

Market-driven production of biospecimens and the role of NHS hospital-led biobanks

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Abstract

Biobanks are vital for biospecimen production in research, despite the regulatory, recruitment and commercial difficulties they face. We conducted interviews with clinicians, researchers, volunteers who recruit biobank participants, regulators and NHS managers about the integration of a biobank into an NHS hospital. We show that medical waste collected for biomedical research acquires its socio-ethical and economic value from the level of integration (both technologically and organisationally) of the biobank into the NHS hospital. There is extensive investment in a range of intellectual and commercial relationships and labour among stakeholders involved in the production of biospecimens. It is not only the boundaries of research, clinical care and commercialisation of biospecimens that blur but also those of volunteerism and citizenship. Hospital-led biobanks provide an opportunity to study the intertwining of biomedical innovation and healthcare.

Keywords: biobank, volunteers, NHS hospital, market, bioresource

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Introduction

Biobanks are seen as a major asset to contemporary biomedical research, providing faster and more effective development of new therapies (Hewitt 2011). Despite this enthusiasm, biobanks have proven to be something of a disappointment (Ursin 2010; Rose and Rose 2013). This is because they have to balance social and research expectations with the realities of collecting high quality specimens for research, meeting regulatory governance frameworks and securing adequate financing (Rose 2006; Stephens and Dimond 2015b). They need to invest in infrastructure and expertise while seeking substantial returns (Turner *et al.* 2013).

Biobanks are sites of tensions between ethical, scientific and commercial values as they struggle to develop a sustainable business model while at the same time threatening “*to undermine both the notion of altruistic donation and the notion that biobanks serve the scientific and public good*” (Turner 2013 *et al.*: 72). The outcome of this struggle often determines how ethical issues around biobanking, such as informed consent and trust, are addressed (Cadigan *et al.* 2013). However, as Cañada *et al.* (2015) note the biobanking literature tends to concentrate on the debate around regulation, sustainability and funding, or on different actors, such as biobanks, funders, and industry, but less on their *relationship*.

In this paper, we analyse the establishment of a biobank by an NHS hospital in the UK ('TrustBank'). A biobank in an NHS hospital is unusual in Britain; most biobanks have been established by universities, commercial organisations, and, in the case of UK Biobank, a consortium of the state and medical research charities (Petersen 2005). The attractiveness for researchers of siting a biobank in an NHS hospital is that it gives them access to a large potential pool of recruits, while for the hospital the biobank is part of a wider development of research as a potential income stream.

Along with a literature around bioeconomy (Mitchell and Waldby 2010; Birch and Tyfield 2013), we contribute to empirical explorations of biobanking by shifting the discussion

from ethical aspects of participation to the economic logics of value and labour that are driving the development of biobanks. We approach biobanking from a relational understanding of the creation of value out of waste tissues. As we demonstrate in this paper, any value for commercial exploitation is not intrinsic in these samples nor is it guaranteed from the outset. It is rather through various socio-technical arrangements as well as the continuous intellectual, affective and technological work of (human and non-human) actors that value out of these tissues will be produced.

We argue that it is the extent to which TrustBank performs *local* standardised normative relationships between people, systems and tissues as well as the scientific, ethical, and economic *values* that it codifies that will ultimately determine its commercialisation project (Hurlbut 2015). We consider a biobank sustainable when it has become able to eliminate uncertainties in the present so as to secure future uses and benefits (Hurlbut 2015). We also discuss how the new arrangements potentially affect the relationship between the NHS and its citizen-patients. In the following section we consider three broad contextual issues relevant to the establishment of TrustBank: the political contract between the NHS and the citizen, donation of tissue by NHS patients for medical research and value creation in biocapitalism.

Biobanking

A biobank is defined as a “rich collection of data plus biospecimens, specifically developed as resources for research” (UK Biobank Ethics and Governance Council 2007). The ethics of biobanking, particularly the debate about individual autonomy versus the ‘common good’ have been considered extensively (Lipworth *et al.* 2011). We will not rehearse those debates further, but instead show how they played out in the local organisational context of an NHS hospital. As Lipworth *et al.* (2011:799) point out, “*donation always occurs in a social context*”, in this case, an NHS hospital.

