REVIEW 322/2015

Patients, business and the state

Translating health information into sustainable benefits

Aaro Tupasela, Karoliina Snell and Jose A. Cañada

Tekes

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Translating health information into sustainable benefits

Policy brief for engagement practices in Canada, Finland, Iceland, Spain, UK and the US

Tekes Review 322/2015
Helsinki 2015

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ISSN 1797-7339
ISBN 978-952-457-606-2

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Page layout: DTPage Oy

Foreword

This report reviews several interesting research results how to govern healthcare information. Especially it raises a question how to manage information derived from biobank research and genetic databases into globally sustainable and socially robust healthcare products and services.

One focus of this study was to compare governance and engagement regimes in Canada, Finland, Iceland, Spain, UK and the US, as well as supranational actors, to manage the collections, storage, use and commercialization of healthcare and genetic data. It also explores the implications that new patient engagement strategies have for the creation and deployment of intangible assets and value creation within the Finnish innovation system. Moreover, the study identifies what are critical elements between the patients, business and the state. Especially what is the sustainability of value creation regimes that can be deployed by companies.

This report was carried out by Aaro Tupasela, Karolina Snell and Jose A. Cañada in the University of Helsinki. Tekes wishes to thank the researchers for their thorough and systematic approach of biobanks. Tekes expresses its gratitude to steering group and all others that have contributed to the study.

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Introduction

This study examines governance challenges posed by the utilization and translation of biological samples and healthcare information derived from biobank research and genetic databases into globally sustainable and socially robust healthcare products and services. The collection, use and distribution of human tissue samples, often referred to as biobanking or tissue banking, and which include blood and diagnostic tissue samples, from which DNA can be extracted and analyzed, has become a major political preoccupation, not only in national contexts, but also at the transnational level (Gottweis 1998) in that increasingly such sample collections are expected to produce commercial value (Tupasela 2006a).

Sociologically, studies of the biomedical collection and use of human tissue sample collections has developed into its own distinct rubric under both the sociology of science and technology studies (STS) and medical sociology as well, which have sought to examine the different ways in which bodies are being commodified and sourced (Schepher-Hughes and Wacquant 2002). These approaches have provided important extensions to studies of gifts as a central component of exchange (Mauss 2004), materialist analysis of production and capital accumulation (see Sunder Rajan 2006; Marx 1977), as well as providing new insights into the motivations and concerns of donors in participating in research (see Table 1). In addition, the rapid development and expansion of biobanking activities has also given rise to a growing literature on the sustainability of these activities (Albert *et al.* 2014; Parry-Jones 2014; Watson *et al.* 2014; Vaught *et al.* 2010).

In Finland, studies have shown that the most important reasons that people would allow for their samples to be used in research was furthering medical research and benefits to future generations. The promotion of commercial ventures was not an important reason for allowing samples to be used (Tupasela *et al.* 2010; Tupasela *et al.* 2007; Sihvo *et al.* 2007) and in fact commercialization raised doubts among Finns (Snell *et al.* 2012; Tupasela and Snell 2012). Therefore, when considering the sustainability of Finnish biobanking it is imperative to consider public perceptions and think through the life cycle of tissue samples and their related health information in a more robust and long-term scenario. In a number of other countries, issues surrounding the relationship between biobanks and the research population have maintained a central role in policy-making and politics as well (Epstein 2007). In the US, for example, The Centers for Disease Control and Prevention (CDC) has placed a great deal of emphasis in developing strategies for community engagement in an attempt to improve public health, as well as improve the quality and applicability of population research (Haldeman *et al.* 2014). Different countries and institutions take different approaches to their engagement strategies with regard to the general public, as well as the research population from which they collect samples (Cañada *et al.* forthcoming).

Table 1. Willingnes of Finns to give a blood smaple for research.

Would you be willing to give a blood sample for research purposes? n = 1184 (Sihvo et al. 2007)

Yes	No	I don't know
84 %	6 %	11 %

Table 2. Reasons of Finns to give sample for research purposes.

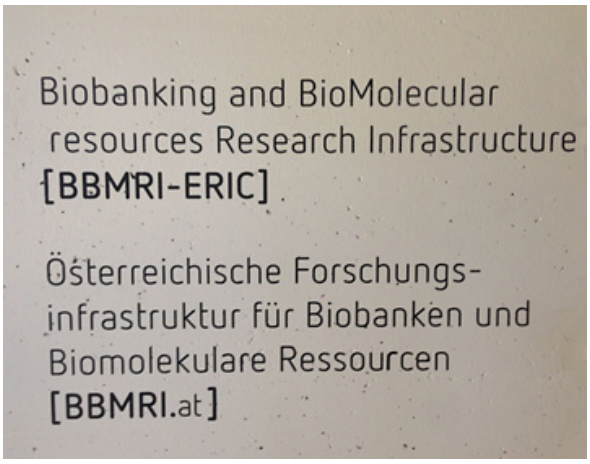
Reasons to give sample for research n=1177 (Sihvo et al. 2007)

Furthering medicine	91
Benefits to future generations	82
Finding out own risks	52
Increasing competitiveness of Finnish researchers	30
Duty	9
Promoting business	3

Although the use of human tissue in biomedical research is not in itself new (Strong 2000), some have argued that recent biomedical research practices using tissue sample collections constitute a new object of study within biomedical research (von Versen 2000, 2). Internationally, the formation of networks of biobanks and protocols for standards indicates a professionalization of the field itself. European networks such as BBMRI signify an intensification of the process of sharing as well as data sourcing with regard to himan tissues, as well as related health information. This change in the context of use and application of collections warrants a better analysis of the conditions surrounding such changes and their consequences.

The biomedical use of human tissue collections also has important connections with the emergence and analysis of the increased commercialization of research as well (Häyrinen-Alestalo and Peltola 2006; Etzkowitz *et al.* 1998; Etzkowitz and Webster 1995). Public-private interaction is not a new phenomenon, but rather has been a central feature of biomedical research for decades (see Kleinman 2003; Hietala 1992). During the past two decades, there has been an interest in intensifying the process of transforming scientific discoveries and knowledge into commercial applications (Webster and Rappert 2000; Tupasela 2000) and this interest has also been reflected with regard to biobanks and biomedical research. This can be seen, for example, with the development of biobanking network infrastructure investments, such as BBMRI-ERIC. At the same time, however, closer linkages have begun to develop between political expectations associated with scientific research, and the theoretical explanations related to the role that knowledge is seen to play in economic development (Häyrinen-Alestalo 2006). In many cases, however, these perspectives might not consider the multivalent nature of participation in research or the challenges in the use of tissue samples and health information without the sources of that information knowing about it. This discrepancy can also be seen to have developed in the healthcare sector as well, where hospitals are playing a more prominent role in the collection and curation of samples and patient information. The commercialization of discoveries and applications based on tissue sample collections play an increasingly important role in how tissue collections are appropriated and how scientific knowledge production is organized (Tupasela 2006a).

BBMRI-ERIC headquarters in Graz, Austria.
Photo credit: Aaro Tupasela



The increase in research policies to bolster the commercial application and long-term sustainability of publically funded research has also been significantly increased by the commercial expectations and hopes that are attached to knowledge production policies. Biomedical research is one such area that has garnered and produced hopes and expectations at the policy level (TEM 2014; Academy of Finland 2003; OECD 2001). Theoretically, such forward looking expectations have come to be studied under the rubric of sociology of expectations (see Brown *et al.* 2006). According to Borup *et al.* (2006, 285-286), "expectations can be seen to be fundamentally 'generative', they guide activities, provide structure and legitimation, attract interest and foster investment. Expectations give definition to roles, clarify duties, offer some shared shape of what to expect and how to prepare for opportunities and risks." In considering the sustainable operation of biobanks in the Finnish context it is important to understand the ways in which hopes and expectations operate in resource deployment since they may play an important role in the ways in which engagement practices are framed and developed. In this sense genomics has proven a fertile gound for hopes and expectations.

