalue: informal human milk sharing between mothers, on the one hand, and drug-development practices that use donated human milk as a source of probiotics, on the other. Both of these practices, in different scales and forms, involve aspects of milk biobanking.

After presenting these three sets of practices, we will proceed to show their hybrid and complex character: how they come to be entangled and, to some extent, dependent on one another. These practices – and particularly the "activation" of donors, the willingness and capacity of

lactating women to donate – rely on complex assemblages, which are full of "hybrid zones" (Hauskeller and Beltrame 2016): things are messier (Law 2004) than they first appear to be.

But this is not the end of the story, as even if hybridity and complexity are evident in these biobanking practices, they have to be restricted, reduced, especially in more formalized and medicalized environments such as a human milk bank or a research lab. In the final section of the paper, we focus on the technical manipulation of human milk in each of these three scenarios and particularly on the way they deal with bacteria and microbiota present in human milk. Bio-objectification refers to processes "in which life is *made an object* in different settings – in and outside of the current truth regime of the contemporary biosciences" (Vermeulen et al. 2012, 3). In processes of bio-objectification, there is a need for purification, for separation. Technical manipulation, standardization and safety and quality precautions can be seen as performative forms of classification (Bowker and Star 1999). The three forms of human milk biobanking that we analyze imply different forms of bio-objectifying milk and of dealing with bacteria. If, as Mary Douglas (1966) argued, impurity and contamination are "matter out of place", what is the place of bacteria here? We argue that bacteria in these three scenarios function as a *boundary object* (Star and Griesemer 1989). Although they gain concrete significance in each particular case, and require specific interventions, bacteria are present in all three cases, "maintaining coherence across intersecting social worlds" (Star and Griesemer 1989, 393). Whether they may be virtuous or wicked, bacteria manipulation, control and regulation become key, then, in defining and performing different kinds of bio-objects, and different versions of what human milk is and does in each of these three scenarios.

2. Methodology and Research Procedures

This article stems from an ongoing research cluster on feminist epistemologies and health activism. Within that broader project our analysis of human milk banking started only recently, and it employs ethnographic and qualitative methods, as well as secondary analysis of protocols and medical and official literature. To date we have conducted ten semi-structured interviews with human milk donors, lactating mothers who suffer from mastitis and HBM coordination, and scientific and technical staff. We are still conducting interviews with HMB donors and we are planning to carry out a second round of field-work with recipient's mothers along with a deeper analysis of the emerging industry of human milk probiotics. HMB staff were contacted through their institutional email addresses. HMB donors and lactating mothers who suffered from mastitis were contacted through snowball sampling, opening lines in different mothering support groups chat and email lists. All the people interviewed were provided with written and oral information about the

research topic and procedures, and they all agreed both in writing and orally to the interviews, following our protocol of informed consent. In this paper, we will mostly focus on two in-depth interviews with donors, two ethnographic visits to the 12 de Octubre Milk Bank, with several on-site interviews with staff (June and November 2017), and auto-ethnographic notes from Carmen's own experiences with mastitis, use of human milk based probiotics and human milk bacterial analysis. We also surveyed scientific articles related to "our" milk bank and, as we will explain later, a patent on human milk microbiota.

3. Biobanking Practices around Human Breast Milk

A human milk bank is a medical institution that collects, screens, stores and processes expressed breast milk donated by lactating mothers, in order to distribute it to newborns – particularly to preterm babies and medically fragile infants who cannot be breastfed by their own mothers. To guarantee the safety and quality of the milk, HMBs implement different protocols, from selection of potential donors to sterility measures, immunological analyses of donors and samples, pasteurization and freezing (García Lara et al. 2012).

The history of HMBs dates back to the beginning of the 20th century. As Swanson (2014) explains in her historical account of blood, milk and sperm banks in the United States, the development of "milk stations" and other doctor-led initiatives since the 1910s that collected, analysed and distributed breast milk from wet nurses – properly monitored on their diet, habits and behaviour and instructed to maintain hygiene and sterility – was one of the first prefigurations of modern biobanks. Swanson suggests, in fact, that "human milk became the first body product to be institutionally organized in disembodied form" (Swanson 2014, 17). The creation of milk banks in different countries – Vienna's milk bank, opened in 1909, is generally considered to be the first – signalled the beginning of a process of medicalization which gradually obscured the long history of wet nursing and other traditional practices of surrogate breastfeeding (Palmquist, 2015: 26). During the second half of the century, changes in breastfeeding rates, pediatrics and social conceptions of lactation and motherhood, as well as biomedical research on human and bovine milk and epidemiological alarms – such as the emergence of HIV/AIDS during the 1980s, soon recognized to be transmitted via human milk –, accompanied transformations in the technical and social configuration of milk banking (Carroll 2014; Swanson 2014).

In Spain, however, the implementation of HMBs is quite recent and has more to do with contemporary developments in neonatal care. The first Spanish milk bank opened in 2001 in Majorca as part of a tissue and blood bank. Our case study, the 12 de Octubre Milk Bank, was initiated in 2007

in Madrid and was the first milk bank set up in a neonatology unit (an institutional location which has become the *de facto* model for most of the eleven banks created in Spain since then). Based on scientific evidence about the benefits of human milk compared to formula substitutes in the feeding of preterm and fragile newborns in Neonatal Intensive Care Units (NICUs), this bank currently provides donated human milk to very low birth weight preterm infants (under 1500 g) and newborns subjected to surgical interventions who cannot be breastfed by their mothers. Donated human milk is prescribed specifically to very low birth weight preterm infants, as human milk it is the only known prevention for *necrotizing enterocolitis*, a relatively common condition in preterm babies that consists of the necrosis of a portion of the bowel, causing high rates of infant mortality (Carroll 2014). While in its first six years of operation its services were limited to the hospital in which it is based, the bank has now become the center of a regional network which coordinates collection points and neonatology units in seven other public hospitals in Madrid and adjacent cities, and there are currently plans to extend the network to three more public hospitals in the region.

As with all HMBs, the 12 de Octubre Milk Bank relies on donations from lactating mothers who regularly express their milk, collect it and bring it to the bank. Since 2007 more than 1600 mothers have donated milk, approximately 250 each year, according to the bank coordinator. In significant contrast with the donation of other tissues, milk donation is not an isolated act, but a prolonged one where mothers are expected to provide milk on a continuous basis, accompanying their own lactation – most donors spend between 6 months and a year providing expressed milk, which they have to deliver to the bank each fortnight at most. Donors are motivated for altruistic reasons, but many are also "pushed" by personal experiences: a survey that the bank conducted with its donors between 2007 and 2010 revealed that 45% of donor mothers had had their own child hospitalized in a neonatal intensive care unit (Sierra Colomina et al, 2014). There is also a relationship with breastfeeding advocacy: the foundation of an HMB in a certain place is said to increase overall rates of breastfeeding in the area (García Lara et al. 2012). As we have seen in our fieldwork, and also according to the bank coordinator, a significant proportion of donors participate in groups and networks related to breastfeeding, and the bank itself targets support groups for recent mothers and midwives' networks in their donor recruitment strategy.

At first sight, the 12 de Octubre Milk Bank seems to be the only place where human breast milk biobanking happens in Madrid. But during our fieldwork we have come across two other scenarios where there are different practices that involve milk banking. The first one has to do with informal practices of human milk sharing. Milk sharing is a practice in which a breastfeeding mother nourishes a child who is not her own, inside privately arranged altruistic relationships with the other mother/s but apart from medical banking platforms (Falls 2017). Palmquist (2015) remarks

that wet-nursing, co-nursing and other forms of cooperative breastfeeding have a long history as popular practices, but that today the popularity – in the US – of certain webpages such as Eatsonfeets.org or HM4HB.net, set up as non-profit human milk sharing platforms, as well as other changes in the understanding of breastfeeding, are giving new life to these practices. In contrast to studies on informal human milk sharing in other countries – mostly in the US (Falls 2017; Palmquist, 2015) – in Spain there are no web pages or similar services that coordinate human milk sharing. Although wet-nursing was common in the past and forms of breast milk sharing may still occur, especially between close relatives, these situations appear to be more rare today. However, in our fieldwork in Madrid we have encountered a few informal arrangements, where some mothers, while breastfeeding their own child, provide their milk to friends or relatives who want to feed human milk to their infants but cannot breastfeed them temporarily – e.g. due to a medical surgery – or do not have enough milk for the baby's needs. In contrast with traditional wet-nursing, nowadays most milk sharing implies expressing milk and not actual breastfeeding. So, even in a transient, informal and non-standardized manner, informal milk sharing also implies biobanking practices. Samples are preserved at home in the fridge or freezer by the donor after expressing as well as by the recipient family who receives it. Even though safety measures to avoid contamination are mentioned in our interviews, informal milk sharing is officially and actively discouraged by the 12 de Octubre Milk Bank as potentially dangerous. This echoes medical discourses and wider controversies around new forms of human milk sharing: for instance, Carter et al. (2015) have studied recent representations in the US press of online peer milk sharing platforms, showing that whereas medically supervised milk banks are represented as safe, sharing milk is repeatedly characterized as dangerous, and mothers who resort to it are considered risky and imprudent.

A third practice around human milk banking moves us away from altruistic practices to other features of the bioeconomy: probiotic products that employ bacterial strains derived from human milk to treat mastitis in lactating women. Mastitis is a common and painful inflammation of a woman's breast during lactation caused by infection, due to a decompensation of mammary microbiota by the overpopulation of a commensal bacteria colony, or by the presence of a pathogenic agent – most commonly *Staphylococcus aureus*. Its symptoms include fever, pain, abscesses, and difficulties with breastfeeding. During the last fifteen years, a Spanish research team based at the Complutense University of Madrid – a public institution – and led by the microbiologist Juan Miguel Rodríguez has been working on mammary microbiota and mastitis physiology, as well as on new mastitis treatments with probiotics, produced out of various strains of lactobacilli isolated from human breast milk (e.g. Arroyo et al. 2010; Marín et al. 2017). Their first results were patented in 2004 (Pey et al. 2004) by *Biosearch Life* (previously *Puleva Biotech*), a Spanish

biopharmaceutical company connected to the dairy industry. After a successful clinical trial in human subjects (Arroyo et al. 2010), in January 2014 the company released a nutritional supplement named *Lactanza Hereditum* directed at breastfeeding mothers and advertised for the treatment of mastitis. Different clinical trials employing strains derived from Biosearch Life's patent can today be found in a variety of national health system registries, including those of Australia, the US, and the Netherlands. Increasingly, these probiotic products are extending their therapeutic aspirations beyond the actual treatment of mastitis to breastfeeding at large, by claiming to have preventive properties, benefits for the immune system and intestinal flora of both mother and child and even the capacity to improve infant colics. All of this informs us of an internationally emergent business based on the promises of probiotics derived from human milk.

The original bacterial strains used in *Biosearch Life* products were obtained from donated human breast milk. In the patent, the only background information given is that it came from a 35 year old woman. There are two practices of biobanking that take place here. The first has to do with the collection of tissues, microorganisms and cells: after being isolated, probiotic cell lines derived from that anonymous woman's milk were deposited at the CECT (*Colección Española de Cultivos Tipo*) in Valencia (Spain). Any company or researcher who wants to access those lactobacilli needs to get them from there. Along with hospital diagnostic collections, type culture collections can be considered one of the earliest forms of biobanks, with a particular orientation towards research in microbiology. Though most tissue collections are integrated into universities or public research centres, since the 1980s they have been developing ties with pharmaceutical and food industries (Taylor 2016). The second instance of milk banking and circulation happens in the laboratories and facilities of the pharmaceutical industry: through the process of drug manufacturing, samples of breast milk bacterial strains are transformed into valuable products which are commercialized as probiotic nutritional supplements.

4. Hybrid Zones and Care Assemblages in Milk Banking

Though these three forms of human milk biobanking – institutionalized banking in a public hospital institution; informal practices of peer sharing; and corporate logics of biomedical research and patenting of milk components – at first may appear to be completely different, there are, in fact, several points of intersection among them. In their re-examination of the narrative of public/private opposition in cord blood banking, Hauskeller and Beltrame (2016) focus on the proliferation of "hybrid zones", areas of institutional intersection between public and private cord

banks that, to some extent, are blurring the boundaries between these two cord blood regimes. Our aim is to extend this notion to all formal or informal practices and arrangements that generate logics of intersection, exchange or confusion between different forms of biobanking.

4.1 Circuits of Solidarity and Donation: Altruism as "Hybrid Zone"

In human milk banking, one of the easiest ways to find these "hybrid zones" is by focusing on donors' accounts. In our interviews with donor mothers, the distinction between formal donation, informal sharing among peers and donation to research is not clear-cut. The story of Laura[1], one of our interviewees, is illuminating in this respect.

As she recounts, after her first daughter was born, Laura got to know the 12 de Octubre HMB. When her own breastfeeding was established, she was willing to donate and phoned the bank to get some basic information about donor eligibility criteria – which she fulfilled – and procedures of extraction and donation. But she lived far away from the HMB, and having to take milk samples herself to the hospital ended up discouraging her. Some time after this aborted attempt at becoming a donor, and after Laura had a second daughter which she also breastfed, two close friends had twins. They were low weight newborns – especially one of them – and required a period of hospitalization, but they did not enter into the category of "very low birth weight", as they did not weigh less than 1500 g. So when the mother had problems expressing milk, they could not resort to obtaining milk from the bank. Convinced of the advantages of breastfeeding and wanting to feed their premature babies human milk instead of formula, they reached an informal arrangement with Laura in which she would altruistically express and collect her milk for them. She did this for the duration of the period they spent at the hospital – not 12 de Octubre but another public one – and three months after that. This practice of peer milk sharing, however, did not take place without the knowledge of the hospital staff. Laura and her two friends had a meeting with the hospital nurses where they were advised on safety procedures and provided with information on freezing, conservation, etc., in addition to being supplied with bottles and other materials for preservation and transportation. Laura continued giving milk to her friends for several months. But this was not the last experience she had with donating milk. Few months later, Laura received word, through a mobile group chat of recent mothers she participated in, of a nurse asking for voluntary donations to an experimental research project on the use of human milk for cancer treatment that was being conducted in Jaén, in the south of Spain. Apparently this nurse had a relative who could benefit from these experimental therapies. Laura and several other women from the group chat – some were also donors at 12 de Octubre – got in touch with the nurse and tried to organise how to proceed with the donations. In the end

the donations were not carried out, as there were some delays and specific instructions that did not arrive, but Laura remarks that she and the other mothers had been willing to donate. In her perspective, it was also an instance of helping others, even if it was less emotionally intense since it involved adults: "Maybe if it had been therapy for kids… Maybe we didn't put as much effort into it because it was for an adult. Being a breastfeeding mother yourself, it is like you feel more empathy for babies than for adults".

We can see in Laura's story the entanglement of different forms of biobanking. In Laura's experience, all forms of donation pertain to a similar altruistic impulse – to help others, to care for them. A mother who is willing to donate to the 12 de Octubre bank would also be open to other practices of donation – even if they are at different levels of "emotional distance", something which explains why Laura's donation to research never happened. As Palmquist affirms in her study of human milk sharing in the US: "donors often enter milk sharing after trying to donate to a milk bank" (2015, 40). We can also see how "circuits" of donor recruitment for different biobanking practices are mixed-up, intersect with each other – we could say that the mobile group chat where Laura got to know about the demand for donated milk for research is, in a way, a "hybrid zone" for donor recruitment. Drastic differences between donation for therapeutic use and to research or experimental therapies are also, to some extent, blurred from the perspective of donors. In the 12 de Octubre bank, in fact, there are currently several ongoing research projects which employ human milk samples. According to the coordinator of the bank, most donors are perfectly comfortable with some of their milk being used for research, even though they are constantly reminded of the scarcity of donated milk. Like in Laura's account, these other uses are probably less valued than the original one – helping extremely vulnerable newborns –, but not a single donor has apparently denied the bank's request for samples for research.

In the donors' accounts we can find a second instance of hybridity, concerning the mix of highly personal and more general motivations. Laura's experiences bring together different levels of emotional distance and personal involvement – from the more abstract ideas of helping premature babies or contributing to biomedical research to the direct involvement with her friends' babies. Even in donation to experimental therapies, as the example of the nurse demanding human milk for a direct relative demonstrates, there is a mix of perspectives, from the embodied and the personal to the abstract and general, which cannot be reduced to an impersonal idea of a "gift". Many qualitative studies of tissue donation also refer to this complex mix of identities, motivations and values attributed to donation for research biobanks. Locock and Boylan (2016, 806) indicate, for example, how willingness to donate, consideration of donations as "gifts" and other views on access to research results, commercial access, etc. vary depending on whether donors themselves have an illness which could benefit from the research. This is also evident in the fact that many donors to the 12 de Octubre bank, have personally

passed through the experience of having their babies in the NICU, something which symbolically enables them to understand the hypothetical position of a recipient's mother and to construct a sense of reciprocity, a sort of "hybrid altruism" where the differences between donating to strangers and helping relatives and friends are not so marked. In contrast to Titmuss's (1970) notion of altruism as a pure "gift to strangers", where its abstract forms of solidarity imply a clear demarcation between donors and recipients, human milk donation often mobilizes strong emotional identifications and symbolic shifts of the position of donor and recipient. In this respect, these donations are not so different to other collective practices of informal solidarity common among new parents. In these chains of reciprocity all kinds of objects circulate and are borrowed – baby clothes, cradles, carriers, breast pumps, wraps, slings, kangaroos, etc. This logic is quite clear in the following extract from the interview with Elena, a mother who became a donor to the HMB following several hospitalizations of her own son:

> We had to put Hugo [her son] in the hospital when he was just two days old… It was so hard. It still sends shivers down my spine. And I imagine myself in the shoes of other mothers who have a baby in the incubator and who can't provide enough milk. Being aware that breast milk helps them so much… So I thought: "If I can do something…". I'm not a doctor, there are few things I can do to help, but if I can contribute by giving milk… It is also an issue of solidarity among women. I think it is also *working for life*, caring for the creatures. There are sometimes babies who weigh a kilo, even less… (emphasis added).

4.2 Criss-crossing Institutional Boundaries

Apart from donors' experiences and motivations, we can also find "hybrid zones" in an institutional and organizational sense. Boundaries and distinctions between public banks, research networks and bioeconomic companies are traversed and re-configured by diverse lines of contact. The most obvious are the formal relationships established between the public 12 de Octubre HMB and other non-public institutions. Part of the funding for the bank comes from a non-profit, but private, organization, Fundación Aladina, that – even though its main focus is on pediatric oncological care – funded the remodelling and expansion of the bank's infrastructures in 2014. Research carried out at the bank also comes into contact with other public and private actors, and significantly, with the Complutense research team on the microbiota of human milk that made the original patent for Biosearch Life on breast milk probiotics. Research personnel, in fact, move between institutions: the full-time researcher currently employed at the 12 de Octubre HMB worked previously, and was trained, at *Probisearch*, the start-up company initiated by the Complutense team. As Hauskeller and Beltrame (2015) point out, hybrid zones also refer to the criss-crossing of different economic regimes – like market and redistributive economies.

Boundaries between therapeutic donation, research and pharma-industry are sometimes blurred here. Also, in the case of informal milk sharing, distinctions between medical and the non-medical are not completely clear-cut, as we could see in Laura's story. Not only because, as Palmquist writes, "milk sharing is not a rejection of biomedicine *per se* and in fact, a scientific evidence base often informs milk sharing decisions" (2015: 34) but, in Laura's experience, because of the direct assistance they found from hospital personnel.

4.3 Care Assemblages and Hybrid Kin

The donors' accounts also evoke another instance of hybridity that we consider relevant: the heterogeneous character of the networks that are formed around breast milk donation and the role care plays in bringing them together. Here we can speak of "care assemblages", where not only donors and recipients, but also many other actors, both human and non-human, are coordinated, as care, affectivity and interpersonal support are not only important in personal peer sharing relationships. Carroll (2015a) argues that breast milk donors to HMBs engage in a significant amount of *care work,* a form of unpaid, invisible labour, in order to follow the donation guidelines and thus be able to provide HMBs with the quantity of milk they need, as well as to comply with the strict safety measures. Our interviewees, accordingly, remarked upon the hard work implied in regularly expressing milk for donation – especially since they have their own babies to care for, and since safety requirements for milk donation are much stricter than those they apply when they express milk for their own children. Indeed, Elena specifically defined her involvement in milk donation as a form of "working for life", as we have seen, emphasizing both the caring involvement and the effort required by the procedure. Our informants commented on how they have to find a quiet moment in their day – moments that are hard to find for a recent mother – so they can express milk for the HMB. Specific organization and discipline are thus required to fulfil the rigorous protocols milk donation entails. Practices of donation are grounded in the everyday activity and micro-decisions of family life[2]. Support from partners, relatives and friends is essential – e.g. in helping to take samples to the hospital.

But care is not only an issue for donors and their families, but instead a rationale that involves all of the actors that intervene. For instance, bank personnel are very close with, friendly and supportive to donors, offering them help and advice if they have any problem with their own breastfeeding. Caring for donors is a way of assuring donations, but it is also part of the greater ideal of promoting breastfeeding and a more humane type of medical attention. Even technical aspects of the donation process are traversed by care and personal relationships. One example is the circulation of breast pumps: the HMB has a number of electric breast pumps that can be borrowed by donors, but usually donor mothers are

asked if they can find one themselves – for these are reserved for women who cannot afford to buy them or get one from acquaintances. According to the bank coordinator, most donors resort to their personal contacts to borrow one. As is typical with other baby paraphernalia such as clothes, breast pumps circulate among friends and relatives, embodying and strengthening, in a certain sense, those care assemblages which constitute an essential part of the social environment of donation.

A final topic regarding "hybrid zones" has to do with forms of symbolically constructing kinship through donation practices. There has been much sociological and anthropological literature on the transformation of traditional logics of kinship brought about by new medical and reproductive technologies (Strathern 1992; Franklin 2013). Catherine Waldby (2002b) characterizes different forms of bodily donation as forms of *intercorporeal sharing*, stressing their capacities of intensifying bonds between donors and receivers in sometimes unexpected ways. "Intercorporeal in the crucial double sense that [they involve] both a material confusion of bodies, a material indeterminacy and that [they make] a relationship – in this case, motherhood, fatherhood and kinship." (Waldby 2002b, 245). In the case of human milk biobanking, one can observe that these practices frequently generate symbolic bonds that surpass the mother-child dyad. Carroll indicates that milk donation "can stretch anonymously across vast geographic and spatial locales, and can even transcend the established kinship and community networks of the donor." (2015a, 177).

Our fieldwork also corroborates how human milk biobanking articulates emergent forms of surrogate, kin-like, relations, "hybrid kin" identities which are, in many cases, openly adopted by donors. Palmquist points out how non-profit donors in informal milk sharing webs are often referred to as "milk mothers", "milky mamas" or "sisters" (2015, 40) and Susan Falls starts her ethnography on milk sharing in the US by referring to the "milk siblings" her own son now has due to those practices (2017, xi). Our peer sharing interviewees employ this vocabulary of kin too: Laura refers to her friends' twins as her "milk sons". But kinship metaphors also appear in the public HMB, even explicitly – the book that donors receive as a gift from the bank at the end of their collaboration is titled *Hermanos de Leche* [*Milk brothers*] (Olza and Burgos 2011) [Image 1].

These symbolic forms of extended kinship, which bring together traditional and modern practices, can also be important for some technical protocols, becoming in itself performative of certain socio-technical ordering. We find a significant example of this in the 12 de Octubre NICU, where, unlike what happens in other milk banks and neonatology units worldwide (Cevese 2015), Muslim families are assured that the donated milk their children may receive comes only from mothers who are breastfeeding a child of the same sex, since traditional beliefs in some Muslim countries consider sexual intercourse between two adults that were "milk siblings" in the past to be incest. This protocol and the

heteronormative logic it implies are only possible because in the 12 de Octubre milk bank, in contrast to most milk banks in other countries, donated milk is not organized in pools of samples from different donors, but instead only samples from the same donor are pooled together. This procedure not only guarantees the highest degree of traceability, but it also allows for the samples to be distributed according to the specific characteristics and needs of the recipient babies.

Fig. 1 – Book *Hermanos de Leche* [*Milk brothers*] (Olza and Burgos 2011). Present offered by the 12 de Octubre HMB to donors at the end of the donation process (photograph courtesy of one of our informants).

Whereas other banks that pool together samples from different donors provide a more homogeneous and standarized product, at the 12 de Octubre bank the preservation of the different samples offered by different donors becomes a useful resource to provide personalized prescriptions. Personalization also returns back to the donor, stressing the bond between donor and recipients: in the diploma that 12 de Octubre HMB gives to donors, a mother can find the exact number of babies who have received milk from her [Image 2].

Fig. 2 – Final diploma given by the 12 de Octubre HMB to donors at the end of the donation process (photograph courtesy of one of our informants).

It is important to note, finally, that this "hybrid kinship" is not without its ambiguities and displacements. Whereas traditional practices of human milk-sharing were based on direct breastfeeding of other infant/s, in HMBs human milk becomes a bio-objectified product that has been processed, one that comes in bottles. The set of lively relationships embedded in breastfeeding, a clear form of intercorporeal sharing (Waldby 2002b), is highly transformed in these practices.[3] Yet human milk remains a deeply charged corporeal fluid, symbolically and culturally. And while in current forms of milk-sharing there is no longer a direct bodily contact, as the milk is bottled and processed, and offered to the baby most commonly by their own progenitors or health professionals, symbolic conceptions linked to human milk seem to travel with the very milk. Donated human milk becomes a caring device, that in some way transports with it the donor mother and caring mothering. This can sometimes be a troubling and disruptive situation for mothers of recipient babies, as they may feel that their own mothering capacities and their mother-child bond are put into question. As Carroll (2015b, 12) notes "despite consenting to donor milk and expressing gratitude, many NICU mothers experienced great affective ambivalence associated with it being a bodily tissue and one with such profound socio-cultural connotations of reproduction and kinship".

5. Microbiota, Pasteurization and Boundaries: The Bio-Objectification of Human Milk

Though human milk biobanking practices are full of hybrid zones, the bio-objectification of milk requires purification and clarification, reduction of indeterminacy, an erection of boundaries. The process of bio-objectification refers to the mechanisms through which indeterminate body materials are stabilized (Vermeulen et al. 2012; Stephens and Dimond 2015). Bio-objectification is a necessary process for biobanking, which requires the coordination of a diverse set of devices. Political, socio-cultural and economic mechanisms of exchange; protocols, patents, standards and analyses; sterilizing procedures, surgical masks and caps, breast pumps, freezer packs, labels. All of these configure and sustain a concrete sociotechnical ordering which is repeatedly activated in its multiple entanglements, disentanglements and re-entanglements (Callon 1998). All of them participate in the construction of a distinctive bio-object (Stephens and Dimond 2015).

One way of approaching the process of bio-objectification is considering the operations of distinction, classification and purification involved in it (Bowker and Star 1999). There are many instances where this boundary work happens, both at a rhetorical level – discourses, metaphors – and at a material level, where "matter out of place" (Douglas 1966) is directly manipulated in the physical sense. The combination of both operations/levels results in a peculiar socio-technical ordering (Law 1994). In this section we will focus on a particular aspect of the process of bio-objectification of breastmilk: different forms of manipulation of bacteria and microbiological organisms naturally present in expressed milk. Preventing contamination is something that cuts across all discourses and practices involving human milk donation, either formal or informal. Set across the "intersection between *breastmilk-as-medicine* and *breastmilk-as-pollutant*" (Palmquist 2015, 30), there is quite a different treatment of microbial and bacterial milk components in each of the three practices we are analyzing, which results in different bio-objects. Human milk is, thus, a fluid bio-object sustained by the entanglements of relations it is inscribed in. Entanglements where bacteria are considered "virtuous", and deserve preservation and cultivation, or "wicked", pathogenic and dangerous, and prone to be eradicated. Quality and safety processes and risk discourses surround bacteria manipulation in all practices of human milk biobanking (Carroll 2014).

5.1 Human Milk Bank at the 12 de Octubre Hospital: "exquisite hygiene"

As Elena mentioned several times in her interview, milk donation at the HMB requires "exquisite hygiene". The quality manager of the bank described to us in great detail the procedures donated milk goes through

> prior to being offered to babies at the NICU, which echo the rigour and attention to security Caroll (2014) describes in her ethnography of two US HMB – although procedures described there are different. After completing a questionnaire to identify lifestyle habits and a blood test, donors are given all the required materials and taught how to properly clean their hands. Before each extraction, donors have to sterilize the breast pump and bottle and be sure to keep them sterile during the whole process of expressing. Milk is expressed with the donor wearing a mouth and hair cover. Once extraction is complete, the bottle is closed, labelled and directly stored in the freezer. Every 15 days bottles have to be carried to the HMB in a cooler bag with a freezing pack to avoid defrosting. Once there, donated milk is added to the database and stored in the raw milk freezers while awaiting pasteurization. The 12 de Octubre HMB follows the Holder method for pasteurization. First, raw milk bottles are defrosted through a controlled process, by introducing them into a bath at 40º C until they are defrosted at 50 percent, and completing the defrost in a refrigerator to keep the human milk properties at their maximum potential. Later, the raw milk bottles are correctly labelled and set into the pasteurizator, where they are processed at 62.5 ºC. In the middle of the machine there is a bottle of cow milk with a probe connected by a wire to a thermometer set outside. This is a security mechanism to guarantee that the temperature is homogeneous inside the pasteurizer. After thirty minutes, the pasteurized milk bottles are placed in another pasteurizer with crushed ice so that their temperature reduces to 4ºC in three to four minutes. Then the bottles are stored in the pasteurized milk freezers. This is the Brazilian HMB pasteurization model, and it is quite cheap and very efficient – around 95% of donated milk is successfully pasteurized. Yet it is quite labour intensive, as it requires a laboratory technician to control the whole process. After that, the milk is analysed so as to eliminate any contamination and sorted for NICU babies' consumption, matching the specific characteristics of the human milk samples with those of the recipients. (Notes taken from the first visit to the HMB in May 2017 and transcribed by the authors) [Images 3 and 4].

Exquisite hygiene, rigorous protocols and quality procedures with severe security controls eliminate all contamination risk and pathogenic bacteria (Carroll 2014). Banked human milk is a pasteurized and aseptic fluid, closer to a therapeutic device (Cevese 2015, 103) than to food. Yet this purification process does not come without its shadows, as the milk bank coordinator points out:

> Also, there is another big gap and that is that donated milk is never as good as milk from the mother herself, because it is processed. Pasteurization offers security, but it also entails some unwanted side effects: it eliminates pathogenic bacteria, but it also kills the intestinal flora that would colonize the newborn's intestine. And there is increasing scientific evidence on the importance of gut flora. In fact, we now provide probiotics to very low weight birth babies. [...] We are giving them Infloran©. It has two strains of lactobacilli [*Lactobacillus acidophilus, Lactobacillus biphidus*].

Fig. 3 – Donated human milk bottles at the pasteurizer following the Holder pasteurization protocol at 12 de Octubre HMB (photographed by the authors).

Fig. 4 – Storage and traceability of donated human milk samples at 12 de Octubre HMB (photographed by the authors).

Pasteurized "donated milk" appears in this discourse as a different bio-object than "milk from the mother herself". Another difference is constructed between "pathogenic bacteria" and "gut flora". Bio-objectification, here, takes place at a material as well as rhetorical level. The terms employed have connotations and motivate actions: we have to eliminate "pathogenic bacteria" but preserve or restore "gut flora". We have to promote breastfeeding from the mother herself, yet we provide pasteurized donors' milk in certain situations. 'Breastfeeding' becomes a contested term in and of itself. Does it refer to milk *originating in* the breast or directly *fed from* the breast? (Rasmussen et al. 2017). Most mothers at the NICU do not feed their babies with their breast, yet they often provide expressed breast milk in different quantities. Words are not elements separated from a given socio-technical ordering but rather an important aspect of it. Definitions and terminology are repeatedly used to reinforce boundaries between different types of biobanking. The HMB coordinator consistently referred to practices of informal human milk donation as "uncontrolled donations". The term places at the forefront the opposition between the rigour and control of HMB laboratory-pasteurized milk and the potential "risk" of raw milk shared informally, to which we now turn.

5.2 Informal Human Milk Sharing: Extending Symbiotic Relations

Issues of potential risks and potential benefits stretch in informal human milk sharing practices. In Laura's account, risks are equated with an indeterminate potential external contamination and not with the "raw" milk in itself, given that she keeps "good habits". Safety practices in this case emulate the HMB ones related to milk expressing, yet the level of detailed protocols and "exquisite higiene" mentioned by Elena is never reached. As Mary Douglas (1966) showed, pollution, contamination and risk are anthropologically related to what is considered "matter out place". Here, risk is contained by keeping expressed milk "in place": caring attention is given to the expressed milk and a significant effort is made to keep the "cold-chain". But there is also an aspect of everyday familiarity to this process that places it closer to other expressing practices by lactating mothers than to those of donors doing it for the HMB.

While they accepted Laura and her friends' decision to share milk informally, the hospital staff did also stress the risks involved for Laura and her friends. The milk would be raw and no pasteurization or analysis of the milk was going to be performed, so a certain threshold of uncertainty would remain. Discussing potential risks in milk sharing practices in the US, Palmquist (2015, 37-38) contrasts the ways risk is controlled in HMBs through informed consent, as opposed to what she identifies as "informed choice" in informal sharing.

Fig. 5 – Frozen human milk samples stored in a household refrigerator along with other frozen food supplies (photograph courtesy of one of our informants).

Boundary work is constructed here both rhetorically and materially. In the relationship between informal donors and recipients, unlike the detached safety of tested and pasteurized milk, trust and personal bonds emerge as relational sources of security. This has a material consequence: sharing goes beyond "human" milk, as human milk is never quite only "human": all the mammary microbiota of the donor's milk is shared as well. Palmquist (2015, 43) suggests that, in informal milk sharing, identities of donor and receiver are in a sense symbiotic. We can consider milk sharing as extending symbiotic relations beyond the human scale to engulf the microbiotic one: flora gut colonization in receivers' babies' may have the imprint of the donor, as each person develops a unique microbiota (Cacho et al. 2017). Extended forms of hybrid-kin and inter-corporeality open possible speculative futures here (Haraway 2016; Waldby 2002b).

5.3 Human Milk as a Source for Cultivating Bacteria

While human milk in HMBs is pasteurized, and in sharing practices it is kept raw, containing both the promise and risk of the ambivalent presence of uncontrolled gut flora, in the production of a probiotic nutritional supplement such as *Lactanza Hereditum*, raw human milk becomes a source for the cultivation of bacteria. This bio-objectification process depends on a different understanding of what human milk is "in

and of itself", an understanding which is based on the natural development of the human mammary microbiota. According to Bergmann et al. (2014, 1121), bacteria appear in the milk ducts during the last three months of pregnancy, with the concentration of bacteria reaching "a maximum during peripartum and then slowly decreases during the nursing period. During the weaning period, there is a sharp decrease in bacterial counts". Human breast milk is, thus, a live tissue inhabited by various strains of bacterial colonies that vary in quantity and composition throughout the breastfeeding process. Changes in this composition can imply an excessive proliferation that may become pathogenic or facilitate the incursion of pathogenic strains. The most common problems related to bacterial proliferation at the breasts are mastitis and obstructed ducts. We could argue that there is certain bacterial choreography, a certain dance in the human microbiota that promotes unstable equilibriums both in the mother's lactating body and in the breastfeeding baby, a relation very often referred to as symbiotic.

The production of the probiotic nutritional supplements based on the patent of Lactobacillus fermentum LC40 (CECT5716) and Lactobacillus salivarius (CECT5713) not only required donated human milk for the isolation of potentially beneficial strains. It also depended on more donated human milk, this time from the lactating mothers with mastitis who participated in the clinical trial and in several studies on the different responses of mastitis to antibiotic treatments and probiotics (Arroyo et. al., 2010; Marin et.al, 2017). Yet procedures to collect human milk samples for research and microbiota analysis entail a completely different procedure to the one proposed at the HMB. Arroyo et.al (2011) describe this procedure in detail, that was experienced by Carmen and described in her own autoethnographic notes[4]. Collection should take place two hours, at the earliest, after the last breastfeeding of the baby. Neither creams nor silicone nipple shields should be used, and if they are, the nipple and areola should be washed. Hands should be carefully washed as milk will be expressed manually, without the use of a breast-pump or associated device. Expressed milk should be collected in an aseptic container and handed in to the lab less than one hour later, at room temperature, or between one to twelve hours later if refrigerated. These samples are then cultivated in Baird-Parker Agar laboratory inverted plates and incubated at 35º to 37ºC in an aerobic atmosphere. Plate readings are performed at 24 and 48 hours (Arroyo et al. 2011). Human milk as bio-object is radically different in this procedure. Far from being an aseptic tissue, it becomes a sort of "primordial soup", involved in the production of magmatic and effervescent bacterial lives. Through the manipulation and ingestion of probiotic nutritional supplements, control over bacterial strain communities is expected, and therefore relief from breastfeeding illness and pains due to mastitis or obstructed ducts. Furthermore, the most recent research developed by the Complutense team and also by Biosearch Life is directed towards the use of probiotic nutritional supplements for

baby feed with formula to promote their own gut flora and to prevent infant colics (Bergmann et al. 2017).

5. Conclusions: Virtuous and Wicked Bacteria at Dance

Throughout the paper, we have surveyed the complexity surrounding human milk banking practices in Madrid. We started with the recognition that hospital milk banks are not the only form of biobanking, but that other practices, notably informal milk sharing and the manufacturing of certain probiotics, also involve forms of human milk banking. We then, proceeded to show the various hybrid zones between these three sets of practices, as can be analysed in donors' accounts, but also in institutional arrangements, heterogeneous care assemblages and symbolic constructions of "hybrid kin". The final section of the paper presented the forms of purification and technical manipulation of donated milk at play in each of the settings. If "purity" may at first seem to be more important in institutional biobanking practices and less so in other forms of milk sharing, our analysis suggests, on the contrary, that ideals of "purity" and "contamination" are present in every setting. That is to say, none of the assemblages can be thought without norms and boundaries that configure what are purity and pollution in each case. The 12 de Octubre Human Milk Bank purification process seeks to eliminate all potentially dangerous bacteria through "exquisite hygiene" requirements, and extremely rigorous processes of pasteurization, manipulation and traceability. At the lab, bacterial grown is favoured – yet only of those strains inhabiting the breasts – , both when producing probiotics or when analyzing human milk during mastitis. In informal human milk sharing, purity includes mutual trust, linking it to other "everyday" strategies for avoiding bacterial pollution. The different ways of manipulating bacteria and microbiota, thus, result in distinct processes of bio-objectification and generate different versions of human milk.