The NHS and the citizen

The creation of the NHS is often viewed as a triumph of socialist policy: egalitarian, universal, and funded out of taxation. However, the NHS is also technocratic, managed by medical, bureaucratic and political elites (Klein 2006). Access to NHS services free at the point of use continues to be seen by UK citizens as a fundamental right. The political contract is one where the state provides the service universally, and all citizens are entitled to use it. Some commentators have questioned whether a wholesale change to this settlement is being attempted. They point to the Private Finance Initiative to fund hospital building (Gaffney *et al.* 2000), and the policy of 'Any Qualified Provider' being able to tender for NHS services (Pollock and Price 2013). Despite these well-founded concerns, the vast majority of NHS care remains provided by the NHS, with no realistic prospect of major policy change (King's Fund 2011).

Titmuss remains one of the key thinkers on how and why the NHS should be provided on this model (Reisman 2004). Based on a study of blood donation, Titmuss (1970) argues in *The Gift Relationship* that a health service like the NHS, founded on the principle of altruism will necessarily be a more moral, and more effective and efficient service than a commercial, insurance-based health service. As Harrington (2009) argues, the NHS is a 'decommodification' of health care in the UK, and that legislation in a variety of areas (such as IVF and surrogacy) is broadly anti-market in nature, in line with Titmuss' view of the moral nature of the NHS. Tissue donation for medical research is always 'altruistic' in the UK. Concerns about this issue meant that UK Biobank has an arms-length relationship with the commercial sector, where tissue remains held by hospitals and universities, but commercial companies can use (and pay for) information derived from it.

However, almost from its inception the question of whether the NHS is 'affordable' has been raised. It has been in financial crisis (real or imagined) since 1948 (Webster 1998). Since the 1980s, NHS hospitals have been encouraged to generate additional income

streams to supplement their central state funding (Price *et al.* 2011). As well as this commercial pressure on NHS hospitals, research is also increasingly commercialised (Schafer 2004). At the same time, recruitment of patients to research studies is known to be a problem for medical research generally (Treweek *et al.* 2013). TrustBank was not inspired by any specific central government policy, notwithstanding a wider policy seeing the NHS as a source of 'national wealth' (e.g. Bioscience Innovation and Growth Team 2003). However, it is against this background of ongoing financial pressure, and a policy driver towards the development of supplementary income for NHS hospitals, that the development of TrustBank needs to be understood.

Realising value

Much of the literature on bioeconomy has focussed on how, through a process of bio-objectification, biobanks attempt to transform human tissue into high quality biospecimens for research (Stephens and Dimond 2015a). This literature speculates on the promise of this medical 'waste' as a new enterprise for capital accumulation in biotechnological market regimes (Cooper 2008; Helmreich 2008; Sunder Rajan 2012). These tissues are often considered as 'promissory assets' (Martin 2015) from which surplus value could be extracted in the future from their monetary circulation within "tissue economies" (Waldby and Mitchell 2006). Through conceptualisations including "biovalue" (Waldby 2002), "life as surplus" (Cooper 2008), "biocapital" (Helmreich 2008) and "lively capital" (Sunder Rajan 2012), these science and technology studies (STS) scholars attempt to account for the capitalisation (Waldby and Mitchell 2006) of extracted tissues. Samples are reformulated, through systems of valuation and exchange, from 'waste' to 'gifts' to 'commodities' within the bioeconomy (Waldby 2002). They approach the issue of samples' commercialisation as one of 'enclosures' where the issue at stake is whether knowledge application and intellectual property regimes facilitate privatised control and exploitation rather than "*open cooperation in knowledge production*" (Birch and Tyfield 2013: 184) and the interests of public health.