Towards the end of the last millennium, the quest to unravel the whole human genome was starting to come to an end, the interest in commercializing university research was gaining increasing political and policy traction and the hopes and aspirations of developing a new and fruitful business sector was starting to look like a real possibility (OECD 2001). Rose (2001, 5) has noted that this can partly be attributed to the fusion of two large technosciences of the 21st century, namely biotechnology and informatics. The attempts to commodify the bioinformation in the Icelandic Health Sector Database, for example, represented only one approach in the production of biovalue by setting up an information monopoly for deCode Genetics. Since the setting up of deCode, the company has had to go through numerous waves of re-funding from the private sector in order to maintain its operations. In relation to long-term sustainability the case of deCode Genetics and Iceland is instructive in that it has highlighted the long-term nature of basic research and the difficulties it has in translating that research to viable commercial products. This can be seen as an example of the challenges which lay in relation to the capture of capital value from genomics projects. The production of capital value from biomedical knowledge is dependent on a number of factors, one of which is the

way in which knowledge is assembled using different information resources, as well as the ways in which biobanks and the policies that are set up to implement them engage with the local populations. Alongside the strides in development that have taken place within biotechnology, there has emerged a large body of literature that has sought to examine and understand the social, ethical, financial and legal aspects associated with the developments in the natural sciences (Lauβ *et al.* 2011).

The developments and strives that have been made in the biosciences have by no means been unproblematic, leading policy makers and politicians alike to developing ways in which the communication between science and society can be strengthened and bolstered. Given the significance that commercialization has been given in relation to the production of scientific knowledge (Jacob 2003) and its role in economic development (European Commission 2010), it is important to better understand the connections between participants and collectors, as well as the various forms of solidarity that these connections may entail (Prainsack and Buyx 2013). Although some have argued that gift giving serves as the basis of tissue acquisition (cf. Titmuss 1970), it should be noted that this perspective is highly normative and entails several assumptions about the way tissues and information on the body and health are acquired, circulated and used. Given the great variety of ways in which tissues and information are acquired, it is also misleading to assert that the gift-reciprocity axis is the main nexus around which tissue economies (Waldby and Mitchell 2006) operate. Tissues are acquired and made productive through numerous paths which rely often on different forms of discourse and arguments for their use and re-use (Tupasela 2011). The scope of different types of tissue which are collected and stored ranges from blood and cord blood for therapeutic treatments to pathology samples and whole organs stored for diagnosis and research. The expectations of both lay people and professionals working with biobanks are based on complex reasoning about the benefits, risks and future developments (Tarkkala *et al.* 2015; Lauβ *et al.* 2011).

Within this field, the biomedical collection, storage and use of human tissue samples and related health and personal information has been an exemplar of the ways in which a field of scientific inquiry has made prominent advances, while at the same time has had to come to grips with aligning and dealing with social, ethical and legal concerns. During the past few years a number of international companies have been developing new ways in which to collect and analyze genetic information and connect it with self-reported health information, namely through genetic self-testing. These can be seen as commercial efforts to develop so-called "joint social efforts" in which notions of community are built in new ways. Companies such as 23andMe and deCODEme (deCODEme was shut down in 2013 due to the lack of public interest in purchasing genetic test kits) have sought to develop business models that utilize the very latest technologies in genetic analysis and combine them with various forms of social media through which to engage customers in their services. Growing commercial uses of the data created by the customers has been labelled as "the digital patient experience economy" (Lupton 2014). Some authors have also noted how biobanking ventures

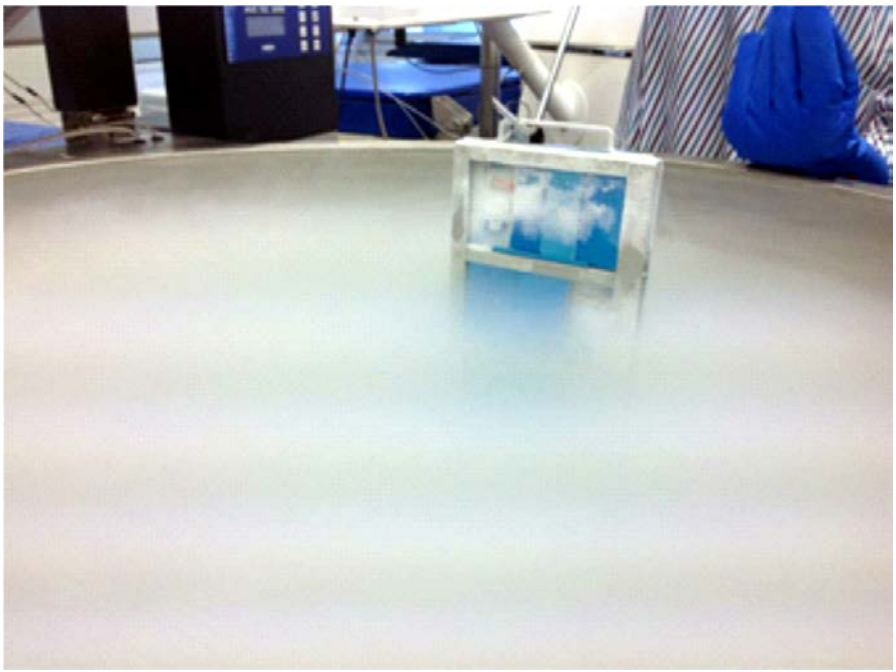


Photo credit: Aaro Tupasela

have sought new ways in which benefits can be distributed between a broader range of actors in an effort to foster trust and legitimacy (Simm 2005). This has also been extended into the realm of policy discourse as to the role that research participants have in the governance process (Corrigan and Tutton 2004). The innovations that these business models represent seek to develop new forms of engagement with research subjects and thus develop forms of social interaction with customers that are commercially sustainable. These kind of participant-centred initiatives use social media technologies to address concerns, such as privacy and trust, but they also try to provide the basis for long-term interactive partnerships (Kaye *et al.* 2012). The main challenge with this participant-centered approach, however, is that it is unsystematic, unlike many of the national research projects in Finland, for example.

For public health initiatives, participation in studies is a crucial element for success and validity. During the past decades, the levels of recruitment of participants to surveys, for example, have declined dramatically (Helakorpi *et al.* 2011; Raisamo *et al.* 2011, 17), posing a serious challenge regarding the future possibilities to gather relevant scientific and medical data for large studies. From a sustainability perspective this can also be seen as a major challenge to legitimacy. The dramatic decline in participation levels raises important policy concerns regarding recruitment and its relation to scientific output and innovations. Given that these resources play an important role in research and future innovations it is crucial to develop mechanisms that support and encourage further participation. On the other hand, a major challenge for businesses has been gaining access to tissue collections maintained by public hospitals, as well as public health care record systems, in a sustainable manner that does not threaten the legitimacy of public health care institutions, but rather helps to build new forms of social engagement between the public and private sectors. The role of the state as a mediator in this process is crucial in that it must strike a balance between public concerns and commercial development.

Accounting for engagement and participation in biobanking

Recently, Kowal (2013) has, paradoxically, noted that no research using samples and information is disentangled from their source, unless they establish and maintain relationships with the communities from which samples come from. In other words, dis-entanglement requires a form of entanglement in order for samples to be used without future tensions between the sources of the samples and their users. This normative observation may provide important insight into the development and maintenance of sustainable global biobanking initiatives and their relationship with the local/national/global context in which they are embedded. Citizen participation and involvement is by no means a new topic in relation to techno-political legitimacy. Arnstein's (1969) ladder of citizen participation is a classic example of the ways in which involvement has been made a political issue in relation to planning and development where increased levels of involvement are seen to be desirable.

Participatory models of engagement rely to a certain extent on an understanding that increased participation also increases the flow of information in both directions, as opposed to being top-down in nature. From a governance perspective, such a position may hold important possibilities for interaction in relation to biobanking. Some have argued that increased involvement makes visible the 'patient work' (Corbin and Strauss 1985) and 'clinical labor' (Cooper and Waldby 2014) that sample donors provide in order for collections to become possible and operable, as well as allows for increased responsiveness to the interests and concerns of those who have participated. At the same time, however, biobanks tend to, either explicitly or implicitly, engage in a type of population branding, whereby particular characteristics are assigned to the population from which they have collected samples (Tupasela 2015). It is, therefore one of the goals of this study to examine the different ways in which various biobanking practices around the world have sought to maintain (or disregard) links to the population from which they have derived their samples to try and ascertain in what ways various engagement practices facilitate (or do not facilitate) and operate within the development of global biobanking practices.

A number of recent studies have examined and explored the role of community engagement (CE) as a central aspect of any biobanking governance scheme (Halderman *et al.* 2014; O'Doherty *et al.* 2011; Shalowitz *et al.* 2009). Although much of the literature surrounding forms of community engagement have stemmed from a concern for the lack of consideration for the concerns of minorities and vulnerable populations in research settings (Israel *et al.* 1998), the basic theoretical assumptions underlying engagement with the research population stem from an understanding and belief that engaging with the research population will bring with it improved understanding of the context in which research takes place, as well as improved results in the outcomes of the research and public health (McCloskey *et al.* 2011).