We could argue that what distinguishes and what unites these three forms of biobanking are bacteria manipulation, definition and treatment. Different processes of purification and bio-objectivization gain shape in concrete assemblages of bacteria colonies and human milk. Bacteria work as a boundary object that circulates and is diversely enacted in different social worlds, such as bio-banks, homes, labs, drug delivery plants, tissue collections, mothering networks, commercialized bio-materials, and in objects such as breast-pump devices, frozen human milk cristal bottles, containers, pasteurizers, samples, syringes. But mothering imperatives to care, construction of trust, emotional identifications, vulnerability, pain and joy are also involved. Far from being detached elements, all of these assemble and reassemble in concrete and recurrent doings, with bacteria running through them all, hybridizing yet differentiating the three sets of

bio-objectification processes. Depending on the particular definition and treatment it receives, microbiota can shift from being wicked and a dangerous pollutant to virtuous and potentially healing.

The practices of human milk donation and biobanking we have analysed here all entail forms of intercorporeal sharing (Waldby 2002b), intensifying bonds and creating ties of care and affect even when donors and receivers are unknown to each other. Those bonds and affects articulate some forms of "hybrid kin". Forms of kinship that sometimes take place symbolically, as with the book offered as a gift to HMB donors at the end of their donation. Other times they are articulated as caring assemblages, as in the case of Laura with her friends and their twins, where she extended her maternal role to others beyond her own children. And other times they manifest in deeply intercorporeal ways, yet overflowing the limits of the human, as in studies on the benefits of probiotics and mammary microbiota. This last aspect is perhaps the most promising one when thinking hybridity and kinship at once. Recent studies on personalization of donor breast milk with the live microbiota of the biological mother's own milk seek to extend the immunological properties of maternal breast milk microbiota to pasteurized donated human milk (Cacho et al. 2017). Yet, in doing so, they work to preserve the mother-child bond besides the donor milk consumption. We could understand, somehow, the inheritance of the mother microbiota as a biological extension of the self beyond the self. This same inheritance happens in informal milk sharing, as milk circulates raw: therefore, the microbiota of the donor mother can colonize the bowel of the baby who receives it. If the latest estimates of microbiota in humans bodies suggest that bacteria cells are as least as abundant as human cells in our bodies (Gilbert et al. 2018; Sender, Fuchs and Milo 2016), circulation and colonization of microbiota imply extended forms of intercorporality and bonds: bacteria sharing in itself configures certain forms of "hybrid kinship". Those ideas, and other recent research such as the Human Microbiome Project, lead us to reconsider limits and boundaries between individuals of different species, in a move closer to Haraway's reading of Lynn Margulis' holobiont figures (Haraway 2016). Bacteria become symbiotic entities, undetachable of ourselves, questioning even the very idea of "self".

These ideas may remain highly speculative, but what our study clearly shows is that, despite it sometimes being treated as sacred or valued, as "white gold" (Falls 2017) or "liquid gold" (Carroll 2014), human milk is never a "pure" and aseptic fluid, but instead a deeply hybrid and enmeshed one. A lively substance that not only changes according to the baby's needs or the mother's physiology, but also one that cannot be understood without addressing the colonies of bacterial life dwelling within it. Understanding the complexities of the circulation and biobanking of human milk requires that we pay special attention to the possible and impossible crossings of microbiota, and to how they draw boundaries and reshape human milk as a specific bio-object. In those crossings and circulations, in their

boundaries and regulations, a whole set of assemblages beyond the technical are re-enacted: identities, kinship ties, solidarity ties, and public and private arrangements. But also, in quite uncertain ways, the boundaries between the human and the non-human.

If we put hybridity and complexity at the forefront when studying biobanking, as we have tried to do throughout the article, a final question could be: how can we account for this "intimacy with strangers" (Haraway 2016, 60)?

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[1] Fictional name – all fragments of interviews have been anonymized.

[2] We would like to thank an anonymous reviewer for this clarification.

[3] We would like to thank the editors of the special issue, Lorenzo Beltrame and Christine Hauskeller, for their suggestion of developing this idea.

[4] Notes were taken in February 2014 after an acute mastitis when Carmen got in contact with Probisearch SL, a spin-off of the Complutense research group directed by Juan Miguel Rodriguez, to get her mammalian microbiota analyzed. She got to know about the group through the midwife in her public health local

centre. The midwife gave her Juan Miguel Rodríguez's email and introduced him as "the veterinarian of mastitis", telling her to get in contact with him as he offered women with mastitis probiotics to hail the infection. Two of the women we later interviewed also had this experience of accessing probiotics informally previous to its commercial distribution.

Contours and Constraints of an Autism Genetic Database

Scientific, Social and Digital Species of Biovalue

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Abstract: This paper examines the *scientific*, *social* and *digital* processes that shape multiple forms of biovalue evident in the development, participation and use of the Simons Simplex Collection (SSC), the largest autism genetic databases in North America. Based on interviews with SSC study participants and investigators, as well as a content analysis of a range of SSC materials, this empirical study makes visible the various contours of biovalue that are entangled between scientists who use this data for autism research, families who donate their blood and medical information to gain access to needed resources, and digital networks of exchange that make hybrid connections between and among these emergent biosocial communities. By examining the production of and interactions between scientific, social and digital forms of biovalue this paper highlights the constraints embedded within this heterogeneous assemblage to offer a critical account of the limits of the SSC and subsequent knowledge production. I contend that while the multi-dimensionality of biovalue built into the fabric of the SSC structure creates various contours of biovalue, it structurally constrains the types of production and knowledge flows that are allowed to be conceived and generated.

Keywords: autism; genetic database; biovalue; biosociality; digital networks.

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> The power of the Simons Simplex Collection (SSC) to clarify the genetic basis of autism spectrum disorder has been made abundantly clear over the last two years…landmark findings are a testament to the creativity of the researchers, as well as to the inspiring commitment of the more than 2,600 families who took part in the SSC.
>
> (Senior scientist at Simons Foundation Autism Research Institute)

> My family entered the study and it felt like we were part of a community working towards healing. Then we were given the opportunity to join the Interactive Autism Network. We thought it would be wonderful to join so that we could be part of a larger community dedicated to connecting parents as well.
>
> (Parent who participated in the Simons Simplex Collection)

1. Introduction

The development, participation and use of disease specific genetic databases in the 21st century is producing selective forms of value embedded in collected samples and creating distinctive relationships and exchanges among and between scientists and research participants. As indicated in the opening epigraphs, data collected for the Simons Simplex Collection (SSC), an autism genetic database, holds exceptional value for scientists of current and future research on autism genetics. At the same time, on-going participation through digital networks creates a distinct community among those who donate blood and medical information for specific genetic research endeavours like the SSC. The emergence of these processes and relationships is due in part to the changing dynamics of the collection, participation and use of genetic information for scientific research on complex human conditions. For scientists, we are seeing a shift from individual investigators collecting data to conduct their own research to collaborative research consortiums working together to develop genetic databases and large multi-sited scientific research networks. For research participants, the donation of blood and medical information may not be a one-time affair, but rather consist of on-going participation and an opportunity to be part of a larger community. Within this context, distinct configurations of participation and research are emerging in genomic science that are shaping various forms of biovalue. The purpose of this paper is to empirically investigate the contours and constraints of biovalue situated within these emergent scientific and biosocial processes.

2. Species of Biovalue and Emergent Biosocialities

Science, Technology and Society (STS) scholars have engaged with both the economic and biosocial exchanges and assemblages involved in the development, participation and use of national biobanks (Tutton and Corrigan 2004; Peterson 2005; Busby 2006; Tutton 2007; Hoeyer 2008) and disease specific genetic databases (Novas 2006; Haddow et al. 2007; Callon and Rabeharisoa 2008; Dixon-Woods, et al. 2008). Ideas about the relationship between the life sciences and capitalization have been articulated within STS through concepts such as "bioeconomics" (Rose 2001) and "biocapital" (Sunder Rajan 2006), and "life as surplus" (Cooper

2008). Catherine Waldby (2002) developed the concept of biovalue, or what she describes as in-vitro vitality produced by the biotechnical reformulation of living processes. More specifically, tissue economies of blood, organs, and cell lines in neoliberal capitalism alongside emergent biotechnologies have enabled donated tissues to take on multiple uses and adopt multiple trajectories (Waldby and Mitchell 2006). In this process, tissue donations are transformed from an act of direct civic responsibility between fellow citizens (e.g., voluntary blood donation) into a complex network of donor-recipient relations heavily mediated by biotechnical processes and a range of institutional complexes. In such instances, we learn how tissues are open to the micro-technical manipulation of productivity and in genomics research, an opportunity for "new circuits of bioproductivity" that can be "mined" indefinitely to contribute simultaneously to public and private value in the present and in the future (Mitchell and Waldby, 2010, 340).

To better understand STS contributions examining the relationship between the life sciences and capitalism Stefan Helmreich (2012) conducted a genealogical analysis of scholarship on biocapital. He identified two theoretical strands, including 1) Marxist feminist approaches, which occupy questions of the binary between productive labour (labour that has monetary value) and reproductive labour (labour that is not associated with a wage) and 2) Marxist Weberian approaches that focus on questions of meaning, information management, and speculation. In the latter, "value in the market sense and value in the ethical sense co-constitute one another in biocapital" (Helmreich 2012, 465). Both of these clusters engage with Marx's political economy and Foucault's biopolitics, since they both consider the integrative analysis of economy, society, and politics (e.g., Marx), as well as mechanisms through which life processes are controlled under systems of authority over knowledge, power, and the processes of subjectivism (e.g., Foucault). In the advent of emergent biotechnological innovations, like genomic science, Helmreich identifies new kinds of financial speculation, academic-industrial biotech hybrids, and the new relations of commoditization embedded in notions of biocapital. Importantly, for the purposes of this paper, Helmreich's genealogical representation of biocapital offers 'different species' of making biology into capital, which he describes as an unstable process consisting of exchanges that correspond to "economic, cultural, social, and symbolic species of capital" (Helmreich, 2012, 474). I interpret Helmreich's genealogy to suggest that classifications of biocapital can take different formulations of (as well as move beyond) financial exchanges thereby opening up the multi-dimensionality of various forms of negotiated systems of value exchange.

More recently, concrete examples of the hybridity and multiplicity of biovalue has emerged based on research of data-intensive infrastructures, including biobanks (Hauskeller and Beltrame 2016; Tempini 2017; Timmons and Vezyridis 2017;) Christine Hauskeller and Lorenzo Beltrame

investigated public and private umbilical cord blood (UCB) biobanking practices and the circuits of UCB biovalue. They found that rather than a dichotomous private-public distinction of economies (e.g., solidarity versus profit), there is an overlap and hybridization between distributive and market economy of UCB. Through different scenarios of UCB donation, they identified analytical distinctions between social, cultural, and biopolitical implications within different regimes of UCB banking–distinctions ranging from life-saving tissue to promissory objects for future use. They contend that these complex bioeconomies coexist and hybridize into exchange systems that do not operate within dichotomous distinctions between public and private (Hauskeller and Beltrame, 2016). Niccolò Tempini (2017) also engages with the multi-dimensionality and hybridity of value by investigating the creation of value in an online community and data-intensive infrastructure called *PatientsLikeMe* (PLM), a social media network for patients. In this example, Tempini identifies four dimensions of value in PLM that depend on the situation of digital data use and circulation, including business, scientific, community, and individual values. For example, scientific value is generated when the data on PLM provides good evidence for conducting health research (e.g., peer review publications). Community value, on the other hand, is generated when the data on PLM can be used to foster social interaction and inclusive communities (Tempini, 2017, 196). Like Hauskeller and Lorenzo, Tempini also recognizes these different values as both multidimensional and situated, where "different kinds of value creation require different sets of engagements with data" (2017, 207). Collectively, these examples offer insightful distinctions about the production, multi-dimensionality, and hybrid contours of biovalue that are developing at the intersection of large data collections involving a heterogeneous assemblage of many actors and materials.

The ideas of 'different species', multi-dimensionality and situated shaping of values in relation to and beyond the early notions of biocapital and biovalue offer insight to the current analysis of actors and biomaterials circulating within the Simons Simplex Collection (SSC). This framing opens the opportunity to investigate the heterogeneity and interconnected biovalues embedded in scientific, social and digital networks of exchange. It is through the development, production and use of these different species of value that we begin to see how biovalue, can be more than the production of commodities that creates financial value; it also entails "the embodiment of intellectual, relational, and emotional resources and capacities" (Birch and Tyfield 2013, 314). As I make evident in the pages that follow, not only do the social and ethical values enable the production and exploitation of scientific and/or economic biovalue in the SSC, these different situated values are also interconnected and co-constitutive of each other. By unpacking the dynamics of these multi-dimensional contours of biovalue, this study offers a nuanced empirical example of the reciprocal and hybrid expressions of biovalue generated

within a heterogeneous assemblage of people, data, and digital networks of exchange. This case study also makes visible the knowledge and biosocial constraints built into the SSC due to the strict criteria for inclusion and the preconceived genetic hypothesis driving the development of this autism genetic database.

Alongside these new circuits of bioproductivity is the emergence of new social relations and collectivities; or what Paul Rabinow (1992) refers to as biosociality. These new forms of social relations are emerging based on people's shared biological identities related to particular bodily conditions such as genetic diseases or illness identities (Rabinow 1992). Social connectedness through corporeal or genetic linkages is especially evident in groups that come together to share experiences or advocate for particular diseases. Paul Rabinow and Nicolas Rose describe this phenomenon as "strategies for intervention upon collective existence in the name of life and health," which are now being specified in terms of emergent biosocial collectivities based on specific genetic diseases (Rabinow and Rose 2006, 197). Chloe Silverman draws on the collectivizing elements of biosociality in autism genetics research based on parent activism in autism science. She argues that parent advocates who speak for people with autism are "legitimated by multiple affinities built on genetic associations and physiological parenthood" (Silverman 2008, 39-40). Silverman argues that genetics establishes a language of affinity and kinship, which serves as a basis for forming biosocial communities.

In the context of donating biomaterials to disease specific biobanks or genetics research that collects large numbers of samples based on a particular disease, there are various ways people come to participate and the types of social connectedness that prevails (Dixon-Woods, et al. 2008; Michie et al. 2011; Singh 2015). For example, families who donated to a cancer tissue bank viewed their participation as a way to become embedded within disease-specific communities; forming "cooperative hybrids" with scientists that rely on "trust, solidarity, shared values" (Dixon-Woods 2008, 76). I also investigate biosociality at the community level based on participation in an autism genetic database, where families of a child with autism felt obligated to participate to help their family and become more involved in the autism scientific community (Singh 2015). The families also conveyed a sense of altruism to participate in order to help the broader autism community. Both of these narratives of participation were tied to the shared emotional experiences of raising a child with autism. As these studies convey, biosociality takes on many different contours that can be shaped by genetics research itself through the language of affinity and kinship, the desire to be part of disease communities, and the shared corporeal vulnerability and somatic suffering.

In the case of SSC, biosociality takes on new contours that manifest through the act of donating blood and medical information to an autism genetic database in combination with continued participation and virtual connectivity with other SSC families. These families are brought together

based on their shared experiences of having only one child diagnosed with autism and biosociality is sustained through digital networks that keep SSC families engaged in a unique autism genetic community. However, I argue that these forms of biosociality are constituted based on the assumptions built into the SSC, which was designed to bring specific groups of people together in order to test a unique genomic hypothesis. Even though virtual modes of interaction were developed to bring together SSC families, these collectives are strictly defined based on the priorities deemed most useful for scientists who conduct genetics research on autism. Thus, the ideas of autism genetic causation and the biomedical classification of autism shape the kinds of biosocial configurations that coalesce around the SSC. I contend that while these biosocial communities are beneficial to the families who participate, they are limited to those families who meet the strict inclusion criteria for SSC, as well as those who choose to remain in contact with the SSC through digital networks of exchange.

Within the contours of biovalue and biosociality discussed above, the aim of this paper is to empirically investigate the multi-dimensionality of biovalue entangled within the production, participation and use of the SSC and how these different forms of biovalue are interwoven and mutually constitutive of each other. As I make evident throughout the paper, these different contours of biovalue and biosocial communities that take shape within the SSC are based on a particular kind of family and specific characteristics of autism, which I assert creates new forms of collective identity and technoscientific exchanges and futures for scientists and research participants alike. At the same time, I argue that these emergent research assemblages build constraints on the kinds of knowledge generated and possibilities for further research on autism.

This paper offers several distinctive contributions that set it apart from other STS analyses of genetic databases in the context of biovalue and biosociality. First, the SSC is a autism specific database, not a population database. Compared to national gene banks that collect biomaterials and clinical information from the general population, the kinds of biovalue generated by families who participate in the SSC holds a different set of meanings given their embodied experiences with autism. Second, the SSC is derived from a very selective group of families who have one child diagnosed with autism (e.g., simplex families), which was specifically designed to identify spontaneously acquired genetic mutations that scientists believe are the cause of some forms of autism. The clinical characterization of the child with autism and their family also had to meet certain criteria for inclusion; strict criteria that holds particular value for scientists. Thus, the specific genetic mechanism, family structure and strict inclusion criteria creates an opportunity to critically analyse the kinds of knowledge production, biosociality, and data flows that are produced and constrained within these scientific boundaries. Third, this study investigates multiple actors involved in the funding (Simons Foun-

dation), development (study coordinators), participation (families) and use (scientists) of the SSC, as well as digital platforms that are uniquely designed to sustain the relationship among these hybrid collectives. This heterogeneous assemblage allows me to investigate the relationship between the SSC and multiple actors, the controversial processes in the development and use of this collection (Canada et al. 2014) and the different forms of clinical labour (Mitchell and Waldby 2010) needed to maintain persistent links between scientists, participants, biospecimans and data in all their multiple forms.

3. Methodology

To investigate the social, scientific, and digital forms of biovalue embedded in the development, participation, and on-going use of the SSC, this paper draws on various sources of primary data, including: in-depth interviews with parents who participated in the SSC (N=23 SSC families) and researchers who were involved in the SSC data collection (N=9). I conducted the interviews between 2008 – 2013, which were recorded, transcribed and coded for central themes using grounded theory methods, including open and focused coding, theoretical memo writing, and generation of themes (Charmaz 2006). This study received IRB approval to conduct interviews from Georgia Institute of Technology, protocol H12077.

A second set of data consists of a content analysis of 78 scientific articles that have used the SSC database as a primary resource. These articles were analyzed to determine the type of scientific knowledge being produced using the SSC. Scientific articles were identified by conducting a literature search in three databases in September 2017 using the search term "Simons Simplex," including PubMed (all fields), Web of Science Core Collection (title/keyword/abstract), and PsycINFO (all text). I also added scientific articles featured on the Simons Simplex Community@IAN (Interactive Autism Network) and the Simons Foundation Autism Research Institute (SFARI) websites, to account for any articles not identified through the database searches. I collected the scientific articles in Endnote referencing software and coded for type of autism research conducted (e.g., genetic causation, environmental causation and/or, symptom measurement – phenotype).

A third set of data is a selective content analysis of two websites. The first is the SSC Community@IAN website, which displays public information and serves as a digital network of 1,500 SSC families who want to remain in contact with SSC investigators and other SSC families. I determined the type of SSC-based research reported to families through this digital exchange compared to the scientific literature identified above. The second is the Simons Foundation Autism Research Initiative (SFARI) website, which is the web portal of information about SSC that offers in-

formation to researchers on how to order SSC samples and/or recruit SSC families using the SSC Community@IAN. These two websites were analyzed to establish the types of on-going transactions between and among parents and scientists who are involved with the SSC.

Collectively, this data makes visible the types of scientific, social, and virtual relations, forms of knowledge exchanges, and biovalue that are emerging in the flows of scientific development and use of the largest genetic database designed to investigate specific genetic mechanisms associated with autism.

4. A "Cadillac Resource" for Autism Genetic Research

The Simons Simplex Collection (SSC) was funded by the Simons Foundation, a private non-profit philanthropy founded in 1994 by billionaire Jim Simons and his wife Marilyn. Jim Simons is a MIT trained mathematician and founder of one of the world's most successful Wall Street Hedge funds. Marilyn Simons is an economist and currently president of the Simons Foundation and board member at the Cold Spring Harbor Laboratory, a research facility specializing in molecular biology and genetics. Initially, the Simons Foundation focused their philanthropy by donating tens of millions of dollars to math and science endeavors worldwide. In 2003, the Simons Foundation formalized their investments in autism research by starting the Simons Foundation Autism Research Initiative (SFARI). SFARI's goal was to increase the scientific understanding of autism spectrum disorders in order to benefit individuals and families challenged by these disorders. The foundation would focus on developing tools that scientists could use to enhance their understanding of autism.

One of the first major projects launched by SFARI was the Simons Simplex Collection (SSC). In 2006, the goals of the SSC were set by SFARI to recruit and carefully evaluate DNA and clinical information of more than 2000 autism families from twelve university research clinics throughout the United States and Canada (SFARI nd-a). At the request and advisement of scientists working in the field of autism genetics, the SSC would be different from other autism genetic collections[1].

First, the SSC was starting from the ground up, what Mitchell (2012) refers to as a de novo approach, where the standardization of biospecimen and clinical information is collected and stored in one uniform manner. As I will discuss in more detail below, the SSC was designed to identify certain types of genetic mutations, which required a certain kind of family structure as well as detailed clinical measurements of autism. The SSC was also designed to recruit and collect data in academic based clinics already serving children with autism and their families. It was presumed that this would not only allow scientists to easily recruit families to

participate in the SSC but also enable allow scientists to effortlessly re-contact families for follow-up studies. The design and scope of the project would not only make the SSC one of the largest autism genetic databases available to scientists and provide a unique genetic collection with associated data consisting of detailed and precise characterization of the individual with autism and their family. As they saw it, "rigorous phenotyping maximizes the value of the resource for a wide variety of future research projects on the causes and mechanisms of autism" (SFARI nd-a). Consequently, scientists refer to the SSC as the "Cadillac resource" for conducting autism genetics research; a metaphor or scientific practice of branding (Tupasela 2016) that identifies how a large database of clinically and genetically precise data is superior to previous autism genetic collections. This type of branding has significant symbolic and strategic value, since the scientific and potential financial gains through diagnostic and treatment developments will be accrued further downstream (Tupasela 2016).

From the beginning of the project, the SSC took a venture capitalist approach to establish a resource that would be of significant value to science. I characterize the SSC in this way because when data collection started in 2008, genetics research on autism had limited successes in finding major genes associated with autism. The SSC was developed based on scientific data that suggested rare spontaneous genetic mutations were involved in a small number of autism cases. The SSC was specifically designed to test this hypothesis with no guarantee that this genetic mechanism would reveal clues to the causes of autism. At the time, it was one of the only leads autism genetic scientists had after millions of dollars of private and public investments had been made in autism genetics research (Singh 2016). Strategically, the Simons Foundation made investments in scientists who were not necessarily studying autism, but who were leaders in a particular scientific field. As one autism genetic scientist involved in the collection stated:

> Some of the best researchers, not in autism, but some of the best neural scientists and functional biologists and geneticists and such…came to the table simply by virtue of money. (SSC scientist interview #1)

Thus, in autism science, as with certain types of financial data, the Simons Foundation made calculated investments based on past performance, which according to Jim Simons is the "best predictor of success" (Regalado 2005). No private philanthropy has made the kinds of financial investments toward autism research as the Simons Foundation, which currently has a budget of $75 million dollars a year and since 2007 has "provided or committed $380 million in external research support to more than 400 investigators in the U.S. and abroad" (SFARI nd-b). A major part of this investments was the development of the SSC. The collection of data for the SSC was completed in 2011 by twelve collection sites

in the U.S. and Canada that acquired samples from 2,644 simplex families, making it one of the largest autism specific databases in the world.

5. Contours and Constraints of Biovalue

There are many species of biovalue shaped through the processes of developing the SSC and the type of data available for subsequent use. I identified three multi-dimensional contours of biovalue situated within the interconnections between scientific, social and digital networks of exchange consisting of various forms of biomaterials, data, and knowledge production. While these contours are not mutually exclusive, this framework helps to highlight the various domains of biovalue embedded in the development and use of the SSC for the scientists who use the data, the families who participate in the database, and the hybrid collectives they form through digital networks of exchange. Further, these different contours help to distinguish the constraints and consequences of knowledge production and flows that are bounded within the selective criteria used to develop the database.

5.1 Scientific Biovalue: Family Structure, Clinical Precision and Biomaterials

Scientific biovalue was structured into the SSC from the beginning in order to test the hypothesis that rare *de novo* (spontaneous) copy number variants (CNVs) are present at a higher rate in children with autism than in unaffected children (CNVs are small genetic deletions or duplications in the genome) (Singh, 2016). Given this genomic style of thought, the SSC is comprised of DNA and clinical information from families with only one child diagnosed with an autism spectrum disorder (ASD), both biological parents, and one unaffected sibling (i.e., simplex families)[2]. Based on this research design, scientists are working under the assumption that rare *de novo* CNVs account for a significant fraction of autism with unknown causes and in order to find these genetic mutations, thousands of simplex families are needed. Thus, the simplex family structure holds particular value for autism genetic scientists who are in pursuit of identifying and understanding the relationship between autism and CNVs. As I discuss elsewhere (Singh 2016), this emergent technoscientific approach offered scientists a path forward in what was essentially a failed attempt by the scientific community to find any major genes for autism despite large investments of time, people, and money.

The SSC also placed significant attention to collecting precise clinical data of the families who participated. Before the SSC was developed, a major challenge for scientists using other collections of autism genetic samples was the lack of consistent and reliable collection of clinical data[3].

Further, the heterogeneity of autism symptoms and lack of clear and distinct clinical phenotypes (traits) makes research on autism genetics challenging. Thus, the SSC sought to collect detailed, valid, and reliable clinical data so that scientists could make meaningful genetic correlations to autism phenotypes. To achieve this level of integrity in the clinical data, the SSC evaluated the autistic child with a battery of diagnostic measures and standardized instruments. SSC clinicians were also trained by a set of expert clinical psychologists and each diagnostic evaluation was validated every quarter. This rigorous approach to measure autism symptoms was taken to ensure that each SSC site was uniformly collecting the clinical data. As indicated below, this level of detail also served in the interest of parents who were seeking an autism evaluation and services for their child. In the end, approximately 6,000 phenotype variables were collected from each family (SFARI nd-a).

The challenges of accomplishing the ambitious goals of the SSC were evident from researchers and coordinators involved in the initial stages of recruiting families and collecting data. Although the rigor and uniformity of the data in the SSC sets it apart from other autism genetic databases, establishing this type data was challenging for SSC collection sites. In 2008, when I was first inquiring about the project, one SSC coordinator expressed to me how many of the investigators were dismayed and frustrated by the 'corporate' or 'business-like' structure of the project. Researchers working at these collection sites did not feel comfortable with the strict inclusion criteria and felt some families were getting overlooked that may be of importance to the collection. Any resistance to the strict inclusion criteria had consequences. I learned that one clinical research site was dropped and no longer funded by the Simons Foundation because of conflicts over diagnostic procedures and whether a child met the inclusion criteria. One coordinator compared the SSC recruitment process to a pharmaceutical clinical trial rather than a clinical research study on autism, since clinical trials typically require strict guidelines for inclusion in order to show very small clinical significance of drug effectiveness. In this sense, the construction of the SSC was developed with strict inclusion criteria to identify specific and rare genetic pathways of autism, which could subsequently be therapeutic targets or at the very least reveal "clues that could lead to important breakthroughs" (SSC recruitment flyer, 2010).

It was also evident from interviewing researchers involved in collecting data for SSC that creating the collection was a major investment in time and money. On average, it took at least two months to recruit and evaluate the families, which made the strict exclusion criteria a point of concern, especially when each group was held accountable to meet their quota of 20-25 families each quarter. These efforts reflect a different type of clinical labour (Mitchell and Waldby 2010) that extends beyond participation in genetics research to include the time intensive and stressful processes experienced by study personal who were required to work un-

der strict guidelines and timeframes to meet research obligations.

In addition to the simplex family structure and detailed clinical characterization of the sample, the range of biological materials available to researchers offers extensive possibilities for scientific investigation and hence, biovalue. According to the SFARI website there is a variety of SSC biological materials for sale that scientists can purchase and use for their research, including DNA, plasma (a liquid form of blood), and lymphoblastoid cell lines (cell lines that live indefinitely). The technoscientific transformation of all SSC blood samples into lymphoblastoid cell lines is deemed extremely valuable for science because these immortalized cell lines offer a renewable supply of DNA for future genetic studies. The most recent biospeciman created are induced Pluripotent Stem Cells (iPSCs), which are cells derived from SSC blood samples that have "essential properties" of embryonic stem cells. According to the SFARI website, these iPSC cell lines can develop into brain cells and have become, "a valuable model in autism research, complementing research studies in animal models" (SFARI nd-c). The developments of these different biomaterials are examples of how the SSC is being maximized through biotechnical processes, where new forms of biovalue are being generated through the various transformations of blood donated from SSC families.

The SSC also provides genetic information generated from whole genome sequencing (WGS). This data is yet another micro-technical manipulation of productivity. Scientists have described the availability of WGS as the next frontier of scientific trajectories of the SSC and genomic science more broadly. In August 2017, SFARI announced that a total of 8,975 whole genomes from the SSC have been sequenced, most of which are currently available for use by all approved researchers (SFARI 2017). In addition to WGS, numerous other SSC genomic and transcriptomic data sets (e.g., RNA transcripts that are produced by the genome) are available for use by scientists. These genomic products are highly valued by scientists given the computational power that can analyze and interpret the data, as well as the seamlessly endless types of experiments that can be conducted using genomic information. As the SSC biomaterials remain available and continue to mutate, the future technoscientific transformations will undoubtedly create new and extended forms of scientific biovalue. This reflects Mitchell and Walby's (2010, 340) articulation of how biovalue is embedded in the biological samples themselves, where they "can be retained and repeatedly minded for a variety of research," and "potentially open to new techniques, methods, and research questions that develop in the future". Indeed, the SSC has this potential through these various technoscientific products, which is harnessed by the ability for scientists to remain in contact with families to collect additional biospecimans as needed; a contour of biovalue which I discuss in more detail below.

5.2 Social Biovalue: Diagnostic Currency and Genetic Answers to Autism

Accounting for and articulating the contours of biovalue constitutes not only the people who are involved in the collection and use of the SSC but also those who donate their blood and medical information. As Mitchell and Waldby (2010, 341, italics in the original) importantly point out, "*both* biobank managers *and* biobank participants are involved in formatting the data necessary for the bank's creation of value. In this section, I investigate how parents place value in the SSC, which is related to their decision to enrol their families in an autism genetic database. Based on interviews with parents who participated in the SSC, a different set of biovalues emerged starting from the initial participation and need for answers to the anticipated outcomes of genetics research using the SSC, especially for the causes and treatments of autism.

The clinical labour involved in donating blood and medical information to the SSC consisted of two visits to one of the affiliated university clinics, where participants completed an extensive parent interview and evaluation of the child with ASD in addition to a blood donation from each family member. As I discuss elsewhere (Singh 2015) there were different narratives of participation from the perspective of parents who donated their family's blood and medical information to the SSC (e.g., altruistic, obligated, and diagnostic parents). When viewed through the lens of biovalue, however, immediate and long-term benefits are evident in the data. First, the compensation for participation was a written research report that included information about the child's diagnosis, cognition and adaptive behaviour, and recommendations for treatment. This diagnostic evaluation is a significant incentive since parents have to wait over a year to see a specialist who can accurately diagnose ASD. Further, the cost of a psychological evaluation is well over $2,000, which many parents have to pay out of pocket since it is not typically covered by health insurance in the U.S. The parents were encouraged by the SSC research teams to use this evaluation to help qualify for services. Thus, for some parents, especially those who did not have an extensive clinical autism evaluation for their child, participation in the SSC offered what Singh refers to as diagnostic currency (2015). This currency took shape in many forms beyond a free diagnosis. First, a clinical diagnosis offered medical and social legitimacy for concerns parents experienced with their children. As one parent stated:

> As a parent, when it's your child, you just want the answers. (SSC parent interview #16)

Parents indicated that it was extremely stressful to be so worried about their child and not know whether something was truly wrong. An-

other parent whose son was never formally diagnosed before the study stated:

> That's what we wanted first and foremost was somebody to say, okay, look, he's autistic. And then tell us what level he's capable of operating at…and you know, evaluate him and kind of help us figure out…the services that he needed. (SSC parent interview #14)

These parents wanted to know with certainty whether their child was on the autism spectrum and assumed that the detailed autism evaluation they received in exchange for participation in the SSC would allow them to seek the most appropriate care for their child. This is reminiscent of research on medically unexplained symptoms (Dumit 2006) and the uncertainty of non-diagnosis and questioning of others of the legitimacy of concerns, which can create significant doubt, distress and chaos. It is evident that these parents clearly wanted to close this gap of uncertainty through their participation.

The extensive evaluation also provided a gateway to autism services, which offered a second kind of diagnostic currency. For example, one mother who had twin boys diagnosed with autism was hoping that the thorough evaluation would help her obtain educational services. She stated:

> I have been paying for evaluations for years and I've been struggling with my school district for years and any opportunity to have a good independent evaluation was something I jumped all over. (SSC parent interview #3)

This parent, like many others, viewed the SSC as an opportunity for her children to get a thorough autism assessment that would be helpful as she negotiated with the school district about qualifying and receiving special educational services. The detailed and free evaluation served as a bargaining document or form of currency in exchange for educational services. However, as I have highlight elsewhere, for some parents this document was not made available immediately and the interpretation of the results were hard to understand (Singh 2015).

Beyond diagnostic currency, parents also saw value in a large multisited study that was seeking answers to the questions of autism causation and treatment through genetics research. One of the first families to participate in the SSC who had a teenage son graduating from high school stated:

> We were really excited to be a part of it just because I still don't know why Carl has to deal with this daily and I'd like to know; it would bring closure. (SSC parent interview #21)

Given the promotional nature of the SSC, many parents anticipated that the study would provide a genetic answer to autism causation, which in their minds would lead to targeted treatment. As one parent stated:

> I am very interested in having scientists find out more about autism if there is some genetic link, make any advancements, and make it easier for the lives of these kids. (SSC parent interview #8)

Likewise, another parent was hoping that the database was going to help scientists:

> Narrow it down and identify where some of the deficiencies are and it *may* be something that in the future they can impact. (SSC parent interview #3)

Parents did not speak of commercialization of the SSC or economic value gained from drugs and/or interventions developed from the data but were rather more optimistic and hopeful. It was almost as if by virtue of their donation the knowledge generated from the SSC would be made readily available to them in the future. Such economies of hope extend beyond a therapeutic cure or economic wealth to include how therapeutic benefits derived from biomedical research involving the donation of human biomaterials should be distributed (Novas 2006) Through these accounts we also begin to see how the realization of value stem from what Hoeyer (2016, 352) refers to as "nonknowledge," where the "research questions themselves perform work similar to the one usually ascribed to certified answers and research results. Beyond the realization of financial and knowledge assets, these parents are relying on the expectations of the SSC to find the underlying genetic cause of autism and in a few parent accounts, possibly a cure. Thus, these participants are what Tutton (2007) refers to as "active recruits," since they are deeply invested in the anticipated outcomes of the research and enthusiastically sought participation to help out in any way possible.

5.3 Biovalue Constraints and Consequences

Although different contours of biovalue are evident in the domains of scientific research and parent participation, I want to reflect for a moment to account for the constraints in these multiple formulations of biovalue. This section offers a critical analysis of constraints and consequences inherent in the structure of the SSC, which creates certain kinds knowledge flows and nonflows to borrow from Hoeyer et al. (2017). However, the nonflows in this case refer to the constraints in knowledge production that are embedded in what makes the SSC valuable, namely the simplex family structure, distinct definitions of autism, and strict recruiting mechanisms. Although appealing for scientists, the simplex fami-

ly structure is extremely limiting and embedded with inherent biases. First, it limits participation to only biological and heterosexual parents, which excludes many alternative family structures, e.g., parents who adopt, same-sex parents who adopt or have biological children, or single-parent families with no contact to the other biological parent of the child with autism. Although the strict inclusion and exclusion criteria is warranted given the goals of the SSC, the exclusion of these families limits not only the type of knowledge produced (e.g., de novo CNV knowledge), but also the potential benefits the study offers to families that participate (e.g., extensive autism evaluation). The prospective interventions will also presumably be made with this family structure in mind, and therefore likely be developed under the assumptions that families are heterosexual, middle class, and have access to healthcare, not to mention the time and resources needed to navigate autism services.

In addition to the limits of participation based on family structure, the families who participated in the SSC were predominately affiliated with one of the twelve research clinics that were recruiting families to participate. This creates additional structural exclusions since there is well-documented evidence to support disparities related to autism clinical service access based on race, ethnicity, and social class (e.g., Liptak et al. 2008; Magana et al. 2013). These disparities are additionally evident in the SSC, which underrepresents race and ethnicity of children with autism in this sample comprising of less African Americans (~4%) and Hispanics (~11%) compared to the 2016 U.S. Census (13.3% and 17.8%, respectively). White families, who represent 76.9% of the U.S. Census, on the other hand, comprise ~78% of the SSC (SFARI Base nd-a). Social class, measured by annual household income, also shows that the SSC is composed of mainly middle class ($51,000 - $100,000, 39.6%) and upper middle-class families ($101,000 to >$161,000, 38.9%) (Goin-Kochel et al. 2015). I do not mean to suggest that racial and class categories should be represented in the SSC to provide evidence for disparities based on biological differences, but rather aim to call attention to how this nonflow of knowledge obscures the understanding of upstream processes of unequal access to autism services (Epstein 2007). These demographics represent the inherent bias of the types of families who compose the SSC, which is likely a result of the structural constraints of accessing clinical autism services as a function of social class, which historically is associated with race, as African Americans are disproportionately working class and poor. In this case, people with limited financial resources are less likely to have access to autism clinical services, much less time to participate in research. This is important because it also limits access to the diagnostic currencies mentioned above, as well as the opportunity to be part of the virtual community of SSC families, which in addition to providing updates on research generated from the SSC samples, offers a range of additional information that would be beneficial to most families who have a

child with autism (e.g., employment, technology use, parenting strategies, etc.).