Consequently, this work attempts to shift the discussion on biobanks from the ethical and civil aspects of participation to the economic logics of value and labour that are driving their development. This illuminates whether research benefits are distributed to donors or are exploited for capital accumulation (Mitchell and Waldby 2010; Birch and Tyfield 2013). For example, Mitchell and Waldby (2010) argue that biobanks serve the purpose of commodifying participants' labour and the value of the samples:

"..biobanks enrol significant sections of national populations as economically productive participants, subjects who lend their bodies and prospective medical histories to create a research resource with significant commercial potential. Although they participate under a rubric of citizenship and public good, their participation is nevertheless formulated in profitable ways." (Mitchell and Waldby 2010: 348)

Waldby (2002), like Titmuss, is interested in the relationship of biological gifts and the imagined communities that biotechnologies make possible through new socialities and subjectivities. However, she is also aware of that Titmuss' (idealised) gift economy *"is becoming more difficult to reconcile with the recent, ever-growing capital value of the biological fragment, and the ability of biotechnology to make cells, tissues, genes and the like ever more productive"* (Waldby 2002: 308). She coined the term 'biovalue' to describe the complex temporal reconfigurations involved in the production of 'a surplus of fragmentary vitality' out of biological regenerative material, such as stem cells (Waldby 2002).

However, Birch and Tyfield (2013) argue that there is not anything unique about biovalue in modern capitalism, even if biotechnologies have permitted the intensification of commercial use of these tissues for profit. Moving beyond commodification, they offer an alternative approach which posits that these tissues do not have a 'surplus vitality' or any other intrinsic value. In fact, it is *"the curatorial practices of biobanks"* that

transform "*worthless human biological waste*" and information into valuable resources for research (Hurlbut 2015: 320).

Therefore, any value that they may hold is always relational and will be 'realised' by the exploitation of the labour of people and the use of technologies that transform 'waste' into commodities that market actors are willing to pay for because of their scarcity (Birch and Tyfield 2013). Citing autonomist Marxists (Lazzarato 2004; Morini and Fumagalli 2010), Birch and Tyfield (2013) point to the fact that what distinguishes biocapitalism today is the move beyond material production and the incorporation of intellect, emotions, and other forms of *unwaged* labour in new socio-economic relationships involved in the 'realisation' of exchange value.

Methods

Sixteen qualitative semi-structured interviews were conducted (in 2014) with the clinicians (n=4), researchers (n=4) and NHS managers who established TrustBank (n=2). Volunteers (n=4) (who recruited TrustBank participants) were interviewed, as were those involved (n=2) in the regulatory processes which approved TrustBank. Interviews covered ethical and governance issues, how they had been resolved and how the interviewees see TrustBank as part of an NHS hospital. Interviews were all conducted by the first author. They were recorded digitally, and transcribed.

Interviews were analysed using a thematic analysis approach and coded in QSR NVivo. Transcripts were read and reread to identify main themes and subthemes that were uncovered by analysing participants' perspectives and using comparison techniques. Negative cases were also identified where the view of one participant was not in agreement with the majority. The main themes and subthemes were identified through their relevance to the focus of the research; the integration of TrustBank into an NHS hospital. Ethical approval was granted by the relevant Research Ethics Committee. Written information was provided to participants prior to interview. Consent was taken in

writing. Data were anonymised at the point of analysis. All data were stored confidentially, and in line with relevant laws and guidance.

Findings

Our findings cover these issues; hospital-led biobanking, participant recruitment, integrating information technology, sustainability and bioresourcing. In purely scientific terms, TrustBank is not greatly different from other biobanks, in that it aims to collect human tissue, and related patient information, to be retained in the longer term for medical research. This biobank collects principally tissue, though its scope includes other material, such as blood. The tissue collected is 'waste' tissue, collected for clinical purposes (usually diagnosis) but surplus to those requirements. This means that *"nothing extra (apart from perhaps a few extra drops of blood being taken) is actually happening ... it's all part of the routine care"* (Participant 3). The majority of the tissue collected was tumours which had been removed surgically, or sampled (biopsy). In the light of the fact that the trend is towards larger, population-based biobanks (Polašek 2013), and international networks of biobanks (Gottweis and Petersen 2008) it is perhaps surprising that such an explicitly local biobank was established (in 2012), and, given the degree of controversy that biobanks have engendered globally (Cambon-Thomsen *et al.* 2007), it is also surprising that there was no controversy about TrustBank and its commercialisation strategy (Winickoff 2007). There are a wider set of factors influential in the establishment of this biobank within an NHS hospital, and these will be considered next.