Studies of patient activism have also indicated that patient organizations are increasingly involved in the organization of research and sample acquisition surrounding specific diseases and rare conditions (Novas 2007; Rabeharisoa and Callon 2002). These novel knowledge making coalitions between patients and research organizations, as well as companies highlight the ways in which citizen and patient participation is in some cases becoming more prevalent

and inclusive in biomedical research (Novas 2007; Epstein 2007). Callon and Rabeharisoa (2008) have noted that such groups play an increasingly important role in the development of technoscience, politics and economic life. Studies of emerging "knowledge-making coalitions" in biomedical research communities have sought to develop a more detailed and robust theoretical understanding of what some have termed medical modernization (Hess 2004, 706; see also Brown and Zavestoski 2004). Medical modernization has been defined as the epistemic challenge by health social movements (HSM) and complementary and alternative medicine (CAM) professions against paternalistic progressivism (Hess 2004), a situation whener traditional medical professional seek to assert their authority over medical issues. Medical modernization is a challenge to traditional forms of medical authority by patient organizations who seek to leverage their networks and resources into marketable research resources. Biobanking lies at a crossroad where patient participation and support is necessary and where the medical authority of experts is also exerted and expressed in different ways.

A number of national biobanking initiatives have sought to draw on a discourse of participation and involvement of citizens in an attempt to garner broader social legitimacy (Tutton and Corrigan 2004). Research on medical modernization has much in common with what Nowotny *et al.* (2001, 54) describe as the emergence of social conditions that allow, and necessitate, that "society is able to 'speak back' to science." The public shaping of science or "citizen science" has taken a central role in current social studies of the public's role in a number of research fields, including environmental movements and patient advocacy groups (Prainsack 2014; Kerr *et al.* 1998; see also Fuller 2000). Along these lines, Barry (2001, 2) has suggested that the technological reflects a "political preoccupation with the problems technology poses, with the potential benefits it promises, and with the models of social and political order it seems to make available." In this context, it is unsurprising that the question of engagement practices in biobanking is of political and practical interest, particularly as it relates to long-term sustainability.

Appropriate engagement strategies can be seen to be important when examining resistance and opposition movements related to biobanking. The organization Mannvernd was created specifically to oppose the deCode Genetics in Iceland being given monopoly rights to use Icelandic information without appropriate public debate and discussion (Mannvernd 2003). Similarly in Tonga, an Australian biotech firm, Autogen, ran into major opposition as a result of failures to account for cultural differences and customs in Tonga. Despite having signed a contract with Tonga's health ministry to perform research on the population, local opposition and churches in the Pacific united to oppose such ventures without extensive prior public consultation. The opposition was primarily based on the fact that the informed consent procedures did not account for the extended family system that plays a major role in Tongan society. Other oppositions included giving patent monopolies to corporations on God-created life forms (Burton 2002, 443). In Västerbotten county Sweden, where a local hospital granted exclusive rights to a private company UmanGenomics to its collections of samples and health information that have been collected for a past study on heart disease ran into major difficulties. Despite having commercial rights that were granted by the Swedish Medical Research Council and the law on biobanking, the venture ran into opposition by the researchers who had conducted the original research. The troubles that UmanGenomics had with the project have not reduced, however, the public's willingness to participate, but has hindered the use of the information that has been collected since one of the major obstacles involves the leader of the research project itself. A major problem in the conflict was that UmanGenomics did not recognize well enough the right of the researchers to the data that they have collected (Hoeyer 2004). Trust in experts in the UK also suffered due to incidents, such as the Alder Hey and Bristol Royal Infirmary incidents where doctors and researchers collected samples from deceased children without their parent's consent. This raised a number of important questions concerning the trust in the medical community in the UK. This has also been reflected in a heightened ethical and legal concern in the setting up of UK Biobank (see Corrigan and Tutton 2004).

The lessons that have emerged from such contentious events have indicated that the collection and use of biomedical tissue samples and related information should not be taken lightly. Instead, there appears to be a movement towards a more systematic and professionalized field of experts who run and operate biobanking activities, who take engagement with various stakeholders as an important function of their overall operations.

Levels and styles of engagement

The notion of public engagement covers a very broad range of theoretical and practical approaches to engaging with the research population, as well as the general population at large. Some authors have noted that biobanking has moved on to a third phase (Biobanking 3.0) whereby there is a shift in the focus towards people/patients, funders, and research customers. This type of periodization would seem to support the idea that engagement practices are becoming increasingly important in biobanking activities. In general, engagement refers to processes or techniques which allow for involvement and communication. As such, this also has significant consequences on the epistemic features and political connotations that engagement may en-

tail at a policy, as well as at a practical level. Due to the brod range of mechanisms through which involvement can be attained, there has not emerged a single form and style of involvement which would have come to dominate the filed of public engagement. Conceptually there are a number of terms that may have a great deal of similarities, but at the same time have different historical and contextual meanings in terms of their approach and practical implications in application. Notions such as community engagement (Haldeman *et al.* 2014; McCloskey *et al.* 2011), community-based participatory research (CBPR) (Shalowitz *et al.* 2009; Israel *et al.* 1998), public participation (Hansen 2006; Elam and Bertilsson 2003), participant-centric intiatives (Kaye *et al.* 2012) sitizen science (Irwin 1995; Prainsack 2014), and the digitally engaged patient (Lupton 2013) are only a few examples of terminologies and ideas of engagement with the public. Kelty and Panofski (2014), for example, have identified seven dimensions of participation that have been used in the literature on participation. Similarly, Rowe and Frewer (2005) have noted that the key concepts have not been well defined in the literature or in the policy domain. Despite this they have described three general types of engagement: *public communication, public consultation and public participation*. These different types of engagement may hold within them numerous different mechanisms through which engagement can be enacted. Some of these mechanisms include task forces, workshops, focus groups, public panels etc.

Furthermore, engagement may entail different levels and styles of action in relation to how involved the organisers of the engagement mechanisms want the public to be (Thiel *et al.* 2014). There may be considerable trade-off involved in seeking to engage the public in an intensive manner since such practices may be expensive, time consuming and yet attract less attention than originally hoped for. Similarly, an engagement strategy that is too "light" may in turn not provide enough opportunity for dialogue and leave both sides of the engagement process without a proper understanding of the interests and concerns of the other side. In relatin to biobanking, there has emerged a broad range of tactics related to engagement, ranging from no engagement to on-going and multifaceted forms of engagement (cf. UK Biobank).

Despite the lack of conceptual clarity and definitions of the notion of engagement, what all these forms have in common in a type of political preoccupation regarding the legitimacy and trustworthiness of certain activities. These issues are seen as central elements within the broader political arena in that the biomedical use of human tissuye samples collections are expected to play an increasingly significant role in economic development. To procure, store, use and distribute such resources without sufficient consideration as to the social, ethical and legal concersn related to them may prove problematic in relation to long-term sustainability.

Blood bank in Madrid. Photo credit: Aaro tupasela

Methods and Materials

This report is based on a two-year project, which sought to understand the forms and styles of engagement that various biobanks undertook in six countries: USA, Canada, UK, Spain, Finland and Iceland. We selected these countries with regard to differences in size, legislative systems, healthcare delivery systems, as well as historical context. We have also sought to include different types of biobanks; large prospective cohort biobanks, disease specific biobanks, hospital-based clnical biobanks, publically run biobanks, as well as privately owned and operated biobanks (see Table 2). The focus of our research was on engagement strategies of different biobanks in these countries. Our data produced also results on the ways in which biobanks come about, as well as the multifaceted contexts in which they operate. We conducted 26 semi-structured interviews[1] with relevant personnel from different biobanks, as well as biobank networks in six different countries. We also conducted interviews with policy makers and regulators to develop a broader picture of the nature of biobanking in the various countries. Some of the interviews were done in person, while others were conducted via telephone or videoconference. In addition to the interviews, we collected policy material and other relevant material from webpages and other on-line sources related to bibanking in each country. These materials included legislation in the countries, recent policy discussions, as well as public debates, which might have taken place in that country or region. We have also participated in conferences or symposiums arranged by or focusing on biobanks i.e. UK Biobank Ethics and Governance Council workshop. The interviews were coded for various themes, including engagement strategies, funding sources, and ethical debates, and their relation to the long-term sustainability of biobanking activities in those countries. We then proceeded to compare and contrast activities between biobanks to get a better picture of the ways in which biobanks conceptualise their engagement strategies. These issues were then compared to other variables, such as national legislation and practices related to the collection, storage and distribution of samples and data. This report provides insights into the findings of our two-year study.