The SSC also consists of an over representation of male children with autism where males with ASD constitute 86.4% of the samples (Goin-Kochel et al. 2015). Although this bias reflects the ASD estimate of American boys who are 4.5 times more likely to have autism compared to girls, the SSC male to female ratio of children with autism is 6.5:1 (2292 males and 352 females). Not only does this imbalance place more emphasis on investigating male autism cases but also reinforces the notion that autism is a representation of the 'extreme male brain'. This theory of autism promoted by Simon Baron-Cohen, an autism researcher at Cambridge University and current president of the International Society for Autism Research, attempts to explain the similarities between male traits and traits typically associated with autism (Baron-Cohen 2002). Again, these assumptions are built into the SSC and hold particular value for scientists. If the gender bias were in the reverse direction, e.g., female to male ratio of 6.5 to 1.0, the utility (and value) of the SSC would be questioned by scientists. Perhaps even more concerning in the context of this unequal representation based on sex is how the division in ASD based on sex is already translating into studies that are investigating gender differences in ASD characteristics (e.g., Frazier et al. 2014; Howe et al. 2015). These studies aim to identify differences in autism symptoms (e.g., behavioural symptoms, cognitive functioning, verbal ability) between males and females. Most troubling is the notion that these differences are rooted in genuine biological differences between males and females when it comes to behaviours such as "higher levels of irritability and externalizing behaviour in female patients," which could imply according to scientists, "the need for greater monitoring of behaviour problems in female patients with ASD" (Fraizer et al. 2014, 701). These limitations and gender biases in the sample, while valuable based on scientific assumptions of autism causality and sex differences, inevitably shapes the kinds of resources available for scientific research and the subsequent knowledge production and flows. In the case of sex differences in autism, the database and subsequent knowledge is built on social norms that promote the gender binary, as well as distinct characteristics deemed male over female (Epstein 2007).

5.4 Digital Biovalue: Interactive and Virtual Networks of Exchange

A third contour of biovalue manifests through digital networks that enable the purchase and flow of biological, clinical and genomic data between scientists conducting autism research and the Simons Foundation Autism Research Initiative (SFARI), the governing body of the SSC. Digital networks bring additional value to samples like the SSC since they establish shared databases, which can allow researchers to access the data

remotely. The organization and configuration of the SSC as a network biobank (Canada et al. 2015), where governance of biomaterials is centralized by SFARI, highly influences the needs for multiple ways of engaging with the SSC. Thus, SSC families who donated their blood and medical information are also brought into this digital network of exchange. These digital and virtual interactions bring scientific sustainability to projects like the SSC but also generate new forms of biosociality among the families who were brought together because of this highly selective research initiative. These virtual interactions take on different shapes and forms depending on how they are used and offer examples of emergent hybrid collectives that sustain and promote evolving species of biovalue.

To maintain and exchange the extensive materials offered by SSC, the Simons Foundation developed SFARI Base, which is a central database of clinical and genetic information of all SSC study participants. It contains over 6,000 phenotypic data points for each SSC family and almost 9,000 whole genome sequences, which researchers can explore remotely before requesting samples (SFARI Base nd-a). This digital portal enables scientists to request samples for their research after they sign up and qualify as an approved researcher, a process that requires a lengthy application, Institutional Review Board compliance, and approval by the Simons Foundation. All approved researchers must also agree to the specific use of the SSC materials, which are limited to projects related to "advancing the field of autism and related developmental disorder research" (SFARI nd-a). According to the Researcher Distribution Agreement, approved researchers are also prohibited from using the SSC materials for commercial purposes and required to share all "Researcher Generated Data" within a reasonable time after generation or collection (not to exceed one year) (SFARI nd-a). The scientific practices of open data exchange before publication of results was instituted by autism parent advocates when they developed the first autism genetic database, the Autism Genetic Resource Exchange (Singh 2016).

Establishing an account with SFARI Base is also the starting point for researchers who would like to re-contact SSC families to collect additional data. To qualify, SFARI must approve every scientist before they are put into contact with a liaison to the SSC families. The ability to re-contact SSC families is particularly important for scientists because of the changing dynamics of genomics research that continuously creates new knowledge and categorizations of people based on individual or family genotype and/or phenotype data. Once particular SSC genotypes or phenotypes are identified as worthy of further investigation, additional clinical data or samples of extended family are typically needed. This exchange network generates future use and indefinite value in the SSC by enabling scientists to not only ask new questions of the data but also gain access to additional biomaterials and clinical information needed to test new scientific investigations.

Although re-contacting families was one of the goals in developing the

SSC, initially there were no mechanisms in place to accomplish on-going communication and recruitment for additional studies with SSC families. In 2013, two years after the data collection was completed for the SSC, a digital network of SSC families across North America was established, the Simons Simplex Community@Interactive Autism Network (SSC@IAN). The SSC@IAN was developed to serve as a conduit for connecting SSC families with scientists who wished to collect additional data from SSC families. The 1,500 families who agreed to sign up were willing to be re-contacted by SSC investigators to provide additional blood and medical data when needed. This platform has created an on-going form of exchange between a sub-group of SSC families and scientists who want to collect additional data in order to ask a different set of research questions not originally conceived in the initial data collection. Initial and on-going participating in the SSC is a form of what Mitchell and Waldby (2010) refer to as distributed and extensive forms of clinical labour. Meaning that the small amount of "productive work" is dispersed across many SSC families (e.g., 2,700 families) and extensive through the on-going engagement through both the biomaterials and clinical information already harvested and transformed for scientific production. In the SSC, the clinical labour is also extended through digital networks that enable continued collection of participant data. This adds another dimension of embodied work performed by SSC families.

A third digital network of exchange is a public website that accompanied the SSC@IAN. This was designed as a virtual home for all SSC families (not just those who agreed to be re-contacted) to remain informed about the scientific results derived from their samples, to learn about different families who participated in the SSC, and to access scientific articles on autism (SSC@IAN nd). Additionally, it provides articles on the latest autism research beyond the SSC and webinars on a range of autism topics that would be of interest to North American families who have a child with autism. To some degree the public website offered through SSC@IAN helped to establish a form of biosociality between SSC participating families. The website does this by sharing stories that highlight families who participated in the SSC. The Maclean's, for example, were the first family to sign up to be part of the SSC@IAN and their story emphasizes how participating in SSC "was the best way [they] could help others who are walking the same road." The story offers a detailed account of participating in the SSC through the words of the mother, who recalled the meltdown her son had when his blood was drawn. Despite the long day and trouble with the blood draw, the mother viewed her participation as scientifically important by stating, how her son's blood sample, "together with those provided by the other SSC families, is part of one of the most important resources in autism research" (SSC@IAN 2011). These sentiments of value and belonging to a community were also central themes among the interviews I conducted with families who participated in the SSC. One mother (SSC parent interview #5) shared with

me that she viewed her family's participation in the SSC as a "moral responsibility" because it would not only help her son but would also benefit the autism community; families like her own who are going through the same struggles. Based on this interview and others, the very act of participating in the study and being involved in SSC@IAN created a collective social benefit for these families because it was not only tied to the value the collection offered the scientific community but also the autism community more broadly. These parents anticipated impactful scientific and social SSC research outcomes that would address major issues facing all autism families such as identifying the genetic cause autism and a clear pathway to helping their children. In this register, participation in the SSC as one parent told me, "benefits everybody, all the way around" (SSC parent interview #4).

In addition to personal accounts of participating in the SSC, the SSC@IAN also provides a list of short reports that highlight studies made possible by SSC families. This serves as another embedded form of biovalue and an alternative way in which biosociality is extended through this virtual exchange network. The introductory paragraph to the list of reports states, "this is autism research made possible by you" (SSC@IAN nd). These reports are based on SSC scientific research and draw on personal stories such as a parent's reflections of the bullying and isolation that occur or the social impairment associated with limited sleep in children with autism. Stories like these and many others are used throughout the reports covering SSC research in the SSC@IAN public website. Sharing these stories unite SSC families beyond their presumably shared genetic mechanisms of autism causation (e.g., CNV mutations) and extend to daily experiences and validation of challenges that families who have children with autism might be undergoing. The use of these narratives also appears to give legitimacy to parent concerns, which in a few cases (e.g., effects of a high fever) are now being investigated using the data available through the SSC. In this register, the knowledge SSC families are able to share with scientists through this virtual exchange highlight new avenues for autism research.

5.5 Selective Non-Flows of Knowledge

A closer analysis of these reports, however, shows that SSC@IAN public website is selective in what is shared with families. Only 19 studies appear in SSC@IAN out of the 78 studies that have been published using the SSC data thus far. According to the SFARI Base website, 197 studies have been approved to use the SSC sample (SFARI Base nd-b). This clearly reflects an imbalance and selective representation of research reported on the SSC@IAN. Not surprisingly, research findings that have much more practical applications for SSC families are typically highlighted (N=13) compared to genetic studies (N=6). For example, studies about aggression and ASD, the stigma and isolation experienced by fami-

lies of children with ASD, or sleep problems linked to autism, are the kinds of research reported to SSC families. The gap in reported studies through SSC@IAN compared to the large number of studies published and approved to use SSC samples is a reflection of the initial priorities of the SSC, which were not necessarily designed to identify practical applications for SSC families and the broader autism community. It also represents what Hoeyer et al. (2017) refer to as strategic ignorance, where some aspects of research are not revealed to research participants because they are expected to dislike them. In the case of SSC, the planned nonflows of information are the exclusion of the majority of studies that are less likely to directly benefit families. It also assumes that families are deficit in the knowledge needed to understand the complexity of genetics research.

Based on this analysis, I do not know why only certain research publications are summarized and made available to families. One interpretation is that the SSC@IAN is strategically filtering what is available to families to give the illusion that the research conducted using the SSC directly benefits SSC families and children with autism more broadly. Another form of nonflows are the recommendations made through these reports to families that are not particularly novel. For example, recommendations made by the study investigators for aggressive behaviour include "the need for interventions to address aggression in children with ASD, and to support families coping with it," or to address family obesity by focusing "on finding ways to be active together and cope with stress without eating" (SSC@IAN nd). As I discussed above, the knowledge produced and recommendations given are bound within the constraints of the sample, which is largely white, married couples of higher socioeconomic status. Therefore, the practical applications of these findings may only benefit families who are situated within these social locations, since they are more likely to have the time and resources needed to acquire the long-term therapies (e.g., behavioural, speech, occupational) and/or special educational services needed for many children diagnosed with autism. Further, the types of stress, access to healty food, and coping mechanisms are likely to be very different based on race and social class.

6. Conclusion

This study identified various contours of biovalue established through the development, participation, and use of the Simons Simplex Collection, an autism genetic database designed to investigate specific genetic causes of autism, certain types of families, and characteristics of autism deemed most important for scientific research. Based on this analysis, there are clear representations of scientific, social, and digital forms of biovalue, which are multi-dimensional and co-constitutive of each other;

enabling the exploitation of biovalue in multiple directions with the aid of various technoscientific processes. Scientific biovalue was generated through emergent genomic science that gave rise to the very idea of a simplex family, namely the development and use of genomic technologies that identified small micro-deletions (CNVs) that were associated with certain kinds of autism (Singh 2016). This genomic research finding, marshalled private funders to invest in a new autism genetic database that would test the spontaneous CNV hypothesis. The distinct family forms (simplex families) and detailed collection of clinical characteristics and biological samples created a resource that was valuable for scientists and families alike. The ability for scientists to re-contact families through the SSC@IAN, collect and develop new technoscientific forms of data, and conduct new scientific investigations allows for the expansion of biovalue to travel to new spaces among this emergent assemblage of genomics research. Social biovalue resides in the benefits of participation for SSC families, who not only gain various forms of diagnostic currency, but also have the opportunity to be part of the SSC virtual community. The opportunity to be part of this larger autism community allows families not only to connect with each other, but also offers a linkage to the science that is being produced with their biomaterials. Finally, the digital networks of exchange (SFARI Base and SSC@IAN) creates additional contours of biovalue since it acts as a glue that creates the connectivity and exchange between scientists, SSC families, and the extensive clinical and biological materials.

Within this context, I show how the SSC digital networks mediate between various social and material forms of the sample, updates and transforms biomaterials continuously, and keeps track of the unfolding clinical and genetic profiles of the SSC families. I contend that the productive relation families have with the SSC resides in the ability for scientists to remain in contact with families through SSC@IAN, which enables new signs, symptoms and experiences to continuously be collected, built upon and connected to the knowledge produced from the SSC. As such, the hybrid and multi-dimensional collectives between scientists, SSC families and their clinical and genetic data combined with the emergent digital networks designed to mediate these relationships and data flows generates a resource that can "mined" indefinitely. This positions the SSC to have the potential to generate new biomaterials, genomic knowledge, and research questions in the future, thereby offering promissory or speculative value that holds much promise in genomic science that investigates complex human conditions.

The SSC also enabled new forms of biosociality to form among simplex families whose children potentially have a spontaneous copy number variation 'causing' their child's autism. This collective identity manifests through initial participation and on-going engagements with the SSC. First, the SSC@IAN allowed families to connect with selective knowledge being produced by the SSC using SSC family data, as well as learn about

other families who participated. This sense of belonging to a unique scientific-based autism community was evident from the SSC parents I interviewed who viewed their participation as a way to be part of a research endeavour that will benefit the larger autism community, especially in the future. However, I provide evidence that the knowledge shared on the website was selective to studies that would be most useful for families (e.g., stigma and isolation); studies that were not part of the original design of the SSC, and minimal in both number and value to genetic scientists. Second, the development of the SSC@IAN also created new opportunities for families to remain engaged in the research process especially for those who agreed to be re-contacted by scientists who utilized the SSC for their research. This technosocial arrangement offers the potential for families to identify with the uniqueness of their child's autism, relate to other SSC families, and engage in "artifice of modifying nature and the creation of social forms" (Gibbon and Novas 2008, 4). Undoubtedly, the SSC created new forms of biosociality beyond the shared experiences of raising a child with autism.

This study also uncovers important paradoxes that highlight how the various contours and constraints of biovalue and biosociality work together. First, the scientific biovalue embedded in the selective inclusion criteria and recruitment of families from clinical sites offering autism services in North America created at data set that is largely white and of high socioeconomic status. This is likely a function of who has access to autism services, and therefore eligible to be recruited to participate. It also signals to larger structural inequalities such as limited access to private insurance, living in poverty, and/or racial segregation that creates evident disparities to autism diagnosis and subsequent services (Singh and Bunyak, forthcoming). A second paradox is how these social forms, as well as the different types of biovalue produced, are constituted based on the assumptions built into the SSC. Even though virtual modes of interaction were developed to bring SSC families together, which indeed created new biosocial communities, these collectives are strictly defined based on the priorities deemed most useful for conducting genetics research on autism. Thus, the ideas of autism genetic causation and the biomedical classification of autism shape the kinds of biosocial configurations that coalesce around the SSC. In other words, if a family had two or more children with autism or a family history of autism, they would not be included in these social networks and will also unlikely benefit from the genetic knowledge produced.

A final paradox comes back to the fact that the SSC is an assemblage of people, biospecimen, clinical data, and technologies built on many assumptions about the potential genetic cause of autism and the predominate characteristics associated with its definition. As I have articulated in this paper, while these characteristics created a "Cadillac resource" for autism genetics research, the limitations of the sample based on family structure, clinical characterizations, and representation in terms of race,

social class and sex constrain the types of knowledge produced and the potential future spaces in which this knowledge takes shape and travels. Given that the SSC is the largest autism genetic database of its kind, the knowledge produced will inevitably be a reflection of these assumptions and constraints built into the SSC. This is concerning given the vast amount of research using the SSC to investigate autism causation, treatment and for much of the scientific thrust, an autism cure (e.g., almost 200 studies have been approved to use the SSC). While private philanthropies can bring funding and awareness to important social problems like autism, there is no accountability to create a represented sample, which could potentially limit the expansion of the data production and flows to include research on structural issues faced in more heterogeneous populations experiencing autism.

Given these analytic paradoxes evident in the contours and constraints of biovalue and biosociality, STS scholars engaged with these issues are poised to think about the multi-dimensionality and co-constitutive processes of these "bio" constructs. Further, we must begin to use our critical STS lens to question how these values and subsequent social formations come to be, who they benefit, and how these contours shape and constrain the knowledge produced. Ultimately, these are critical questions of STS and we must pay attention to how heterogeneous values are embedded in artifacts like the SSC and the implications this has for what we come to know about complex human conditions like autism and the primary beneficiaries of this knowledge.

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[1] See Singh (2016) for a detailed account of the problems of previous collections, namely the Autism Genetic Resource Exchange and the Autism Genome Project.

[2] This is different than a multiplex family that consists of two or more children diagnosed with an ASD.

[3] See Singh (2016) for history of the Autism Genetic Resource Exchange and Autism Genome Project.

Participation in the BioResource
Biobanking and Value in the Changing NHS

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Abstract: The National Institute for Health Research BioResource is not a typical biobank. It banks biological samples and other data, but also volunteer commitment to potential future research participation. Researchers can then, using the BioResource as an intermediary, invite volunteers who meet specific genotypic or phenotypic criteria to participate in studies. Using participant observation and semi-structured interviews with those involved in recruiting new and engaging existing volunteers, this paper explores how participation is understood and cultivated, and how (bio)value is produced in routine BioResource work. We contribute insights into a different configuration of biosocial participation where the engaged individual, as opposed to biological sample, is the site of value. Foregrounding the often ignored work of biobank staff, we demonstrate the iterative and reflexive way value is created and maintained through staff activity, and the different way actors make sense of the site and stability of this value.

Keywords: participation; biobank; biovalue; NHS; labour; health research infrastructure.

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1. Introduction

Rushing down a long, sanitised, hospital corridor on my way to a meeting, I hear my shoes clatter on the hard, vinyl floor. Clinical staff in their colourful uniforms and rubber shoes glide with purpose towards me while other bodies look lost, eyes searching the corridor for signs to direct them. As I move further down the chair lined passage, I encounter three members of hospital staff at a table, trying to make eye contact with those who

> pass by. Their table is laden with leaflets, clipboards, mugs, pens and, most distinctly, a large model of a double helix. A banner tells me that "Research Needs You." At first glance, it appears to be a fundraising exercise, typical of the English hospital. However, this is something different. As I quickly pass by the stall, an individual is sat completing a form while another approaches the table, asks about the double helix model and, for the few seconds, I hear snippets of information about genetics and health research. This was my first encounter with the BioResource.
> (David Wyatt)

The BioResource, discussed in this paper, is part of wider transformations in the National Health Service of England (NHS). Since the publication of *Best research for best health: A new national health strategy* (Department of Health 2006), the NHS has embarked on a process where its focus is not only on the provision of universal health care to the population but also on positioning itself at the forefront of medical research. One of the ways the Department of Health pursued this vision was by establishing the National Institute for Health Research (NIHR) (Department of Health 2006). The NIHR presents itself as "the most integrated clinical research system in the world" and claims to "drive research from bench to bedside for the benefit of patients and the economy" (https://www.nihr.ac.uk/about-us/our-purpose/). It aims to do this by funding research projects, supporting the training and development of researchers, working with industry, and providing research facilities and infrastructures. The BioResource discussed in this paper is one of these research infrastructures.

In 2005, through a collaboration between the University of Cambridge and the Medical Research Council Epidemiology Unit, a BioResource was established in Cambridge. Building on this BioResource's perceived success, the NIHR funded its expansion. NIHR BioResource is now constituted by a federation of thirteen independent BioResources across England. These BioResources work independently and together to streamline and support the recruitment of research participants for specific studies. BioResource staff recruit volunteers, with or without existing health conditions, who are willing to take part in future research studies. To join the BioResource volunteers provide biological samples containing genetic information, lifestyle and health information and, for those with existing health conditions, access to their clinical records. Healthcare professionals, academics and members of the commercial pharmaceutical industry can then apply to the BioResource to identify volunteers that meet specific genotypic and/or phenotypic criteria and invite them to take part in new studies. The details of those willing to participate in the specific study are then passed to the researcher to contact directly.

David's initial exposure to the BioResource, recounted above, affords an insight into some of the routine practices of BioResource recruitment. Drawing on findings from ethnographic observation of the day-to-day work of a BioResource and semi-structured interviews with its staff, we

explore how BioResource participation is performed, understood and configured. We examine the labour of running this biobank and focus on the mundane and often invisible work involved in facilitating participation in the BioResource and the production of value. Existing accounts of (bio)value in biobanking situate value in biological fragments (for example, blood or tissue samples), and the potential these fragments offer for medical innovation and research. We contend that the BioResource represents a distinct form of biosocial participation where its value is the engaged volunteer (as opposed to their partible samples and associated data) and this value is the product of the labour of both volunteers and BioResource staff. Value in this context is not fixed, inevitable or linked to the market but produced and maintained through the structured activities of the BioResource and ongoing engagement of volunteers. Our account suggests existing concepts of clinical labour and biovalue are insufficient in conceptualising and encapsulating all the work involved in producing value.

2. Biobank Participation, Biobank Labour and Biovalue

In his influential study of blood donation, Titmuss (1970) examines two different ways of developing a supply of blood for transfusions post World War II. While the United States offered payment for blood, Titmuss found that in the UK a better quality and quantity of blood was achieved through a system of donating for no financial reward. Titmuss claims this is a gift relationship and the act of giving blood contributes to the social good and creates ties between individuals, establishing communities. Titmuss' account infers a hierarchy of participation, with gift donation held firmly aloft of commodity purchase. Others have highlighted that the divide between gift and commodity is neither static nor mutually exclusive (Frow 1997; Harris et al. 2013; Lipworth et al. 2011; Waldby and Mitchell 2006) and have questioned the compatibility between Titmuss' 'gift' and Mauss' account of gift exchange (Tutton 2002), Yet, Titmuss' work remains important today, providing a compelling argument in support of the welfare state (Frow 1997) and embedded in public guidelines, such as the UK Medical Research Council's 2001 *Human Tissue and Biological Samples for Use in Research* (Tutton 2002).

For Titmuss, altruism was a central feature of the rationale to give blood. While altruism dominates clinical researchers' understandings of participation (Adams and McKevitt 2015), in research and biobank participation there is an acknowledgement of a more complex set of rationales (Adams and McKevitt 2015; Tutton 2007). For example, in the Swedish context, Hoeyer (2006) foregrounds the issues of trust in the organisation and notions of fairness, (see also Cool (2016) and, in the Norwegian context, Steinsbekk et al. (2013)). Hoeyer (2006, 791) reports that some experienced participation as "taking part in a shared welfare state

project." In the NHS, participation in research has been framed in a similar way: healthcare is provided, and in return, citizens have a responsibility (or at least are expected) to "give back" by participating in research as a moral duty, civic virtue, matter of citizenship (Chadwick and Berg 2001; Mitchell 2012; Woolley et al. 2016) or even as an entitlement – patients have a right to be aware of opportunities to participate in research (Adams and McKevitt 2015; Wienroth et al. 2018).

Tutton's (2007) focus group study on biobank participation adds texture to our understanding of what counts as participation and how this term can be operationalised instrumentally by institutions. "Participation" is often used to infer a democratic process linked to notions of public involvement or 'active citizenship', said to "emphasise people's rights (and duties) to participate in decision-making processes" (Tutton 2007, 174). Such accounts present citizens as informed, engaged and knowledgeable. In practice, however, participation rarely provides space for citizens to enact these qualities (Tutton 2007). Instead, it often entails the provision of samples, the completion of forms and the ad hoc receipt of news from the biobank about recent research. Viewing citizens as informed, astute, and able to make free, rational choices is the cornerstone of contemporary informed consent (Corrigan 2004). Yet even this is complicated further by biobank participation, as being able to define how data will be used in advance is not always possible (Shickle 2006; Tutton and Prainsack 2011) and the right to withdraw is difficult to facilitate (Melham et al. 2014).

In the UK the most prominent biobank is the non-profit, publicly funded charitable company, *UK Biobank*. Having collected samples, lifestyle information and established links to the "cradle-to-grave" NHS health records of 500,000 volunteers, it is lauded as "a major national and international health resource" and claims that, "over many years […] will build into a powerful resource to help scientists discover why some people develop particular diseases and others do not" (UK Biobank n.d). Tutton and Prainsack (2011) suggest that *UK Biobank* utilises a notion of "public good" and report that it promotes a particular kind of subjectivity in its participants, that of the "altruistic self." The altruistic self "is addressed through a discourse of communitarianism, and […] enrols in the biobank, freely giving of themselves with no expectation of anything in return" (Tutton and Prainsack 2011, 1090). Busby and Martin (2006) frame participation in *UK Biobank* slightly differently. Rather than altruism specifically, public good is operationalised in terms of British identity, community, the benefits for the country now and for future generations. Across both accounts, participation in research with the potential to benefit the wider community is, at least in part, expected.

The NIHR BioResource has many similarities with *UK Biobank* but differs in some noteworthy respects. Whereas *UK Biobank* is supported by but situated outside of the NHS and NIHR, the BioResource is funded through the NIHR and thus the NHS. While both occupy a landscape

where in the last twenty years the UK government has set ambitions on utilising the life sciences industry to invigorate the economy and develop its competitiveness on the international markets, the NHS context of the BioResource is significant for how we understand participation. With the publication of *Best research for best health: A new national health strategy* (Department of Health 2006) and numerous initiatives (including establishing the NIHR), the NHS situates research and support for research not as peripheral to its jurisdiction but embedded at the heart of its work. Though for some time there has been an expectation that patients are willing to participate both in defining research priorities and in health research, it was only in the NIHR (2015) publication, *Going the extra mile,* that participation in health research was framed not as an altruistic act but as a patient duty. This shift to develop a "research culture" in the routine functions of care provision (Malby and Hamer 2016) and transform the NHS into a research leader, reframes the relationship between citizen and state: universal healthcare is provided as a right (and from taxpayers' money), but citizens also have a duty to participate in research and, by extension, contribute to the health of the wider population and the wealth of the nation through the bioeconomy.

The biobanks also differ in how they can be used for research. *UK Biobank* records remain viable research data unless the individual withdraws consent. BioResource records can only be used by BioResource staff to identify and contact those who meet the specific genotypic and/or phenotypic criteria required for a research study. *UK Biobank* has the ability to re-contact participants too, but this is a secondary function. For the BioResource, this is its only function. It is dependent on volunteers enacting their supposed duty to participate in research when invited and researchers opting to utilise the BioResource in identifying eligible research participants.

The specific NHS/NIHR and English socio-historical contexts foreground a convergence of biotechnology and capital production in what was previously a site of solely healthcare provision. This "implosion of capitalism with 'life itself'", referred to by Sunder Rajan (2006, 171) as biocapital, brings into focus questions about how value is created, how it circulates and to whose benefit. We focus on the first of these points in our analysis, exploring how BioResource value is constructed, understood and reinforced in the practices of BioResource staff.

To understand value, we first draw on Waldby's concept of biovalue to emphasise the potential offered by the collection and use of biological fragments in the bioeconomy. Defined as "the yield of vitality produced by the biotechnological reformulation of living processes" (Waldby 2002, 310), biovalue is not rooted in an inherent property of biological material. Instead, it is realised in market exchange or in its potential to improve the health of the population. While in this initial conception, the fragment is divorced from the individual who donated it, in the context of biobanks, this continued link between individual and biological sample can be an

important part of biobank biovalue (Mitchell and Waldby 2010). For example, access to an individual's ongoing medical records provides more data and context to any biological samples held and may offer a greater potential for biomedical research.

We believe biovalue is useful in foregrounding the often explicit promise of biotechnology and the bioeconomy, but also in demonstrating the process of actively producing and nurturing value that we argue takes place through the work of BioResource staff. It is, however, limited through its conception of biovalue as a commodity rather than an asset. This point is stressed by Birch and Tyfield (2013) who suggest that viewing biovalue as a commodity forces us to see biovalue as situated in market exchange. In market logic, increased supply should decrease value. Viewing biovalue as an asset, Birch and Tyfield (2013) argue, allows for tangible and intangible artefacts to have some value independent of the market. It also allows for the accumulation of artefacts as a means of increasing value.

In our case study, this distinction is important, particularly when one sees the emphasis some actors placed on accumulating new volunteers as a means of increasing the size and, by extension, the perceived value of the BioResource. As such, we avoid using Waldby's term, biovalue, in the following sections, adopting 'value' instead. The value of the BioResource is, however, neither fixed nor consistently understood by different actors. We argue that it is through an attention to the labour of both volunteers and BioResource staff in rendering the BioResource of value to biomedical research that we see processes of creating and maintain value that are both iterative and ongoing. Clinical labour, introduced by Mitchell and Waldby (2010) and developed by Cooper and Waldby (2014), encapsulates the embodied actions completed by volunteers in participating in research. Ranging from allowing their blood to be drawn and used in research, through to surrogacy, clinical labour foregrounds the work involved in and expected of participants giving access to in vitro biology for research and, by extension, aids in the creation of value. It does not, however, allow us to consider all of the different forms of labour involved in value production.

In their examination of *23andMe*, Harris et al. (2013) separate the clinical labour of providing a saliva sample and completing initial paperwork involved in purchasing the direct to consumer genetic testing services, from the ongoing "free labour" (Terranova 2000) involved in participating in *23andMe's* research arm. The transfer of the genetic test data paid for by the consumer to the research arm of *23andMe* is presented as a gift, donated by the consumer for the purposes of research. The consumer is then inducted into a community of other donors and invited to complete further acts of free labour such as the completion of online health questionnaires, participating in online fora and taking part in research studies. Entry into this research community promotes sociality and is framed as altruism. Harris et al. (2013) argue that this distracts con-

sumers from the free nature of their labour in the process of generating economic value for *23andMe*.

23andMe differs from the BioResource in some respects, particularly as the *23andMe* research database has value independent of the additional free labour completed by the community of volunteers. Once donated, the data obtained through genetic tests can be mined, aggregated and used in research. Its value, although enhanced by additional information from the community of volunteers, is not predicated on this additional volunteer work. It does, nonetheless, help us see clinical labour as just one form of labour at play in the production and enhancement of value. Our study extends this point further to highlight the limits of associating clinical labour straightforwardly with (bio)value production, the already held samples and other data as consistently sites of value, and the isolated (or collective) participant as an unmediated asset. In fact, our analysis highlights how the routine work of BioResource staff in not only accumulating new volunteers but in maintaining an engaged cohort of willing, stratifiable volunteers for future research is iteratively and practically accomplished in the everyday work of the biobank and how this contributes to the BioResource's value. Such work includes the labour involved in the recruitment process, negotiating recruitment sites, the maintenance of the database and ongoing engagement work. We contend that by looking at the labour involved in the formation, recruitment, engagement and participation in the BioResource, we are able to see a particular form of biobank where value is not situated solely in samples or links to individuals, or in its potential for research or market exchange, but in ongoing, biosocial participation by the engaged volunteer. While biosocial participation here does not neatly reflect more established kinds of groupings presented by Novas (2006) in his work on patient groups, the BioResource does, nonetheless, present a case where new groupings of biologically knowable volunteers are being formed and used for knowledge production. The BioResource is predicated on individuals acknowledging the importance and potential of biology, in particular genetics, in health research and believing they have a role to play in this research. However, in the case of the BioResource, as framed above and below, there is also a duty to participate; the BioResource produces "experimental subjects" (Sunder Rajan 2008) from the citizenry at large. Our focus here however is on how participation in the BioResource, along with the mundane, everyday work of BioResource staff, facilitates value and extends our understanding of the labours involved in this production process.

3. Methods

The BioResource where this research took place is located in one of the NHS Trusts in London, England, where four of the thirteen infra-

structures are based. Data was collected over a ten-month period. Interested in the mundane work of BioResource biobanking, we spent one day a week observing the everyday activities of the BioResource, including recruitment and office work. We attended weekly team meetings, one national BioResource coordinators' meeting and monthly management meetings within the NHS Trust. We conducted semi-structured interviews with seven of the eleven individuals employed by the NHS to work for the BioResource during the research period. Three members of staff, including the previous BioResource Manager, and two research assistants, left before the interviews took place. Of these three, only the manager was replaced. The other individual, the research nurse, declined to participate in an interview, giving no reason, but agreed to be observed. Interviews lasted on average 43 minutes. Despite having different roles, for example, laboratory technician or BioResource manager, all staff were involved in active recruitment. Interviews focused on their everyday work activities including the recruitment process, interactions with current BioResource volunteers and other BioResources and the interviewee's understanding of the role and function of the BioResource. These were recorded and transcribed verbatim. All resulting data was open-coded and analysed thematically (Miles and Huberman 1994). Codes were discussed with and agreed by all authors. In the following sections, we explore the everyday realities of doing BioResource work. Unless otherwise stated, we use "BioResource" to refer to our specific BioResource research site and not the overarching federation of thirteen locations.

To maintain the anonymity of the research participants, pseudonyms have been used throughout.

4. Forming the BioResource

The BioResource was established in 2014 with the target to recruit 10,000 volunteers in a two-year period. To meet this ambitious goal, the BioResource initially employed six members of staff - a manager, a research nurse, a research assistant, an administrator, a database coordinator and a laboratory technician. All staff were trained in the recruitment process, but only the research assistants and research nurse were able to take blood samples from volunteers. When not contributing to recruitment work, the other staff supported the BioResource by processing samples, managing data, reporting to management and organising the everyday activities of the BioResource. During our fieldwork, staff numbers fluctuated due to staff attrition and the employment of additional research assistants.

Staff numbers and structures differed between the local BioResources. This was particularly evident when we attended a National BioResource meeting. Some had small teams but partnerships with other organisations. Others had large teams who not only recruit for the BioResource but oth-

er projects too. While the overall aim of recruiting volunteers to join the BioResource was consistent across different BioResources, recruitment strategies and practices were dictated by local NHS Trust managers, a point returned to in the next section.

Interested in the development of the BioResource at a local level, we pursued the process of setting up the BioResource with James, the database coordinator and the only member of staff who had worked at the BioResource from its inception. His initial task was to build from scratch the database that houses all volunteer information and draft the data procedures for staff. He was supported in this process through three monthly meetings with other data coordinators. However, there was no common database framework from which to start. The disconnect between national infrastructure and local practice from the very beginning, particularly the lack of a common database, was not lost on James, especially now that local BioResources are trying to integrate datasets, as he explained:

> We've encountered some issues. I mean, the whole purpose of the BioResource in the first place was to have a national database. 100,000 people in the database [...]. The first years it was 10,000 patients [per local BioResource], then it was going to be merged into sort of a national database. The issues [we]'ve been hitting are merging each local BioResource's database into a national one. We haven't got there yet. We're still working on it but there's obviously lots of issues involved with data types and [getting] everybody working from the same page because there's not a centralised [system]. […] It's not been organised from the top, it's been very federalised. Each BioResource is working to their own standards and things, so that's been an issue where when you want to actually merge it together.
>
> (James, Database Coordinator)

This image of the National BioResource, developing from the bottom up in a "federalised" way with different local database systems, contrasts with more sophisticated biobanks like *UK Biobank* and *23andMe*. Mapping fields between databases, streamlining recording and coding practices are all necessary prerequisites for an integrated and efficient system. James' acknowledgement that the merge of records was not to take place until the "10,000 patients" target was met infers a priority for recruiting volunteers over other aspects of work. This is reflected in our experiences in the field and represents an important point of disjuncture in understandings of the site and stability of value. We explore these themes in the next two sections.

5. Recruiting BioResource Volunteers

The BioResource's initial recruitment strategy targeted outpatient clinic attendees. BioResource staff trained clinic staff (clinical nurses and phlebotomists) to recruit for the BioResource as part of the patient's visit

to the hospital. Fitting into wider imperatives to support and facilitate research within the NHS, as discussed earlier, the BioResource attempted to situate itself within such a narrative where recruitment activity is part of routine hospital work. With the paperwork completed and blood or saliva samples obtained by clinic staff, the BioResource team would then process this information. This approach to recruitment, however, proved difficult. An unpublished BioResource report on barriers to recruitment stated that clinical staff did "not recognise [BioResource recruitment] as part of their routine duties", despite the national drive for research and this project taking place in a research-intensive hospital. This report also stressed that clinical staff see "no evidence of benefits for their careers" by contributing to BioResource recruitment work and that the "relevant managers/Principal Investigators do not ensure recruitment is happening." Equally pressing were the "staffing issues and busy clinical workload" that prevent the undertaking of additional work. These barriers were reflected in informal conversations with the BioResource staff. Completing recruitment in this way not only relied on clinic attendees being receptive and willing to join the BioResource, but on clinical staff seeing research work as a crucial and routine part of their everyday work. This account speaks to a broader disconnect between the stretched healthcare workloads of hospital staff and the vision of a research-led NHS where research is embedded in everyday practice.

With a target of recruiting 10,000 volunteers, pressure to increase BioResource volunteer numbers was high. Local hospital management meetings often involved discussion of recruitment numbers and targets. Jennifer, the former BioResource Manager provided some context to this focus on numbers. She explained that participant recruitment is important in the research function of the hospital. Recruitment data is tracked and has implications for the NHS Trust and its future NIHR funding. As such, the accumulation of BioResource volunteers received significant attention. With the limited success of recruitment in outpatient clinics, senior NHS managers suggested a more direct method - weekly stalls in public spaces at the different hospital sites (Unpublished BioResource Recruitment Strategy 2015a). Approved by the hospital Trust, and enacted by Jennifer and her team, the adoption of this method not only asserted the importance of research to the hospital but presented communal hospital spaces as legitimate sites for research recruitment work. It transferred the responsibility and enactment of recruitment work from clinicians to BioResource staff and provided the BioResource with access to those visiting the hospital, not just those attending appointments. To support this greater focus on active recruitment work, two additional research assistants were employed. Figure 1 shows recruitment data for the BioResource. The adoption of stall-based recruitment occurred at Month 10, demonstrating the substantial increase in volunteer numbers this approach generated.