Regulation for hospital-led biobanking

The Human Tissue Act (2004), introduced in response to the scandal over the illegal retention of human tissue at Alder Hey Children's Hospital (Redfern *et al.* 2001), emphasised the altruistic character of research, and made *"informed consent the supreme touchstone of legitimacy in dealings with the human body"* (Liddell and Hall 2005: 216). It established the Human Tissue Authority (HTA) which governs the storage

of all human tissue in the UK. The relatively strict regulatory regime now in force means that hospitals and universities have little alternative but to set up a biobank if they wish to store human tissue. Although it was not the intention of the framers of the Act to create biobanks, this was the unintended consequence.

HTA has ... actually has been a force for good. There are a lot of things enshrined in the HTA which make research better ... like making sure that everyone uses appropriate standard operating procedures for collection and storage so that you don't waste tissues (Participant 6).

Consequently, TrustBank, one of the few "*biobanks in the country who are hospital-led*" (Participant 1), had to be managed within HTA and NHS governance frameworks, including research ethics approval (granted by an NHS Research Ethics Committee which specialises in the ethical review of biobanking projects), information governance, driven by data protection legislation, and the NHS's own rules and processes (usually referred to as the 'Caldicott' principles). However, compliance with 'extensive' NHS regulation was not seen as problematic.

From our point of view, it is much easier for us to meet those [data protection] regulations, with the biobank sitting on the NHS side (Participant 12).

This is also because a biobank in the UK does not need separate research ethics approval as it is able to use its samples under the terms of its HTA licence (Chalmers *et al.* 2016).

A biobank within NHS means that compliance:

actually gets taken care of through NHS R&D and it's actually directly managed by them (Participant 13).

Interviewees did not, therefore, see TrustBank as facing any substantial regulatory problems, although for some this additional infrastructure for compliance was seen as "*probably unsustainable, too expensive, unnecessary*" (Participant 10). Nevertheless, a NHS hospital-led biobank held other advantages. Firstly, though the financial

arrangements were complex, there were wider organisational benefits to the hospital, particularly in financial and regulatory independence from central NHS control:

The hospital wanted to get 'Foundation Status' and one of the key initiatives is to embed research in the NHS (Participant 1).

Secondly, there is the benefit of high quality samples with convenient access to rich patient data:

The NHS is the natural repository of patient data, of biosamples, a lot of which are just gathered anyway...it seemed simple, the natural thing to do, to set up a biobank in the hospital (Participant 3).

For this, biological specimens need to be collected correctly, stored quickly and catalogued fully, otherwise they are of diminished (or no) value for research.

We are within Pathology which means that a proportion of my staff are trained in Pathology as well [...] So the quality of the sample we get is absolutely pristine (Participant 1).

A hospital-based biobank is, therefore, uniquely positioned to transform the hospital's *legacy* pathology tissue collections, which have the characteristics of an asset, into commodities after new knowledge labour is applied to them (Birch and Tyfield 2013). It acts as a more efficient route to the market as it minimises friction from collection to research and from production to consumption. It also aims to solve the problem of recruitment of participants, which is particularly telling as biobanks rely on recruiting large numbers.

Localising participant recruitment

Debates about trust and consent (e.g. in UK Biobank) are usually narrowly framed around conventional methods of securing consent, which may contribute to lack of trust in biobanking, and hence slow recruitment (Petersen 2005). TrustBank has a different

approach to recruitment and consent where ideas about locality were quite significant. Typically, biobanks delegate recruitment to clinicians, to overcome issues of privacy and to concentrate on processing samples (Cañada *et al.* 2015). In TrustBank, potential participants are recruited at outpatients appointments by lay volunteers.

While studies have found that laypeople are involved in biobank governance structures (Cañada *et al.* 2015), the use of lay volunteers for recruitment is unusual. It was originally introduced by TrustBank for practical reasons. Research nurses are usually dedicated to a specific project and so cannot work on a more broadly-based project like the biobank.

If you're employing nurses just to consent for tissue, you've got to employ a lot... the Trust have got no interest in this because it's not delivering healthcare. It's supporting research (Participant 10).