In the following sections, we will describe the national contexts related to biobanking in six countries; Iceland, Spain, UK, USA, Canada and Finland. We first examine the historical contexts in which these various biobanking initiatives operate, then we describe the legislative and regulatory frameworks that surround them, and finally we explore the forms of engagement that the various biobanks and actors have sought to utilize in their biobanking operations.

Table 3. Countries and types of biobanks examined.

Finland	THL Biobank Auria Biobank HUB AMCH Biobank FHRB	Population biobank Clinical biobank Disease-based biobank Clinical biobank Disease-based biobank
Iceland	DeCode	Population biobank
UK	UK Biobank Confederation of Cancer Biobanks	Population biobank Biobank network
Spain	Basque Biobank IDIBAPS Biobank National Biobank Network (Now 'Biobank Platform')	Clinical biobank Clinical biobank Biobank Network
Canada	CARTaGENE The Tomorrow Project Canadian Partnership for Tomorrow Project	Population biobank Population biobank Biobank network
USA	23andMe	Consumer genetics company

[1] Interviews were conducted in three different languages: English, Finnish and Spanish. All quotes have been translated by the authors trying to stay as close as possible to the original meaning. All identifiers have been removed from the quotes for the sake of preserving the privacy of our interviewees.

Iceland

Background and history of biobanking

The first case that we will examine in this study focuses on Iceland, which has a small population and excellent records of its population history. Iceland emerged onto the biobanking scene relatively early and some might say it has been a quintessential example of a nation-state leveraging its population and healthcare records to the use of commercial biomedical research. Surprisingly, unlike Finland, Iceland's population is somewhat more heterogeneous in relation to the number and frequency of alleles. Nonetheless, it has been seen as a veritable 'gold mine' for the study of disease aetiology within a relatively homogenous population since it has very accurate records through which it is possible to trace ancestry.

Iceland is best known for its association with the deCode controversy (Rose 2001) that arose during the turn of the millennium when a private company was given monopoly rights to the use of national health records. The entrance of deCode onto the Icelandic scene was preceded, however, by other nationally funded research that had been going on for decades before deCode. One major example of this is the Icelandic Heart Association and its Reykjavik study which examined the causes of heart diseases within the capital region. The study began collecting samples already back in the 1950s. It was not until 1996 that it began doing genetic studies on its research participants. The Heart Association received some of its early funding from the National Institutes of Health (NIH) in the USA. Today, the Heart Association is a major collaborator with deCode and one might argue that the work that is done by the patient organization has had an impact and willingness of people to participate in later studies conducted by deCode.

Sample cold storage. Photo credit: Aaro Tupasela

The case of the Icelandic Health Sector database is perhaps the best known and first to attract major attention around the world. As Rose (2001, 5) has noted, what was being traded by giving deCode a 12 year monopoly over the health information of Icelanders was not nature itself, but information about nature. The Act on Biobanking that was passed in 2000 that gave deCode exclusive rights raised a number of sharp criticisms against the Icelandic government (Pálsson and Harðardóttir 2002). Not only had the government given a monopoly to a private company, but it had also failed, in the original version of the law to provide Icelanders the opportunity to opt-out of the database that was being used. As we already mentioned, the organization Mannvernd played an essential role in the controversy leading 10% of the population to choose to opt-out of the database (Mannvernd 2003). The majority of Icelanders, however, have chosen to participate in it, which reflects research results on the attitudes and acceptance rates of the general population towards biomedical research and biobanks (Árnason and Árnason 2004; Thorgeirsdottir 2004). DeCode sought, however, to set in place a research system in which people could trust and feel that they wanted to participate in.

It should be noted that deCode has had to go through a number of financial restructuring projects. The latest of which was at the beginning of 2013, when Amgen purchased deCode. Despite the restructuring, the ethical and legal framework that was put in place back when operations began still were in place preventing samples and data from being moved abroad. This, however, was not a problem for the acquisition for Amgen and it does not appear to have caused alarm among Icelanders.

DeCode was not the only start-up company in Iceland. Urdur Veldandi Skurd (UVS) was a privately held cancer research company operating in Iceland. Like deCode, it sought to make use of the Icelandic population and the healthcare system to collect data, recruit research subjects and develop novel therapies. In 2006, however, UVS was acquired by deCode. As one researcher in Iceland commented on the acquisition:

> *I think maybe their operation was too small to survive, because they didn't have the funds to invest in the infrastructure that was needed. And, but I mean the operation has been, the project is still ongoing here, and it's one of our more successful fields, the cancer. So actually the key people there that were interested in joining us were all offered to come here, and some of them are still here, some did not want, so..* (Interviewee, 2013)

Despite its financial difficulties, the work that was being carried out at UVS could, as a result of the acquisition, be continued at deCode. It should be noted that the work of UVS was also very reliant on cooperation with the local patient organisation. Despite its small size, Iceland has been able to accommodate one of the most famous genetics companies ever created and has managed to weather numerous difficult financial situations to produce a large amount of research results based on the Icelandic population.

Legislation

Biobanking in Iceland is regulated through the Biobanks Act, No 110/2000[2] and Regulation No 1146/2010, on the storage and utilization of biological samples in biobanks. The scope of the Act applies to the collection of biological samples, as well as their keeping, handling, utilisation and storage in biobanks. The Act does not cover the short term storage of samples which are collected for clinical testing, treatment, or for specific scientific studies. These samples must be destroyed when the tests, treatment or research are completed. Temporary storage has been defined as storage for up to five years, unless the National Bioethics Committee authorises a longer period. If the samples need to be stored or preserved for a longer period, they should be stored in a biobank.

The Icelandic legislation defines a biobank as a collection of biological samples which are permanently preserved. From a research perspective, however, this is problematic since using samples ultimately will lead to their destruction, while at the same time converting the biological material into data-based format. Biobank samples only have a finite number of times that they can be used before the sample material is exhausted. Research biobanks are defined as collections of research samples to be preserved for more than five years, while clinical biobanks are collections of clinical samples to be preserved for more than five years. The scope and purpose of the biobank legislation is to authorise the collection, keeping, handling and utilisation of human biological samples so that confidentiality is ensured, the interests of donors of biological samples are safeguarded and that the utilisation of the biological samples serves the purposes of science and medicine, and is conducive to the public good. The license to operate a biobank is issued by the Minister of Health. The responsible party for the biobank shall be responsible for the implementation of internal monitoring, and that security assessments are carried

[2] A legislative proposal for a new Act on Biomedical Research was put before Althingi in November 2013. Amendments to the Biobanks Act will be made simultaneously.

out regularly. The Data Protection Authority is charged with monitoring the security of personal data in biobanks, while the National Bioethics Committee oversees the activities of research biobanks. The Directorate of Health monitors the activities of clinical biobanks (NCBio 2014).

In acquiring samples informed consent is required if samples are collected for research purposes. As per international standards, the consent must be given freely and in writing after the donor of a biological sample has been given information regarding the objective of the sample collection, the benefits, risks associated with its collection, and that the biological sample will be permanently stored at a research biobank. Presumed consent may be used if the sample is stored in clinical biobank and the sample was originally collected for diagnostic purposes, provided that general information on this is provided by a healthcare professional or health institution. Sample donors are allowed to opt out at any time – but in the case of a biobank with clinical samples, the board of the biobank may, with the approval of the National Bioethics Committee and the Data Protection Authority, authorise the use of the sample if important interest are at stake. Interestingly, the biobank manager (licensee) is not considered to own the biological samples, but rather has right to dispose them under certain conditions set forth by the law. The biobank manager is also responsible for their proper handling so that it meets the provisions of this Act, and of government directives based on it. The licensee is not authorised to pass the biological samples on to another party, nor use them as collateral for financial liabilities, and they are not subject to attachment for debt (see NCBio, 2014 for an excellent overview of Icelandic legislation).