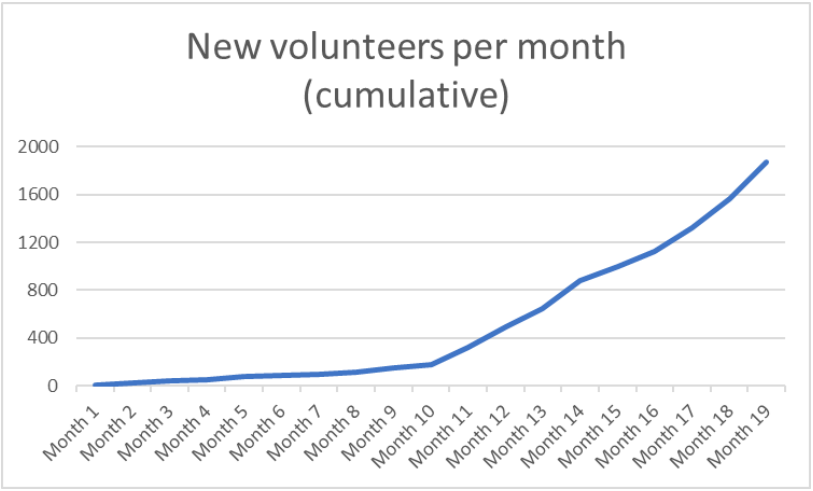

Fig. 1 – BioResource recruitment data
(Unpublished BioResource Recruitment Strategy 2015b).

When our fieldwork commenced, these stalls were embedded in routine recruitment work, and staff had developed strategies to perform recruitment in this public setting. Sitting in a weekly BioResource staff meeting early in our research, we observed some of the mundane discussions and decisions that take place in facilitating this type of recruitment. They decided who would attend each of the hospital sites the following week and on which days, the recruitment targets by site and by day, and when couriers would be required to move blood samples to the laboratory site. News was shared about the previous week's recruitment figures and a recent senior management meeting. At the end of this meeting, interested in how the stall recruitment process works in practice, we asked how they recruit in these public spaces. The BioResource staff's responses reflect David's experience, reported in the introduction. Stressing that they do not actively approach individuals, they explained that they use "the stand", "banners", "put catchy stuff on the table" and "offer mugs", all to attract the attention of those on the corridor. In an interview with Matt, a Laboratory Technician we probed further:

> Normally we would have something, I don't know, fun maybe on our table. We might have a model of DNA or something and you would just make a remark about that maybe and try and engage them in a little bit of light conversation. Then introduce the thought of 'do you want to actually partake in some medical research?' I mean for people who actually go on the stall regularly I think it's quite hard to be motivated and keep repeating the same [thing]. (Matt, Laboratory Technician)

These stalls were set up for five hour periods with up to three BioResource staff members there at a time. Matt's account presents an ideal situation where the potential volunteer approaches the table and then he can start speaking to them and introduce the BioResource. However, the need for substantial motivation, repetition and the location in busy public spaces, imply the difficulty of this work. The generally polite hospital visitors were often either unwilling to participate or unwilling to commit to the twenty minutes necessary to complete the relevant forms and provide a blood sample. While this recruitment site was more fruitful than the clinic, a good day still only resulted in ten new volunteers against their 10,000 volunteer target.

These stands present a particular vision of participation and the BioResource. With a model of the double helix representing "science" and a leaflet and banner both proclaiming "Research Needs You", reminiscent of the British 1914 wartime call to arms, "Your Country Needs You", participation in scientific advancement is presented as a collective, national duty. While this rhetoric is in line with *Going the extra mile*, mentioned above, it differs from the motives reported by staff through their interactions with volunteers. They reported volunteers emphasising "giving back" to the community or to the hospital for the care they received, having an illness themselves or having family or friends with an illness and wanting to help future research. While altruism is a convenient framework in which to understand volunteer action, as mentioned above, rationales for health research participation focusing on altruism alone oversimplify a complex array of motives. Nonetheless, these motives, however compelling, did not result in huge jumps towards the 10,000 volunteer target. Furthermore, the practice of using public spaces for this recruitment, such as hospital corridors raised some concerns for staff:

> I don't particularly like the stall that much because for me, personally, if I were walking down a corridor, and it's a busy corridor, and somebody stopped me and I have to fill out information that might require disclosing my medical condition, I wouldn't feel comfortable doing it in an open space. (Claire, Research Assistant)

Despite airing this unease, practice did not change and corridor recruitment remained the main recruitment strategy. In authorising this work to take place in the corridor at an institutional level, the push to increase the number of volunteers trumps the ethical concern of privacy, raised by Claire. Our observations of everyday work and NHS management meetings reinforce this focus on increasing volunteer numbers. Numerous line graphs were projected on walls and distributed in handouts. Tables breaking down recruitment by hospital site and clinic were discussed and unpicked. Upward trends, such as that presented in Figure 1, were used as markers of success, milestones were celebrated

with cakes for the BioResource staff, from the first volunteer to the x thousandth. This association between the accumulation of volunteers and ideas of success was also present in numerous pieces of formal documentation (Recruitment Strategies and management reports), information presented at National BioResource meetings and in weekly team meetings, where recruitment statistics and targets formed a staple component. The focus on increasing numbers presents the value of the BioResource and its potential to contribute to the bioeconomy as situated firmly in the one-time clinical labour of volunteers joining the BioResource. This is an asset to be accumulated and is the central focus of the BioResource.

Even when acknowledging the ongoing relationship with volunteers necessary for the BioResource to function as a broker of research participants, participation in later research is either assumed or ignored. Such an approach is consistent with the assumption that participation in research is a duty but is not reflected in the laborious process of recruiting small numbers across extended periods of time. BioResource staff, however, acknowledged more is necessary to transform this closed repository into a useful and valuable resource in the research process – as Claire notes, "…even though they've said yes, you can't really do anything with the sample unless you contact them a second time and they say it's OK." As Claire recognises, recruiting a volunteer to the BioResource is just the first step in contributing to future research. Aware of the importance of volunteers remaining open to participating in future research through the BioResource, staff discussed the need to do something to develop and nurture a longer-term relationship with volunteers. Looking to the original BioResource in Cambridge as an example of success in this type of bio-banking, the BioResource staff noted how Cambridge incorporated engagement activity into their routine practices. With this precedent, and staff agreement, Jennifer decided they should also complete some engagement work with BioResource volunteers.

6. Engaging BioResource Volunteers

Sat around a table scattered with pens, paper, plates of biscuits and mugs of steaming coffee, BioResource staff discussed what they could do to enhance and develop a relationship with BioResource volunteers. They had many ideas - from newsletters to performance art, social media platforms to public debates. While some ideas were already used by other BioResources, such as social media platforms, these were not viable options for the BioResource as they did not have the capacity to run social media accounts and maintain their recruitment activity without increasing staffing. This limited the type and extent of engagement activity the Bio-Resource could commit to. They focused on on-going engagement activities as opposed to a one-off effort. Equipped with a small budget from the BioResource's own funds, limited staff time and

guided by Cambridge who also use this method, they decided to produce a biannual newsletter for all volunteers.

The resulting newsletter, completed over an eight-month period, went through six substantive versions. BioResource staff sketched infographics; decided on exact content; drafted, redrafted and edited text; calculated postage costs; and arranged a platform to host and monitor the electronic version of the newsletter. The content provided updates on the BioResource, details of the recruitment figures and news on the BioResource team. The BioResource was situated in the context of the National BioResource and readers were told about the process of collecting and storing volunteer samples, data and the potential use of this data. The newsletter also provided accounts from volunteers, describing their experiences of joining the BioResource and the positive benefits of health research. BioResource staff had hoped to include examples of how the BioResource itself has contributed to medical research but as it was relatively recently established this was not possible.

The resulting newsletter did have an effect, as Helen the BioResource Manager highlights:

> When we sent our recent newsletter out, people were keenly replying saying 'you haven't contacted me yet, do you want me?'. They're so keen to be involved, which is really good when you think about it because the first lot were emailed out and, you're a busy person too, not everybody looks at their emails religiously. It's good that people are responding positively and clicking through. (Helene, BioResource Manager)

Luke, the Database Administrator, expanded further on these interactions sparked by the newsletter:

> We sent out some newsletters recently and we are getting responses back, so I had to reply to these people, lots of them. […] Some wanted to join the BioResource as well, having heard about it from family. […]
> We got some [responses] where people were very happy to receive the newsletters and to know that they are really contributing, assisting the BioResource. Some wanted to know if there are studies which they can participate in. They were really willing. (Luke, Database Administrator)

Luke and Helen's accounts present an encouraging response to the newsletter. The newsletter served to inform and generated interaction from some volunteers. It also resulted in the recruitment of new volunteers through introductions from the existing cohort. Luke's account reflects this positivity. Responses such as these led the BioResource to judge the newsletter a success. This success was particularly focused on its role in creating dialogue between the BioResource staff and volunteers. Staff saw it as a way of reminding volunteers of the BioResource and, by extension, the need to keep contact details up to date and maintain willingness to participate in research. The newsletter became part of an active process

of maintaining and nurturing the utility of the BioResource. These activities and the perceived need to sustain long-term engagement with volunteers present the BioResource as not constituted by the properties of the database entries and samples, but by individuals and their labour.

7. Discussion

We have explored how participation in the BioResource is understood by different actors and how this relates to understandings of the site and stability of its (bio)value. Drawing on ethnographic data we document some of the mundane aspects of BioResource work, from recruitment activity through to engagement, along with local and institutional drivers for how these activities are configured. Embedded in these drivers are different understandings of the value of the BioResource. At an institutional level, the BioResource is understood as something with a tangible, stable and material value; it is not contingent on further activity. Graphs plotting upward trends in recruitment numbers are viewed as symbols of success. In this conception, database entries are the asset viewed as of value to the bioeconomy. The institutional understanding conforms to an audit culture where success is measured within the NHS Trust and more broadly by the NIHR through simple metrics. The need to demonstrate consistently increasing volunteer numbers was instilled further by the suggestion, approval and adoption of recruitment in hospital corridors and the provision of dedicated staff for such work. These stalls also present a visible shift in the nature of the hospital, signalling that public spaces within this typical care site are now legitimate sites for recruitment and research work.

Viewing the value of the BioResource as material, the institutional understanding does little to acknowledge that volunteers have not agreed to participate in research studies by joining the biobank. Instead, it follows the logic pressed by the NIHR in *Going the extra mile* that research participation is a duty and, thus, participation can be assumed. In this configuration, it is not altruism (Titmuss 1970) or an imagined community alone (Busby and Martin 2006), but an obligation between citizen and state. While we did not include interviews with volunteers in our data collection, the practices of recruitment and the reported volunteer motives for participation suggest a more complex picture. The recruitment labour of the BioResource staff does not result in large, new volunteer numbers - on a good day, five hours spent on a recruitment stall results in just ten new volunteers and numerous rejections. Citizens do not appear to rush or feel compelled to participate, at a general level, to "give back".

Whereas at an institutional level increasing volunteer numbers is the focus of the BioResource, its staff acknowledge the importance of also maintaining the existing cohort's willingness to participate and, in doing so, draw on a more granular understanding of the BioResource as a bro-

ker of research participants. Biosocial participation in this context is ongoing, long-term and not to be assumed. It is through our attention to the everyday practices, and the labour involved in BioResource participation, that this disconnect between institutional and local understandings of value and participation is brought into stark relief. In particular, our case study of staff demonstrates the importance of not only considering value, but the varying ways it is assumed, produced and maintained, by different actors. In the context of everyday practice, this occurs through the ongoing labour of BioResource staff and volunteers. The activity of recruiting new volunteers (often absent in other studies) and engagement work of BioResource staff help to target and sustain engagement. A volunteer's clinical labour in joining the BioResource and their free labour (albeit less sophisticated than that envisaged by Terranova (2000) or highlighted by Harris et al. (2013)) in keeping contact details up to date and remaining willing to participate in research are not taken for granted. They are nurtured through engagement activity and, we contend, all contribute to this BioResource's value as a broker of research participants, but also the value of each individual asset, a willing research volunteer. Unlike other conceptions of value in the bioeconomy, which focus on the potential of biological fragments and/or database entries, the BioResource staff's labour present BioResource value as best understood as situated in the ongoing biosocial participation of the willing research volunteer. This value is not fixed, but iteratively produced through the accumulation of more volunteers, and, significantly, through the nurturing of the existing cohort. The practices of the BioResource, through an attention to the everyday labour involved in running this biobank, present participation and value production as an ongoing practical accomplishment. In doing so, it further highlights the limits of using the concept of clinical labour alone to conceptualise biovalue production and the process of participants giving access to their in vitro biology. While this is an important aspect of BioResource participation, the ongoing labour of participants and BioResource staff in maintaining involvement are needed to produce value in an ongoing way. The BioResource complicates understandings of the site of (bio)value as the result of commodity exchange or the production of knowledge assets. In the case of the BioResource, value resides not only in the biological fragments and associated data held within the database, but most significantly in the maintained willingness of these genetically and phenotypically known individuals to engage in future research projects.

As one example of the developing research capacity of the NHS, our study of the BioResource and BioResource routine work highlights different ways in which emerging research infrastructures, their value as well as citizen participation can be envisaged and understood by actors. We provide insight into this process by focusing on labour and value production. We have not examined how the BioResource translates its value into varying forms of capital by fulfilling its purpose of brokering willing research

participants. A focus on the performance of this brokering role would help illuminate how value circulates and for whose benefit. Although important questions for further research, these points are beyond the scope of this paper. Our account does, however, foreground the importance of considering the routine labour involved in running a biobank and the role it can play in (bio)value production and expand our understanding of the potential sites and scope of (bio)value beyond fragments, to include long term biosocial participation of engaged volunteers.

8. Conclusions

In this paper we have highlighted how volunteer labour, staff labour and ongoing volunteer participation converge in the work of the BioResource and in value production. Value, in this context, is produced not in the laboratory or situated in the partible sample of the individual, but in the willingness of the BioResource volunteer to participate in future research. We demonstrate the different ways the value of the BioResource is understood from within the NHS, with management focused on the accumulation of biobank entries and BioResource staff working both to increase volunteer numbers and maintain the engagement of existing volunteers in this biobanking project. We contend that BioResource draws into relief the routine labours involved in the value production process. Clinical labour and free labour may present certain aspects of this activity, but they fall short of encapsulating the numerous decisions and negotiations that are involved in the everyday work of maintaining (the value of) volunteers. The BioResource presents an example of a biobank where value is not fixed or predictable, but iteratively constructed through the ongoing labour of volunteers and staff. In doing so, it questions the limits of existing conceptions of value as commodity or asset and of clinical labour as the (sole) means of value production.

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Banking on Participation:
Exploring the Co-production of Population and Public in Swiss Biobanking

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Abstract: This paper explores enactments of participation in two Swiss biobanking configurations, a cohort biobank and a general biobank. It sheds light on the role of Personalized Health endeavours, in which biobanks play a crucial role. In order to contribute to the understanding of the role of participation in biomedical research dynamics, the analysis focuses on the processes of co-production of identity and biobanks (Tupasela et al. 2015). It documents the overlaps between the *population* – providers of biological samples – and the *public*, the collective who is expected to give its opinion on issues raised by the reconfiguration of the research/healthcare interface. It shows that modalities of participation impact the potential scientific value derived from the biobank's population, but also that the reconfiguration of the research/healthcare interface at the core of biobanking contributes to the current blooming of discourses and practices of participation. It argues that the forms of collective identity shaped through participation as *population* and/or *public*, exceed formal strategies of participatory governance and may play an even more important role in the shaping of biobanking configurations.

Keywords: biobanks; public participation; biosociality; personalized health; genomic research.

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1. Introduction

"Nowadays we do not do research *on* patients any more, but *with* patients," said the Dean of the Faculty of Medicine at a medical conference organized by the cantonal University Hospital on the theme of clinical

research, which featured a local cohort study as its hallmark (Public Event 08/06/2017). He explained this transformation by some infamous public scandals generated by the mistreatment and exploitation of patients enrolled in medical experiments. "Now we need to hear them, to take their voice and their families into account," he added. In this way, he stressed how they had impacted the patient's status in relation to the traditional authority and paternalistic attitude of doctors, not only in clinical settings, but also in research. No more passive subjects, taking risks for the sake of medical progress, sometimes without their knowledge, the new figure of the patient he alluded to was that of a well-informed research participant, whose opinions and personal situation would from now on be taken into account.

In contrast with this ideal figure, in Switzerland, patients' voice does usually not appear prominently in the debates around biomedical research and they are not engaged in the new forms of participatory governance which flourish in neighbouring EU countries in the "politics of life", comprising controversial new biotechnologies or entities challenging social and cultural understandings of what "life" is, such as genetic testing, GMO, or human embryonic stem cells (Gottweis 2008). The country has so far rather been characterized by the frailty of patients' social movements and the absence of so-called 'public participation' initiatives in relation to biomedical research[1]. However, calls for doing "research *with* patients" have recently started to be voiced in the Swiss landscape in the specific context of "Personalized Health" (hereafter PH). Used along with other similar terms such as "personalized medicine", "precision medicine" or "predictive medicine" (see, for example, Redekop and Mladsi 2013), PH is used in Switzerland to designate the broad and rapidly advancing field of biomedical research and healthcare which draws on the combined advances in the field of big data analytics and genomics. Characterizing the move to a data-driven paradigm of biomedical research and healthcare, it aims at improving prevention and treatment interventions according to the personal characteristics of individuals (Meier-Abt and Egli 2016). Biobanks play a crucial role in PH endeavours. Indeed, they are sites where tissues from which genomic data are collected, analyzed, and correlated with other health-related data, are stored, preserved and made available for researchers. Due to the need to preserve some connection between biosamples, data and the individuals they come from, they have raised issues debated internationally, especially around consent, incidental findings and the return of individual research results (Neresini and Viteritti 2014; Wadman and Hoeyer 2014: Hogle 2016; Tupasela et al. 2017).

While most experts in Switzerland agree that the scope of societal, ethical and political issues raised by PH and its associated biobanking is such that a public debate and participatory procedures would be needed, most strategic decisions have been taken by experts and there has not been any public controversy on the subject yet. However, at a local level,

2017 marked the emergence, at a local level, of institutional demands for "public participation" in the governance of biobanking, along with a growing number of research projects in medical and social sciences engaging with the 'societal' aspects of PH, as illustrated by the launch of the "Personalized Health & Society Initiative"[2] by a nonprofit foundation. How can we explain the current emergence of demands for 'public participation' and the sudden importance of lay opinion in experts' discourses in the domain of PH? What kinds of factors contribute to the rapid transformation of experts' view of participation in biobanking, from a relatively unproblematic act, restricted to hospital-based biomedical research – providing biological samples – to a societal matter, worthy of a wide social debate? Finally, what is participation in these emergent discourses and practices and how is it shaped?

In order to unpack the notion of participation and contribute to the understanding of the role it plays in biomedical research dynamics, we draw on the argument made by Tupasela et al. (2015) that biobanking configurations and identity are co-produced, meaning that people participating in biobanking by providing samples and/or giving their opinion, and from which biobanks draw their legitimacy, contribute to define the characteristics and identity of biobanks, as much as those shape the identity of the collectives that they study and/or engage with. This allows us to understand how the collectives involved in biobanking shape their configuration as much as biobanking generates new forms of collective identity or biosociality (Rabinow 2008; Gibbon and Novas 2007). In order to understand these processes, we need first to situate them in the context of PH endeavours in Switzerland. Our analysis will then turn to two biobanking configurations and their enactments of participation: 1) a cohort biobank, and 2) a general biobank which are based in the same Canton. Focusing on the perspective of experts engaged in PH – biobankers, researchers and clinicians – we will show that while, in the promissory discourses of PH advocates, all Swiss citizens might turn their daily lives into a reservoir for data production for the stake of research, blurring in this way the boundary between research and healthcare, in biobanking practices, this boundary is very present. We will show how its reconfiguration is entangled with how participation is framed and may both facilitate and hinder the production of scientific and health values resulting from the collection, storage and use of human biological samples for biomedical research.

2. Between Public and Population: Biobanks and the Co-construction of Identities

While the collection, storage and use of human biological samples for biomedical research is not new, during the last decade, biobanks have gained political and public importance due to the crucial role they play in

the knowledge-based bioeconomy by transforming waste tissues into valuable goods and a source of commercial, scientific, political and social values (Tutton and Corrigan 2004; Mitchell and Waldby 2010; Tupasela 2011). The productivity of biological material in terms of scientific, health and financial value has been conceptualized in terms of 'bio-value' to refer "to the yield of both vitality and profitability produced by the biotechnical reformulation of living processes" (Mitchell and Waldby 2010, 336). However, bio-value is not intrinsic in samples themselves and depends on "the various socio-technical arrangements as well as the continuous intellectual affective and technological work of human and non-human actors" (Timmons and Vezyridis 2017, 1243).

Needless to say, biobanks depend very fundamentally on individuals supplying them with health-related data and biological samples – blood, urine and tissues. The role of these bioproviders is all the more crucial insofar as biobanks need a critical mass of data and therefore large population sets, in order to gain statistical power, produce solid scientific knowledge and possibly develop new treatments and prevention strategies. However, people contributing to biobanking are much more than bioproviders, as the literature exploring the political, ethical and social interplay between biobanks and their participants has demonstrated. Two strands of analysis can be identified. Firstly, literature documenting and discussing the growing role and changing status of biobanking's *public* in terms of governance. The term "public" is used here to connote the "political body of people which is engaged with [it]" (Tupasela et al. 2015, 4). Secondly, literature analysing the politics of identity and community at stake in the constitution of the *population* recruited for biobanking and defined as the "collection of individuals which are studied and acted upon scientifically and medically" (Tupasela et al. 2015, 4).

While it is rooted in the long history of public health policy, the participation of lay experts – citizens, patients and other stakeholders – in the governance of science and technology took a novel turn in the EU in 1990 (Gottweiss 2008). Developed in response to the legitimacy crisis and critique of a democratic deficit, principles of openness, dialogue and transparency, as well as public participation strategies, have increasingly become central issues in the governance of scientific research (Levidow and Marris 2001). As a political and institutional response to public concerns and ambivalence towards science and expertise (Tutton 2007), these strategies have flourished in the last decade, particularly in relation to genomic research and biobanking. This is due, among others, to the many ethical, legal and social issues they raise. Specific topics have especially been put forward, such as the management of consent, data protection, incidental findings and the return of research results (Tutton 2004; Tutton and Corrigan 2004; Gottweiss and Petersen 2008; Kaye and Stranger 2009; Solbakk et al. 2009; O'Doherty and Hawkins 2010). Increasingly formalized and institutionalized, public participation strategies aiming at fostering trust and allegiance among their participants, have thus become

key to their success, legitimacy and long-term sustainability (Welsh and Wynne 2013).

The role of patients' associations in transforming the relationship between researchers and patients or research participants towards more inclusive and symmetrical approaches has been widely recognized in the context of medical research and especially in genetics (Kaufman 2004; Rabeharisoa 2006; Epstein 2008). Inspired by these democratic forms of scientific knowledge production, STS scholars have supported public participation principles and strategies for opening up the possibilities of subverting the epistemological, political and practical hierarchical division between lay and expert knowledge and for broadening the number of political subjects considered relevant, to be included in debates and deliberations (Levidow and Marris 2001; Joly and Kaufmann 2008; Gaskell et al. 2013; Burgess 2014). However, empirical studies show that practices are more contrasted. In the context of biobanking especially, the ambiguity and ambivalence of public engagement strategies in reproducing the same mechanisms which motivated their implementation in the first place is highly discussed (i.e. Wynne 2007; Voss and Amelung 2016). The role they play in silencing dissident voices, and controlling opposition groups and uninvited or "unruly public" (De Saille 2015; Hess 2015) is given particular emphasis. In addition, their legitimating role in gaining public support without questioning the neoliberal ideology of progress underlying the dynamics of scientific innovation has been criticized (Busby 2004; MacNamara and Petersen 2008).

In parallel, a second strand of scholarship has explored more specifically the role played by biobanking configurations, especially large national biobanks, in constituting different forms of subjective and collective identity through the constitution of their *population*. Biobanks often appeal to a rhetoric of identity and to notions of 'authentic' or 'indigenous' anchored in a past of shared national history (Tupasela and Snell 2012; see also Kowal 2013). Genetics, which "plays an important role in stabilizing categories of origin" (Tupasela and Tamminen 2015, 415) is especially salient in their constitution. This contributes to defining the collective identity of their participants in interplay with the genetic, historical, social and political characteristics they are supposed to share initially, and might result in "population branding" (Tupasela 2017) or in "racialized notions of populations" (Reardon and TallBear 2012).

Highlighting the national characteristics of biobanking participants might be used to promote research in a national scientific market driven by competitiveness and technological innovation (Tupasela and Snell 2012; Tutton and Prainsack 2011; Busby and Martin 2006). As a result, it shadows the private and international networks necessary for biomedical research (Busby and Martin 2006; Hauskeller and Beltrame 2016) and transforms the population contributing to the biobank's collection into a form of national capital and reservoir from which commercial value can be derived (Mitchell and Waldby 2010).

Tupasela et al. (2015) have analyzed the construction of the population identity in a dynamic way through their emphasis on co-construction. This term is used to designate the processes "whereby the population from which the biobank draws from, helps to define and characterize the biobank", and inversely, those through which "identification, collection and distribution of samples and data […] give rise to the construction of a population at the same time" (2015, 2). They argue that this co-construction process may lead to the bio-objectification of the population. This concept is used to refer to "the way in which life is *made an object* in different settings" (Webster 2012, 3, my emphasis). Initially, it designated the biological entities that are technologically transformed, blur boundaries, become sites of capitalization and raise ethical, legal, political and social issues, such as Umbilical Blood Cord (UCB) (Beltrame 2014; Brown and Wiliams 2015) or synthetic biology (Dabrock et al. 2013). In a broader sense, it means that participation in biobanking as *population* might lead to a form of reification, essentialization or financial exploitation. In other words, the collective of bioproviders feeding the biobank in data and biological samples might be reduced to a life form abstracted from its broader, social, economic and political context.

In contrast with the population's collective identity constructed by biobank operators and researchers, and serving above all the production of biovalue, one can ask whether other forms of identity might emerge from the constitution of the "public" engaged with a specific disease, patients' rights or biobanking governance. Indeed, participation as *public* is supposed to add social value to the pure provision of samples, and is sustained by a democratic ideal, which could provide a space for the critique of the capitalization of the biotech industry (Tutton 2004) and for alternative forms of reciprocity between researchers and samples donors (Busby 2004).

Literature on identity construction of the public recalls us that the implementation of governance strategies might contribute to a form of bio-objectification, as much as the identity construction of the population does, especially when it is used to legitimate biobanking practices without engaging in a meaningful two-way dialogue. A nagging question is whether it might also lead to new forms of collective identity that could be described as biosociality, scientific citizenship or civic agency (Weldon 2004). The concept of biosociality initially coined by Rabinow (2008) refers to collective identities forming around biomedical knowledge, biological entities, and associated institutions (Gibbon and Novas 2007) and is used to describe the process of identity production in active participation from lay experts themselves. It is not possible to refer to an active form of biosociality construction when the terms and agenda of public participation are already fixed and that lay experts have no room to influence wider issues (Weldon 2004; MacNamara and Peterson 2008). However, caring relationships and mutual understanding between lay experts and biobanking experts might also open up some possibility for more active

forms of civic engagement and practical reciprocity (Busby 2004; Weldon 2004).

Our article contributes empirically to the exploration of these questions by focusing on the co-production dynamics of identity between biobanking and its participants in the context of PH endeavours in Switzerland. The distinction between *public*, as the political body of lay people which are consulted to give their opinion or who are engaged in the governance of biobanks, and *population*, as the collective of bioproviders from which biological samples and health-related data are taken, about which biomedical research is done, and to which possible research results might be returned, is analytically useful. However, we want to show that in practice, this distinction is not so clear and is rather the object of constant overlaps and shifts. In particular, we want to shed light on the overlap and shift between *public* and *population* in participation enactments and show how, more than formal public participation strategies, which are considered as time- and resource-consuming activity, the collective identity produced through participation is valued by some experts. This additional collective value legitimizes their research enterprise, preserve its autonomy and provide them with the feeling of caring for their participants, but might also open up a space for the agency of participants which does not seem incompatible with the goals of biobanking.

3. Methods

The data presented in this article were collected as part of a research project commissioned by the Public Health service of Vaud Canton. It consists of two successive parts: 1) a qualitative study investigating local stakeholders' views of an hospital-based biobank and the development of personalized medicine in Vaud Canton (2014-2015); and 2) a qualitative, empirically grounded research project exploring stakeholders' views of PH, focusing especially on the issues it raises for public health and on public engagement, combined with the development of several collaborative initiatives around public engagement (2017-2018). These two long-term studies used a combination of methodologies, including semi-structured interviews, focus groups, observations at conferences and other events associated with PH, and qualitative and quantitative surveys. This article focuses on data collected since the beginning of 2017 on the views of medical and scientific experts involved at various levels in the field of PH on participation in the context of PH and biobanking, including 10 semi-directed, transcribed, interviews with researchers, clinicians and biobankers, and 6 with cantonal lead physicians, as well as ethnographic observations taken at about 20 workshops, conferences, round tables and meetings organized around PH, such as the Swiss Salon Planète Santé[3], or events organized by the Leenaards *Personalized Health and Society* initiative[4].

The two biobanking configurations we explore in this paper were chosen because they are emblematic of the current shift in biobanking we can observe in Switzerland. The first illustrates biobanking based on more traditional epidemiological research, starting to integrate genomics and turning towards a PH approach, but not driven by it. The second one is thought of from the outset as a tool at the service of PH research and inscribed in a data-driven paradigm. It is not focused on specific diseases like the first one, but collects data and biological samples for various prospective research purposes. Moreover, they are situated in the same canton and a similar network of actors revolve around them. While it would be interesting and relevant to document the perspective of participants in biobanking, this paper focuses rather the perspective of scientific and medical experts. It explores their vision of participation in order to highlight how the choices they make and the challenges they meet in terms of infrastructure and organization impact on participation enactments.

4. Personalized Health Made in Switzerland

Motivated by the potential of an ever-growing number of health-related data – genomics and other -omics, medical, and self-tracked – which could be exploited for the benefit of medicine and health promotion thanks to advances in big data technology and analytics, several initiatives were recently introduced in Switzerland. The two most prominent ones are the CHF 68 million[5] "Swiss Personalized Health Network"[6] (SPHN) and *Health 2030*[7], both launched in 2016. They aim at implementing the infrastructure needed to use a massive amount of data for the 'personalization' of healthcare and to promote PH.

Biobanks, as sites where biological samples such as blood, human tissues, or DNA are stored for the use of research, have become key sites at the core of PH transformations. In Switzerland, there is no national biobank and until recently, most biobanks were of small size. Based in university hospital services, they could be viewed as unproblematic infrastructural tools serving specific research projects. It is only in the context of PH developments that biobanking has gained in public visibility and has become a political and technological instrument for the promotion of research and innovation. In 2016, notably, the Swiss National Science Foundation (SNSF) started funding a Swiss Biobanking Platform[8] working towards the standardization of biobanking governance and practices related to the collection, conservation and use of biosamples. Focusing on the improvement of health strategies and the detection of diseases at a very early stage, the financial efforts of these initiatives are justified by the benefit for the health of the population as a whole a data-driven optimization of healthcare is expected to bring (Meier-Abt and Egli 2016).

4.1 Personalized Health – Participative Medicine?

The idea that tomorrow's medicine will be not only be predictive, but also participative, is very present in the discourse of PH advocates[9]. The scope of the transformations brought by the prospect of PH is potentially such that many societal, legal, and ethical challenges – for example data protection, the costs of the healthcare system or the lack of public understanding of genomics – are identified by experts as exceeding their field of expertise. Opening up a public debate is seen by them as a way of engaging people in the PH project, and of gaining their trust and support. "It will work better if they are active and not passive" expressed a genomic researcher and one of the PH advocates who is very committed institutionally and scientifically, as well as vocal in the debates (Researcher 1, workshop 20/02/2017). As a result, emerges from these discourses a figure of an imagined "participatory subject", that is a person from whom responses to the multiple societal issues raised by PH are expected:

> There is no easy answer, and it depends on individuals. Everybody has something to say and we need to put the questions on the table from the very beginning, to bring them to the streets. It concerns all of us, we need to pass the message that YOUR ideas are important, that YOU have something smart to say, and that people start thinking about all this (Researcher 1, workshop 20/02/2017).

The distinction between "public" and "population", that is between the collective, who is expected to give its opinion on issues raised by PH, and the one which provides samples and data, is conflated in these discourses. The participatory subject of PH is imagined as both an individual who participates in PH by providing data and biological samples, and somebody who gives its opinion and joins in the public debate, the participation as public being supposed to increase the size of the population, in a kind of virtuous circle based on trust and valorisation of the common good. The importance of the common good underlying the social contract at the core of participation in PH can be read in the following quote: "When it comes to data protection, citizens have the right to be protected, but in exchange they have the responsibility of donating their data for the benefit of the common good" (Researcher 1, interview 20.03.2017). In order to contrast this idealized vision of a responsible and active citizen, we now turn to two biobanking configurations in order to document the visions and challenges of researchers and biobankers and highlight how participation is enacted, not only in discourses, but also in practices.

5. Two Biobanking Configurations: The Cohort Biobank and the General Biobank

The first biobanking configuration has emerged in the context of a longitudinal, observational population study aimed at assessing the prevalence of cardiovascular and psychiatric disorders, and identifying their phenotypical, molecular and genetic determinants. The biobank in this configuration is considered as a tool at the service of the cohort study and not as a prominent element that is publicly visible *per se*. The recruitment of the cohort drew on the registers of the City Residents' Office and a first selection was made randomly in order to represent the population of the city between age 35 and 78. While the project was initially funded by a pharmaceutical company, public funding has since taken over. Over time, the original project has expanded into a variety of sub-projects exploring the association of the disorders studied with specific related aspects of health, such as sleep, exercise, pollution or noise. Presenting the study at a conference, one of the researchers at the head of the cohort explained the procedure the study participants go through. After giving their informed consent, which is specific to the study, they undergo a series of physical tests (for example, weight and blood pressure), and respond to an extensive questionnaire of over 900 questions detailing their lifestyle, state of health, and personal history. In addition, they have a blood sample taken and 40 biological markers are tested, in addition to genetic markers. Blood samples and data are securely stored in the cohort's biobank. The data are analysed through Genome Wide Associations[10] (Researcher 2, public event 8/02/2017). Participating in this study as a population requires thus an important "clinical labour", defined by Mitchell and Waldby (2010, 334) as "the regularized, embodied work that members of the national population are expected to perform in their role as biobank participants". This comprises the bodily and mental efforts demanded freely to participants by the various medical examinations, analyses, interviews, trips and other organizational tasks necessary to the realization of medical research.

Opened in January 2013, the second biobanking configuration represents a first attempt, in Switzerland, at systematically collecting biomaterial and health-related data from hospital inpatients. In contrast with the cohort biobank, which is built around a specific research project, this general biobank emerged as a primary goal in itself, prevailing over future PH research projects, which had yet to be defined. It was therefore not organized around research into a specific health disorder, and a broad consent was developed in order to address the specific needs of this hospital-based cohort. Unlike the collection of data characterizing the first biobanking configuration, very little is demanded from inpatients in terms of clinical labour and only an additional blood sample is taken, and stored for further biological and genomic analyses, in addition to health-related data taken from medical files.

A special team of recruiters was created in order to inform patients and ask for their consent to contribute to the collection of samples for the biobank. They visited the various medical services, providing patients with information about the biobank's objectives and asking them to sign a broad consent. While the hospital-based biobank was heralded with great promise at the point of its creation (Dessibourg 2012), at the beginning of 2017, it appeared rather as a disappointing enterprise. With 25,721 patients (Bochud et al. 2017), the biobank had almost reached the symbolic threshold of 30,000 biosamples, which was presented as its objective from the very beginning (Nicollier 2014), but no research project had been developed to use them for a long time. It is only in 2018 that a precision medicine unit was created at the University Hospital and that its research team obtained funding for a project exploiting the data and samples of the hospital-based biobank. Moreover, the role, objectives and activity of the biobank remain unclear or even unknown to many health professionals who are not involved in PH developments, as well as to the general population (Biobanker 3, interview 14/03/2017).

6. Constituting a Population: A Matter of Quantity or Quality?

When we started our research, the cohort biobank was often presented to us as an example of both successful research and participation in the sense of a sustained enrolment of the population in the cohort. As the description above indicates, participation in this study as a population requires a significant level of clinical labour and a long-term involvement. However, as one of the researchers of the project told us, the participation rate has remained high and participants are willing to take part in associated subprojects, even though these require them to carry potentially invasive sleep-monitoring devices or geolocalisation trackers (Researcher 2, interview 09.02.2017). Our interlocutor explained the motivation to participate based on two main elements. The first concerns the direct health benefits and care participants may derive from the medical investigations they undergo for research. While the medical examinations provide data, which will be analyzed and might lead subsequently to potential future clinical and preventive applications, they also provide cohort participants with direct information about their health in the present, for example about their blood pressure or sleep apnoea. In this way, the research examinations are presented as a form of medical check-up, whose results are shared with the people enrolled in the cohort and their general practitioners. In addition to the somatic investigation and the direct health value it might bring, the care relationship between the research team and the cohort participants is also presented as a way of maintaining the enrolment of those involved in the study over the long term. According to the researchers, this relationship is characterized by the way the

participants are welcomed and the time spent in interviews. It was presented with pride as a way of giving something back for the sustained engagement of the population. The fact that some people came back from abroad especially for a subsequent phase of the project provided the evidence of the success of this form of personalized care towards research participants, the researcher added (Researcher 2, interview 09.02.2017). The idea that the study allowed people "to learn things about themselves" was fostered publicly by a cohort participant reinforcing the narrative of a population receiving as much as giving (Cohort participant, public event 6/06/2017).

6.1 The City Population, the Cohort Population?

The cohort is named after the city where the research takes place, but also from which its participants come from, as a recruitment criteria was that they were residents of the city. The local dimension of the cohort was particularly highlighted by researchers: "people are proud of being a member of the city cohort" (Researcher 2, interview 09.02.2017). Researchers did not appeal to genetic relatedness or a shared past history to characterize the identity of the cohort's population, but rather to the city itself. Participating in the cohort is seen by experts as acting as a good citizen of the city, contributing with other residents to a collective enterprise which surpasses their individual benefits, creating a sense of belonging and shared identity which maintains the high and sustained level of participation over the long term. The figure of the participant which emerges from the researchers' discourses is thus that of a city resident, ready to engage in clinical labour for the future benefit of their city, and who in return, gets an immediate benefit for their own health, care, and the gratification of contributing to a collective enterprise.