These volunteers were all local, retired people. Drawn as they were from the hospital's existing community of patients and carers, they were perceived by potential biobank participants as being 'people like us'. A role previously carried out by nurses (Caixeiro *et al.* 2015) is now re-delegated to these volunteers, exerting a new kind of influence on the shaping of TrustBank as a local institution, part of the hospital and the NHS. Volunteers consider themselves to be more successful than traditional methods in recruiting patients to TrustBank.

We've got a higher success rate than medical staff asking, the volunteers. ... they maybe feel that it's on a more kind of peer level... (Participant volunteer 1).

In my case on a typical week, there will be about 32-35 appointments and I would expect out of that many to get about 20 or 25 who consent, so that is pretty good (Participant volunteer 2).

Therefore, having dedicated, trained, staff, and at little cost (Lazzarrato 2004) to TrustBank is a significant advantage since "*consenting is probably one of the most*

onerous ... cost exhaustive processes" (Participant 1). Acting as intermediaries and liaising between patients, the hospital and the biobank, they ease the additional administrative burden of recruitment.

[I see] 35 to 40 in an afternoon ... it is quite hard work, because I have to talk for four hours constantly, but it is also very rewarding, knowing that people have said yes (Participant volunteer 3).

TrustBank operates on a 'broad' consent model (Elger and Caplan 2006) since it is impractical to obtain approval for all future, ethically-approved uses of samples for research which is yet to be specified (Levitt 2011). Participants are invited to fill in an enduring and generic consent for the retention of any relevant tissue, at any point in their relationship with the hospital. As outpatient appointments in the NHS typically involve waiting, TrustBank takes advantage of this 'wasted' time:

They love it. Complaints ... have gone down drastically... (Participant 3).

Lot of people that who come in are a little bit anxious. ... We can lighten the mood slightly (Participant volunteer 4).

Using other facilities within the hospital gave TrustBank additional financial and practical benefits. The ability to incorporate consenting and recruiting into the clinical procedures of the hospital provides this biobank with '*ethical efficiency*' (Hurlbut 2015):

We piggy-back onto hospital processes, like sending out the patient information and consent forms, they have an appointment letter going out, we stuff our forms [in] (Participant 1).

TrustBank was seen as being for the 'local' hospital, not a national agency like UK Biobank, or a university. The local hospital, especially one that has cared for participants or their relatives is trusted (Lipworth *et al.* 2011):

Participant 6: funding wise, people want to donate money and to generate money for their local community rather than...

Interviewer: Rather than the NHS as a whole.

Participant 6: So there might be something about local tissue donation.

On-going trust is established based on an affirmative relationship between participants and researchers (Kelly *et al.* 2015) and on the mobilisation of those social, emotional and intellectual relationships that can support this scientific and socioeconomic activity (Morini and Fumagalli 2010). As Martin and Hollin (2014) note, the place of consent (e.g. an NHS clinic) exerts an influence on individuals' decisions to participate in research; more so than the information given to them (Nobile *et al.* 2016).

Integrating information technology

Biobanks require the integration of biobank workflows into routine clinical practice in order to acquire quality biospecimens (Caixeiro *et al.* 2015). Integrating TrustBank into the hospital avoids unnecessary duplication, providing a single home for the samples and their data:

If the biobank is set in university space, rather than in NHS space, we would probably end up duplicating the biobank, ... duplicating the storage and the product because we would need it for that delivery of care to the patient (Participant 12).

TrustBank uses software specifically designed for use with the hospital information system, to facilitate cooperation and avoid administrative errors:

To have it done electronically, in a way that's linked with ... the clinical record is fantastic so you just get a live download and the way it ... work[s] is that when clinicians are interacting with patients, generating letters or whatever, the data

that's used to generate those letters ... will also be used to populate the biobank (Participant 10).

Our aim... is to design it so that it can be used as the clinic interface and when a clinician's sat in the clinic, they can actually be inputting directly into that database (Participant 4).

The NHS is now in a unique position to support biomedical research activities with extensive and detailed data (Chalmers *et al.* 2016). TrustBank's software is now the basis for a new hospital information system being designed at the time of the study. This will lock TrustBank into all of the hospital's clinical and administrative systems, thus making it easier to collect a much richer dataset:

We capture data in a way that is informative, it's more refined or granular, ... the data's stored in an information model that can be searched, [it] contains all clinical data, we gathered all other NHS data so we've got e-health records, ..., we've got core data of diagnosis, treatment, a phenotype that describes the patient and their response to treatment, labs, x-ray reports, everything's in the system. ... you can search in real time (Participant 3).