Although there was some controversy when the Act on Biobanking came into force, it appears that deCode has been seen as a national success story in Iceland. The law that was put in place has been seen by many as serving its purpose for the most part. One of the main points that were written into the law regarded the handling of samples and data from Icelanders. One interviewee discussed the conditions that are specified in the law concerning samples and data:

> *no samples will be leaving Iceland, the databank has by law and by the operating license to reside here. We are not allowed to transfer health information, we are not allowed to transfer individual level data, which we think is very good for us, because the operation cannot be transferred from Iceland to anywhere else. They will not have access to our data, they will have, see our results before they're published, that sort of.. We will continue with the same way of working, with the same projects.* (Interviewee, 2013)

This can be seen as way to increase trust and willingness to participate in biobank research since there is a high level of clarity as to how and in what ways samples and data are handled in Iceland. Also our research in Finland has showen that people are more willing to participate in national efforts and are scptical about samples and data going abroad. International cooperation does not guarantee that the benefit come back to own nation and national health (Tupasela and Snell 2012).

Engagement practices and social aspects related to biobanking

In this study we are looking at forms of engagement that relate to biobanking activities in a broader sense. This means that engagement does not have to denote an active process whereby biobankers or administrators seek actively to engage in public debate, discussion or consensus meetings over specific biobanking activities. Rather, engagement with populations and individuals can also be seen to take place through mundane practices, such as visits to the clinic, as well as the ways in which biobanking activities and regulations in and of themselves may engender forms of trust and reciprocity between actors. In addition, biobankers engage with a host of other actors, such as companies, venture capitalists and authorities in order to maintain the operations of biobanks and prevent the operation from going bankrupt (Tupasela and Stephens 2013). In this sense we can argue that biobanking itself is a form of governance through which daily practices in research, as well as in clinical treatment give rise to forms of interaction and trust building over time (cf. Hoeyer 2013).

One example of this relates to the ways in which biobanks as entities and biobanking practices sometimes come about. Although population scale biobanking has garnered a great deal of attention recently, many of these larger activities have grown out of much smaller efforts to study specific diseases. In a number of cases, studies have looked at specific families or smaller population isolates where the work of clinicians and researchers has perhaps been more intimate. One researcher noted this progression in an interview regarding Iceland when he said:

> *And in the beginning it was sort of family based, where we have many cases in the family. Now we are very much just recruiting everyone that has a specific diagnosis.* (Interviewee, 2013)

As the task of collecting more samples and people has increased, so has the form and style of engagement along

with it. With larger population sizes, the ability of people involved in research and clinical work changes in relation to the population that is being studied. In this sense, engagement practices should be seen as very context and practice specific. It also means that engagement practices are dynamic in that their original purpose may succumb to pressure to leverage their use for new, more ambitious uses, whereby new forms of engagement become necessary with new sets of actors.

When discussing the type of consent that deCode has with many of its research participants, one interviewee noted the following:

> *No, not all with broad consent, but over, I think it's about 120 000 totally, 105 000 that we have (chip typed), and a great majority in all diseases have a broad consent. So what we are more doing now is not recruiting new people but retrieving additional information. And when they sign the consent they also allow us to retrieve any relevant clinical data, of course the Ethics Committee has to approve the data. They allow us to re-contact them, and for quite many years it's stated that that re-contact can be based on a phenotype or on a genotype. So for example if we are interested in recruiting people that have or do not have a specific mutation for … we can do that. We will not reveal to them whether they have the mutation or not, but we will say, we will recruit so many people, half of them have the mutation, half does not, or 80 percent have the mutation (the other don't), because we are not allowed to give any feedback to them. But we can still recruit based on a genotype (-). Then they also allow us to, that we contact them to ask them to, ask their relatives, family members to come, and so on. And they allow us both to re-contact them for additional studies and also to answer questionnaires or come and get new samples and so on.* (Interviewee, 2013)

The above interview excerpt highlights the way in which engagement has been framed very clearly within the informed consent framework and that formal re-contact is based on the needs of the researcher. At the same time the legal framework also prohibits the researcher from providing any information regarding possible findings in the research. These clauses in the informed consent framework set very clear boundaries for what is expected and allowed among those who are involved in the biobanking process. It also has clear consequences in relation to what research subjects may expect to receive back from the studies, which in this case does not include any information on personal risks. while the return of results may have been framed in a different way when research was conducted at a smaller scale, such as in family studies, the scaling up of activities has meant that researchers seeking to set up a larger collection have been confronted with a new set of actors and problems with which they need to engage with. In many western countries, this form of engagement can be seen as being highly contractual in nature. This point regarding the contractual nature is further highlighted in the following interview excerpt:

> ***I:*** *Yeah, so, that will, when you give broad consent it means that you will be in some form of engagement with…*
> ***R:*** *Yeah, we can contact them, but they can always refuse, (--) but they, now it's really stated that they allow us to re-contact them, and then we do it by sending them a letter saying now we have a new study, do you want to participate, and they just say yes or no. And of course they can any time leave a study. We have less than ten that have left the whole studies, in the 16 we have been operating, so..* (Interviewee, 2013)

In discussion of what the researchers felt that they were able to give back as a result of their work, they discussed the significance of their work in relation to the translation of the research into practical benefits. One researcher noted that:

> *we are providing I think seven tests now, for, diagnostic purposes. Risk assessments that are CLIA certified and, so we can actually provide this genetic testing in the US through the health system there, and are doing so. (Interviewee, 2013)*

In some cases the legal framework that has been set up to govern the biobanking and research process was felt to be problematic in terms of return of individual research results to participants. In relation to engagement this is an important feature that many biobanks are dealing with; how to deal with incidental findings, as well as individual results in biobank research? For some participants in biobanking studies have shown that people's reason for participating was related to them being able to receive health information on themselves (Sihvo et al 2007, Snell *et al.* 2012; Meulenkamp *et al.* 2010). With the case of Iceland this is not allowed within the legal framework which some interviewees considered a hindrance and problem in terms of uptake of research results from biobank research:

> *so that is the obstacle when we feel that the health system is not ready yet to make use of what they should use, or what they could use, however you like to look at it. But of course, everything we publish can be translated into the diagnosis, and of course like for BRCA, it's used, all women in the US who can afford, they have a BRCA test.* (Interviewee, 2013)

This 'obstacle' should not be seen simply as a problem to the translation of research, but also as a trust building mechanism within the Icelandic society. As one researcher noted:

> *So I think the strict regulations that deCODE was set under and then the Heart Association followed, the (UVS) followed, were really improving a lot the conditions that we had. And I think the Bioethics Committee in general has functioned very well. There have been sometimes delays, big projects have been started and people want to go through very thoroughly and so on, but in principle I think it has worked quite well. It has been difficult for those that are working in the public sector to meet the requirements. Because I mean they feel the paperwork is heavy and so on, and..* (Interviewee, 2013)

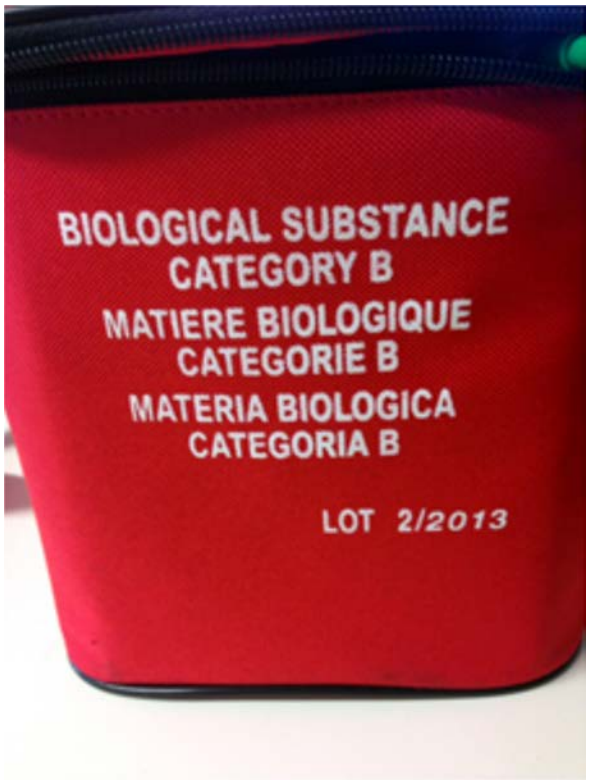
So within the context of the legislative framework in Iceland the law acts both as a type of hindrance in relation to bureaucracy, paperwork and limiting the return of incidental findings and individual research results to people, but it can also act as a mechanism that builds trust in the system itself by creating a formal system in which transactions and re-contact operate. The forms and object of engagement that biobank managers need to participate in do not only relate to research participants (with whom their engagement is limited through legislation), but rather a much larger and broader set of actors, including ethics committees, government authorities, as well as venture capitalists who may provide the financial backing for the operation.