As in other genomic research biobanks, a logic of accumulation drives the objectives of the cohort biobank. However, the principle according to which more is best is not enacted in this configuration and the modalities of research participation contribute to the productivity of samples, by improving their quality: "Ideally, in research, one needs a lot of data, and with a very good phenotype, but what made the success of the cohort, is that we are not very big, but we have a very dense phenotype. This is our strength" (Researcher 2, interview 09.02.2017). According to their perspective, the sense of community, created through the participation of the population, plays therefore also a role in the production of scientific and health values, by contributing to increase the quality of health-related data. In order to refine correlations and produce biomedical knowledge, the quality of data matters more than its quantity in this configuration, and the population's cohort can itself be seen as a technology through which good quality data can be cultivated. However, the restricted size of the population is also a limitation: "The problem for us is size, i.e. statistical power. If we focus on rare mutations or uncommon variants, when we

only have 6,700 participants, we encounter a problem of statistical power" (Researcher 2, interview 09.02.2017). Therefore, the constitution of the cohort through the administrative and geographical unit and social image of the city constitutes both its strength and its limitation in terms of scientific value production.

In contrast, the general biobanking configuration does not constitute its population through long-term participation in the study. As the required clinical labour is minimal and there is no specific disease defining the goal of biomedical research based on the samples provided, the population remains without a well-defined identity. Inpatients are rather thought of as bioproviders and their potentially increasing number seen as an asset. Indeed, this biobank is configured as a tool for biomedical research whose potential for generating scientific and health values rests on the greatest accumulation of data and biological samples possible. The assumption underlying the strive for quantity is that accumulation itself is useful for researchers by providing them with a lot of material ready to mine and with significant statistical power. In this respect, this biobanking configuration is characteristic of the data-driven paradigm of PH, where the accumulation of data is the primary goal (Hogle 2016).

6.2 Turning Accumulation into Waste

However, over time, critical voices among experts have pointed to the limitations of the logic of accumulation. Accumulation was initially valued because of its potential for producing scientific knowledge, but without any research project exploiting these data, the value of samples diminished: "I mean, all these samples, because they do not all have their DNA, and the buffy coat, one knows that after two or three years, or even five, it is not that good any more. One needs to extract the DNA and then it is stable. But it is a disaster if it takes too much time. It is a waste. […] It is a sample cemetery, whose quality deteriorates day after day, and it is such a shame" (Biobanker 3, interview 14.03 2017). Here, time turns accumulation into waste and decreases the potential productivity of samples, if they are unused or not transformed into a more stable or durable form, such as DNA (Stevens 2016).

Moving from a revolutionary innovation and tool at the service of biomedical research at the moment of its creation, the hospital-based biobank has, over time, reverted to being part of the invisible infrastructure of the hospital. Its name itself has disappeared and been changed, and turned into an appellation valorizing biological samples and data, and not the biobank. In this way, the potential biovalue of samples and data is spotlighted, rather than the instrument of collection and storage. If, initially, the institutional unit of the university hospital was thought of by the researcher-biobanker team as an unproblematic reservoir for inpatients, and thus for the collection of data and samples, it has proven to be rougher than expected. Indeed, the biobank team ended up transforming

the modalities of recruitment and had to stop using data in research in order to face political and institutional demands to meet the standards of the Taipei Declaration regarding the return of research results, incidental findings, and patients' rights (WMA 2016), and integrate them into the governance of the biobank. In order to understand the difficulties met by this hospital-based biobank, we need to examine how participation has been enacted and has shifted over time.

7. Constituting a Public: Between Bioprovision and the Production of Collective Identity

In the cohort biobanking configuration, the boundary between research and healthcare is crossed when the results of research investigations feed immediately into clinical intervention, and when the space of research consultations becomes a place where people may feel cared for, in the sense of listened to and taken into account, but not in regard to genomic biomarkers. Rather, it is reconfigured in a way that draws a distinction between biological results of relevance for the clinic in the present and genetic findings tainted with the uncertainty inherent to the future of research progress and the complexity of understanding the genome. "Clinical and research sequencing are not the same in technical terms," explained our interlocutor and "we need to be very cautious about it" (Researcher 2, interview 09/02/2017). In this biobank configuration, maintaining a clear distinction between research and healthcare goals and techniques works as a way of leaving the uncertainty associated with the use of future research results in prevention and treatment, in the hands of researchers. This also provides them with the space and time for developing research without being concerned by returning genomic results to participants and questioning the social and ethical issues this may raise.

Interestingly, this configuration has not involved any formal public participation in governance so far. The cohort's population is not part of the governance committee of the study, is not consulted to give its opinion on issues which might be relevant for them, and has not expressed any demand for it either. In the expert's eyes, the strength of the collective identity generated through the "personalization" of the care for the cohort's population, which is identified with their city, replaced the need for a more institutionalized form of participation. This gave researchers the feeling that they engaged with their participants and took them into account, while enabling them to pursue their research activities without what is considered as the time- and resource-consuming burden of formal public participation strategies. However, due to the researchers' apprehensions regarding the reconfiguration of the research-healthcare interface and in order to meet the European standards for governance in biomedical research necessary to keep the cohort funded, a formalization of public participation is considered in the next follow-up phase of the

study (Researcher 2, interview 09/02/2017). While a rather clear temporal and practical distinction between the two domains has been maintained since the beginning of the study, the idealized vision of participation it enacted is challenged by these new prospects. Indeed, the form of collective identity constituted through the cohort population's bioprovision seems to lose its foundation with the transformation of the research-healthcare interface, opening up a space for the constitution of a public whose basis and common identity are open questions for the researchers, who are worried about how to construct it.

7.1 Providing, Donating or Advising?

In the general biobank, political and institutional demands for formal public participation strategies also played a role in the constitution of the biobank's public. During the first years of the hospital-based biobank, participating in the biobank was understood as a safe and unproblematic technical act – providing a blood sample taken during hospital routines – and signing a broad consent for it to be used for further research. During this first phase, the collection of samples was a primary goal and participation only considered as a form of bioprovision, supplying the biobank with samples. However, in the meantime, the notion of broad consent has started stirring controversy beyond the walls of the hospital, casting a shadow over this form of passive participation. At stake is the impossibility of completely severing the link between the biosamples, associated health-related data and the people they come from, in this case the inpatients. In addition, the complementary possibility of returning research genomic results and incidental findings, which might be of relevance for the clinic, was also considered problematic (Barazzetti et al. 2017).

In an attempt to respond to the critiques regarding the use of broad consent, stemming from both public health experts and patients' associations (Dessibourg 2017; Leroy 2017), bioprovision was then recast in terms of a donation to research by the biobankers' team. Intended to valorize inpatients' participation, it indicates a shift from a technical understanding of participation to a moral one: "The idea is to focus on donation in the sense of solidarity, of a collective engagement for a cause: scientific research, which is a marvellous thing and serves the common good, and thus the population. Research cannot advance without donations and the goal is to sensitize the population. Perhaps they don't know how to contribute in general, but they can participate philanthropically in research, they can donate their samples" (Biobanker 2, interview 28.02.2017). Turning to a rhetoric of solidarity – donation – for the promotion of biomedical endeavour (Aguzzi 2017) – which from these biobankers' perspective represents a common good in itself, turns the providers of biobanking samples into an altruistic and acritical population, sharing with the researchers the optimistic and idealistic vision of bio-

medical research as an enterprise which is worth donating and will ultimately benefit the whole society.

This tends to erase the economical dimension of research, as well as the exact nature of what can be given back to these participants. Instead of providing research participants with health benefits directly in the present, as was the case in the cohort biobank, here participants are expected to participate in the name of the promissory future of progress in biomedical research, without asking about the possible benefits biomedical research might bring to them or to society. This rhetoric masks the fact that potential clinical and preventive applications might be minor, are very uncertain and distant in time. Instead, it points to the importance of moving beyond the individual benefits one might draw from participation in the present, to contribute to the "common good" of research. In this way, it places participation in a moral economy based on a social contract of solidarity, which silences the issues raised by the reconfiguration of the research-healthcare boundary at stake in biobanking practices when they are put to the service of PH.

Framing participation in terms of donation for research was meant to address the external critiques concerning broad consent and issues raised by the blurring of the research-healthcare boundary in an attempt to publicly revalorize the biobank as an enterprise. Trying to constitute an external public with the idea that they could ideally be turned into the biobank's population and provide samples, through a rhetoric of donation, the biobank's team organized an open-door event centred around "donation for research" (Event 10/06/2018), but it remained unattended by the general public and the cautious actors, who had encouraged the biobank's team to give greater consideration to the concerns of citizens and patients. The difficulty the biobank team encountered when trying to constitute a public, which was initially thought of as passive, trusting, and donating, led to an internal reorganization of the biobank and prompted researchers and biobankers promoting PH and who needed the biobank, to develop more formal attempts of "public participation". To do so, they turned to the biobank's bioproviders, in order to ask them about their opinions and preferences regarding the issues broad consent and the return of results. This turned the inpatients' population, which until then had not been characterized or well identified, either by a specific disease or by some genetic, cultural, socioeconomic characteristics or an administrative/geographic unit, into a public, sharing a kind of sociality, as the enthusiastic and repeated involvement in the consultancy focus groups we organized with the biobank team indicates.

This public is expected to help the researchers' team to address the uncertainties associated with the sensitive issues raised by the circulation of data and biomarkers and to orient future governance and practices in response to the critiques blaming them for ignoring social, legal and ethical issues. Whereas the issues raised by the porosity of the boundary between research and healthcare opens up a space where a need to consti-

tute a public emerges, which might in turn influence its reconfiguration process, it also enables researchers to go on with their scientific activities and to continue recruiting and enlarge the number of bioproviders. In a way, the constitution of this public, allows them to redefine the field of their expertise based on the technological and scientific dimensions and responds to external critiques and political demands, while leaving to the public the responsibility of deciding how they want data and research results to circulate between research and healthcare.

8. Conclusion

What is participation in emerging biobanking configurations in Switzerland? And how does this specific case illuminate the entanglements between identity and participation? This question stemmed from our observations about the recent local blooming of discourses and practices of participation in PH endeavours and the many different realities this umbrella term conveyed. In order to tackle this question and contribute to the understanding of the co-production dynamics of identity between biobanking and its participants, we focused on two contrasted biobanking configurations and explored the perspective of biobank operators and researchers. One is an epidemiological longitudinal cohort biobank centred around specific phenotypes and diseases, while the other is a prospective hospital-based general biobank. In both configurations, the modalities of participation determine the possibility for scientific, and ultimately health, values to be produced. Our analysis of the researchers' perspective working in the first biobank indicates that a form of collective identity is constituted through the sustained participation of the population and its identification to the city. According to them, the sense of community created through the population's participation in the cohort, which provides the reservoir for recruitment, also serves the production of scientific value as it contributes to increase the quality of data, necessary for research. Researchers consider that the form of personalized research care they provide and the sense of contributing to the common good of their city, for the sake of the health of future generations, work as a counter-gift for the participation of the population, in a way close the practical reciprocity described by Busby (2004) and Wadmann and Hoyer (2014). The second configuration, in contrast, is not focused on specific diseases. Based on a logic of accumulation proper to a data-driven paradigm, it aims rather at collecting the greatest number of samples and health-related data, assuming that the quantity will increase the potential scientific productivity of samples. Its population consists of inpatients, but has no well-defined identity and is rather initially reduced to a bioprovision role.

In the promissory discourses of participatory medicine advocates, the Swiss population's daily lives are turned into a reservoir for genomic and

other health-related data for the sake of biomedical research, and in exchange for data protection. In addition, the population seems to collide with the public, as Swiss citizens are also expected to give their opinion on the important issues raised by biobanking in PH. These discourses contribute in this way to shape an ideal figure of participant as morally attuned, caring for future generations, concerned by the common good, and engaging democratically in public debates. In other words, being a good citizen means participating in biobanking both as a bioprovider and as part of the public. This ideal figure is very much aligned with the need for health-related and genomic data, solidarity and trust, necessary to the development of PH. In contrast, in the two biobanking configurations examined, the reconfiguration of the research/healthcare interface characterizing the move to the data-driven paradigm of PH, is very much present and at the core of shifting enactments of participation.

In the cohort configuration, the collective identity, generated through the population's enrolment, works as a substitute for formal public participation in the governance of research, allowing researchers to avoid what they consider as a time- and resource consuming activity out of the scope of their field of expertise, while giving them the sense of caring for their population. However, the prospect of having to deal with issues raised by the return of results and incidental findings, as well as the call for participatory governance from the funders to meet EU standards, challenge this idealized version of participation, in which researchers and participants are apparently both satisfied by maintaining a boundary between research and healthcare leaving an open ground for the constitution of a public whose shape remains to be defined.

In the general biobank too, the role of participants as simple bioproviders is challenged by the need to keep a traceable connection between the identity of the inpatients supplying the biobank and the biological samples for the purpose of research, but also in order to return possibly relevant incidental findings and research results. In a first phase, bioproviders were requalified as donors for research, in an attempt to increase the public legitimacy of the biobank's activities and goals, and respond to external critiques around broad consent. The underlying assumption was that valorising donation would increase the mass of the population of bioproviders by turning them into a passive and trusting public. However, this altruistic rhetoric remained unable to meet the challenges raised by the reconfiguration of the boundary between research and healthcare. It is only through the transformation of the inpatients' population into a public, consulted about its opinion and preferences regarding the return of results, that another form of collective identity as public started to take shape.

Does the collective identity constructed by biobankers leave room for the agency of participants or are the public and/or population passive collectives enrolled for the sake of biovalue production? Our analysis shows that the constitution of a biobank public allows researchers to pur-

sue their research activities by delegating the work and moral responsibility of the social and ethical implications raised by the blurring of the boundary between research and healthcare to its public, without questioning the epistemological and political distinction underlying it. As a consequence, while this reconfiguration generates a possibility for doing research *with* patients, to go back to the Dean's introductory expression, opening up a space for a new kind of relationship between researchers and the biobank's population and public, it also seems to reinforce the boundary and hierarchy between the technical and epistemological goals of research left in the hands of experts and the responsibility for ethical and social issues raised by the increased circulation of samples and data, which is delegated to the public.

Our analysis of the overlaps between the population of bioproviders and the public which is engaged in participatory governance, as one replaces or is transformed into the other, indicates also that the production of a collective identity plays an essential role in the implementation of formal strategies of participatory governance, and seems to be necessary for the continuation of biomedical research, both in terms of tissue provision and in terms of increased legitimacy. In our case, this collective identity is not based on shared genetics or common past history, but is constituted through participation in biobanking, as population or as public. The specific conflation of research and healthcare on the one hand and of population and public on the other shapes an ideal figure of a biocitizen. While the constitution of this figure might be used for the benefits of PH research, we suggest, that it might also provide the participants with the conceptual and symbolic tools and space, through which other forms of agency and collective identity might unfold. At the present moment, instead of representing a threat, it seems that some biobankers welcome this more active form of participation, aligned with the ideal of the biocitizen providing samples *and* contributing to biobanking governance, as long as it remains compatible with the biobanking enterprise and increase the production of biovalue. Whether, this model will be actively appropriated by participants and lead to other forms of resistance, contestation and identity remains an open question, that only future exploration of PH in Switzerland will be able to answer.

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[2] https://www.leenaards.ch/interdomaines/sante-personnalisee-societe (accessed 29/07/18).

[3] https://www.planetesante.ch/salon (accessed 29/07/18).

[4] https://www.santeperso.ch/Agenda/Bien-vieillir-au-21eme-siecle-la-sante-personnalisee-au-service-des-seniors (accessed 29/07/18).

[5] About 70 500 000 US dollars or 60 000 000 Euros.

[6] https://www.sphn.ch/en.html (accessed 29/07/18).

[7] *Health 2030* benefits from the burgeoning innovative high-tech health sector situated in the Lake Geneva region of Switzerland (Genier 2017) and contributed to the opening of the first Swiss Genome Center in May 2017. For more information see: https://health2030.ch (accessed on 22/10/2018).

[8] https://swissbiobanking.ch/ (accessed 29/07/18).

[9] While experts speak of personalized health and medicine, the reference is often made to the '4P medicine', which is Predictive, Preventive, Personalized and Participatory (Auffray et al. 2010).

[10] For more information on genome wide associations, look at https://www.genome.gov/20019523/genomewide-association-studies-fact-sheet/ (accessed 30/07/2018).

"It's Actually Part of Clinical Care"

Mediating Biobanking Assets in the Entrepreneurial Hospital

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Abstract: A core aspect of the entrepreneurial hospital is the mobilisation of the means of care beyond care itself. In previous work, we showed how the entrepreneurial hospital uses its unique access to patient populations, whose health needs make them available, in order to facilitate research into therapeutic, diagnostic, or service delivery innovation. It 'entrepreneurialises' care, we argued, to meet research needs. What may be less obvious in this process, however, is that research, too, is entrepreneurialised to meet care needs. That is, the entrepreneurial hospital not only constitutes its patient populations and care infrastructure as distinctive assets that serve its entrepreneurial aims, but also positions its entrepreneurial aims as a decisive element in the service of care. This article develops the concept of the entrepreneurial hospital to help theorise biobanking. It foregrounds the views of biobankers – drawing from our ethnographic research and especially our interviews with key-informants (2008-2009) who work in some relation to biobanking in a Canadian province – thereby providing a window onto an important, yet under-examined, set of rationales motivating the entrepreneurial integration of care and research through biobanks.

Keywords: biobanks; public participation; biosociality; personalized health; genomic research: healthcare.

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1. Introduction

How should we think about biobanking in relation to the entrepreneurial hospital? In earlier work, we argued that – unlike the much-discussed "entrepreneurial university" (see, among many: Bok 2003; Etzkowitz 1998; Owen-Smith 2005; Slaughter and Leslie 1997) – entrepre-

neurial hospitals have been largely unnoticed, in spite of their significant, distinguishing characteristics. For whatever reason, research theorizing the rise of the "commercial ethos" (e.g. Etzkowitz 1983) in bioscience has largely tended, until recently, to ignore the specificity of the hospital setting. What is missed, in overlooking this setting, are the particular ways that patient populations and care infrastructure are constituted as *distinctive assets* in pursuit of entrepreneurial aims (French and Miller 2012). From where we write, in Canada, our investigations into entrepreneurial hospitals have illuminated some of the tensions underlying their efforts to hybridize multiple logics of healthcare, with those of innovation, comercialisation, technology transfer and economic growth. Insofar as they are positioned to care not just for health, but also for wealth, entrepreneurial hospitals reflect a considered attempt on the part of the health research and care communities to "leverage a joint solution to parallel problems of constrained public finances, growing need, and the limited success of persistent, independent efforts at reform" (Miller and French 2016, 1541). Key focal points within this considered attempt, as we discovered in the course of our empirical work, are biobanks. Insofar as biobanks represent sites of accumulation (of tissue, data, expertise, and so on) within the entrepreneurial hospital, they act as crucibles for both the intensification and mitigation of the tensions mediated by this organization. The goal of this article is to examine the relationship of the biobank to the entrepreneurial hospital, with reference to sociology's and science and technology studies' (STS) engagements with biobanking.

A core aspect of the entrepreneurial hospital is the mobilisation of the means of care beyond care itself. For example, the entrepreneurial hospital uses its unique access to patient populations, whose health needs make them available, in order to facilitate tailored research into therapeutic, diagnostic, or service delivery innovation. In this respect, the hospital-based biobanks we examined are different from 'national biobanks' – analysed by Busby and Martin (2006), Mitchell and Waldby (2010), and Tutton (2002; 2007), among others – where there is a need 'to drum up volunteers' independently of their access to medical care (Mitchell 2012, 231), and where many of the volunteers would be healthy. The biobanks we studied typically receive tissue samples and patient histories from individuals who, as part of their care, have been asked to donate their materials and information. Patients, according to a website of one of the biobanks we examined, "are offered the opportunity to participate [in research] at the time of their first appointment", when they are asked to provide a blood sample and also for permission to be contacted for future research projects. This biobank thus takes advantage of the entrepreneurial hospital's patient population and care infrastructure to meet its research goals. We might therefore say that care is here 'entrepreneurialised' to meet research needs – this is an example of the mobilisation of the means of care beyond care itself.

What may be less obvious in this process, however, is the potential of research to be 'entrepreneurialised' to meet care needs. Indeed, this article will present data illustrating how biobankers working within the entrepreneurial hospital make sense of their efforts with respect to care. We will also highlight discourse arguing that biobanks, in this context, do not only aim to realise their research needs, but also position their research and entrepreneurial aims as decisive elements in the service of care.

Although it may be tempting to dismiss such positioning as a form of rhetoric designed to mollify public sentiment in contexts where the "core publicness" (Anderson 2012) of care is increasingly instrumentalised according to non-public (e.g. professional, organizational, commercial, etc.) interests, we identify in this article its potential to play an important mediating function. Indeed, it seems that the entrepreneurial hospital excels at mediating between incommensurate value systems. This mediation work, as we will show, is deftly performed in the biobanking context (Tupasela and Snell 2012), illustrating how biobanks can operate as intermediaries that help maintain the entrepreneurial hospital's social license and legitimacy (Dixon-Woods and Ashcroft 2008; Dixon-Woods and Tarrant 2009). It may also help to explain why patients willingly participate in research initiatives like biobanking when the direct benefits to their health may not be apparent[1].

Moreover, by empirically advancing the concept of the entrepreneurial hospital to help theorise biobanking, this article makes two contributions to the literature. First, it pulls the substantive-theoretic scholarly focus upon biobanks to a meso-organizational level, emphasising the layered, complex socio-technical networks in which biobanks are embedded. Second, it shifts the empirical focus (dominant in the sociology of biobanking) from the views of lay-participants to the views of biobanking and health professionals, thereby providing a window onto an important, yet under-examined set of rationales motivating the entrepreneurial integration of care and research through initiatives like biobanks.

In what follows we first provide a brief discussion of the entrepreneurial hospital, focusing on its emergence and contemporary context. We next discuss literature on biobanks with a focus on two strands of work, 1) related to hybridization of public- and private-sector logics, and 2) related to the incommensurate (bio)values mediated by biobanks. Then, following a discussion of method, we present data from our ethnographic research, drawing primarily from twenty-six semi-structured interviews with key-informants (2008-2009), who work in separate but networked organizations at a number of physical sites, with responsibility for the provision of care for a geographically defined population. Taken together, the network possesses a substantial research infrastructure, well developed affiliations to the local, university-based medical school, as well as connections to other universities. We discuss biobanking in the context of this network, and the entrepreneurial hospital more generally. We present two discursive orientations that emerged in our data, which,

while complimentary, may also evince some tensions. We conclude with a reflection on the implications of these tensions for the future of biobanks – and the entrepreneurial hospital more generally – focusing in particular on tensions between the imperative to grow the biobank's network and the imperative to maintain its social license.

2. Entrepreneurial Hospitals: The Emergence of a Novel Organizational Form

In Canada – the site of our empirical work – entrepreneurial hospitals have emerged against the backdrop of a pervasive effort to re-imagine the meaning and hidden potentialities of publicly-funded healthcare. At issue is how to transform a long-standing commitment to public-funding for care into a national competitive advantage in biomedical innovation. The visualization of this transformation has become a matter of policy for governments and other organizations involved in the funding and conduct of health research (e.g. ACAHO 2007; CIHR 2006 and 2009; Government of Canada 2007; Naylor et al. 2015; see also Atkinson-Grosjean 2006; Miller and French 2016).

By no means unique to the Canadian context (e.g. BIGT, 2004; CFST, 2011), the aspirational policy discourse aimed at producing national wealth by leveraging healthcare infrastructures and patient populations reflects organization-level developments designed to mobilise care in commercial ways. For example, a characteristic feature of entrepreneurial hospitals in Canada is the articulation of mission-statements, policy, and funding priorities meant to accelerate innovation, technology transfer and commercialization. Consequently, a number of entrepreneurial hospitals have developed in-house expertise in technology transfer and commercialisation, offering their health researchers a range of services related, for example, to intellectual property (IP) protection, material transfer, and non-disclosure-agreements, patent searches and applications, business development planning, and so on.

Given this policy focus, it is apparent that the *entrepreneurial* hospital is designed to do far more than merely provide care. At the same time, because it is a *hospital*, care provision remains core to its mission, providing a basis for hybridizing multiple logics, including logics for health research, health care, innovation, technology development and commercialization. For its proponents, the entrepreneurial hospital's cutting-edge biomedical expertise, supported by data-sets on treatment regimes and outcomes, growing tissue repositories, and large populations of patients, make the organization into a catalyst of biotechnological innovation.

To the extent that it embeds entrepreneurial aims into the traditional organization of care, the entrepreneurial hospital must maintain the capacity to address a diversity of problems, and not just those directly related to care. For this reason, it would seem that at least two types of re-

search are privileged by the entrepreneurial hospital: 1) research that is seen to have direct clinical applicability; and 2) research that is seen to have clinical applicability in future (French and Miller 2012; Miller and French 2016). Biobanks – characterized by accumulative practices that harvest patient tissue and information on a routine basis in the course of care – derive utility in the context of the entrepreneurial hospital by straddling and enabling both types of research. They may be used as platforms that address well-defined research questions articulated in present circumstances. Yet their value stems also from their potential to collect a population's past, lived experience with disease (registered in tissue and information) in case it may serve future and as yet undefined research needs.

We turn now to a discussion of sociological and STS engagements with biobanking. Then, following a brief discussion of method, we present data that illustrate how the entrepreneurial hospital seeks to leverage its biobanking potentiality.

3. Sociological and STS Engagements with Biobanking

Sociological and STS accounts of biobanking have grown substantially in the past decade (see, for example, Lipworth et al. 2011) and we cannot be exhaustive in our review of the literature. Instead, we concentrate on two strands of work related to 1) the hybridization and entanglement of public and private-sector logics in biobanking, and 2) the incommensurate (bio)values mediated by biobanks.

3.1 Hybridization and Entanglement

Against the backdrop of earlier research that had discussed biobank development according to two different and mutually exclusive logics (those of the public sector and those of the private sector), a number of sociological and STS accounts of biobanking have taken up the 'hybrid' nature of biobanks – more specifically, they have focused on the hybridization of public and private interests, on how they intersect, reinforce each other, and work within complex social, political, ethical and economic spheres. For example, Hauskeller and Beltrame, in their study of umbilical cord blood banking, argue that there is no clear-cut division between public- and private-sector biobanks; rather, viewed as biotechnological platforms (Keating and Cambrosio 2000), cord blood biobanks exhibit "a growing hybridization between the public and the private model" (Hauskeller and Beltrame 2016a, 416). As they note, 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" (Hauskeller and Beltrame 2016a, 416).

Central to understanding how all kinds of hybridization flow from, and contribute to, the network of public-private bioeconomies made up by the global system of biobanks is the concept of "entanglement". Callon (1998, 19) uses the concept of entanglement as a way of theorizing "the process of 'marketization' and the relations that are either hidden or surfaced in the performance of market transactions". Hauskeller and Beltrame (2016a, 425) build on this by pointing, in the context of cord blood biobanking, to the way that entanglement is formed through "cooperation across the public and private sector", as well as to how this cooperation "produces configurations within the regimes of [cord blood] biovalue exploitation that account and serve both institutional forms and maintain them in their differences and hybridity". In other words, the concept of entanglement highlights for analysts the fact that there are relations that – to use Callon's term – "overflow" the boundary between public and private. For Hauskeller and Beltrame (2016a, 429) the concept of entanglement helps illustrate how even apparently public biobanks operating on a redistributive model have developed in "symbiosis" with the market economy. Ostensibly public biobanks are, thus, also governed by economic principles. However, "the search for profit is not the central engine of this market"; instead, the "economic principle that is dominant in public banking is one of self-preservation and sustainability" (Hauskeller and Beltrame 2016a, 429).

Given this situation of entanglement, it is important to locate and study what Hauskeller and Beltrame (2016b) elsewhere describe as "hybrid practices" in biobanking. Hybrid practices play across, and reshape, the boundary between public and private biobanking practices. They blur the borderlines between research, clinical care, commercialization, volunteerism and citizenship within the biobank. They may, for example, invoke ideals of nationhood and supposed genetic homogeneity that reach back to time immemorial while also mobilizing a "diverse and multicultural national identity" to ensure the participation of "ethnic minority groups" (Busby and Martin 2006, 245-246; see also Busby 2004). They may encourage patients to see their participation as combining "their personal health project with a sense of contributing to efforts undertaken by the welfare state" (Hoeyer 2003, 235). They may seek to manage – through rhetorics of standardisation and governance, as well as through public engagement exercises – the uncertainties of public opinions about the "substantial commercial interests" (Tutton 2004, 20; see also Tupasela et al. 2015) that direct public funding of biomedical research and the development of biobanking platforms. They may blend narratives of health with those of wealth, emphasizing how biobanking can benefit wider national economies (Lewis 2004; Cooper and Waldby 2014). Hybrid practices, in other words, emerge in relation to the structural realities of biobanks that straddle public- and private-sector boundaries; they work not just to navigate these boundaries, but also to actively constitute them.

In this sense, we might think of the hybrid practices developed by biobanks expressions of the "tension between ethical, scientific and commercial values" (Timmons and Vezyridis 2017, 1). For example, Timmons and Vezyridis (2017, 11), in their study of what we would characterize as an entrepreneurial hospital in the UK, observe how the biobank "broker[s] the commodification of its own assets between academia and the market", acting as "both a producer and seller of biospecimens". Similarly, Turner and colleagues (2013, 70) find that biobanks are "caught directly between the values and rights of the participants and the potential commercial and scientific value of the samples and data", while at the same time "construct[ing] a business model that will ensure the long-term sustainability of the biobank". These tensions give rise to, but are also managed by, hybrid practices. Indeed, it is worth stressing here that tensions are not necessarily impediments to development. Bunton and Jones (2010) demonstrate, for instance, how biobank stakeholders envision commercial as well as global scientific and public health value in biobanking efforts. Biobanks may thus deploy hybrid practices to negotiate with – and even leverage – the tensions that accompany public- and private-sector boundary "overflow".

Taking these observations together, it is clear that contemporary scholarship on biobanks must examine efforts to mediate between commercial and healthcare logics (Miller and French 2016), as well as the entanglement of (hybrid) practices that these efforts entail. Moreover, in our view, it is important to turn scholarly attention to the precise ways that the intermediary role of biobanks is configured and enacted. As we shall suggest, in the biobanks that we studied – with their specific relation to the mission of the entrepreneurial hospital – the configuration of mediating hybrid practices seemed to be optimized to walk the razor's edge between achieving economic growth and maintaining social license. A key question, therefore, is whether and how particular types of organisations and expertise are called into being by the effort to successfully balance amongst all of the various biobank's entangled commitments.

3.2 The Incommensurate (bio)Values Mediated by Biobanks

A number of concepts are available to help theorize these mediation efforts and their entangled hybrid practices in biobanking and in the contemporary biosciences more generally. Some have turned to the concept of commodification (e.g. Sharp 2000; Rose 2001); others have advanced the idea of biocapital (Sunder Rajan 2006); and others have been critical of these developments (e.g. Helmreich 2008; Birch and Tyfield 2012). As we developed our work on the entrepreneurial hospital, we found Waldby's (2000; 2002) conceptualization of biovalue to be particularly useful, especially as elaborated with Mitchell in their book, *Tissue Economies* (Waldby and Mitchell 2006), and in subsequent work (e.g. Mitchell and Waldby 2010).

Waldby, drawing from a range of theorists (and not just Marx, as some critics have seemed to suggest), provides the foundational articulation of biovalue in her book on *The Visible Human Project*, where she defines it as "a surplus value of vitality and instrumental knowledge" (Waldby 2000, 19) derived from nature's participation in technology, and the configuration of this participation so as to solicit compliance from the productive capacities of living matter. Biovalue, in other words, is the "the yield of vitality produced by the biotechnical reformulation of living processes" (Waldby 2002, 310).

Waldby and Mitchell (2006, 108) elaborate on this idea in the context of their work on biobanks, arguing that biovalue "refers not to the stable and known properties of tissues but to the capacity of tissues [under the conditions of the types of socio-technical configurations made possible by biobanks] to lead to new and unexpected forms of value".

In the context of their work on national biobanks, Mitchell and Waldby (2010) further specify their conceptualization, noting two different modalities of biovalue, one that depends on the separation of individuals from their biological materials, and one that requires the maintenance of linkages between them. These modalities, while different, operate together and we certainly see both modalities in the biobanks we studied, expressed, as we shall argue, in the way that tissue is both separated from and reconnected to patients and patient groups. Indeed, as we shall indicate, we can understand the mediation work done by biobanks, and by the entrepreneurial hospital more generally, as mediating between these modalities of biovalue.

In making this observation, we are also sensitive to Birch's critique of the concept of biovalue (and the other 'bio' concepts), which, he argues, tend to allow analysts to over-emphasize the bio aspects of the bioeconomy at the expense of understanding its political economic aspects. While we do not entirely follow Birch (2017) in his critique of the bio-concepts because, in our view, it is perhaps too dismissive of their analytic utility, we have nonetheless found his account of *assetization* useful for thinking about the nature of the incommensurate (bio)values mediated by the entrepreneurial hospital.

Birch's conceptualisation of assetization is grounded in a broader discussion of financialization and capitalization, which, owing to space constraints, we cannot fully cover here. For our purposes the key points of Birch's analysis can be summarised as follows:

1. For firms in the life sciences sector, profits are just as – if not more – likely to come from "licensing, partnerships, royalties, and so on (i.e., asset-based income)" as they are to come from "product sales (i.e., commodity-based income)" (Birch 2017, 465).
2. Asset-based income for firms in the life sciences sector is rooted in a range of valuation practices that can, when taken together, be thought of as the discounted present value of a future stream of earnings (Birch 2017, 466).

3. "the configuration of value through these diverse valuation practices involves the transformation of something into a recurring source of revenue – that is, turning something into an 'asset' – rather than its transformation into a commodity" (Birch 2017, 468).

Birch conceptualises assetization "as a process in which value is constituted by the management of value and valuation, especially as they relate to organizational entities and their capacities" (Birch 2017, 470). It reflects "a dual process" involving the transformation of knowledge into IP, "and the monetization of that knowledge asset as a source of value (e.g., out-licensing IP)" (Birch 2017, 474).

For our analysis of the way that the entrepreneurial hospital mediates amongst incommensurate biovalues, it will be important to think about what it means for biobanks to produce economic value not from *commodities per se* – not from bringing scientific knowledge from bench to bedside – but from *assets*. This may have, as we shall suggest, important implications for the maintenance of the social licence of the biobank and the entrepreneurial hospital more generally, especially if it comes to be perceived in terms of "non-reciprocation" (Carter et al. 2015). Beyond this, and riffing on Birch's argument for the analytic decomposition of the concept of bioeconomy into its constituent 'bio' and 'economic' parts in order to better specify its bio-technological and political-economic components, we want to suggest that the concept of biobank might admit a similar analytic decomposition into its biological (bio) and institutional (bank) components; however, it is precisely because of the mediation work done by the entrepreneurial hospital that the biobanks we studied avoid such decomposition.

4. Method

The data presented below are part of a larger study designed to examine biotechnological innovation in entrepreneurial hospitals in Canada (French and Miller 2012; Miller and French 2016). Following ethics review and clearance from the University of Toronto, we undertook (between 2008-2009), ethnographic fieldwork including extensive review of organizational documents, field-site visits, and twenty-six semi-structured, key-informant interviews with participants working in networked organizations within a single Canadian province, in a health system that provides publicly-funded, universal access to physician and hospital care. In this article, our analysis concentrates primarily on our interview data.

Initially our purposive sampling strategy targeted potential study participants working at the "bench-bedside interface" (Wainwright et al. 2009, 960). We interviewed senior hospital administrators, clinicians and researchers, as well as professionals working in the hospital's technology transfer office (n=15). Then, to better understand issues specific to the

commercialisation of innovations derived from research with patient biomaterial and information, we focused on finding informants involved in biobanking. We interviewed administrators, researchers, clinical staff and information technology specialists working with biobanks housed in, or affiliated with, the entrepreneurial hospitals we studied (n=11). Averaging about 1 hour in length, interviews were conducted in person (n=13) and by telephone (n=13) and were audio recorded and transcribed verbatim.

Our analytic approach was informed by constructivist grounded theory and methods (e.g. Bryant and Charmaz 2007), and especially situational analysis (Clarke 2005). Working collaboratively, we analysed our interview data for emergent themes.

5. Results

Our participants are involved, to varying degrees, with different dimensions of biobanking – they may get tissue from biobanks to facilitate their research (researchers), procure patient material and data (clinicians – nurses and doctors), secure patient consent for participation (research assistants), negotiate partnerships with external parties (technology transfer professionals), directly oversee the day-to-day operations of a biobank (administrators), or create strategies that align biobanking activities with broader organizational missions (senior administrators). All position biobanking as an integral research undertaking within their healthcare organization. Accordingly, while having diverse views on what biobanking is, and what it ought to accomplish, all see biobanking as an enterprise with the potential to contribute to the overall healthcare mission of their hospitals.

Below we have broadly categorized our data according to two overarching discursive orientations. On the one hand, we see a discourse that emphasizes the fundamental materiality – *tissue* – at the heart of biobanks. It describes biobanks as tissue repositories, access brokers, and as holding the currency of translational research. This orientation may be said to reflect the "bio"-ness of biobanks, (problematically) evoking notions of tangible goods that possess an inherent value, which, under the right conditions, may be extracted and leveraged. On the other hand, we see a discourse that emphasizes *patients*, which locates the biobank within the broader context of the entrepreneurial hospital. It describes biobanks as entangled with universally accessible healthcare systems, as well as with the work of clinical care. This orientation may be said to reflect the "bank"-ness of biobanks, (problematically) evoking notions of the institutionally-housed intangible dimensions of tissue collections that see them as deriving value through their relation to data about patients, treatment outcomes, and the broader, institution-level logics of care that characterize hospitals[2]. These orientations are not mutually exclusive. Indeed, we argue that they are made to work together by the entrepreneuri-

al hospital, and therefore, when read in conjunction with all of their tensions, they exemplify the crucial mediation work performed by the entrepreneurial hospital.

5.1 Tissue

There are differing accounts in the literature over what, exactly, are the important, defining characteristics of a biobank (e.g. OECD 2006). On the surface, the necessary (if not sufficient) condition for constituting a biobank would seem to be the possession and/or accumulation of (human) biological tissue. However, as we shall suggest, this focus on tissue presents a rather minimalist representation of what makes up a biobank, and of what biobanks can do.