Tightly integrating biobanking into the new hospital information system shows that the aim of both TrustBank and the hospital is to recruit most patients as participants in the biobank, and for TrustBank to have access to the fullest possible set of information about these patients and their tissues. Therefore, another regulatory advantage of hospital-led biobanking is that information about participants could be moved more easily from 'clinical' space to 'research' space in a safer and more secure environment for both clinicians and researchers:

If you don't have that data, you can't do stratified medicine. So we wanted to evolve an informatics strategy to capture that, again using the NHS as a platform (Participant 3).

All our data's held on the Trust servers, which are backed up every night and [in] everything we do we only access the patient's record if they've consented (Participant 1).

Sustainability

The hospital's management required that TrustBank become financially self-sustaining in the long term in return for their initial investment. The only way that this is possible for a biobank is for it to have a plan to commercialise (Bunton and Jones 2010). This took the form of pricing structure (widely used but challenging for income sustainability when demand is low (Chalmers *et al.* 2016)) whereby 'local' researchers (those from the hospital itself and the associated university) could use TrustBank's resources free of charge. University researchers from elsewhere in the UK were charged at cost. Commercial users of TrustBank were charged market rates, effectively subsidising the costs of the biobank for other users (Cañada *et al.* 2015):

The hospital charge us for space, ... staff overheads plus premises, we do charge Pharma full, for the actual price, it's not inflated and there's a sliding scale then for academics outside of [city] (Participant 1).

However, providing better prices for (local) researchers was not seen as preferential treatment vis-à-vis the pharmaceutical industry. If academic researchers have lower access fees for biospecimens, then the pharmaceutical sector is seen as benefiting, in the long run (Sunder Rajan 2003).

So it's a circle, if you support local researchers, they're the ones who'll inform the Pharma, of phase 1, phase 2 trials, [pharma] get something out of it in the end (Participant 1).

Integral to TrustBank's cost recovery model is the need to collect 'waste' tissue and process it into accessible biospecimens of value to biomedical researchers (Mitchel and Waldby 2010):

Once you've taken the samples, done something sciency to them, made them different then you can make, ... if that's valuable, if other people want to pay for it, you can ... (Participant 6).

The commercial value of biospecimens can be seen from the fact that there are well established companies who enable biomedical researchers to source a wide variety of human tissue globally (Brown *et al.* 2011).

To give you an example of how valuable the stuff is, I know two big Pharma companies in the UK... both of their [] units within the UK buy in [] tissue from America ... you can get it within two to three days ... it's £3000 (Participant 6).

Financial returns, institutional backing and competition from other (NHS) biobanks (Turner *et al.* 2013; Stephens and Dimond 2015b) will determine TrustBank's place in an increasingly competitive market where '*precariousness*' and '*momentariness*' abound (Stephens and Dimond 2015a):

Either biobanks aren't cost effective; a lot shut down because of that, they don't balance or else as in the Welsh bank, got lots of funders, like national government, ... regional government, charities. We don't receive any external support at all (Participant 3).

it's still probably unsustainable because the NHS is always going to be cash-starved and Trusts will see this as not directly care. It's very hard to develop a sustainable model, there has to be infrastructural backing ... I see biobanking as a very fragile thing to sustain and I think it will remain fragile for the foreseeable future (Participant 10).

Nevertheless, this market context was also seen as an opportunity, since companies requiring TrustBank's biospecimens *and* data are unable to develop their own biobanks, providing custom for this biobank. Unlike some hospital-based biobanks, which outsource their samples to larger private biobanks that have the resources to benefit

from economies of scale, TrustBank mobilises its own resources in order to provide high-value samples directly to potential customers and thus remove other intermediaries between provision and consumption.

Biotech companies just don't have the resources to set up their own biobanks ... Big pharmaceutical company, their view is that they can get everything they want from here so ... they're closing their own biobank so they're just going to use us to supply them with the tissues as and when they want (Participant 10).