Spain

Background and history of biobanking

The history of biobanks in Spain goes back to the 1980s. In 1985, the first collection of biological tissues was established in Barcelona, inside the Institute of Biological Research August Pí I Sunyer (Institut de Investigaciones biològiques August Pí i Sunyer, IDIBAPS). This first collection would not become a biobank until 2006, after the enactment of the new Biomedical Research Law (Ley de Investigación Biomédica, LIB). In Spain, as we will see in the section about the legal framework, collections and biobanks have different legal status. Until the enactment of the law, biological material would be organized in small and individual collections. Nevertheless, this does not mean that such collections were completely isolated. During the 1990s, Spain was a pioneer with the creation of the first biobank cooperative network. This biobanking model, has served as an example for many other countries when it comes to organizing a shared effort to face complex research designs, which requires critical mass. This pioneering cooperative project was named the National Network of Tumor Banks.

Field collection bag for samples. Photo credit: Aaro Tupasela



> *Then, we did not have easy access to samples. This led us to imagine and start some sort of collaboration network between different hospitals and we promoted and started what we then called the National Network of Tumor Banks in which we got to associate up to 20 hospitals in whole Spain with which we had a treatment of privilege, in the sense that when we needed some sort of sample we would request them and they would send them to us. That way we created what possibly was, and not only possibly, in my knowledge, the first experience of a cooperative network, definitely in Europe, but possibly in the world"* (Interviewee, 2014)

This network would later become the Spanish National Network of Biobanks, which was recently renamed as the Biobank Platform. It served as a guide for many international cooperative network models (Romeo Casabona *et al.* 2011). What made the Spanish case special was its open and cooperative character.

Another big temporal marker took place in 2007, when the Biomedical Research Law (Ley de Investigación Biomédica, LIB) was enacted. This changed the whole system. Since then, collections, in order to be recognized, need to be registered as biobanks. Therefore, collections are turned into biobanks all around Spain at the same time as new biobanks are founded. But in order to keep the collaborative frame going, the Instituto Carlos III began the National Network of Biobanks (Red Nacional de Biobancos, RNBB). This network has been helping with the initial stages of setting up many biobanks (as most of them were just reacting to the Biomedical Research Law). Since biobanking has become a bit more stabilized, and despite the economic problems, the RNBB has begun a new phase, marked by the name change to the Biobank Platform, where they will focus more on research and collaborative endeavors.

One of the first organizations to turn collections into biobanks was the Basque Biobank. This biobank is a network biobank that organizes and coordinates 9 different hospitals in the Basque Country turning them into a single entity considered a biobank. This kind of model is categorized in the LIB as a "network biobank". Because of its early creation (founded in 2003), this experience meant a very innovative approach in the Spanish context and was able to have a prominent role in the development of the LIB.

Currently, the Spanish national registry of biobanks, administered by the Instituto de Salud Carlos III contains listings for 90 biobanking entities[3]. Only collections registered in the biobank registry as such have the qualification of biobank. A study carried out by the National DNA Bank in 2005 (Romeo Casabona *et al.* 2011, 312), showed some interesting data. Geographical distribution of biobanks is quite irregular as 70% of the facilities are located in Madrid and Barcelona, the two biggest cities in the country. The oldest biobanks were hosted and created by hospitals and more than 90% of the total amount had been created from 2001 onwards. No new studies have been carried out since the implementation of the LIB.

One of the latest defining events for the Spanish biobanking industry was the rejection by the Spanish government to take part in the European biobanking network BBMRI because of disagreements in the representation system. Because of this, all the responsibility to take part in international activities is left to individual biobanks instead of being channeled through the RNBB. This makes the international projection of the Spanish biobanking sector difficult. Nevertheless, we can find some examples where a Spanish biobank is leading international research projects, such as the Biopool project, led by the Basque Biobank.

Another defining feature of the biobanking landscape in Spain is the financial crisis, which has been a big setback for the development of the sector. The amount of available funding coming from public institutions has decreased significantly to the point that many biobanks needed to be left out of the RNBB in terms of funding although the plan is for them to be incorporated later to the governing organism without receiving any extra funding for it (as the current 52 members do receive). A final important point to take into account is the fact that the first Spanish Bioethics Committee was not set up until 2008, as a consequence of the enactment of the LIB.

Legislation

In Spain, biobanking is regulated mainly by the Biomedical Research Law, which was enacted in 2007 (Ley 14/2007, de 3 de julio, de Investigación biomedical, LIB[4]). This was complemented by the Royal Decree 1716/2011[3], which establishes the basic requisits to authorize and run a biobank with the objective of biomedical research and the treatment of biological samples of human origin. The Royal Decree also regulates the functioning of the National Registry of Biobanks. As we discussed in the previous section, there are two different pathways for the collection of biological samples in Spain:

- Biobanks: a private or public establishment, non-profit organisation, which host a collection of biological samples conceived with the objective of diagnosing or doing biomedical research and organized as a technical unit with quality standards, order and end use. It also needs to be registered in the National Biobanks Registry.
- Sample collections: anything that does not fit the definition of biobank needs to be considered a collection of biological samples.

In the field of biobanking, a biological sample is defined as "any biological material of human origin that is susceptible to conservation and that may contain information about a person's genetic characteristics" (Art. 3, LIB). This excludes:

- Whole organs not susceptible to preservation while maintaining their structure, vascularization, and capacity to develop physiological functions with a significant degree of autonomy.
- Gametes (as they do not include an individual's complete genetic information)
- Human embryos and fetuses (nevertheless, cells and tissues extracted from them are considered samples)

For a biobank to receive authorization, at least three responsibility positions need to be fulfilled in the organizational chart of the biobank: a director/owner, a scientific director, and a file supervisor. The biobank is also required to be in constant contact with two different external bioethics committees: a scientific and an ethical one.

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3 A public list can be found at https://biobancos.isciii.es/ListadoBiobancos.aspx

4 The State Official Bulleting (BOE) which describes the enactment of the law can be found at https://www.boe.es/boe/dias/2007/07/04/pdfs/A28826-28848.pdf

Biobanks, depending on the internal organization and their projection, can be categorized in four different categories:

1. Hospital biobanks: biobanks associated to a hospital. This means that most of the collection and research activities are carried out inside the same institution.
2. Biobank networks: cooperative systems between different biobanks.
3. Network biobanks: biobanks that count as a single entity, but that have their samples and collection centers scattered among different geographical points (usually, different hospitals).
4. National banks: biobanks that have a national scope.

One of the controversial points in the biomedical law is related to informed consent. This point has been treated very carefully in the LIB in terms of what kind of information needs to be included in the document. So, any informed consent document needs to include, at least, the following information (Romeo Casabona *et al.* 2011):

1. Purpose of the research
2. Expected benefits (both for donor and society)
3. Potential inconveniences associated to the collection procedure
4. Identity of the person responsible for the research
5. Right to revoke the consent
6. Place where the analysis will be performed
7. Right to know the genetic information obtained from the analysis
8. Ensuring the confidentiality of the information by indicating the identity of individuals with access to the sample
9. Possibility of knowing information regarding their health from the genetic analysis and the right to choose whether or not to be given this information

If the sample is to be anonymized, only conditions 1, 2, 3 and 4 are necessary. Consent can be revoked at any time. In addition to the above 9 points, it is also appropriate to provide the following information:

1. the sample should be given freely
2. the subject does not have any economic rights on the sample
3. the source of financing for the research
4. Individual and family have the right to use the sample for health purposes
5. If the sample is preserved: conditions of its preservation, objectives, future uses, transfer to third parties and conditions for sample withdrawal.

Regarding the collection process, if the risk of an invasive procedure is considered to be high, the collection, and the consquente research, cannot take place at all. In case of the risk evaluation allowing the collection, invasive procedures must always be insured.

As for the ownership of the sample, this point is not clear within the law. What seems to be clear is that the donor waives all financial rights or other kind of rights derived from the results (Art. 7). Other than that, the law does not cover what happens to the sample in terms of ownership when it moves from one custodian to another.