Biobanks as tissue repository

To be certain, human tissue is regarded as fundamental to biobanking in the context of the entrepreneurial hospital, which emphasizes the importance of translational research. Indeed, so central has been the possession of human tissue to the development of biobanking in this context, that one veteran of the field – a biobank director we interviewed – expressed the following axiom in his concluding remarks to us: "he who has the tissue rules" (BIA-39).

Conveying a sense of exasperation with the slow development of biobanking research in Canada, especially with respect to biomarker discovery and validation, our study participant prefaced his axiomatic statement about the centrality of human tissue by asking:

> How are you going to find frickn' solutions for things? In vapour ware? […] the reality is in the final analysis, you have to try it out in humans […], with human urine, blood, joint fluid, biopsy tissue… (BIA-39)

Biobanks, in this sense, are fundamentally repositories of *human* tissue that enable the discovery of healthcare solutions. As a biobank administrator notes:

> Being able to make that jump from a cell line or an animal model into a human tissue model really advances the science, but you need those specimens to be able to do that research. (BIA-42)

These observations underscore the importance of the human biomaterial resource at the heart of biobanking. This resource is rooted in access to patients and patient populations, well-developed, computerised medical records systems, and a range of other affordances that attend hospital care, thus making the apparatus that brokers ethical access to patients essential.

Biobanks as access brokers

Describing a situation in which access is brokered, one of our participants notes that "a lot of the work I do" is with:

> commercial entities, often with very good ideas […] for some sort of novelty test […]; in theory it works well, but what they do not have access to is our, let's say, large pool of anonymized patient specimens. (BIA-36)

In the absence of trying their theories out using the hospital's "specimens", the commercial entities in this example "cannot actually go ahead and develop their tests" (BIA-36). Our participant, who was a laboratory researcher, was – following a process of ethics review and "ethics paperwork" (BIA-36) – able to access anonymized human tissue samples stored in a hospital biobank. For diverse users, including those working in the private sector, access to tissue is both made possible, *and legitimated*, via an oversight and governance process, brokered by the entrepreneurial hospital.

The biobanks we studied were described as resources that could support translational research at the local, national and international level. This orientation towards translational research sometimes means forming partnerships with private sector organizations because, in the words of one participant, "we [the entrepreneurial hospital] don't have the resources here to actually take something to market" (BIA-28). From this perspective, the biobank plays an important brokering role, adjudicating proposals for research with the interests of its patient population in mind, while also perhaps bringing a solidaristic sense of legitimacy to research undertaken by its private sector partners. We see, here, not only the hybrid practices associated with adjudicating proposals, but also the institutionalized capacity to govern adjudication according to standardized, international norms. Indeed, as one biobank manager noted, "we are able to facilitate the access to bio-specimens, which are needed for translational research": "the way our infrastructure is set up, it opens up channels for researchers to have access to it [patient tissue]" (BIA-42).

This point was underscored in our interviews with researchers who do not themselves maintain biobanks, but who rely on their biobanking colleagues to broker their access to (human) biological tissue. As one researcher noted, "we have technologies, genomic technologies, that can interrogate genetic material but only if we can obtain samples" (BIA-28). Access to patient samples is, in this case, seen to be a necessary condition of advancing the research and collaboration that takes place within the entrepreneurial hospital. Another researcher we interviewed also emphasized the importance of tissue access for the kind of research privileged by the entrepreneurial hospital. Engaged in a technology development project aiming to construct and validate a diagnostic device, this study

participant stressed the importance of developing "the referral pathway", and of being able to access archived tissue, as well as a prospective stream of samples (BIA-49). Without this access to patient tissue, it would not have been possible to identify the molecular biomarkers used by this technology.

These observations link up with descriptions of biobanks as institutions that broker and legitimate access to patient tissue. As Waldby and Mitchell argue, biobanks play a central regulatory function in "tissue economies": they accumulate tissue from donor populations and medical intermediaries; they process this tissue according to established technical and ethical guidelines, as well as legislation; and they redistribute it in legitimate ways that aim to maximize its utility (Waldby and Mitchell 2006, 35). Accordingly, while tissue accumulation is an essential feature of biobanking, so too is the brokering of legitimate access to tissue. This involves doing 'public engagement' and working on "public perception of what it means to be a biobank" (BIA-42). In doing this work, in brokering and legitimating access, the biobank becomes much more than a mere tissue repository. By governing social relations amongst researchers and publics, the biobank enacts a key, regulatory function of the entrepreneurial hospital, namely, the mediation of (new) uses of the patient population.

Biobanks as the currency of translational research

Several of our participants underscored how fundamental biobanks were to health research, especially translational research. One of the biobank directors we interviewed stated:

> Biobanks are crucial. Dry data and wet data are the currency – I don't like using the word currency – but they are the currency of innovation with respect to translational research and understanding human biology […] translational research, for whatever purpose, for whatever question, requires exquisite, exquisitely phenotyped patients and exquisitely phenotyped and quality assured biobanks. (BIA-39)

As this study participant explained, the translational research conducted by his organization would not be possible, would "not be even imaginable, without quality assured, quality controlled, agile biobanks" (BIA-39).

Another participant, a clinician-researcher, draws a similar connection between biobanking and translational research. In response to our opening question designed to elicit information about our informants' relationship to, and interest in, biobanking, this participant described "a desire to create a significant research program". He stated: "we realized that, to have a research program that we envisioned, which was translational, it had to be biobanking" (BIA-46).

5.2 Patients

To this point, the characterization of biobanking is highly tangible, in its sources, practices and impacts. Below we present a more expansive conceptualization of biobanking, characterized by a care-focused orientation that is not well recognized in the literature. It is given a particular valence by the embedding of biobanks *within* the entrepreneurial hospital. It explicitly entangles biobanking with care, thereby emphasizing the networked nature of the biobank and—in tension with the emphasis described in the previous section—de-centering the idea that biobanks are all about tissue.

Biobanks as entangled with population-level, patient group treatment outcomes

Although possession and accumulation of tissue may be a defining characteristic of biobanks, many of our informants were careful to specify that, without the capacity to understand tissue *in relation* to patient records, personal health histories, collective geo-demographic information, risk exposures, treatment regimes, future patients, and the like, the biobanking enterprise would add limited value to health research.

To see how biobanks transcend their attachment to purely corporeal artifacts by producing 'bioinformation' (Parry and Greenhough 2018), consider how our study participants situate tissue in relation to information gleaned during the course of clinical care. With reference to making genomic discoveries, for example about the ways that complex therapeutic interventions interact with the genetic pre-dispositions of individuals and groups, one study participant succinctly stated: "omic [genomic, proteomic, etc.] knowledge is based on care of patients" (BIA-31). To contextualize this statement, our participant described his research in the following terms:

> I work […] to discover new omic information. And, the nature of [this] work is based on, the study of patient material. […] So, we will look at populations of patients, not just one, but a whole population of patients with a similar type of [disease]. We will take an omic discovery and we will correlate that with the clinical features of the patient group when they first present with their disease and then follow information on how they respond to therapies over time. And, so we very closely correlate an omic piece of information with a diagnostic or outcome result, and that outcome result is really what makes the omic piece important. (BIA31)

In this description, research using patient materials is made valuable through its linkage to, its correlation with, clinical information.

This correlative capacity of biobanks to connect up with information gleaned during the course of care was similarly underscored by another

participant we interviewed, a clinician researcher who linked tissue samples with patient outcomes data:

> I set up a lab […], which uses tissue samples from [the hospital] and links them to outcome data […]. And, the [tissue] archives wouldn't have been valuable without the [outcome] data. But, by putting them together we're able to make something really good happen. (BIA-29)

By situating biobanking initiatives within a broader organizational setting characterized by relations of care – a unique feature, we believe, of the biobanks we studied – our participants' discourse illustrates that the materiality of tissue is profoundly entangled within the broader networks of the entrepreneurial hospital. We suggest, moreover, that the entanglement of biobanking materials and practices with materials and practices mobilised for care is a key function of the entrepreneurial hospital.

Biobanks as part of clinical care

Biobanks have been described as serving therapeutic, forensic, diagnostic, and research-related ends. In spite of their potentiality to serve these diverse ends, a great deal of focus in social scientific literature has been concentrated upon future-oriented, research-related ends (Hoeyer 2008, 430). Somewhat missed in this focus is the potentiality of biobanks to serve clinical ends in the present.

As our participants describe, this clinical utility of biobanking stems not solely from its promise of future improvements in care, of better, more tailored treatments, but also from the symbolic capital it provides to health professionals in the here and now of bedside interactions. Tapping into the embodied, emotional and affective dimensions of patienthood (cf. Kerr and Cunningham-Burley 2015), this way of thinking about and articulating the role that biobanks can play in care typifies how the entrepreneurial hospital not only constitutes its patient populations and care infrastructure as distinctive assets in service of entrepreneurial aims, but also positions its entrepreneurial aims as a decisive element in the service of care. It presents a benefit that off-sets risks associated with biobanking (e.g. risks related to discrimination, or breach of privacy). Although this way of articulating the value of biobanks could be understood as a form of self-justifying rhetoric, it also depicts an attempted virtuous cycle in which care feeds into research and research feeds into care, all the while functioning in a way that aims to be respectful of patient interests. This notion of a virtuous cycle, resulting from pursuing both care and research, seems to be fundamental to the *raison-d'être* of the entrepreneurial hospital.

One of our participants, a biobank director, made a sustained argument that biobanking is "actually part of clinical care" (BIA-43). His analysis is nuanced and bears quoting at length:

> […] the other facet of biobanking, which is not just satisfying, but I think it's very important, is that donors want us to ask them to provide their tissues and data. They say it loudly and resoundingly […]. When you ask somebody when they're sick with a disease, do you want to donate to a biobank, it's actually part of clinical care. When people come into a centre and they're facing a problem, they want… Forty-nine percent of what they want is advice, management, treatment, to be cured or to resolve the pain, or whatever it is that is their problem. And, fifty-one percent of what they want, I believe, is they want us to provide them an opportunity to do something about it so that they don't get a recurrence or their daughter doesn't get the same disease or their neighbours and their friends. So, in that sense, when you treat a patient or provide advice, I think it's incumbent on us in healthcare to offer that opportunity at the same time as giving our advice and our drugs and our treatment. And, so, in that sense, that fifty-one percent of the reason is, of why we should offer biobanking, is offering opportunity for patients to *do something* – they make a decision. Their decision might be no, I don't want to, but that's therapeutic. A patient's been given a chance to make a decision about their condition and their disease and their interaction with their healthcare. (BIA-43)

In this passage of the transcript our study participant mobilizes a line of argument that could be emblematic of the entrepreneurial hospital. As with the entrepreneurial hospital's investments in technology transfer, innovation, and commercialization initiatives (French and Miller 2012; Miller and French 2016), biobanking is here also constituted as part of a broader, moral obligation owed to citizens, which stems from their support of publicly-funded healthcare.

Although its mission involves constituting its patients and patient populations as distinctive assets in the service of entrepreneurial aims, these entrepreneurial aims are themselves enrolled, in a broad sense, in the service of universal care. Our informant continues:

> [...] one additional point is that many patients are offered the opportunity to be involved in research and knowledge development that deals with their disease [...], but most of what is offered comes with entrance criteria and guidelines, which relate to the specific research question being asked. So, this is one of the benefits and the advantages of biobanking – you ask a patient a much more generic and fundamental question around involvement in research. You know, would you like your tissue and your blood sample and your health data to be collected, organized and then made available for research in the future and we're not sure what that research project is, but we'll set up the appropriate mechanisms to make sure that, if it's used, it's used appropriately, ethically, and for good science. And, that's essentially the biobanking transaction. But, when we offer that to patients, we can offer it to all patients. [...] And, so, essentially, it's a very equitable and open opportunity to be involved in research that biobanking offers, which is distinct from most other kinds of research like a clinical trial which is very specific. You've got to have this disease. You've got to

> be going to a centre where the clinical trial is open and you have to meet all these criteria. And, if you don't meet those criteria, we can't offer this to you; whereas we can offer biobanking to everybody. (BIA-43)

As noted, our research was conducted in a health system that provides publicly-funded, universal access to care. In the above passage, participation in research biobanks is also framed as a matter of access (as opposed to, or perhaps in addition to, a matter of obligation). As our participant asserts:

> …I think it's incumbent on us to offer biobanking for free, and biobanking in the broad sense, meaning that we offer a patient an opportunity for their tissue and their data to be used for health research that generates new knowledge. (BIA-43)

These points, of course, bear some critical reflection. As scholars studying national biobanks have argued, patients may not experience the offer to "do something" by participating in biobanking research as empowering (e.g. Tutton 2002; Busby and Martin 2006). Nevertheless, what we wish to underscore by highlighting the above passages is that biobankers actively work to make sense of their efforts with respect to care, and this is indicative of the entrepreneurial hospital's reconfiguration not only of care so that it is addressed to research aims, but also of research so that it is addressed to care aims.

6. Discussion

In some senses, the discursive orientations that we have identified are complementary discourses: they each speak to overarching aims of the entrepreneurial hospital. Yet, in other ways, they exist in tension, one emphasizing tissue as the key locus of biobank activity, the other foregrounding the patients, populations, information systems, and so on that entangle biobanking practices with clinical care. To theorize these orientations, let us circle back to the two strands of work we highlighted in our literature review: 1) hybridization of public- and private-sector logics, and 2) mediation of incommensurate (bio)values by biobanks.

Hybridization of public and private-sector logics

Dixon-Woods and colleagues (2008) argue that conceptualizing biobanks and their publics as interdependent, mutually constitutive multiplicities is useful for understanding the existence of competing views of tissue use. Drawing from Star and Griesemer (1989), they describe tissue as a boundary object, an object that lets people cooperate without necessarily having to agree upon how the object is defined, classified or valued.

By emphasizing multiplicity in conceptualizations of biobanking – in understandings of public views and professional motivations – the authors trouble analyses that characterize biobanks as drivers of body commodification. They are critical of analyses that depict biobanks as:

> a particular, though pervasive and especially disturbing, case of a more general inclination on the part of biomedicine, bioscience and bioindustry to defile the sanctity of the body and the dignity of individuals. (Dixon-Woods et al. 2008, 58)

For Dixon-Woods and colleagues, the problem with such accounts of biobanking is that they assume 1) that participants can be easily duped into colluding with their own objectification, and 2) that "tissue samples, once they have crossed the boundary into the social world of the 'researcher' inevitably become part of a commodified tissue economy" (Dixon-Woods et al. 2008, 75). Having made this critique, the authors argue that there is nonetheless a need to understand how biobanks operate in institutional contexts that might encourage individual researchers to pursue commercial objectives. Regulating such pressures, they contend, are powerful incentives, which can be regarded as a form of social or reputational capital. In order to maintain this capital, biobanks must operate, they argue, in ways that "sustain their social licence", that are seen "to act in the interests of donors", and that do not risk the cooperation of donors nor that of "the hospital staff who spend time and effort to seek [patient] consent" (Dixon-Woods et al. 2008, 76).

Drawing from Dixon-Woods (2008) and colleagues, one way to interpret the statements of our study participants is as an effort to manage, in an entrepreneurial way, the social capital of their initiatives. This involves acting in ways that protect, but also *grow*, the investment made by biobanking participants. We see elements of the effort to grow, while sustaining social license, in both of the discursive orientations we described. Yet, the harmonious hybridization that this entanglement seems to have accomplished might be undone if disagreements over fundamental characteristics (definitions, valuations, etc.) are surfaced. And, in an almost counter-intuitive sense, this is precisely what the patient-emphasizing discourse might do if the entrepreneurial hospital's biovalue yields are expressed in assets (Birch, 2017) rather than, say, commodities.

Mediation of incommensurate (bio)values by biobanks

We can see this unsettling potential if we look at the apparently harmonious hybridization of the growth- and social license-imperatives through the prism of biovalue. As noted, the concept of biovalue describes "the yield of vitality" that is gained "by the biotechnical reformulation of living processes" (Waldby 2002, 310). It foregrounds the tradeoffs and (unintended) consequences that stem from different modalities

of biovalue, for example those that depend on the separation of individuals from their biological materials, and those that require their linkage. The entrepreneurial hospital, as we have argued, is well positioned to mediate amongst these incommensurate values.

Yet let us hypothetically push this mediation work beyond a threshold and ask what would happen if the biobanking initiatives we have studied do not lead to the hoped-for production of new diagnostic and treatment technologies for future patients? Assume here that, when patients are offered the opportunity to "do something" by participating in biobanking, this *something* means contributing their tissue and information for translational research, which aims to help future patients through the creation of new, life-saving diagnostic and therapeutic technologies. This *something*, in other words, is the creation of value ultimately through the production of *commodities* (i.e. diagnostic and therapeutic interventions that can ultimately be bought by the entrepreneurial hospital and deployed in the clinic). However, the concept of assetization highlights the fact that value in the life sciences sector frequently comes less from commodity production than from financialized transactions involving the exchange of assets (Birch 2017). For example, Lazonick and Tulum (2011), drawing on the work of Gary Pisano (2006), argue that in the US biopharmaceutical sector, which is heavily subsidized by public funds, there is something like a perverse incentive to try to monetize assets instead of pushing scientific discoveries to market as commodities:

> …the highly financialized US business model in the BP [biopharmaceutical] industry tends to undermine innovation by placing strategic control in hands of those who, primarily through stock-based compensation, have an incentive to make allocative decisions that, through speculation and manipulation, increase their firm's stock price even when such decisions impede the organizational learning processes that can result in a commercial drug. (Lazonick and Tulum 2011, 1185)

In other words, those who stand to make millions from stock options have an interest in raising stock prices, even if the tactics used to achieve this end ultimately impede drug development. If we see this as a more general trend that will frustrate the efforts of biobanks and translational research to produce new, life-saving technologies, how long will the entrepreneurial hospital be able to maintain its social license? Birch provocatively suggests that innovation strategies in the life sciences could be conceptualized as a kind of reverse Ponzi scheme (cf. Mirowski 2012):

> it is the final private financier (e.g. late stage venture capitalist) who either accrues the highest returns *or nothing at all from their investment*, while the first financiers (e.g., friends, family, government, etc.) accrue the least. (Birch 2017, 465 – our emphasis)

From this perspective, the key question is, when will the bubble burst?

7. Conclusion

Our aim in this article was to examine the relationship of the biobank to the entrepreneurial hospital. Drawing from sociological and STS accounts of 1) the hybridization of public- and private-sector logics in biobanking, and 2) the ways that biobanks mediate incommensurate (bio)values, we suggested that biobanks act as crucibles for both the intensification and mitigation of the tensions mediated by the entrepreneurial hospital. We emphasized a meso-level analytic approach, using our study participants' discourses to reflect on organizational and network dynamics. This approach underscored how the entrepreneurial hospital works as an intermediary to confer legitimacy on its research *and* care aims. Indeed, our analysis suggests that the entrepreneurial hospital is not only entrepreneurialising care to meet research needs, but also trying to entrepreneurialise research so that it meets care needs.

In rendering this mediation work visible, we have also raised questions about its viability over the long-term, particularly as it relates to the wider set of valuation and value-creation practices evident in the life sciences sector, which have tended to favour the creation of assets rather than commodities per se. Here, the key questions are: will the public and biobank participants ever realize the promised returns of biobanking research, and if not, (how) will the entrepreneurial hospital continue?

In raising these questions we are suggesting the need for further research. We are here mindful of the limitations of our study, namely that we did not focus on the views of biobanking participants, that we did not attend in extended depth to everyday biobanking practices as a longer ethnographic study might, and that we focused on biobanking and the entrepreneurial hospital in one province in Canada. These limitations mean that we have been unable to explore participants' views of the opportunity to "do something" via biobanking. We have not been able to explore how variation in everyday practice might complicate the discursive orientations we identified. And we have not been able to explore how "generalizable" these phenomena are beyond our empirical setting. These points, we suggest, represent fruitful avenues for future research.

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[1] According to one of the biobanks we studied, for example, 92% of referred patients agreed to participate.

[2] The strong distinction between tangible and intangible goods here could be likened to the equally problematic distinction sometimes drawn between materiality and immateriality, tissue and data, and so on.

Beyond the Formal Mechanisms of Public Engagement

Communicating Biobanking Research with Other Means

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Abstract: In this contribution we explore novel, different ways of promoting public engagement in biomedical research using biobanks. Starting from a discussion about the limits of traditional formal procedures of engaging participants in biobanking activities, the contribution proposes two approaches to public involvement that use the Science Museum as an agora for communicating and representing the complex scientific, societal and ethical issues involved in contemporary biomedical research. The role of museum exhibitions, metaphors and languages of art and theater, as well as other forms of dialogues, are discussed as a way of shaping popular imaginaries about scientific research, in order to complement mechanisms of public engagement with novel forms of stimulating public understanding of scientific research using tissues and genomic data.

Keywords: science museum; art, theater; dialogues; biobanks; public engagement.

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Introduction

Lorenzo Beltrame

Issues related to participation are, likely, the most debated in STS literature on biobanking. In fact, biobanks rely on the willingness of volunteers to donate tissues and to give access to their medical, genealogical and lifestyle data. The provision of tissues and bioinformation clearly involves issues of privacy, confidentiality, informed consent, ownership, benefit-sharing and commercial exploitation (Hoeyer 2008). As noted by Tutton (2004, 19) the willingness to freely give samples and personal in-

formation has been promoted by medical institutions by emphasizing ideals of social solidarity and personal altruism, the common purpose of improving human health through research and by resorting to powerful discourses of gift and 'gift-giving'. But, as Hoeyer (2008) remarked, the wide plethora of social and ethical issues has been dealt mainly with the same organizational solution, that is the informed consent.

Informed consent is considered a sort of technology of neoliberal governmentality, which produces the donating subject as an empowered, autonomous citizen who makes choices based on risk-benefit calculations, who is oriented to the fulfilling of her/his wellbeing and endowed with the right and duty to participate (Corrigan 2004; Hoeyer 2004; Tutton 2007). Even if it is largely still in use, however, the mechanism of informed consent is under criticism by STS and bioethics scholars.

First, its predominant focus on individual rights has been called into question. The so-called 'communitarian turn' in bioethics (Chadwick and Berg 2001; Knoppers and Chadwick 2005) has highlighted how this juridical mechanism is insufficient to deal with the collective nature of benefits and risks involved in biobanking research, by claiming the need to develop mechanisms to deal with ethical principles locating at the level of community and/or groups such as reciprocity, mutuality, equity and solidarity.

Second, the strong opposition to the Icelandic biobanking initiative – promoted by family doctors, the Icelandic Medical Association and *Mannvernd* (the Association of Icelanders for Ethics in Science and Medicine see Pálsson 2008) – showed the need to adopt more participative approaches to ethical oversight. Mechanisms of broad consent, in which participants are given information about the wide range of aims and objectives of biobanking research, have been implemented resorting to forms of public consultation through focus groups and other forms of participative ethical oversight (Corrigan and Tutton 2009).

Public engagement is thus the key word for assuring legitimacy in biobanking participation, even if the concrete strategies for enabling engagement vary a lot across different initiatives (Tupasela et al. 2015). As noted by Weldon (2004), several public engagement mechanisms are inspired by a logic of promoting scientific citizenship (Irwin 1995) by involving participants in dialogues, consultations and in participatory forums of decision-making. Indeed, a scientific citizen is not simply one fully informed, but is one who has to be made able to negotiate and influence policy decisions and research projects.

However, STS scholars are also aware of some limits of the participatory tools adopted in formal mechanisms of public engagement. McNamara and Petersen (2008), for example, have shown how these mechanisms are not neutral tools, but reflect – and work according to – assumptions about those who are to be engaged, shaping thus their participation toward forms of ethical oversight which have little substantial impact on issues of ownership, access and broad public benefit. Weldon

(2004) has discussed how public consultations are often weak in giving participants a real opportunity to influence the direction of research or to exert a true civic agency on the claimed wider societal issues (such as what counts as the common good). In fact, these mechanisms are suspected to be mainly oriented to channel participation toward a more readily provision of samples than toward an effective partnership in biobanks governance (Tutton 2007; Cañada et al. 2015).

Several researches have shown how often participants in biobanks can be uninterested in being informed and in active participation, while they donate just out of altruism through consolidated institutional practices of trusted organizations (Busby 2004; Busby and Martin 2006; Tutton 2007). Hoeyer (2004, 100-1) have brilliantly demonstrated, by interviewing biobanks participants, how uncertainties, worries and vague, inaccurate if not wrong understandings of the aims and scopes of the research outcomes characterize participants. Notwithstanding informed, participating donors appeared affected by an imaginary of cloning, eugenics, "designer babies" and genetic manipulation, largely shaped by mass media and other popular representations of science.

This has raised the main questions addressed in this contribution: how to promote effective forms of public engagement without making participants fully aware of the real aims and scope of scientific research? Is it possible to conceive forms of engagement in lack of a public understanding of what biobank research is currently doing? How to communicate the implications of biobanking research using languages more apt to the familiar popular imaginaries of science? What are the spaces, beyond the formal sites of public engagement in biobanking, to promote a public understanding of scientific research?

In the following interview, Lucia Martinelli explains how the science museum and the theater can be considered possible *agoras* to explore forms of public engagement with genomic research using the languages of museum exhibition, theater and art. Lucia Martinelli has been responsible of the curatorship of the 2018 temporary exhibition *'The Human Genome. What makes us unique'* at MUSE the Science Museum of Trento (Italy). As she argues, this exhibition devotes a large part to the exploration of the implications of genomic research both through direct to consumer (DTC) genetic test and through biobanking. And she illustrates how to communicate the social, cultural and ethical issues related to these technologies using metaphors and the language of art and exhibition. She has also a long experience in interacting with theatrical artists with whom she narrated the social implications of contemporary biomedical innovations. Lucia Martinelli's professional career is exemplary of the search of new ways of engaging the public, involving it and promoting public understanding of science. Formed as a biotechnologist, Martinelli progressively moved to STS, to become finally a science communicator using the science museum and the theater as means to vehiculate engagement and public understanding of lay people, by offering narratives of the complex

issues rotating around current biomedicine and biotechnology that resonate with shared and familiar imaginaries. Her contribution shows how to promote a different understanding of the aims, scopes, potentialities and perils of modern biomedical research, how to conceive the museum as an important agora to involve people and, then, to complement formal mechanisms of public engagement in citizens' participation to biomedical research.

The topic of alternative spaces to enable people to explore the meaning and the implication of contemporary biomedicine is discussed also by the science historian Ilaria Ampollini. She discusses the substantial lack of public engagement mechanisms in biomedical research in the Italian context. Then, she presents the program *CLaSTer. How Science Works. Dialogues between University and the Region* (CLaSTer. Come Lavora la Scienza. Dialoghi tra Università e Territorio). It is a local project aimed at enhancing collaboration and dialogue between University and research institutes, the Province Health System, healthcare professionals and, above all, patients, patients' families and patient associations. This project is largely based on public dialogues with citizens representatives, and is hosted by the MUSE – Science Museum – complementing the exhibition on Human Genome as a way of exploring multiple languages of communication. The local setting allows, indeed, to coordinate the work of the local University Department of Biomolecular Sciences, the Department of Sociology and Social Research, the Province of Trento Health System (with its Trentino BioBank and the Clinical Service for Medical Genetics) in order to develop a wide-scope program of public engagement.

The fact that both the experiences discussed by Lucia Martinelli and Ilaria Ampollini have a local setting should not be considered a limit. On the contrary, what has been argued in this Special Issue is that participation has to be conceived and studied as the outcome of concrete practices enacted by actors involved in situated institutional settings. What these contributions add to the analyses presented in the original research articles, is the need of complementing both the interactions between actors and the formal mechanisms of engagement with novel forms of dialogue and communication, in order to promote a better understanding of the aims, scopes, implications and issues involved in biomedical research using biobanks. The experiences and examples presented by Lucia Martinelli and Ilaria Ampollini, clearly show how exploring popular imaginaries and communicating biomedical research with the languages of art, theater and museum exhibitions can play an important part in solving uncertainties and in promoting the voices of common, lay people who decide to participate in biomedical research.

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The Science Museum as an *Agora* for Public Engagement in Research Using Biobanking

Lucia Martinelli (interviewed by Lorenzo Beltrame)

Can you tell me the path that led a biotechnologist to became an STS scholar and then to move to explore new languages in communicating biomedical and genomic research?

My research activity in the field of plant biotechnology started in early 1980s with the internship for the degree thesis on genetics, when the term "biotechnology" was neither in use. Since then, for three decades, I have carried out research in industrial and public institutes in Italy and abroad. Therefore, I am a witness of the biotech development concerning both the technoscientific aspects and its growing impact on society (Martinelli et al. 2013a). If during the 1980s biotech has been regarded as a carrier of important achievements for humankind, since 2000 it has become an icon of citizens' distrust toward science innovations. This shift had a strong impact on research and led the European Union to launch specific programs to face the gap between science and society.

I always like remembering a photograph I have personally taken in May 2000 in Genoa, during the first Italian major protest of the rising no-global community against TEBIO, an important conference on biotechnology. In this shot, a wall of armed police forces between the scientific community and the civil society portraits two conflicting visions about biotechnology whilst it seems to underline the gap between science and society. Being strongly involved in a controversial field of research, such as gene transfer (Martinelli and Mandolino 1994) and also interested in the social and political responsibilities of science, my projects started to have a multidisciplinary feature, also including humanities and social sciences in the laboratorial activity. This was the case of the OSSERVA3[1] and EcoGenEtic.Com projects (supported by Trento Autonomous Province) where forums of dialogue and tools to manage risks perception (Martinelli et al. 2006) were experimented.

Then, since 2011 at MUSE, my main research interest became STS. I was involved in multidisciplinary networks connecting experts in life sciences, social science, philosophy, bioethics, biolaw and art. In the COST action "Bio-objects and their boundaries"[2], for instance, the products of biology innovations were analyzed as bio-objects sharing peculiar features at the intersection of society, politics and science: they promise a better quality of human life whilst rising controversy, undermine the boundaries between living/non-living and natural/un-natural/artificial, may result as "out of place" entities and require specific regulations and communication. In particular, I focused on contested products of biobanking such as *HeLa* cells (Svalastog and Martinelli 2013), animal de-extinction (Marti-

nelli et al 2014), gene transfer (Martinelli et al. 2013b; Pavone and Martinelli 2015), and assisted reproduction technologies such as preserved human eggs (Martinelli et al. 2015) and human embryos (Piciocchi and Martinelli 2016).

From theory to practice, in the framework of European projects, at MUSE we are developing tools for public engagement, based on the view of a more responsible research and innovation in various fields of biotechnology, such as synthetic biology (SYNENERGENE project[3]) and nanotechnology (NANO2ALL project[4]).

Usually lay people concerns are dealt with participatory decision making tools. How did you, instead, explore this issue using the language of exhibition?

Since public acceptance and legitimacy in decision-making and governance of biotechnological and biomedical innovations is a critical issue, inclusive communication is required. The metaphor of the *agora* well represents the mission of cultural institutions to act as elite forums for shared communication involving the various actors of science. Today, science museums are recognized as suitable *agoras* and "safe spaces" where science and society can meet and engage in challenging conversations (Svalastog et al. 2014). In a project concerning assisted reproduction technologies, for instance, during focus groups at MUSE[5], parents/potential parents were even surprised about their own comfortable feeling – as they never experienced before – in revealing their private experiences to the other participants.

Starting from this open concept, we designed the main 2018 MUSE temporary exhibition *'The Human Genome. What makes us unique'*. In particular, in a core section of the exhibition, focused on genetic predispositions, we projected a scenography recreating a square where getting together the knowledge and the experiences of the main actors of the biomedical field in our society: lay people, the scientific community, medical care professionals and policy makers. During the preliminary brainstorming it was suggested to place the experts in the center of the square and, on the border, the lay people, as a metaphor for inviting exhibition visitors to approach for listening, in intimacy, those personal stories mentioned above. Finally, however, we decided to completely reverse the setting. We put lay people at the center of the scenography, to emphasize their central role and highlight their stories. We recreated a sort of "speaker corner" where private stories could become public. Video-interviews to experts, reporting on clinical experience and healthcare policies, were located at one border of the square, while the center of the agora is now for some silhouettes giving voice to "common people". They narrate "stories-of-everyday-genetics", inspired by cases reported in the scientific literature, mass media news and real experiences shared through the Internet or available on the websites of medical organizations and pa-

tients associations. These narratives aim to enhance the understanding of museum visitors about the impact of new genomic knowledge and applications on our lives. Moreover, at the exit of 'The Square', in an intimate room, visitors of the exhibition are invited to leave their own stories about genetic predispositions. We have already collected a great number of significant narratives about their "everyday genetics", which are still under analysis.

In some cases, current genomics is struggling with determinism, both inside the laboratory and outside in the wider society, where genetics is often perceived as an inescapable fate. How did you try to disentangle these opposed and overlapping perceptions in a Museum exhibition?

What are the reasons of our physical and psychological traits and of the talents and diseases recurring in our families? Is it a question of "destiny" marked by inherited genetic predispositions, or can personal options, responsibilities and experiences shape us? In genetic studies, the interaction between genotypes and environmental factors is a very important aspect of the phenotypic variability. The "nature versus nurture" relation to explain our traits and how we "function" has been object of countless studies, favoring alternatively one or the other component. This question also involves sensitive personal and social issues, as for instance in the case of complex traits associated with behavioral disorders related to psychic and social distress.

Already more than 2400 years ago, to explain the athletics excellence Hippocrates analyzed personal predisposition, exercise, nutrition, age, geographical origin, time of the year and also changes in wind and climate, finally considering the hereditary component as a major factor. This issue is still nowadays a hot research topic of International networks of sport medicine. The scientific literature of the last 200 years reports countless studies based on twinship aimed to associate genetic variability to specific genes or to the interactions between the same genes and different environments. One of the most original research is the recent "Twin Study" in the framework of the *NASA Human Research Program* which is analyzing the data collected from two identical twin astronauts, the one spending one year in the space and the other remaining on the Earth[6].

At the end of the 1990s, when the Human Genome project was launched, the scientific community was strongly divided: a vision considered the gene as the central matter, the other pointed out the need to explore more in depth the complex interactions between genes and the context in which they interact and express (Fox Keller 2000). Recently, this latter approach has become the subject of new attention focusing on epigenetics, that is on how experiences, choices, behaviors and many environmental factors, including nutrition habits, smoking, pollutants and stress, have an effect on our DNA through mechanisms of gene regulation. Contrary to expectations (and to opponents' concerns), the results

of Human Genome project questioned the deterministic approach. The new millennium started with the recognition that we are both the result of a complex genome, mostly still to be known, and of an intricate interaction between biological events and environmental and social experiences. Moreover, contemporary genomics knowledge calls even more into question the classical definition of the gene.

This debate is quite fascinating and is also a remarkable example of how scientific knowledge is more a source of uncertainty than of certainty. This is one of the most difficult aspects to be communicated to the general public. However, the growing knowledge about the human genome already applied in several fields, including healthcare. Easily accessible information about our genome, and the availability of markers for genes involved in important diseases diffuse the awareness of predispositions that may lead citizens to undertake a deterministic approach toward their biology. Moreover, results of genetic analyses, in particular concerning health, may be difficult to manage from a psychological point of view, being linked to mere probabilities (will a predisposition to develop a disease turn into a disease?), to events related to the future (when will the "predicted" disease occur?) or to anxiety (how to face diseases without therapies?). For these peculiarity of genetic analysis, it has been established the "right not to know", to make people able to choose not to know certain information. On the other hand, according to analysis of patients' narratives, the awareness of carrying a genetic predisposition to a certain disease may produce, in different people, different impacts. Besides anxiety and distress, a feeling of relief from a sense of guilt has also been noted when the cause of an illness can be assigned to a "sculptured fate" (of which one is not guilty) rather than to a lifestyle (of which one is responsible).

In this framework, in line with a non-deterministic view, the narratives of texts, multimedia and exhibits of *The Human Genome* exhibition at MUSE are meant to stimulate reflections and questions about contemporary genomic knowledge and, moreover, about the knowledge still to be achieved, rather than feeding visitors with notions and dogmas. Worth mentioning some examples. Genetic predispositions are constantly proposed as a probability, rather than a fate, to be translated into traits. The metaphor of the human language, with its "cultural" and "structural" variability, as well as its unknown aspects, is always constant in the various sections of the exhibition. The four letters of DNA – the chemical bases of the genetic code – fluctuate in combinations, of which some have meaning, some not, almost like an ancient language whose alphabet has been decoded, but whose meaning is still little understood. Similarly to a puzzle game, genetic mutations are proposed in an interactive game, where reversing, deleting and duplicating letters and words in a text are used for producing new meanings or non-senses, signifying genetic mutations. The slogan "it's not just a matter of genes", repeated like a mantra in different languages, is the crucial and final message left to visitors. Fi-

nally, epigenetics is central, also proposed through an impacting sculpture, which immerses visitors in emotions to feel the interaction between some environmental and psychological situations and the DNA.

One of the main issues in biobanking is trust. How did you communicate about the issues of confidentiality and the commercial use of personal and genetic data?

In genetic analysis, biobanking regards the storage of both the biological samples to extract DNA and data and information generated from the analysis. These latter are the most intimate part of a person and, what is specific for the genetic information, even of his/her family and relatives. This practice may produce the risks of violations of privacy and confidentiality, it could lead to possible discriminations and involves issues of property rights and of informed consent, concerning bioethics and regulation. A renewed example of privacy violation, faced by a symbolic agreement between the U.S National Institutes of Health and Lacks Family[7], was the publication of the genome sequencing of two cell lines deriving from *HeLa* cells (Adey et al. 2013; Landry et al. 2013), which could reveal some hereditary biological information about Henrietta Lacks' offspring.

Population genomics studies require a huge collection of phenotypic trait data on health, lifestyles and behaviors and genomic data to study genetic variability and interaction between genes and environment. Consequently, population databases are indispensable infrastructures for research in the biomedical field, which requires a large number of samples to process data and obtain statistically significant results. Some populations, because of their geographical, historical and social isolation, are precious "genomic blocks" for accomplishing these studies. In the Sardinian Ogliastra region, for instance, the close collaboration between the local communities and the researchers during the whole *SardiNIA project*, as well as a careful design of informed consent, was considered a virtuous example of wise involvement of volunteers (surpassing 80% of the population) for sample collection, which resulted in the production of a huge genetic biobank with samples from 11,700 individuals (Piciocchi et al. 2018).