The appeal of TrustBank is not limited to the number of high-quality biospecimens it can collect but also the legacy samples it has incorporated from the pathology department. These have been collected over decades, along with all the associated data the hospital has collected as part of routine clinical care.

it's not difficult for pharmaceutical companies ... to get human tissue, but the important thing that they need is the data linked to the tissues ... it's the knowledge of what the patients were treated with, how they've done (Participant 10).

Bioresourcing

UK research policy-making increasingly mobilises the NHS brand to instil a sense of community where each citizen becomes "*a particular sort of altruistic subject, one that offers individual labour, body and time without immediate calculus or expectation of direct return [...] in the contemporary ideological nexus that relocates the contemporary UK citizen/patient within the nostalgic of the 'NHS ethic'*" (Adams and McKeivitt 2015: 139). There is now a widespread expectation of embedding tissue donation in the healthcare system to support scientific and socioeconomic activities around biospecimens. Some participants in this study thought it necessary that biobanks be placed within the wider healthcare system, with generic and enduring consent:

I think biobanking needs to be embedded within the health service wherever that is in this country and genetics and genomics and everything else needs to be embedded in it (Participant 7).

We could put in place a network that would be far more powerful than anywhere else (Participant 3).

A much stronger view was held by one (researcher) participant, questioning the necessity of consent, appealing to a collective morality and a rhetoric of 'infinite benefit' (Sarewitz 1996):

In a democratic society, it's actually unethical *not* to donate your tissue. Because it's of ... no loss to you but it's of benefit to society, for research (Participant 10).

One participant thought that the future of biobanks is moving towards bio-resources with rich data, allowing for samples from both healthy and patient populations to be used for research:

I think we are moving to a bio-resource style model rather than bio-bank, because bio-resource is all about bio-recall, mix of health population and patient population, who are willing to be recalled for clinical research (Participant 5).

As calls are made by the scientific community to embed research in the NHS (Academy of Medical Sciences 2011), it seems that the individual choice of participating in research is gradually converted into a duty of citizenship (McHale 2013). For example, the UK National Institute for Health Research (NIHR) has already set up a federation of local panels of volunteers which recruit individuals to participate in biomedical research (Bradshaw 2015). Everyone is welcome to volunteer, irrespective of their health status, since *"everyone is unique and everyone is of interest to us; the more individuals we recruit, the more unique and valuable BioResource will become"* (NIHR BioResource 2016).

Conclusions

This study analysed the integration of a biobank into an NHS hospital. We identified the social, technical, political and economic reconfigurations that were established and analysed the "*range of cognitive, informatic, and affective activities*" (Birch and Tyfield 2013: 314) for the transformation of 'waste' tissue (originally collected for clinical purposes) into biospecimens for research and market exchange. We explored the extensive effort and capital investment in relationships and information systems, as well as in recruitment, clinical, scientific and other labour processes involved in the realisation of value (Birch and Tyfield 2013) for these commodities.

These tissues do not have one promissory value but multiple values (Birch and Tyfield 2013; Martin 2015) that need to be translated and supported *here and now* for this transformation to be successful, and for the biobank to be sustainable in the longer run. It is these promissory values that drive the negotiation and formation of socio-material networks between the state, the market and the public hospital (Rose 2007; Waldby 2012). Scientific, clinical and commercial promises can then co-exist so that waste tissue can move from collection to production and consumption.

Our findings point to a context-specific form of an 'entrepreneurial hospital' (French and Miller 2012) within the UK NHS. Here, instead of tissues travelling to remote, state-backed organisations, this hospital attempts to broker the commodification of its own assets between academia and the market. It takes over production and distribution of tissues, becoming both a producer and seller of biospecimens. By firmly embedding its operation in the local NHS hospital and the University, including the commercialisation of tissue donation on a cost recovery basis, TrustBank has managed to overcome many of the organisational, technical, cultural and ethical challenges of bigger (inter)national biobanks. As everything takes place within the same spatio-temporality, it guarantees administrative, clinical, informational and scientific *efficiencies* necessary for a high-quality commodity that will be consumed by interested customers.