In terms of anonymization, we can find three types of samples: a) biological samples associated with an identified person, b) biological samples associated with an identifiable person and, c) anonymous biological samples. When talking about privacy, there are some data which are more sensitive than other. High level measures of confidentiality to be applied with regard to ideology, union membership, religion, beliefs, racial origin, health, or sexual lifestyle (Art. 81.3).

Regarding feedback to the donor, there are three points to take into account: 1) the donor has the right to access general results of the research, 2) If the donor requests so, she will be informed about relevant health issues derived from the analysis of her samples, and 3) even when not especially relevant, the donor can still access the information.

The enactment of the LIB has provoked some consequences that have changed the landscape of biobanking in Spain. Mostly, it has forced many institutions to take a more stable and better defined legal form. In addition, the law has influenced the liberty of biobanks to interact with patients.

Engagement practices and social aspects related to biobanking

In the interviews with Spanish biobankers, it was interesting to see how the idea of engagement was developed. While most literature pays attention to the engagement with the public, and we did stress this point in our interviews, the conversation always turned towards other actors that also need to be engaged with, but are usually not considered in those terms. The list includes other biobanks, industry, doctors, clinicians, researchers, funding organizations, public administration and, of course, patients and donors.

Biobanks are rarely able to exist on their own. It is much more common to find them associated with other

biobanks and being part of a network. Such coexistance is more or less difficult, but it is, in any case, decisive for their survival. Engaging with one another and cooperating allows them to participate in larger research projects, which is sometimes difficult for an individual biobank. This kind of framework offers a very specific kind of sinergy that makes "one plus one be more than two" (Interviewee, 2014). Having biobanks working together allows for more complex strategies to achieve quality. This includes harmonization of data collection for all the members of the network. But once this is done, the capacity of the network to cover the necessities of researchers is increased greatly. But this is not only the pooling of samples, it is also a combination of efforts. They may set common goals and common strategies to pursue them.

Another necessary relation for biobanks is the one they hold with different sources of funding. This seems to be an especially relevant topic in Spain as the financial crisis has impacted greatly on the whole research sector, making biobanks very difficult to become sustainable economically. Charities, in comparison to other countries such as in the UK, do not play a role at all. Most funding comes from the public administration, but this seems to not be sufficient. Furthermore, sometimes the public administration does not have the time or the resources to even pay attention to biobanks that they have themselves helped to set up. The relationship is sometimes reduced to authorization and funding of the biobank. Therefore, many hopes are put in the private industry, although there seems to be many difficulties to engage with this sector. In other cases, as the one of the Basque Biobank, there is a successful relationship with the public administration. In this case, the public department of industry provides more support to the Basque Biobank than the health department. This already marks the orientation of the creation of the biobank, which is focused more at developing biotech industries that can render products than at interacting directly with health institutions.

Because of this funding issue and, as it happens in most of the other analyzed countries, the private/public dichotomy is always central to the discussion. Collaboration is not only necessary among biobanks but also with industry. To carry out activities, funding is necessary and the national organisations are not able to reach the required level of funding to utilize the potential of the collected samples. Lack of funding or disinterest from part of industry may lead to underuse of samples.

Despite the difficulty of engagement with industry, when it does takes place, the objectives are more shared than one would think:

> *Then, the difference, as you will well know, is that, one thing is a SME, a for-profit enterprise to distribute among associates and stockholders, but we are also for profit with that* ***know how*** *that we are investing, so to get more funding to be able to reinvest it. [...]. Logically, the interests are different but the strategy and the objectives are very similar.* (Interviewee, 2014)

As can be seen in the last fragment, biobanks also look for profit although their objectives are quite different from those of private companies. While companies are interested in creating profit to be shared among stakeholders, public biobanks look to create profit that can be reinvested in their own activity in order to keep developing as a biobank. This appears again as a way of solving the funding problem. If a biobank is able to produce money, it will be able to survive on its own. If not, it will always depend on public funding (not always available) or private funding (difficult to secure in a stable manner).

One interesting example of engagement with the private sector is the agreement between the Basque Biobank and some funeral homes. The Basque Biobank pays funeral homes in order to arrange the transportation of samples for the brain biobank. This shows how biobanks need to be creative in order to maximize efforts and resources in order to achieve high quality connections. This sort of engagement maximizes costs and it translates into an improvement of the samples to increase knowledge.

According to one of our interviewees, biobanks should aspire to be the most useful and rentable resource for the biomedical industry. The orientation of the biobanking sector in Spain seems to clearly lean towards the interaction with the private sector and that seems to be the future for the sector if it wants to achieve sustainability.

Another common way of looking for funding is through international engagement. Sustainability and globality are deeply intertwined in many cases and it seems difficult to achieve the former without the latter. The situation in Spain is now especially complicated as the central government refused to fund the entrance of the RNBB into the BBMRI. Therefore, the responsibility of international engagement has been left to individual biobanks. This way, Spain has lost its representation in the most important European biobanking association and international engagement has been seriously hindered.

Engagement with the public administration is not only relevant because of the funding possibilities. Another way of interacting with public administration is related to the the creation of the biobank law. Being able to engage with lawmakers, thanks to the expertise of biobankers, has made it much easier for biobanks to later adapt to the law. By helping to develop it, the law will be shaped more similarly to the way biobanks actually operate. If, on the other hand, the biobank needs to react to it, this means the biobank needs to adapt to it and carry out more changes.

This has been the case if we compare the Basque Biobank and IDIBAPS. Established in 2003, the Basque Biobank was able to lead and indicate the path for the development of the law, having therefore less problems to adapt to it. IDIBAPS, on the other hand, has been struggling to adapt to the new law when it was enacted. Being able to participate in the development of the law has probably made iteasier for the Basque Biobank to adapt to it as many points were developed inspired by the way the Basque Biobank was already working.

Sometimes, when paying attention to these more bureaucratic issues, it seems easy to lose focus on what are the primary objectives of a biobank. So that funding and those high quality collections can be properly used, biobanks also need to engage researchers in their plans. This proved to be difficult in the case of the RNBB as researchers are not used to the biobank format. They were not willing to share their samples and did not understand that that did not mean they were going to be taken by other researchers. Because of that, the RNBB had to spend several years teaching researchers what biobanks actually are. This opinion is shared also by the Basque Biobank, where they think they need to educate the researchers, as well as the clinicians.

One of the consequences of engaging clinicians is that they are in constant contact with patients. This is what we call mediated engagement, engaging one community allows to engage another one. This is important because engagement of the public is a very complicated process. It is highlighted as an important issue but the practices carried out by biobanks are scarce. For example, some of our interviewees expressed that privacy issues are not something to worry about. The main reasons given are that the data is not sensitive and that the security system is difficult to break. Still, one of the objectives mentioned included to not have any complaints from donors. One strategy to achieve this is to not interact directly with donors and leave that part to clinicians. For the biobank, that makes it much easier to preserve the identity of the patient and avoid privacy issues. So, in this case, the engagement is delegated to actors that are often external to the biobank. Still, interest was expressed in having donors and general society know what biobanks are, what their objectives are and how informed consent works. However, some of the biobanks admit that they have not done much to achieve this objective. Some planned strategies to engage donors, which would include making leaflets for waiting rooms in clinics, using media to reach them or having a website.

In general, engagement in Spain is an ongoing process. With most stakeholders, the process is still in a very young state, very far from reaching any sort of stability and, still further from achieving sustainability. Nevertheless, there is a strong conscience about it and the efforts to develop are as big as time and resources allow. There is a lot to be done but there seems to be the will to do it.

United Kingdom

Background and history of biobanking

In the UK, donation has traditionally been seen as a national altruistic practice. This vision, according to Busby (2006, 851), is a "distorted and highly truncated reading of Titmuss", which prioritizes the individualistic merit instead of a systemic one. According to Busby, such vision has also rendered antiquated in front of the irruption of new technologies as it does not fit very well with the new approaches to biobanking incarnated by projects such as the UK Biobank.

As Zika *et al.* (2010) explain, the UK has a strong publicly funded healthcare system which has potentiated the expansion of the biobanking sector in the country. Most such biobanks are small, but we can also find some larger projects. Some examples are Generation Scotland, the EPIC project on cancer and nutrition, the UK Women's Heart Study or the Twin Research Unit Laboratory. An especially interesting project is the UK DNA Banking Network (UDBN), funded by the MRC, and based in the University of Manchester. This is not so much a research project, but a biobanking infrastructure trying to offer scientists "a modern and efficient infrastructure for management of samples and data" (Zika *et al.* 2010, 53). Links are created between databases holding samples and data while the custodianship remains with the collectors.