Trust in institutions managing such precious and sensitive data is, therefore, a main issue. If direct contact with the institutions managing the biobanks seems to be an important aspect of trust, it is reasonable to wonder why people turn to the genetic testing offered by private companies on the Internet. Direct To Consumers (DTC) genetic testing is a multifaceted product of genomic research intended to extremely varied applications, from medical to leisure purposes, and bearer of a series of personal and social meanings. The wide range of tests available includes diagnostic tests and tests for predisposition to certain diseases, pharmacogenetic tests for responses to pharmacological treatments, nutritional tests

focused on diets and obesity, and tests variously oriented to the search for personal characteristics and talents that go beyond the medical field. These include tests for origins, paternity, athletic talent, affective/amorous compatibility and even sentimental betrayals and responses to beauty treatments.

In literature, DTC genetic testing has been discussed as a symbol of people empowerment, a means of emancipation from a top-down health care system, a potential road toward democratization of medicine and care, but also as a source of concern, complacency or fatalism, a support of narcissistic approaches to manage (personal) genetic data, an incentive to misleading use and consume of scientific and medical information, and finally as a form of lucrative use of a technology (Turrini and Prainsack 2016).

For these features, in our exhibition on human genome at MUSE, we regarded DTC genetic tests as an excellent topic to be (re)presented, to stimulate reflections about crucial questions arising from genomics applications where scientific, economic, personal, social and legal aspects are intertwined (see Martinelli and Tomasi 2018). In 'The genetic test supermarket' exhibit, we recreated a consumerist setting where visitors can virtually buy the four DTC genetic tests we consider exemplary for this purpose. They are: PATOGEN ("A test to discover your genetic predispositions to oncological, cardiovascular and neurodegenerative diseases"), PATERSCREEN ("A reliable test to know who your father is, reunite relatives or determine rights of inheritance"), GENEOTEST ("A test to discover your roots and reveal the origin and native land of your ancestors") and GEN&AMOR ("Find your soul mate through modern genomic analysis"). Prices of tests and narratives to describe and advertise them were *ad hoc* studied to resemble the real products sold by the various genetic companies through the Internet.

The core part of this exhibit is based on two self-checkout machines, with a video-talked interactive multimedia questionnaire for museum visitors, proposed by two animated talking cartoons. The former is the "salesman", representing the interests of the biotech companies, and the latter is the "scholar", representing the bioethics and bio-law expert. Developed thanks to a cooperation with the BioLaw Project of the Department of Law of the University of Trento (Marta Tomasi), the questionnaire is intended to make museum visitors aware about the main issues concerning DTC genetic testing, i.e. intended use, reliability and accuracy of the analysis, comprehensibility and competency in interpreting results, impact of the results in people's understandings, and privacy and regulatory frameworks (Martinelli and Tomasi 2018).

In biobanking are involved questions of individual, collective and populations' identities. People can develop biosociality and sense of belonging and, in some cases, forms of collective action. How to deal with these issues in an exhibition?

The knowledge of our own genome seems to deeply involve identity. In the case of the DTC genome testing, for instance, the analyses are generally proposed by companies as tools "to know yourself better" (in a sort of modern, technological "γνῶθι σεαυτόν" exhortation) and "to build your own identity". On the other hand, what do motivate people to undergo a genetic test? According to the few studies investigating on this question (Harris et al, 2014), motivations are to know health status, to trace origins, curiosity about a new technology, the desire to be innovative in experimenting a new technology or in participating in the scientific progress, and just pure leisure. Narcissistic motivations are clear when tests' results are shared through social media and YouTube, from sample collection to result reading and sharing through the web, with videos and "genetic narratives" full of emotions and expectations. In the narratives of tests aimed at tracing origins, curiosity, joy and wonder are shown as people discover a sense of belonging to a group in a new form of "biosociality" where the genetic information becomes at the same time a personal and social issue. These tests, in fact, have a big social component, requiring to be shared through specific Internet sites.

The perception of belonging to a group is quite important in the cases of genetic diagnosis for major and rare diseases, which lead patients to participate (increasingly often through social networks) in disease-specific mutual-help groups to exchange information and suggestions on treatments, as well as feelings, fears and psychological support to face their state. In the cases of hereditary pathologies, involving relatives with various degree of kinship, there are also involved some ethical issues that can give rise even to pressing individual and family conflicts, concerning for instance sense of responsibility/guilt to likely transmitting a disease, privacy issues and the right to know/not know. This is quite clear when analyzing the confidences in reliable web sites of patient organizations of woman carrying the genetic mutations BRCA (Breast Related Cancer Antigens), related to breast and ovarian cancer in the female population and to prostate and breast cancer in the male population. In addition, a sense of "genetic identity" is quite clear since these patients introduce and refer themselves as "mutated", in a sort of identification with their genetic mutation rather than with a person affected by a disease. Here, the description of their self is mostly based on their own biological data. To represent these issues, in the exhibition on human genome, in the above mentioned "square" section, among the personal stories of "common people" we imagined the story of a young woman and future mother, about to take the decision to undergo the genetic test for the BRCA mutation, a test requiring responsibility for herself and for the child she is waiting for. She is represented right in the moment she knows from a close member of her family, who already resulted positive to the test, about this family predisposition and has to face the difficult choice to know/not know about the chance to carry - or not - this hereditary genetic mutation. Her

narrative is meant to give voice to a deep personal conflict as well as to an advice to prevent/manage the disease thanks to the knowledge about the (eventual) genetic predisposition.

Commercial exploitation is another big issue in biobanking. People freely give tissue samples and information as a gift, that could be turned into a commodity. How to communicate this complex question?

The biological materials stored in the repositories – as well as the information processed from them – are goods donated by patients. Being these essential to the progress of medical research, patients' trust is fundamental to implement biobanking. Commercial exploitation of samples would certainly undermine their trust not only in biobanking but also in the general accountability of biotechnological and biomedical innovations. Therefore, as already pointed out (Piciocchi et al. 2018) biobanking is an interesting example of controversial relationship between research institutions and civil society, which requires transparency and legal regulation. Here, public trust and civic engagement are particularly important features.

At MUSE, to deploy suitable communication strategies for science communication on topics with relevant bioethical and biosocial implications, we adopted a new format, a kind of science theatre named "science lecture-performance", where a science expert and an actor/actress dialogue on the stage without losing their specific features and roles. *'ETERNeETÀ – la vecchiaia può attendere'* ['ETERNeETÀ - aging can wait'] was the result of a fertile interaction between the sensitivity of a director (Elena Marino) and an actress (Silvia Furlan) of the company *Teatrincorso* and myself[8]. Scientific and theatrical texts and artistic representations, including projections, multimedia and music, were the tools to deliver concepts and new insights by reaching the public's emotions.

Among the various bio-objects, the case of the immortal *HeLa* cells has been an amazing "good story" to be represented, in particular because of its biosocial implications and symbolic meanings, as previously discussed (Svalastog and Martinelli 2013). They are emotionally impacting, being invasive and frightening, immortal and of extraordinary value for science and humanity[9], but also an example of fraud and abuse of a woman of marginalized origins[10]. Therefore, these cells are suitable to both deliver knowledge and to engage debates specifically on the topic of biobanking and in general on the impact of biomedical innovation, also by reaching the public's emotions. This latter is an important aspect of communication. For instance, a very inspiring moment of the performance 'ETERNeETÀ was when the actress rolled up herself in plastic wrap to be kept in a freezer, in an attempt to "aging without aging" and to last forever, with an emotional metaphor of her dramatic wish to escape the inexorable fate of biological decay and death. I believe that this was an interesting example of a successful integration between scientific

concepts and theatrical performance.

With the same company, we staged the performance *'Vite sintetiche'* ['Synthetic lives'], a monologue performed by the actress and inspired by synthetic biology[11]. Topics were the controversies (opportunities and risks, promises for a best life quality and a sense of disorientation) produced in the every-day life of a family by various bio-objects, including – reference to biobanks – the tissues of extinct animals preserved for de-extinction experiments. In this case, in the refrigerator of a housewife it was stored a piece of bone of a dinosaur stolen from a science museum (MUSE) by the youngest son.

Why did you feel the need of using the language of theater and art to communicate, and how did you interact with artists?

There are numerous successful experiences in scientific communication based on art. Art and science show many points of contact. Both are based on creativity, innovation and a rigorous attitude. Science offers interesting topics to art and results in a fertile source of ideas and metaphors. On the other hand, by eliciting emotions, art induces curiosity and passion.

As for the scientific theatre, in general, the texts are written by the artistic counterpart, whilst scientists inspire the topics and validate the accuracy of scientific information. In our intense relation with the company *Teatrincorso*, on the contrary, a high interdisciplinary attitude was essential during the creative brainstorming, text writing and even the participation on stage in the case of 'ETERNeETÀ'. Motivation leading scientists and artists to cooperate has been analyzed (Dowell and Weitkamp 2011). On the basis of my personal experience, I agree that, in this challenging relation, the "scientist" should be a person quite motivated to exploit public engagement, curious about the new experiences that the theater can offer and open to new forms of communication; the "artist" should be a person very interested in science and in new ideas and incline to engage with challenging topics. Finally, a science performance would result successful when it is not distinguishable whether it is science that offers art subjects to perform or whether art is a vehicle for communicating scientific concepts and opportunities for reflection to the publics.

Another challenging experience of science-art communication was the collaboration with Claud Hesse, a visual arts practitioner, known as the "DNA artist". For the section focusing on epigenetics of the exhibition on human genome at MUSE, she specially created 'DNA EPIGEN', an interactive sculpture involving visitors to discover epigenetic concepts. By causing changes on cubes interacting with a large double helix of DNA, visitors are invited to experience some epigenetic imprints produced by the interactions between the genome and the environment (including life style and stress such as light, darkness, peace, violence, abundance and famine). In this case, the production of the artwork involved various sub-

jects with specific multidisciplinary skills: the artists, the curators and the architect of the exhibition, the epigeneticists, the manufacturers and the experts in information and communication technologies and technical assistance. I believe that the most critical aspect of this science-art experience was the need to suitably balance the correct scientific presentation of a complex concept - as epigenetics - with the artist's creative action for freely interpreting the topic, to generate a piece of art and not (just) a scientific model.

What people learn from an exhibition on human genome? And why do you think is important communicating genomic research and biobanking activities with other means?

Genomic research and biobanking, because of their importance in the current science landscape and of their significance on society, are suitable topics to engage people in reflections about scientific culture. Scientific exhibitions are particularly suitable sites where presenting hot topics of science nowadays and reaching different publics of various ages and backgrounds. In the case of our exhibition on human genome, and in particular for the hot topic of DTC genetic testing, for instance, we can evaluate its effectiveness in engaging a great number of citizens. During nine months (February 26th – November 27th, 2018) 16,086 people completed the food-for-thought questionnaire offered in 'The genetic test supermarket' exhibit above described. Visitors involvement, moreover, can be analyzed in the many "stories of everyday-genetics" they are leaving in the "memory book" in the intimate room –mentioned above – at the exit of 'The square' section. According to a preliminary analysis, we can conclude that the various inputs we offered resulted in effective stimuli for reflections on important issues of genomic knowledge, concerning personality, traits and disease. It has emerged, for instance, the desire – never felt before – of visitors who were adopted at an early age to start investigating about their biological and geographical origins.

Finally, aiming at promoting reflections and new questions about science rather than offering certainties, in the concluding section of the exhibition we proposed a series of questions about genome – without giving answers – collected during focus groups with citizens to investigate about their interests in the topic. Questions as: "Is there is a DNA test to know the length of someone's life?", "Can human genes be put on sale?", "Do criminals have a particular 'killer gene'?", "Is happiness linked to our DNA?", "Are people born gay or do they become so?". If they might at a glance appear naïve, conversely they point out important issues about genome knowledge still waiting for (conclusive) answers.

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Communicating Genomics Research. Participative Models in a Local Context

Ilaria Ampollini

The active involvement of citizens is today at the core of many international initiatives where an effective cooperation between scientific research and society is needed. This is particularly true when it comes to biomedical research, which increasingly addresses to patients, patients' relatives or patient associations: during the last years, in fact, growing prominence has been given to patient engagement in the developments of therapeutic solutions or in designing new research projects. Although these elements precisely meet the EU objectives and requirements established by the *Science with and for Society programme – Horizon 2020 for the Public Engagement and a Responsible Research and Innovation*, different pathways and answers have been put in place by European countries.

As it is well known, one of the most innovative approach has being experienced by the UK. The England National Health System (NHS) has a wide range of policies for the enhancing of patient participation. The involvement of patients and citizens includes not only *ad hoc* social media or standard surveys, but, more importantly, online forums, focus groups and deliberative events. For instance, in case of proposals of policies for new therapies, open consultations are launched and people can express their own views. Most notably, the UK National Institute for Health Research (NIHR) supports the *INVOLVE programme*: established in 1996, it encourages "active public involvement in NHS, public health and social care research". Another example is that of the *Patient Led Research Hub* (PLRH), founded in 2015 by Cambridge University Hospitals, NHS Foundation Trust and the Cambridge Clinical Trials Unit from the University of Cambridge. Interestingly, the assumption at the basis of PLRH project is that the other initiatives do not actually take into account patients priorities in setting the research agenda. This is why PLRH aims at collecting and supporting research ideas coming from patient organizations.

Another almost unique scenario is offered by the French context. Here, the involvement is more generally addressed to all citizens, through the *États Généraux de la Bioéthiqu*e. According to the French system, laws regulating bioethical issues are subjected to revision every seven years (as minimum requirement). On the occasion of revision, citizens committees are summoned and asked to express their own opinion, via web or during dedicated meetings, on the main bioethical concerns. Committees' final reports are then presented to the French Parliament, which is expected to take them into account when assessing the new regu-

latory acts. Last revision took place in the first half of 2018. Among the revised Articles, many obviously concern biomedical issues, such as cloning, assisted reproduction techniques, organs transplantations, DNA tests and genetic medicine.

Italian context is quite different both from the UK and France contexts. We do not have a National Health System which directly promotes the involvement of patients neither do we submit bioethical dispositions to citizens' revision. Since the involvement of citizens and more specifically of patients is not officially promoted by state bodies, the importance accorded to patient participation is left to the responsiveness and the responsibility of hospitals, research groups, actors of the pharmaceutical industry or patient associations. Moreover, one must consider that the initiatives of science communication in Italy still show a clear predominance of a top-down approach as well as an unjustified, and often unaware, commitment to deficit model's practices.

These two elements – on the one hand the absence of centralized actions aimed at patient and public involvement, on the other hand the limited use of participative models by people engaged in science communication – obviously do not foster an effective engagement of citizens when it comes to matters related to medicine and health issues.

However, during the last years a good number of projects was born: at least a couple of them deserve to be mentioned. The first one is the *Research Lab for Citizens' Involvement in Healthcare System* (Laboratorio Ricerca per il Coinvolgimento dei Cittadini in Sanità), promoted by the Mario Negri Institute in Milan. The Lab includes a remarkable number of initiatives, such as projects about informed consent and aware decisions – it is quite common that the concept of patient participation is merely intended as a proactive choice of treatments and therapies. Nevertheless, the Mario Negri Institute also promotes a series of Citizens Committees (Giurie dei cittadini), which are expected to evaluate the necessity of screening programmes for cystic fibrosis and prostate cancer. The project is a pilot one and it is currently run in the Verona area.

Another example is the European project EUPATI, started in Italy in 2013, which aims at creating a collaborative consortium involving and connecting pharmaceutical industry, academia, non-profit organizations and patient associations. EUPATI partners provide information and training courses to patients willing to know more about the processes behind medicine development and clinical trials, thus becoming "expert patients". As part of the project, in 2014 the Patients' Academy was founded in Italy, as well as in other European countries – France, England, Germany for instance. There is also an Italian Stakeholders Board, which includes prominent stakeholders, such as AIFA (Italian Medicine Agency), Farmindustria (Association of pharmaceutical industries) and the Ministry of Health.

It is within this framework that in Trento, during the exhibit *The Human Genome. What makes us unique* at MUSE, an initiative to in-

volve patients, patients' families, patient associations and more in general citizens was designed . It is obvious that, compared to the projects listed above, we are talking about a small initiative at local level. However, it shows some points of interest on which it is worth to focus on. The two-days meeting is part of a wider project, called *CLaSTer. How Science Works. Dialogues between University and the Region* (CLaSTer. Come Lavora la Scienza. Dialoghi tra Università e Territorio), a three-years project funded by the Autonomous Province of Trento and hosted at the Department of Sociology and Social Research at the University of Trento. The main goal of CLaSTer is to draw attention to scientific research and the ways it works, through two combined approaches: the use of history of science and the recourse to participative models. In cooperation with CIBIO, the Department of Biomolecular Sciences of the University of Trento and MUSE itself, we decided to organize two days of consensus conferences on the topics of genomic and precision medicine.

The reason of the initiative relies on the awareness that it is essential, generally speaking, and even more within a small local context such as Trento, to enhance and enforce effective and long-term collaborations between research institutes, the Province Health System, the doctors and the healthcare professionals working at the public hospital, and the patients, patients' families and patient associations. It is clear that a strong partnership where each of these actors can bring their own experience and where clinical practice can constantly benefit from working closely with academic research, while patients can express their needs and priorities, would not only certainly boost local scientific research, but also help increasing citizens trust in researchers and healthcare.

Notwithstanding all this, we must point out that in Trento no participative models have been put in place to build and strengthen this stakeholders' network, partly because the communication of science in the Province is still mostly constituted by top-down models, and partly because the development of partnership between academia, healthcare system and patients usually goes through different channels. The exhibit GENOME at MUSE offered the right occasion to experience new pathways, especially considering that the themes addressed are strongly linked to the research being done at CIBIO (which in fact has collaborated in designing the exhibit's contents), as well as to the directions in which the Province Health System is today working – for instance the Trentino BioBank, which collects samples of tissues and blood, or the Clinical Service for Medical Genetics.

The initiative, named *From Genome to Precision Medicine. Discussion groups between Citizens and Scientific Research*, was planned to be developed through two days. During the first day, four roundtables, constituted by two experts and five citizens each, took place: each table was asked to discuss a specific issue linked to genomics and precision medicine, that is to say risks and benefits, ethical issues, bio-law and economic sustainability. The aim of this first day was to collect concerns, opinions

and priorities emerging from citizens and to draw special recommendations based on them. During the second day, yet to take place, the results from the first day will be displayed by citizens representatives (one per table) to doctors, policy makers and researchers.

Since the initiative is still ongoing, it is too early to outline a proper research paper on it, or even to draw any kind of conclusions. However, there is at least one element which has already come up during the first date and which is worth to be reported. It especially concerns the phase of the recruitment of participants, during which we tried to reach those citizens potentially interested in the themes of the Consensus conference through the various associations actively working in the Trento area. We are of course referring to those associations promoting research funding and citizens' awareness on a wide range of diseases, that is to say, for instance, different forms of cancer, neurodegenerative illnesses, such as Huntington's, diabetes or cystic fibrosis. Moreover, there are also other associations whose focus is on active citizenship and therefore deliberative democracy. We also contacted teachers and members of the association Friends of MUSE, a group of citizens who support MUSE activities.

While teachers and Friends of MUSE members easily accepted to take part to the experience – and, by the way, also the doctors and the researchers we contacted in preparation of the second appointment did so – the response from the majority of patient associations was far lower than we expected. The reasons can be of course numerous – and we can not provide an in-depth analysis here – and one of the reasons, beyond the organizational details that can be always improved, may be that people, and especially patients, are not familiar with this kind of initiatives in the Trento area.

This is exactly why it will be even more important for the University and its research groups to create a stronger link with the territory and not to stop proposing similar projects in order to make them more familiar to citizens and, at the same time, make citizens more willing to participate. Obviously, it will also be necessary to demonstrate that this first initiative has been effective and will have some concrete and positive impacts on all the actors involved.

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[1] https://www.youtube.com/watch?v=ymN6sZf9mmM

[2] https://www.univie.ac.at/bio-objects/index.htm

[3] https://www.synenergene.eu/

[4] http://www.nano2all.eu/

[5] https://www.youtube.com/watch?v=ds0gSoAs7Bg

[6] https://www.nasa.gov/twins-study/about

[7] https://www.nih.gov/news-events/news-releases/nih-lacks-family-reach-understanding-share-genomic-data-hela-cells

[8] The trailer is available at https://www.youtube.com/watch?v=FvxFcFJ0BNY

[9] *HeLa* was the first immortalized cell line, established in the late 1950s from Henrietta Lacks' rare cervix adenocarcinoma, an aggressive lethal cancer, and its descended lines are still used in the laboratories all over the world. These cells have been the basis of thousands of scientific publications and important biomedical innovations, some of them also awarded with Nobel prizes.

[10] Henrietta Lacks, a poor, black woman, has been never informed about her cells' use whilst they became economically valuable for the biotech industries.

[11] https://www.spazio14.it/vite-sintetiche-al-muse-il-29-e-30-settembre/

Collective Biopolitics
The Rights of Indigenous Peoples in Genetic Research

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Abstract: This essay considers issues implicated in biobanking with indigenous peoples, a population increasingly recognized as having a collective right to participation under international law (e.g., the United Nations Declaration on the Rights of Indigenous Peoples (2007)). In contrast, prevailing notions of participation within the field of human rights (including the right to health) presuppose an individualist notion of citizenship. This essay compares the indigenous collective right to participation with "molecularized biopower", the theory that biopolitics in modern democracies is becoming increasingly individualized in an unprecedented way. Using a US biobanking case study, this essay argues that two aspects of the indigenous collective right to participation (i.e., self-determination and the "empowerment" framework), not only counter the claim for a pervasively individualized biopolitics, but also demonstrate the importance of collective rights for indigenous participation in genetic research generally.

Keywords: indigenous, biobanking, biopolitics, genetic, collective, biopower

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1. Introduction

In early 2015, the Precision Medicine Initiative (PMI) was announced by then-US President Barack Obama. The major undertaking was billed "to develop the nationwide infrastructure necessary to implement precision medicine in the United States" (Sankar 2017). The central endeavor of the PMI is the formation of a genetically diverse cohort of one million volunteers through the *All of Us* Research Program administered by the National Institutes of Health (NIH). Volunteers' biospecimens indexed to their health data will provide a centralized resource for researchers to investigate the varying impacts of genes, lifestyles, and environmental fac-

tors on the etiology of different diseases.

Another crucial component of the PMI is a central biobank, defined as "an organized collection of human biological material and associated information stored for one or more research purposes" (Kaufmann 2008). The PMI repository will be hosted under contract by the Mayo Clinic in Rochester, Minnesota. Although several significant repositories indexed to volunteer health data exist in the US (e.g., the Department of Veterans Affairs *Million Veteran Program*, and the National Genome Research Institute-funded eMERGE Consortium), the PMI biobank will support the country's largest longitudinal study to date.

Because the *All of Us* Research Program aims to recruit a genetically diverse cohort, the program has actively engaged the nation's nearly 600 officially-recognized indigenous peoples to encourage enrollment. US indigenous peoples have raised concerns regarding participation that touch on a variety of issues including informed consent, secondary uses of biospecimens, and privacy (NCAI 2018). These concerns present an opportunity to consider the social and political factors that influence participation in genetic research and associated activities such as biobanking.

Indigenous peoples provide an interesting case study to explore these factors, because the collective aspects of indigenous social and political life contrast with the individualist models of citizenship prevalent in most modern democracies. These models also form the implied backdrop to scholarly discussions in the fields of international human rights and Science and Technology Studies (STS). By focusing on the rights of indigenous peoples in the context of genetic research, this essay further diversifies existing literature on human rights and global health, which has been dominated by the individualist framework expounded in the Universal Declaration of Human Rights (1948) (Mann 1997; Meier and Fox 2010). In addition, the essay's emphasis on indigenous peoples enriches STS literature by discussing the impact of advanced health technologies on societies whose structures do not fit the conceptual categories typically applied in sociological and critical analyses of modern political life.

In this essay, I use indigenous participation in the PMI as a case study to discuss the effects of individualist models of citizenship on analyses of participation in genetic research. In particular, I focus on the concept of "molecularized biopower" as articulated by Paul Rabinow and Nikolas Rose, a notion advancing the view that biopolitics has taken a drastic turn, from population-based top-down state interventions, to citizenship driven from below by novel forms of individual participation. Focusing on recent developments in international law and on STS work on biopower, I argue that a claim for a new individual "biopolitics from below" is not borne out by current state practice with respect to indigenous peoples. Additionally, I argue that collective forms of participation are crucial for fostering indigenous participation in genetic research. I begin with a brief overview of the status of indigenous peoples in international law.

2. Indigenous Peoples in International Law

In international law, the term "indigenous" has a technical meaning that is not merely a synonym for "native," "local," or "colonized." The most influential definition of indigenous peoples was developed by Jose Martinez Cobo (1986), a UN-appointed expert on minority rights:

> Indigenous communities, peoples and nations are those which, having a historical continuity with pre-invasion and pre-colonial societies that developed on their territories, consider themselves distinct from other sectors of the societies now prevailing in those territories, or parts of them. They form at present non-dominant sectors of society and are determined to preserve, develop and transmit to future generations their ancestral territories, and their ethnic identity, as the basis of their continued existence as peoples, in accordance with their own cultural patterns, social institutions and legal systems.

Indigenous peoples are communities that descend from societies predating foreign subjugation, and who view themselves as distinct from the general population of the states that have developed as a result of such historical domination. As suggested in Cobo's definition, indigenousness has a subjective component (i.e., self-identification) and an objective aspect (i.e., shared experiences of dispossession, and a common agenda focused on preserving identities, traditions, institutions, and territories). By this definition, groups who consider themselves distinct from the rest of society and who have also continuously inhabited the same territory for many generations, but who lack a history of sustained and systematic dispossession may not meet the formal requirements of indigenousness (e.g., Andalusians of Spain) (Anaya 2009).

In contrast, other groups who have been conquered and colonized may not qualify as indigenous peoples because they do not aim to separate themselves from the population of the resulting postcolonial state (e.g., the majority of ethnic groups in sub-Saharan Africa). The global population of indigenous peoples is around 370 million persons (World Bank 2018), and a few examples include the Maori of New Zealand, the Aboriginals of Australia, the Inuit of the Arctic (Canada, Greenland, Alaska), the Sioux of the United States, the San of Southern Africa, the Miskito of Central America, the Chacobo of Bolivia, the Sami of Scandinavia, and the Adivasi Janajati of Nepal.

3. Molecularized Biopower

In discussions of Michel Foucault's thoughts on biopower, the writings of Paul Rabinow, Nikolas Rose, and their colleagues have been espe-

cially notable within the scholarship of theorists who have extended Foucault's ideas to recent developments in the life sciences (Rabinow and Rose 2003, 2006; Rabinow 1996; Rose 2001, 2006; Rose and Novas 2004). In particular, their notion of "molecularized biopower" is characterized as a stark departure (Rose 2001; Rose and Novas 2004) from the model of societal regulation at the population level, which, Foucault argued, had become the dominant mode of control at the dawn of modernity (Yang 2018). Such governance at the population level – "a power to *foster* life or *disallow* it to the point of death" – was described by Foucault as gradually displacing "the ancient [sovereign] right to *take* life or *let* live" exercised on individual bodies (i.e., "anatomo-politics") (Foucault 1978).

Rabinow and Rose (2006) update the concept of biopower to consist of the following three elements, which may vary in expression over time:

> (1) One or more truth discourses about the "vital" character of living human beings, and an array of authorities considered competent to speak that truth. (…)
>
> (2) Strategies for intervention upon collective existence in the name of life and health, initially addressed to populations that may or may not be territorialized upon the nation, society or pre-given communities, but may also be specified in terms of emergent biosocial collectivities, sometimes specified in terms of categories of race, ethnicity, gender or religion, as in the emerging forms of genetic or biological citizenship.
>
> (3) Modes of subjectification, through which individuals are brought to work on themselves, under certain forms of authority, in relation to truth discourses, by means of practices of the self, in the name of their own life or health, that of their family or some other collectivity, or indeed in the name of the life or health of the population as a whole (…).

The three elements together provide complementary perspectives on the bases of the claim that biopower, in its current molecularized form, signals a seismic change from the previous iterations described by Foucault (i.e., anatomo-politics of the human body and biopolitics of the population). The first element refers to "truth discourses" about human life and their legitimating institutions. For Rabinow and Rose, the relevant discourse for this new form of biopower comprises the life sciences, specifically the field of genetics (Raman and Tutton 2010). As Rose (2007) argues, genetics has altered the discourses surrounding medicine by fragmenting the human body into a composite of molecularized units, thereby facilitating the application of biopower at the molecular level. The second element refers to interventions aimed at collective life, with the qualification that the collective in question may not refer to a predefined group such as the territorially defined population of a state. This point acknowledges a diminution in the power states have historically wielded to implement collective interventions for hygienic and eugenic purposes (Rose and Novas 2005). This decline in state power corresponds to an increasing transfer of responsibility for personal and collective

health to individual citizens, the "subjectification" described in the third element. Part of "work[ing] on themselves" involves citizens leveraging scientific knowledge and forging partnerships with various stakeholders (e.g., patient support groups, disease advocacy organizations, pharmaceutical companies, scientists) in new forms of civic engagement, biosociality, and citizenship: a biopolitics rising from below, rather than imposed from above (Raman and Tutton 2010).

4. The Limits of Molecularized Biopower: A Case Study

The new account of biopower proposed by Rabinow and Rose has been assessed by various writers (Raman and Tutton 2010; Arnason 2013; Heinemann and Lemke 2014). In this essay, I am particularly interested in critiques that challenge the contention that the "molecularization" of life in Western democracies has wrought an unprecedented change in the manifestation of biopower in those societies. Building on these assessments, this section argues that two factors associated with the development of indigenous peoples' rights under international law demonstrate clear countercurrents to the prevalence of molecularized biopower in modern states. The two factors are (1) explicit recognition of collective rights to complement individual rights, and (2) adoption of the principle of self-determination as a prerequisite for indigenous peoples' participation in state "citizenship projects" (Rose and Novas 2005) such as the PMI.

4.1 Collective Rights and Indigenous Sovereignty

In their evaluation of molecularized biopower as described by Rabinow and Rose, Sujatha Raman and Richard Tutton (2010) assert:

> It is misleading to assume that state biopolitics has simply given way to "ethopolitics" where individual judgment and reshaping of the self are paramount and where the state merely exerts pastoral power in the domain of life. By focusing on cases where biopolitical claims and counterclaims are framed in terms of individual choice, there is a danger of implying that individualism is the only discourse that is permitted in the political landscape today and that one must necessarily work within its confines even to challenge dominant practices. Even if we allow that the language of individual choice, rights, and freedom is clearly dominant, we need to examine how it is linked with or challenged by political discourses that appeal to some notion of the collective.

In their critique, Raman and Tutton point to the underlying premise of molecularized biopower expressed in the term "subjectification": a focus on the individual as the driving force of biopolitics, often at the expense of the state. Against the pervasive individualism presupposed in the work of Rabinow and Rose, they argue that research design in the life sci-

ences continues to be framed in population categories. Raman and Tutton cite the example of the US Health Revitalization Act of 1993, which mandated the National Institutes of Health (NIH) to require inclusion of women and minority populations in funded research. The field of public health genomics also exemplifies the persistence of population level models and interventions, including in genetic research (Khoury et al. 2017; Meslin and Garba 2011).

4.1.1 International Law

The focus on the individual in molecularized biopolitics has an analogue in international law. Since the end of World War II, the global mechanisms of human rights protection through the United Nations have focused on individual claims "of freedom, equality, participation, and economic and physical security vis-à-vis the state" (Anaya 2009). However, developments in indigenous peoples' rights have trended toward an increasing recognition of collective rights due to the failures of the individual-based system to protect indigenous communities adequately. In this section, I briefly trace this evolution in international law and note its implications for molecularized biopower.

Due to their adoption both as a legal standard and as a requirement for membership in the United Nations, human rights have been influential in shaping international policy since the middle of the 20th century. Starting with the Universal Declaration of Human Rights (UDHR) (1948), an impressive edifice of treaties with associated monitoring institutions has evolved to protect member states' citizens. Alongside the wide-ranging International Covenant on Civil and Political Rights (ICCPR) (1966) and equally expansive International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966), other human rights agreements address the rights of women, children, the disabled, and migrant workers while others address issues such as racism, genocide, torture, and forced disappearances.

As the genetic revolution gained momentum, the United Nations Educational, Scientific and Cultural Organization (UNESCO) took advantage of the adaptability and transnational influence of human rights by adopting three declarations to address the novel ethical issues being raised by genetics. These were the Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003), and the Universal Declaration on Bioethics and Human Rights (2005). Treaties, being legally enforceable agreements between states, represent the strongest form of obligation in international law. Breaches of such agreements can trigger a variety of measures to ensure compliance. However, because treaties on complex issues involving a large number of states take a long time to negotiate and sign, groups of states (e.g., United Nations, Organization of American States, European Union, African Union) sometimes opt for declarations. Though lacking

the specificity and detailed sanctions of treaties, declarations take less time to enact, outlining an area of concern while establishing a platform for coordinated action. Declarations also typically serve as drafts of future treaties (as the UDHR did for ICCPR and ICESCR). At a minimum, the UNESCO declarations reflect a consensus among member states on the need to address the implications of genetic research for the international community.

However, even as human rights were being endorsed as an ethical, legal, and policy guide for genetic research, discussions persisted on their limited application for engaging certain populations, among them indigenous peoples and other sociopolitical collectives (e.g., ethnic groups in sub-Saharan Africa). A recurring critique of the human rights system, an edifice based on the UDHR as noted earlier, was the structure's emphasis on the individual person as the chief focus of ethical and legal analysis (Anaya 2009; Mutua 2008; Cobbah 1987).

Provisions of the major human rights treaties ratified since the UDHR's adoption (e.g., ICCPR, ICESCR) have generally been construed as protecting the rights of individuals, not collectives. For example, the right to health has been interpreted by ICESCR's monitoring body as an obligation that governments owe to their individual citizens (UN Committee on Economic, Social and Cultural Rights 2000). Even when a right has patently collective dimensions, as with minority rights to language and culture, the relevant monitoring body has consistently adopted an individualist hermeneutic (UN Human Rights Committee 1994).

In contrast, political institutions (e.g., systems of restorative justice) and economic practices (e.g., common ownership and stewardship of land) among indigenous peoples give substantial weight to collective considerations (Zehr 2002; Ortega 2004). This inattention to collective aspects of social life in the UDHR-based system spurred efforts to bridge the normative gap in indigenous communities, resulting in the incorporation of collective rights in the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) (Anaya 2004; UN General Assembly 2007). Although there have been treaties that have addressed issues of concern to indigenous peoples through the International Labor Organization, UNDRIP is the first international instrument drafted with significant indigenous input (Anaya 2009).

UNDRIP's Preamble describes collective rights as "indispensable for [indigenous peoples'] existence, well-being and integral development". Among other provisions, Article 1 secures for indigenous peoples, as both individuals and collectives, the enjoyment of all human rights codified in international law and in major UN documents, while Article 7.2 describes "a collective right to live in freedom, peace and security as distinct peoples". UNDRIP also incorporates collective features pertaining specifically to the right to health. Article 21 of UNDRIP describes a collective right "to the improvement of . . . economic and social conditions, including... health," while Article 24 recognizes the collective right indigenous peo-

ples have "to their traditional medicines and... health practices".

In summary, the collective features of UNDRIP have incorporated into international law a maturing consensus on standards for protecting the rights of groups as groups, not merely as aggregates of individuals. Alongside the persistence of population categories in research design, this consensus on collective rights adds to arguments against the claim by Rabinow and Rose that growing "subjectification" marks a revolutionary restructuring of biopower in the direction of individual activism in modern democracies.

4.1.2 United States Case Study

Although they are not recognized as sovereign states under international law, the 573 indigenous peoples in the US have a unique government-to-government relationship with federal authorities. The qualified sovereignty implied in this arrangement is a result of past treaties between them, court decisions, and executive orders. Tribal sovereignty is the basis of collective existence for the nation's indigenous peoples, and also shapes the policy context for engaging them in projects such as the PMI.

As the Tribal Collaboration Working Group (TCWG) (2018) of the *All of Us* Research Program explains,

> [t]his sovereign status, which is a political designation, gives tribes legal rights and privileges that are distinct from racial and ethnic groups. Research partnerships with [indigenous] populations require unique considerations, including greater input and oversight by tribal communities on data and biospecimen policies, beyond those for other groups.

The distinction highlighted here between the country's "racial and ethnic groups", on the one hand, and indigenous peoples, on the other, echoes the difference noted in the earlier discussion of international law. Like the individualist interpretations of the major UDHR-based human rights treaties, US constitutional law protects citizens as individuals, not collectives (Chemerinsky 2016). In its report, however, the TCWG affirms that the sovereign status of US indigenous peoples furnishes "rights and privileges" that justify their treatment as collectives.

In the context of the PMI, an important means of implementing the collective principle is the TCWG's recommendation to obtain community (or tribal) consent prior to recruiting indigenous individuals on indigenous territory (TCWG 2018). In making the recommendation, the TCWG acknowledges complexities that can arise in certain situations, such as deciding whether community consent may still be required when recruiting indigenous persons permanently living outside indigenous territory or judging what level of data to record upon enrollment to protect collective indigenous interests.

These complexities notwithstanding, the TCWG's recommendation aligns with ethics guidelines for research with indigenous peoples that

propose applying both individual and collective analytical frameworks. The use of both frameworks in research regulation is a function of the collective social organization of most indigenous societies (as noted above), as well as the risks of identification and stigmatization associated with genetic studies in small populations (Kowal 2015; Garrison 2013).

The increasing recognition of both individual and collective frameworks in US indigenous research is consistent with the critique of molecular biopower advanced by Raman and Tutton: state biopolitics continues to play out at both individual and population (i.e., collective) levels in modern democracies. The claim by Rabinow and Rose of a revolutionary "subjectified" (i.e., individualized) biopolitics warrants qualification given the case study of the PMI.

4.2 Self-Determination and the "Empowerment" Framework

In reference to a discussion of biological citizenship by Rose and Carlos Novas (2003), Vilhjalmur Arnason (2012) comments:

> The distinctive feature of deliberative democratic theory is its emphasis on the quality of arguments and reasons used to justify policy and that validity of these reasons needs to be tested in communication that is free from deception and coercion. (…) [T]he first social purpose "served by deliberation in democracy" is promoting the democratic legitimacy of political decisions.