The public hospital gradually becomes the place where the "*solidaristic moral economy of gift and altruistic participation in imagined community and nationhood*" (Brown 2013: 98) enters a complex and interrelated network of social, material and economic relations (Waldby 2002). It mobilises established local social networks and personal/institutional relationships with donors that go beyond monetary exchanges and contractual agreements (Haase *et al.* 2015). Donation becomes one (but crucial) element (Hauskeller and Beltrame 2016) for the continuous sourcing and supply of "premium bioeconomic resources" (Brown *et al.* 2011) for domestic and international markets. At the same time, it is within a reciprocal relationship that patients-citizens, as members of the local community, might see participation in biomedical research as their duty, in order to give something back to help others, as well as the clinicians and the NHS hospital that has treated them (Haase *et al.* 2015). It is possible that this biobank's commercialisation plans were not resisted because of the 'communal framing of *their* biobank' (Steinsbekk *et al.* 2013: 159) and the expectation (whether based on lack of awareness or not) that any income generated would go to support their local NHS institution.

The NHS is perceived very strongly, especially in a British context, as being for the 'common good', which is also a key concept in the rhetorical justification of biobanking. Consequently, the idea being drawn upon, in the case of TrustBank, is not the 'imagined national community' discussed by Busby and Martin (2006), but instead is an 'imagined local community', united by the NHS and the hospital. Rather than basing its reputation and trust on being an independent experienced institution, such as a medical research charity, TrustBank appears to frame a similar narrative but this time via the local NHS hospital; an institution embedded in the local community, members of which it has always cared for. It is possible that TrustBank points to a new relationship, where the expectation from the state is that patients and even healthy citizens will participate in research by donating their tissue and information, in return for free health care. For example, the 100,000 Genomes Project (Genomic England 2015) is another project in

bioresourcing for the NHS where patients with a rare disease or cancer and their close relatives could have their whole genome sequenced (WGS). Although it is mainly used for research purposes, some participants may get a diagnosis and a particular treatment for their condition for the first time. These are considerable re-imaginings of the relationship between the NHS and its patients-citizens, and also marks a departure from the conventional way in which participants are recruited to biomedical research in the UK.

The limitation of this study in not interviewing patient-participants is acknowledged, though this group has been studied (see Dixon-Woods *et al.* 2008; Steinsbekk *et al.* 2013; Locock and Boylan 2015). These studies found participants tend to be more interested in the perceived benefits of research for individuals and society as a whole rather than the associated risks. They tend to trust public and publicly-funded institutions (Nobile *et al.* 2016) which are thought to deliver more health benefits and fewer risks to society as they are not driven by profit (Levitt 2011). Individuals' decisions to participate in biobanking research are driven more by emotional, and experiential factors, such as optimism, curiosity, and solidarity, and less by rational evaluations of the costs and benefits of research based on a thorough examination of the study information (Nobile *et al.* 2016). Nicol *et al.* (2016) have found that independence from funders and even government is a defining characteristic of a well-governed biobank, while commercial activity should be limited to cost-recovery.

Despite this limitation, our data adds to a growing literature that acknowledges that tissues do not hold any socio-ethical and economic value that automatically makes them exchangeable products in the market. Biocapital formation and circulation is a highly contextual and spatio-temporal endeavour. It requires biobanks to firmly localise these assets and bring production as close to donors as possible. It needs considerable investment in an organisational and technological infrastructure that will facilitate the collection and preparation of high-quality biospecimens *and* their associated data for research locally and beyond. Lastly, this intertwining of biomedical innovation, financial

sustainability and healthcare also requires a range of affective, intellectual and commercial relationships with donors, volunteers, clinicians, researchers and customers.

Although hospital-led biobanks are relatively new organisations in biobanking, there is yet much empirical work to be done to explore whether this closer sociotechnical relationship of (*inter alia*) tissues, systems, clinicians, scientists and volunteers will actually become a sustainable model of biobanking, facilitating better biomedical and translational research. We should consider not only whether such arrangements attempt to transform research participation into a duty for each citizen but also the extent to which a transactional understanding of research participation, where the patient receives care in exchange for tissues and data, gradually becomes the norm in the context of a national health system.

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