Arnason's remarks are made in response to what he views as the broad and, therefore, vague models of biological citizenship described by Rose and Novas (2005). By extension, he questions the analytical purchase of molecularized biopower as characterized by Rabinow and Rose (2006), a view that features declining state interventions "from above" and creative alliances by individual citizens to advance life claims "from below". He argues that "[t]he notion of citizenship implies not just any activity of citizens. It refers to activities that are different from … those characteristic of a colleague, a customer or a consumer" (Arnason 2012). Arnason here questions whether the alliances individual citizens forge with certain entities (e.g., pharmaceutical companies) to advance their individual life claims fall properly under the rubric of citizenship. In other words, Arnason is concerned not just about the fact of participation but its quality.

4.2.1 International Law

Arnason's focus on legitimacy as a condition for genuine democratic participation reflects trends in the rights of indigenous peoples. The principle of self-determination in UNDRIP underscores the continuing importance of collective institutions for fostering "democratic legitimacy" in deliberations, an emphasis that is inconsistent with the individualizing subjectification that characterizes molecularized biopower. In this sec-

tion, I discuss the principle of self-determination and how, through the "empowerment" framework, the principle helps ensure meaningful participation in state projects among indigenous peoples.

Stated simply, self-determination recognizes the inherent capacity of indigenous peoples *as collectives* to develop culturally, socially, and economically along lines consistent with their respective histories and values. The principle appears in the UN Charter and is codified in identical language in the two principal human rights treaties mentioned earlier (i.e., ICCPR, ICESCR): "All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development." Self-determination is unique in both treaties because it is, by definition, a collective right, whereas, as noted earlier, other treaty provisions have consistently been construed as applying to individuals.

As the text reads, self-determination applies to "all peoples." The principle was crucial in establishing new states in formerly colonized territories after World War II. UNDRIP applies the right specifically to indigenous peoples, using identical phrasing in Article 3. Indeed, self-determination can be seen as the touchstone of UNDRIP, providing the policy framework for indigenous rights across a variety of areas, including land, culture, religion, health, education, and political structures.

The connection between the right to self-determination and collective rights is straightforward: collective rights provide a legal mechanism for preserving the ability of indigenous peoples to exercise their right to self-determination. Given the fact that they are, by definition, embedded in states from which they "consider themselves distinct" (Cobo 1984), indigenous peoples must strike a balance between exercising their right to self-determination and managing the inevitable impact of state dominion on their affairs. Self-determination in UNDRIP gives indigenous peoples a measure of control over the terms of their engagement with state power (i.e., participation) through what Anna Cowan (2013) calls the "empowerment" framework.

The main features of the empowerment framework can be understood by tracing the complementary relationship between "internal" and "external" aspects of participation.[1] Article 18 of UNDRIP provides for indigenous peoples to participate in states' decision-making processes when the measures in question affect indigenous interests (i.e., external participation). This article corresponds to Article 25 of the ICCPR, which describes a right for the individual citizens of states to participate "in the conduct of public affairs." In contrast, Article 4 of UNDRIP contains a right to indigenous self-government and autonomy with respect to "internal or local affairs" (i.e., internal participation). This collective right of indigenous peoples to autonomy over their internal affairs does not apply to other constituencies in the ICCPR (e.g., non-indigenous minority groups).

Article 5 of UNDRIP combines both internal and external aspects of

participation. The provision acknowledges indigenous peoples' right to "maintain and strengthen their distinct . . . institutions" (i.e., internal participation), while preserving an indigenous right "to participate fully, if they so choose, in the political, economic, social and cultural life of the [s]tate" (i.e., external participation). Empowerment refers to the ability of indigenous peoples to govern indigenous affairs through their own institutions as well as to influence decisions made outside indigenous communities that affect indigenous affairs.

A metaphor useful for describing the complementary fit of internal and external participation employs images of a sword and a shield. External participation functions as a sword, equipping indigenous peoples with a means of influencing outside processes potentially bearing on indigenous affairs. Internal participation works as a shield, creating a protected communal space in which indigenous peoples can deliberate on their collective destinies insulated from the dominating influence of state power. Both aspects are essential for a meaningful exercise of the right to self-determination.

The empowerment framework, comprising both internal and external participation, reinforces Arnason's point on the importance of legitimacy in participation. To extend his analysis, the ability of indigenous peoples not only to participate in "the political, economic, social and culture life of the [s]tate" (UNDRIP 2007) but also to deliberate on state action in their own indigenous institutions increases the legitimacy of indigenous decision-making. Moreover, the recognition of "internal participation", which adds a collective component to "democratic legitimacy", runs counter to the relentless individualizing trend claimed of molecularized biopower by Rabinow and Rose.

4.2.2 United States Case Study

The 573 federally-recognized indigenous peoples in the US have a legal right to self-determination. The national policy on self-determination is codified in the Indian Self-Determination and Education Assistance Act (1975). Along with the governments of Canada, Australia, and New Zealand, the US government initially voted against UNDRIP when it was adopted in 2007, but endorsed the Declaration in 2010.

A major component of the federal policy on self-determination is the tribal consultation policy, a function of the government-to-government relationship described earlier. The policy requires federal government agencies considering a measure that could significantly affect indigenous peoples (e.g., drafting regulations, making budgets, crafting policy) to consult with tribal leadership throughout the planning process. Several federal departments have tribal consultation policies in place, including the Departments of Interior, Education, Treasury, and Health and Human Services. Subsidiary agencies within a department may also adopt a tribal consultation policy tailored to their narrower mission. For instance,

the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) within Health and Human Services both have tribal consultation policies that provide for agency leadership to meet regularly with their respective Tribal Advisory Committees. Because these policies are based on the government-to-government relationship, committee members are required to be officers of their tribal governments (National Institutes of Health).

Being a major undertaking with potential to affect the nation's indigenous peoples, the PMI has been a topic of consultation with the NIH Tribal Advisory Committee. This committee has 17 members, 12 members corresponding to the geographic regions served by the Indian Health Service and 5 at-large members. At various meetings since the presidential announcement of the PMI, NIH officials have briefed committee members on the history and features of the program, updated them on developments, responded to their questions, and consulted them on the impact of PMI on their communities (NIH Tribal Health Research Office).

Consultation through the NIH Tribal Advisory Committee is an example of external participation in the empowerment framework, a form of engagement that enables indigenous peoples "to participate fully … in the political, economic, social and cultural life of the [s]tate" (UNDRIP 2007). Furthermore, because committee members are officers of their respective governments, they are also in a unique position to facilitate internal participation when they return to their communities. In this position, committee members are able to mediate their communities' concerns about the program such as the collection, storage, and use of tissue in the PMI central biobank. For example, the *All of Us* Tribal Collaboration Working Group (TWCG 2018) observes that,

> [i]n some tribal cultures, everything that comes from the body, including blood and hair, is sacred, so donation of a biospecimen is a significant act, as it may feel like the researcher is taking a piece of the individual's spirit and soul. Due to these cultural beliefs, [indigenous] individuals will be especially interested in knowing how their biospecimens will be used, where they will be stored, and how they will be disposed of upon the donor's death.

Addressing such concerns that implicate cultural, spiritual, and ethical issues requires intentional and thoughtful deliberation. The empowerment framework (i.e., internal participation through tribal government; external participation through the NIH Tribal Advisory Committee) creates a legal channel for indigenous peoples – who make up only 1.7% of the US population (TCWG 2018) – to engage in as complex a state undertaking as the PMI as collectives, not just individual citizens.

This engagement "as collectives" fosters what Arnason describes as democratic legitimacy, because the quality of deliberation made possible through the empowerment framework would not be possible were US in-

digenous peoples to approach participation in the PMI as individuals. This collective form of deliberation supports Arnason's contention that the individualized forms of participation presupposed in molecularized biopower do not adequately define the range of biopolitics in modern democracies.

5. Conclusions

This essay responds to the work of Paul Rabinow, Nikolas Rose, and their colleagues on "molecularized biopolitics." In particular, it addresses their claim that "subjectification" – the increasingly central role of the individual citizen in animating a biopolitics from below – is part of a radical transformation of biopower. This essay argues, in contrast, that developments in the rights of indigenous peoples reflect the continuing salience of collective biopolitics, from perspectives of both the state (i.e., policies of self-determination) and indigenous governance structures (i.e., the "empowerment" framework).

The essay also raises crosscutting issues with other STS scholarship. For example, the empowerment framework, featuring internal and external aspects to enhance the democratic legitimacy of collective decision-making, has implications for "technical democracy" (Callon et al. 2009; Lamard and Lequin 2017). Both notions are concerned with ensuring that citizens potentially affected by major technical endeavors (in this case, biobanking to support genetic research) have effective channels to participate in deliberation.

Finally, the essay demonstrates the utility of multidisciplinary work for analyzing the sociopolitical impacts of complex technical undertakings. In the PMI case study, bringing to bear the concept of indigenous self-determination on biobanking allows the application of analytical tools from international law to illuminate issues surrounding democratic legitimacy for major state-sponsored technical projects. In a similar vein, the observations of Rabinow, Rose, and their colleagues on receding state power as well as the rising prominence of individual activism in contemporary biopolitics help identify and frame issues needing thoughtful engagement from the field of international law. It is hoped that this essay will be but one among a growing number of multidisciplinary explorations of strategies to harness and manage the promises and risks of advanced technology for all segments of contemporary society.

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[1] The distinction made in this essay between "internal" and "external" participation is based on the distinction made between "internal" and "external" self-determination (Cowan 2013).

T. Seitz
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Tim Seitz

Design Thinking und der neue Geist des Kapitalismus. Soziologische Betrachtungen einer Innovationskultur [Design Thinking and the new spirit of capitalism. Sociological consideration on an innovation culture], Bielefeld, Transcript, 2017, pp. 142

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Design thinking is one of the most renowned aspects of the current expansive trend of design, a shift from the design of mere artefacts to the design of product systems, to the design of services and practices, to the idea that innovation process as a whole can and should be design-driven. The specificity of design thinking is to recognize (and exploit) the tacit capabilities of design possessed by human beings, in particular by the users of possible innovations. It implements a kit of design tools to enable innovators to make decisions based on "what future customers really want" – according to the movement's rhetoric – instead of relying purely on historical data or making risky bets based on the designer's instinct. Design thinking is originally based on a deep interest in developing an understanding of the people for whom products or services are to be designed. It aims at helping innovators both in the task of observing and developing empathy with the target user, and in the process of questioning the problem, the assumptions, and the implications it involves. Within such framework, the professional designer is the one who, thanks to the mastery of the designer's toolkit, is considered able to identify, organize and make productive the vision skills of those who will actually use the new product or the new service.

More tangibly, design thinking is a method to foster creativity in the process of industrial innovation involving envisaged potential users in the process. Although the designerly way of thinking has been discussed by a number of scholars in the second half of the last century (Bruce Archer, Nigel Cross), the name "design thinking" is now linked with the method developed by the IDEO design company and theorized by Tim Brown. This is an iterative process, in which designers seek to understand better the user of an envisaged innovation and to redefine problems. Ideas are stressed in brainstorming sessions and the adoption of a hands-on approach in sketching, prototyping and testing. The method aims at identifying alternative strategies and solutions that might not be instantly apparent with the initial level of understanding of the problem. It is not only used by IDEO offices and other design agencies, but also taught in some schools and high schools, and translated into toolkits that can be bought.

This particular feature of design thinking, which is both a method for designing in the contemporary complex world and the symbolic mark of an organization and a community of experts, makes the case particularly

interesting to be inquired into through the tools of Science and Technology Studies (STS). With this in mind, Tim Seitz undertook an ethnographic research on the world of design thinking seen through the Berlin viewpoint represented by a school in Potsdam and a design agency in the German capital. Attending the agency for two months (actually a rather short time for an ethnographic work), the author has not only been able to observe the life of the organization and collect dominant discourses, but above all he could observe a number of workshops for the implementation of design thinking by attending them. His goal was to study design thinking as a practice, namely, as a set of interconnected actions performed by a community of people who recognize themselves in that practice and share ideas on how it should be performed optimally. In his view, considering design thinking as a practice allows us to avoid being trapped in the network of discourses about it.

The ambition of the book he published after the research, *Design Thinking und der neue Geist des Kapitalismus* ("Design thinking and the new spirit of capitalism"), is to "follow the design thinkers" (p. 15, English in the original, thus winking at the famous motto by Bruno Latour), treat design thinking as a practice (p. 18), and take the materiality of design thinking processes seriously (p. 57). The expectation that it creates is, therefore, to interpret design thinking through practice theory and actor-network theory, and consequently to emphasize the collective aspects (translations, assemblages, inertias) underlying the choices of actors and the idealizations of official rhetoric. Consistently, Seitz claims to base his research on the theory of practice that "directs its attention to aspects that previously could hardly be perceived by culture theories that overlooked practices: the temporality, corporeality and materiality of social practices" (p. 18).

Accordingly, chapter 1 is devoted to the temporality and chapter 2 to the materiality of design-thinking workshops. The temporality is surprisingly characterized by a strong subjection of the envisaged workshop actions to a pre-established pace that is functional to the quick and foreseeable unfolding of the workshop rather than to a full exploitation of the creative resources deployed by participants. In this way, the theoretical model of the process ends up prevailing over the situated practice and binding it to needs that seem to be extrinsic to the expected outcomes. Materiality acts through the objects envisaged by the design-thinking method, which in Seitz's analysis end up incorporating and thus stabilizing the lively individuality of participants. In his book *Change by Design*, Tim Brown wrote: "The mission of design thinking is to translate observations into insights and insights into products and services" (2009, 49). Tim Seitz sees in Callon's sociology of translation a conceptual tool to deconstruct those translations into what they really are. Although the ambition of design thinking is to come closer to the real needs of users, the materiality of the method that it uses separates the results from real people and relates them to the

personas arising from the workshops' job: "The persona should refer to the interviewees *out there* in the real world. [However,] from now on it will be designed for the persona and not for the interviewees. It no longer needs to be thought of as the diffuse and unpredictable amount of different people [out there]" (p. 68).

Yet, the most interesting part of the book is the third chapter, bearing the same title of the book (pp. 102-122). Here the author renounces to the use of concepts that are common in STS, and turns to the sociological theory of Boltanski and Chiapello (*The New Spirit of Capitalism,* 2005) to argue that design thinking is a typical form of criticism of capitalism "becoming endogenous" (*Endogenisierung*). According to the French sociologists, the "new spirit" of capitalism consists precisely in internalizing the classic critiques of capitalism (for example that of promoting useless, wasteful and inauthentic consumerism) by using them as sources for more acceptable – even if capitalistic in nature – forms of production that impose themselves for their apparent "diversity" compared to traditional capitalism. Design thinking appears to embody such kind of strategy. Seitz highlights two ways in which it does so: through a "promise of authenticity", and through a promise of work emancipation. Here the distinction between discourse and practice of design thinking, discussed in the previous chapters, emerges as particularly useful.

Consider first the promise of authenticity. While design-thinking discourses share positions very close to the critical theory ("The torrent of cheap goods that began to flow from their factories and workshops has fed into a culture of excess consumption and prodigious waste" states Tim Brown, 2009: 2), in design-thinking practice those discussions are resolved into the design of more "authentic" products, which respond to the "real" needs of users. "Design thinking is thus the result of criticism becoming endogenous, which makes the addressing of *true* needs its task, but also offers the prospect of gaining a competitive advantage over conventional products. […] Products and services are created whose *diversity* is considered a selling point" (p. 109).

Regarding the promise of work emancipation, a similar contradiction occurs between discourses that present design thinking as an instrument for the liberation of individual creativity and emancipation from the constraints of hierarchical work, and a practice structured by timing that is functional to the efficiency of the process rather than to the expression of participants' creativity, as described in chapter 2. "Instead of the demand for limitless release of creativity, design thinking seems more likely to have established a domestication of creativity within creativity reserves" (p. 114).

To sum up, the interpretation proposed by Boltanski and Chiapello of the new spirit of capitalism makes it possible to find a convincing explanation of the apparent divergence between design-thinking discourse and the operative modalities in which it is expressed, in the form of both applied methods and goals pursued. The critical discourse has become little more

than a particularly effective tool in the competition for gaining markets.

However, although Seitz's thesis is convincing, a sense of incompleteness lingers at the end of the story. A sense of flaw that will particularly affect STS scholars. Many of the ingredients of this story are familiar to them: ethnography, the emphasis on the materiality of non-humans, the use of practice theory, the sociology of translation. However, as you enter the text, the feeling grows that a conceptual toolkit has been borrowed from the STS without having read the user manual. Flaws start cropping up when concepts should be aptly used to give accuracy to the interpretation of field data. It then becomes clear that the author is acquainted with practice theory exclusively in Robert Schmidt's account (*Soziologie der Praktiken,* 2012). The contributions of Schatzki, Shove, Turner, Warde are overlooked. The whole debate about the agency of objects is missing, although it would markedly enrich the book's understanding of materiality in design-thinking activities. As a matter of fact, Latour is often referenced, but the lack of a general understanding of the actor-network theory produces a series of blatant misunderstandings of his thinking, e.g. regarding the concept of script or the relationship between researcher and social actors. Taking into account *Reassembling the Social* would have helped avoiding part of those misunderstandings. Finally, the sociology of translation is summed up in isolation from the discussion that derived from its elaboration.

Some books produce dis-pleasure. I mean that you do not just dislike them, e.g. because they are obscure, incomplete or badly argued. They appear to be lost opportunities. They miss the opportunity (and the urgency) to fill an empty space in shared knowledge that they have been able to recognize. When a book fails to grasp this opportunity, when it does not keep a promise that seemed exciting, it is not just disappointing, it actively produces a destruction of potential pleasure, it severs an anticipated fulfillment. In fact, it produces dis-pleasure. It is with this feeling that I finished reading *Design Thinking und der neue Geist des Kapitalismus.*

* * *

Sarah Pink, Kerstin Leder Mackley, Roxana Morosanu, Val Mitchell and Tracy Bhamra
Making Homes. Ethnography and Design, London, Bloomsbury, 2017, pp. 176

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Any academic essay is a node in a network of knowledges and researches that we can retrace mainly, but not only, through citations. *Making home. Ethnography and Design* is a portal. Not only a node in a network of other knowledges and researches, but a platform that works as an entry point and a synthesizer for a research project, its results and its further branchings.

The research to which this book provides access and insight is *LEEDR* (*Low Effort Energy Demand Reduction*), an interdisciplinary project drawing together anthropologists, engineers and designers in order to achieve a deeper understanding of how energy and media consumption fit into everyday practices and habits in home life.

The LEEDR research was based at Loughborough University and ran between 2010 and 2014, with the collaboration of the Design Research Institute of the RMIT University. RMIT University is, indeed, the seat of Sarah Pink, first author of the book, who has provided the general epistemological, theoretical and methodological framework for the research in terms of "sensory ethnography" (Pink 2009), as well as connections to other related research projects. The other authors of the book are, tellingly, two social scientists, Kerstin Leder Mackley (cultural and media studies) and Roxana Moroşanu (anthropology), and two designers, Val Mitchell (user experience design) and Tracy Bhamra (sustainable design).

The first node to which *Making Homes* provides access and insight is the internet site *Everyday and Digital Living* (http://energyanddigitalliving.com), which complements the book – there, all the videos to which the book refers are stored and the design outcomes of the research – still in concept form – are introduced with a much greater detail. However, the Internet site is not just a repository of materials referenced in the book. It has its own autonomy and provides an overview to the research, by displaying in a summarized way the theoretical-methodological framework, some stories of everyday living in homes, design inspirations and design concepts resulting from the research.

The book, instead, provides a deeper reflection on the theoretical-methodological framework of the research, illustrating it through various empirical example from the LEEDR research fieldworks, as well as from other researches. It addresses the issue of how to best research, understand and design for change in and through the home.

Thus, the book and the Internet site are two complementary ways of introducing a research, which however, can be actually grasped in all its details and developments only by following the various links to the various publications, reports and design projects.

The fact that it is "just" a theoretical-methodolgical introduction to a research project, written, moreover, "in an accessible form for interdisciplinary researchers" (p. 6), thus, without articulated theoretical-epistemological discussions – a fact highlighted by the absence of notes –, does not mean, however, that the book is not worth reading, especially if you are

interested in issues related to everyday life, design, sustainability and change from a STS point of view or, more in general, from a social point of view.

Indeed, the book is ambitious and challenges STS in various ways. In between the lines, we can read an introduction to a whole research program, not just to a research project. It, delving on, but also going beyond, the material culture researches on homes, like those carried out by Daniel Miller, lays the foundation for a different approach to issues tackled by the various strands of the theory of social practices, as well by Actor-Network Theory and by other STS related approaches. In doing so it provides a clear framework for the emerging and variegated field of "design anthropology", here however addressed only as "design ethnography".

Besides the first introductory chapter, the book is divided into three parts: an introduction to the framework of the research project; an introduction to the research methods used to engage with homes and to collect information and data; a conclusive part, where also the design outputs of the projects are touched upon.

Whereas the second and third part take only one chapter each, the first part is much more articulated and unfolds across three chapter (Chs. 2-4). Each chapter introduces "a conceptual theme concerning researching and designing for homes and everyday life in homes: temporalities, environments, and activity and movement" (p. 19).

As underlined in the introductory chapter, "[e]ach theme", emerged also through various researches that have predated LEEDR, "represents a set of engagements between research and design in and about homes and theoretical understandings" (p. 19).

In "Temporalities" (Ch. 2), various temporalities related to homes and everyday life, but also to the disciplinary approaches of ethnography and design, are interrogated, looking at the way they coalesce in the practice of design ethnography of homes.

On the on hand, the chapter questions the "ethnographic present", i.e. the crystallization of people, culture and societies into a moment set in a specific present. Such "ethnographic present", through which most of ethnographic research has characterized itself, is clearly at odds with design, which is future oriented, as well as with the way people live their homes, future oriented too. On the other, the chapter provides various example of the intertwining of temporalities in homes' everyday life. These, for the most part, are future oriented: the home is perceived as an incomplete or not yet completed project, activities are run through various forms of timings and various forms of planning.

One of the results of this attention to temporalities is the fact that homes needs to be considered always as processes. This feature also characterizes "environments" (Ch. 3). In the book, they are considered as continuously constituted through the entanglements of diverse processes, among which human activities, part and constitutive of environments. Environ-

ments are considered as material, digital, sensory and affective and analyzed mainly through the kind of atmosphere they enjoy, thus through the way they are perceived and felt. Taking into account various temporalities and environments as atmospheres are interesting and productive moves. In so far as they are innovative, they are not groundbreaking and pursue, as acknowledged, various threads of contemporary social, aesthetic and design research. On the contrary, the choice of focusing on "Activity and movement" (Ch. 4) – and, especially movements – is introduced as break away from contemporary social research, focused on the concurring notions of behaviors and practices.

For the book, movements allow focusing on what people do, without providing too strict categorizations into more or less coherent, discrete and *a priori* established practices. Moreover, movements, which unfolds contingently and improvisationally in relation to the affordance provided by the environment and in relation to what takes place next, allow focusing on the tension between present and future. Therefore, the research has followed movements in homes, mapping them in various ways, and looking at how various activities are articulated through various movements.

Through the examples provided in the book, we can see that the framework outlined in *Making Homes* allows attending details and features of homes, which sound actually relevant and not previously considered, as well to thematize homes as felt process, which seems productive.

In this way, the research seems able to provide grounds to understand how homes can or cannot be sites of sustainable practices, as well as of human well-being and happiness. Through such insights, it is also able to provide indications for design interventions that would allow to foster sustainability and well-being.

In any case, as I have said, this is just an introduction – though a promising introduction. Therefore, in order to actually understand, if the approach used in LEEDR is as productive and innovative as the book paints it, we will need to consider the research thoroughly, by looking at articles as well as at the details of the design outcomes.

As for now, I cannot but notice few things which can provide a sort of guideline for possible weaknesses to prove, while considering the research thoroughly.

Firstly, in the conclusive part, where designing and its outcomes are actually addressed, the book touches upon the fact that the LEEDR designers had the need to propose and explore a further methodology to gather data: PORTS (People, Objects and Resources through Time and Space). PORTS, thus, seems a sort of redoubling of a work already done through the design ethnography. Therefore, it seems that there is a sort of division of labour between a sensory ethnography – which however should, then, not be called "design ethnography" anymore –, which provides only "inspirations" to designers (as acknowledged in the Internet site) and an-

other kind of more behavioral observation which provides the actual information designers can work with. If it is so, the results of the LEEDR project in terms of dialogue between social sciences and design would be very weak, not adding much to existing attempt of dialogue between social sciences and design. Moreover, if the proper ethnographic part is only tasked with providing inspirations, there is no need to carry out sensory ethnographies anymore, since inspirations related to improvisation, how the house is felt and movements (see http://energyanddigitalliving.com/design-inspirations/) have been already provided. What needed for further projects would then only be observations using the PORTS methodology carried out by the designers alone.

Secondly, it does not seem to me that the outcomes of the observations are more future oriented than usual research result. Considering future, expectations, hope, what to do next, etc. in order to produce analyses of activities and movements does not make these analyses more future oriented: the resulting analysis or descriptions cannot but freeze a certain moment – just look at the results of PORTS or other methodologies used in order to collects data like Tactile Time collage (p. 120). Despite the interesting reflections emerged within design anthropology about the future orientation of design and the past-present orientation of sciences – I would say sciences more in general, not just social sciences –, in my opinion it is not an issue of what is considered in the observations, but of what Latour (2013) would call "modes of existence" of sciences and of organizations. Recovering the classic STS notion of "*script*", Latour (2013) shows how organizations are future oriented, because they are based on "*scripts*", inscribed in verbal agreements or in technologies, that tell what to do next. Sciences instead pertain to another mode of existence, where inscriptions beget other inscriptions, which only allow to recover, backwards, the first source of these inscriptions.

Thirdly, among these future oriented elements there are, then, "*scripts*", as classically elaborated by Akrich and Latour and recently recovered in a proper future oriented framework (Latour 2013). Thus, *description*, as proposed by Akrich and Latour, can provide the adequate categories to *de-scribe* and analyze movements, as proposed in the book, taking into account their future orientation. This would maybe provide directly usable insight for designers, not in form of general "inspirations", but almost in forms of specific guidelines. This is actually what proposed also in the book through an analysis of the affordances (p. 78) – notion strictly related to the one of *script*. However, such cited analysis of the affordances has not been carried out within the LEEDR research project, but in another project, by a completely different team, which does not seem to have anything to do with LEEDR (Paay et al. 2015).

Making Homes sets a promising perspective for the dialogue between social sciences and design – and because of that it is worth reading, especially for those interested in the issue. However, such promises are clearly

future oriented, since at the moment the book provides inspiring ideas more than empirical evidences.

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Damon Krukowski

The New Analog. Listening and Reconnecting in a Digital World, Cambridge MA, MIT Press, 2017, pp. 240

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The New Analog: Listening and Reconnecting in a Digital World is a book by the musician, journalist and poet Damon Krukowski, focused on the implications of the shift from analog to digital technologies in music production and circulation. Although this is not a book rooted in science & technology studies, but an essay for a wider and non-academic, it anyway offers several relevant points of interest for a STS audience interested in music and sound technologies. This is especially true for those of us involved in the field of *sound studies*, which is the way STS has approached, in the last fifteen years, the role of technology in relation to music, sound and the acoustic environment – a field distinctively leaded, among others, by prominent STS scholars such as Trevor Pinch and Karin Bijsterveld (Pinch and Bijsterveld 2003; 2012).

Before entering more deeply into the issues *The New Analog* raises for STS-oriented sound studies scholars, let me quickly present what the book is about and its major thesis. First of all, *The New Analog*'s author, Damon Krukowski, is a musician (drummer for the late '80s alternative rock band Galaxy 500) and journalist (for major music magazines like "The Wire"

and "Pinchfork"), also having a scholarly affiliation with the Berkman Klein for Internet and Society at the Harvard University (where Krukowski has also been student when younger). The book presents an outline of music digitalization's process from analog devices to digital technologies, expanding its insights across the whole history of recorded music (for instance, making parallels between the issues raised by the technology of player piano at the end of the nineteen century, with the case of the file sharing platform Napster one century later) and mixing this story with author's own experiences as both listener of LP and Spotify and musician approaching analog recording studios at the beginning of the '80s. Hence, the seven book's chapters deal with many relevant issues related with the shift from analog to digital technologies, including the role of stereophonic hearing and microphones in creating the listening space, the change in sonic media and supports, the relation between music volume and perception, the means to exchange music and the role of noise as sonic as well social element. The main thesis of the work is that the adoption of digital technologies, in production, circulation and consumption, mainly produced a "demolition" of the role of "noise", intended not just as the noise characterising analogue recordings, but more generally the noise as the presence of a real life in our mediated environment, an important part of our situated experience of time and space. Above all, as the author points out in the conclusion, digitization results in the filtering of all information not considered relevant by entities like Spotify or Facebook, thus contributing to lose those pieces of humanity and the sense of situatedness that were represented, in the analog age, by a stratified and unavoidable noise.

As the reader can see from this quick picture, the points of interest for scholars involved in sound studies and music technologies are manifold, first of all because the author delivers what, as STS scholars, we would address as the consequences of a change in music infrastructuring process. However, at the same time, as STS scholars we could also be deceived, as the author does not intercept any of the major literature in sound studies and especially among STS works dealing with some of the major topics of the book, notably the role of noise, the topic of Karin Bijsterveld's 2008 book *Mechanical Sound*. By the way, the intellectual references enriching Krukowski's work fall short also to grasp many of the most recent contributions in the social and cultural study of sound, excluding notably the first book by Jonathan Sterne on the cultural history of sound reproduction (Sterne 2003); hence, most of the intellectual references of the book remain anchored to classical – but at the same often addressed – works, including for example the writings by John Cage, Glenn Gould and Walter Benjamin. While it would not be fair to complain about the lack of STS-oriented references in this kind of book (as said mostly devoted to a non-academic audience), what is anyway interesting to ask is how much Krukowski's book could be interpreted as a lack of penetration of STS-inspired litera-

ture in sound studies among essays, journalist accounts and other dissertations targeting a general audience of listeners, musicians and music enthusiasts.

That said, the book not only is very enjoyable to read for scholars in music technologies, but it also offers several examples that resonate very loudly with STS concepts and sensibilities. As anticipated, many of the issues raised by the author are good instances of what occurred, at different level, during the deep and quite fast modification in music infrastructures, in doing so bringing light to some rarely addressed consequences of digitization of music circulation. A very nice example is the account, partially based on author's own experience, about the changes occurred in music shops (by the way, an issue very poorly addressed both in sound studies and popular music studies, maybe with the notable exception of Pinch's study on the Moog synthesizer; Pinch and Trocco, 2002). Indeed, in chapter 4, the author describes some of the infrastructural consequences of the shift from LPs to CDs, a change which included not only issues in sound quality, but also a transformation in shops' political economy: the reconfigured materiality of the smaller and less prone to be damaged CD was instrumental in the emergence of huge mega-shops, like those established by the chain Tower Records, which opened a big flagship store in Boston in 1989. However, changes triggered in music infrastructures by the CD were not affecting just issues in political economy and distribution systems, but also smaller and more situated issues, like for passage from LP to CD. The question was not only that stealing music records became easier, due to the smaller dimension of a CD over a LP, but also because the new digital format allowed for different surveillance and anti-thief systems, which evolved from the human bag-checker, located at the entrance of the shop, to non-human metal detectors, able to reveal the presence of metal strips attached as anti-thief systems to the CD, enclosed in plastic boxes. As consequence, "employees no longer had to watch while you browsed to make sure you weren't pocketing good. And there was no reason for them to engage you in conversation" (p. 96).

Insights like this discussed by Krukowski (many other regard, for example, the change in how musicians experienced the relationship with technology in recording studio) can enrich the understanding of the infrastructural shift in music, especially when translated through STS notions (i.e. in relation to "delegation" processes to non-human artefacts of previously human-based activities; see Akrich & Latour, 1992). In sum, despite not being a book based on STS concepts, *The New Analog* represents anyway an inspiring reading for those scholars that aim to explore further the implication of digitization and over the music world.

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Elisa Giomi and Sveva Magaraggia

Relazioni brutali. Genere e violenza nella cultura mediale [Brutal relationships. Gender and violence in media culture], Bologna, Il Mulino, 2017, pp. 240

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Identity and differences are seen as the effects of relationships, technoscience – thus media – as the expression of male instances. This work is to be read as a thoughtful investigation to which Science and Technology Studies feminist scholars have much contributed. Giomi and Magaraggia have focused their attention on media products starting from the classical assumption that, in order to narrate the social world, media draw conceptual and linguistic tools from the same social world, and, by narrating it, they also build it in a certain measure. Within this framework, the authors relate gender violence, gender order, and media representations one to the other, in order to support the idea that violence representations contribute to the process of gender status, and that gender representations supply the construction of violence. They show how this double process is achieved between different media objects gathered around two discursive knots, i.e. violence against women and – on the other hand – violence performed by

women. The acknowledgement of these two elements gives back the idea of violence as of a complex, relational, and collective phenomenon – against the simplistic approach to media representations. The authors thus detect a red thread inside media discourse by following the perspective by which media take part in the articulation of phenomena and contribute together to our perception of reality. Thus, they confirm the existence of a representation policy that informs *media production practices*. They get to this point, by using a framework related to the social constitution of the feminine. More precisely, the authors look at the violence developed within the family and the couple transversally to social classes and geographic areas through the magnifying glass of a tradition of studies that interprets them, not as a residual phenomenon, but as a *function* suited to keep the social arrangement as it is.

Such perspective includes in some points issues that seem to anticipate a certain degree of an interdisciplinary perspectives. For instance, they mention researches that take into account the consequences on the fetus of the stress of women that undergo violence during pregnancy. Reference is also made to the need man has of a mirror-woman able to give back an increased image of himself; they quote Virginia Woolf as well as Jessica Benjamin, psychoanalyst, when she writes of male narcissism bound to female sight (p. 34 and following). However, what they actually focus on, in the volume, are the aspects of violence linked to the topic of gender – meant as the organized sphere of practices and relationships that defines the forms of manliness and womanliness. Intimate violence is thus interpreted as a way to keep power, or as the consequence of feeling vulnerable, where elements like body, sexuality, various aspects of dominion, and their social representations are fundamental.

Public space versus domestic dimension as the cradle of gender violence, romanticization of intimate violence, reduction of the perpetrator to victim of the same violence (seen as a disease that afflicts the same relationship of the couple), normalization of violence. These are findings that confirm what shown by literature, also the international one, and that in Italy have been recently denounced by the report of the parliamentary commission on femicide (Senato della Repubblica 2018).

The sources taken into consideration for the research have been the Italian press, infotainment shows, television series, as well as movies and pop music, by following the narrations of violence and about women in order to draw data to be analyzed.

Among the most interesting contributions the book provides the debate with, is the consideration of those controversial aspects that enliven the public sphere related to the need to shed light also upon abuses suffered by men (Bandelli 2017). Part of such reflections on abuses suffered by men shows how the violence of women on men is often interpreted in such a way to mitigate its extent and therefore denying that the woman criminal has acted autonomously, intentionally, and consciously – be it in a law case,

be it by public opinion where women are always justified as being affected by mental diseases. The book thus shows how media create a specific interpretative pattern: women's violent acting is represented in strong contradiction with the mainstream idea of femininity and they link it to tendencies like being mean, sexually deviated, or mad. What ensues is a diminished female capacity of action.

When women are instead narrated as being intentionally violent, the exceptionality frame is activated, together with a contrastive comparison with *true women*, who are violent because they do not know how, or they are not able to, avoid it. The number of violent heroines has grown in fiction with features previously typically associated to men (physical strength, courage, the use of weapons), they are represented as pathological and, through a fetishization of their body, are led back within the dichotomy passive-female/active-male. When, instead, the gender binary distinction is questioned, it is questioned through a masculinization of the woman's body that inflicts violence. Thus, a further contribution to the articulation of the female as the object of violence emerges. Such further contribution favors therefore the reproduction of structures and hierarchies.

Giomi and Magaraggia try here to make the role of media visible in the perpetuation of an asymmetry. Anyhow, in order to understand such asymmetry better, it would be useful to think not only to the contents. The social work of the media is not reducible to the mere spreading of meanings – something that complies also with perspective of the authors. It is partly a process close of what Latour means when he speaks of mediation by which the same elements of mediation are transformed. This happens also thanks to the same development through a network of relationships, an aspect that is not highlighted by Giomi's and Magaraggia's approach. Moreover, if it is true – as conventional studies have taught us – that media contribute to the formation of knowledge, believes, opinions, values, rules, behavioral models, it is anyhow difficult to imagine how their contents alone can directly structure the reproduction of a configuration of the world. It is difficult to think of them as docile tools pre-set for the attainment of specific interests to give an answer to the self-preserving needs of society. The output cannot be foretold by the input in a mediation process (Latour 2005, 39). What is thus interesting to keep in mind are the various elements and moments in which that mediation process is articulated.

We should think of the competing mechanism between various sources, of the information overload for the public, and of the need to offer news that should cause alarm, for example (Castells 2009). There are also elements like newsworthiness criteria that contribute to the gap between reality and what media covers, as much as the spectacularizing processes that answer various needs that involve the mere description of events and situations. Some of the aspects that come from the study of the contents of the media can thus be at least partly an unforeseen effect by the socio-technical acting that produces them. To know them for what they are could

show greater adequacy of the actions by the institutions to reach the objective to contrast violence. Moreover, the study could be further developed by including the sphere of the public that cannot be so neatly separated by the one of production/circulation (Couldry 2012) – since research related to the de-codification of violence on women is not that consistent and since the studies on sexual objectification in the media show that it is a process which could trigger violent phenomena, as highlighted by the authors. Imageries themselves could offer opportunities for a breach or at least for contrast. The point is that there are no autonomous media texts (Couldry 2000) although they are often studied as separate, as abstracted from all. The observation of the social stereotypes and representations crystalized by the media implies the risk of a textual determinism already underlined by Cultural Studies.

Finally, if on one hand the reading of the book confirms how media contents are of great importance to understand some aspects of our culture, on the other it elicits the issue of the adequacy for media research of the assumption of an analytical separation between the contents, their fates, and the various levels of instances that articulate their agency. The overcoming of such assumption is also clearly related to the issue of how to join competences and resources to succeed in describing the relationship between media and gender violence through a perspective related to various mediation processes (Boczkowski and Siles 2014).

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