Sample storage. Image credit: Aaro Tupasela

The history of biobanking in the UK is closely tied to the development of the UK Biobank which is the largest biobank in the country, and also one of the biggest in the world. This project has heavily conditioned the development of the biobanking sector in the UK. Of course, the biobanking scene existed before and smaller biobanks remain active and do a lot of work. Nevertheless, the entrance on scene of the UK Biobank significantly boosted the biobanking sector. The main result is that the topic started to get massive attention from social researchers and media. UK Biobank became integrated in the existing biobanking structure by filling a role that did not exist before. While smaller biobanks keep a narrower focus and are usually tied to hospitals or focused on specific diseases, the UK Biobank has a much broader focus, trying to cover an immense ground of biomedical research related to common diseases. The funding for the project was allocated in 2002, although the first stages towards the project happened in 1998, when the MRC received extra funding to establish a DNA collection (Busby 2006). The funding which came from the MRC, a government body, was combined with additional funding coming from the Wellcome Trust, a charity. Both institutions started conversations to develop a joint project in 1999 (Peterson 2005) and now have the responsibility for the direction of the biobank, while they receive advice from the Ethics and Governance Council, established expressly for the project. The combination of a public institution and a charity makes an interesting combination that conditions the main aims of the biobank. The first recruitment phase started in 2006. In 2012 the data and the samples started to be available for researchers under the condition that results needed to be made public, although not necessarily in an open access journal (Watts 2012).

There is also a private biobanking sector in UK, which is mainly associated to pharmaceutical companies. Although their collections are proprietary, it is difficult to gather information about them (Zika *et al.* 2010, 55; see also Lewis 2004). It is also worth mentioning the UK Cord Blood Bank which is a private enterprise that gives service to parents accross Europe wanting to store cord blood samples of their newborns. In this case, the parents retain proprietary rights on the samples. Because of ownership issues, research remains a marginal part of the company.

The UK has also had a very heated public debate on the ethical issues and consequences of research with human biological samples. A great part of the debate has been stirred by GeneWatch UK, a stakeholder group interested in the development of genetic technology. The group has accused UK Biobank of being based in false assumptions and of being a waste of public money (GeneWatch 2006). Some of the main issues raised by GeneWatch represent doubts about privacy and the use of samples and data for commercial purposes. To counteract these criticisms, one of the main strategies of UK Biobank has been the creation of public debate with different types of stakeholders (citizens, researchers, scientists, clinicians, industry, etc.) so all the interested parties get the chance to comment on the project. Also, the creation of the Ethical and Governance Council has been an attempt at responding to the criticisms. Public consultations were considered by some stakeholders as a "bolt-on activity to secure widespread support for the project rather than a genuine attempt to build a consensus on the project's aims and methods" (House of Commons Select Committee on Science and Technology 2003, 7, cited in Petersen 2005)

Legislation

In November 2004, the Human Tissue Act (HTA) was passed as a law but it would not come into force until the 1st of September of 2006. This Act meant "a compromise between the government's desire to put patients' consent at the heart of the legislation and the research lobby's requirements" (Busby 2006, 856). It was an answer to the previous law on the removal, retention, and use of human tissue, which contained many uncertainties (Zika *et al.* 2010). The new law was also highly motivated by a series of scandals about organ-retention in some hospitals of the UK. This made evident that the old regulations were not useful anymore. The enactment of the act established the Human Tissue Authority in the UK, which regulates research/medical use tissue banks. The Human Tissue Authority (HTA) was established under the HT Act and is sponsored by the Department of Health. This same authority has the responsibility of issuing licenses for research with human biological samples. The HTA needs to be seen in combination with the Data Protection Act, from 1998, which regulates privacy and data protection issues in the UK. This act is the application of the EU Directive 95/46/EC that deals with the protection of individuals and the processing of their personal data as well as the free movement of such data (Zika *et al.* 2010, 58). The HTA itself states that its main aim is "to set standards that are clear and reasonable, and in which both the public and professionals can have confidence"[5].

5 See http://www.hta.gov.uk/aboutus.cfm

So one of the first standards that need to be set is what type of material is considered "human tissue". For HTA this is "defined as material that has come from a human body and consists of, or includes, human cells"[6]. The basic definition of what is "relevant material" for the Human Tissue Act can be found in the Section 53:

1. In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells.
2. In this Act, references to relevant material from a human body do not include:
   a. embryos outside the human body, or
   b. hair and nail from the body of a living person.

This relevant material is then divided into four different categories:

1. Cell deposits and tissue sections on microscope slides (as they will probably contain whole cells)
2. Specifically identified relevant material
3. Processed material
4. Bodily waste products (including excretions and secretions)

As these definitions may be confusing, the HTA offers a list on its website with more specific examples of what "relevant material" is[7].

In the new law, informed consent becomes the fundamental principle behind its composition. According to the Act, consent needs to be given voluntarily, can only come from a person who has been properly informed and with the capacity to agree to the activity of donation. Having any human tissue, with the intention of its DNA being analysed and without the proper informed consent, it is considered an offence according to the Human Tissue Act. In the guide about informed consent issued by the HTA, they state that "appropriate consent is defined in terms of the person who may give consent. This is either the consent of the person concerned, their nominated representative or (in the absence of either of these) the consent of a person in a 'qualifying relationship' with them immediately before they died" (Human tissue Authority 2014, 8). The duration of the consent may be variable as expressed in the articles 37 and 38 of the Code of Practice. The donors have the capacity of setting a time limit or withdrawing their consent any given time. It is also advised to discuss this issue in the outset of the consent relationship.

The Law applies to England, Wales and Northern Ireland, while Scotland has its own Human Tissue Act, which was passed on 2006 and derives heavily in all its provisions from the one covering the rest of the United Kingdom.

Engagement practices and social aspects related to biobanking

Engagement was considered an essential activity for our interviewees in the UK. According to them, the sustainability of biobanks, the quality and amount of their samples, the funding, their capacity to produce good research, depends on their ability to engage with other social actors. In our interviews we have two examples, which represent individual biobanks and network biobanks. From the first category, we have the UK Biobank, which stands as the main example of a big and global biobank, and from the latter one, we have the Confederation of Cancer Biobanks (CCB) which is a network that allows smaller biobanks to be associated and facilitates collaboration.

In that sense, the first thing we noticed in our interviews is a tendency in biobanks to associate and collaborate with each other in the form of networks. These initiatives include often smaller biobanks, especially at the national level. Being part of a network from the beginning represents some an advantage as original members are able to give shape to the network so they do not need to adapt later on, which is what new members need to do, having sometimes difficulties to do so. Therefore, not all biobanks engage in the same way with the networks they belong to.

But UK seems to lack a proper national coordination body. While there are several biobank networks, these are usually focused on specific diseases (e.g. cancer). Such national coordination center, planned by the MRC, will also help in terms of global engagement, as it will act as the node for interaction with European structures such as the BBMRI-ERIC. The center would do similar tasks to those smaller disease based-networks and some of those as, for example, the CCB, could be absorbed by it.

One of the main advantages of belonging to a network springs from the possibility of cooperation. Communication and sharing of samples between biobanks is facilitated by a network infrastructure. Still, many biobanks are reticent to fully participate. The main issue is that networks make them more public, which is, in principle good, but presents a higher risk in terms of privacy due to issues related to the sharing of samples. This makes it more difficult for researchers to find proper samples for their projects. Because the main aim of a biobank network is to increase visibility, refusal to share would prevent them from joining the network.

It is because of this reason that networks usually have a set of standards that regulate and evaluate the activity of the members and the access of new ones. But not only that,

6 See http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm

7 List available at http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial/listofmaterialsconsideredtoberelevantmaterialunderthehumantissueact2004.cfm

also developing the standards is an activity that creates engagement and collaboration between biobanks as they work together to develop the standards. Standards also determine which biobanks will be part of the network. One of the challenges when developing them was to set them at the proper level. Setting the bar too high would leave many growing biobanks out while setting it up too low would make the biobank unattractive for more developed biobanks. Therefore, homogeneity in the working method among biobanks makes it easier for them to collaborate and to fulfill the potential needs of collection users. If the members do not share the same standards, it is easy to find more difficulties. But heterogeneity also has benefits. Having more experienced biobanks makes it much easier for smaller biobanks to develop and learn from them, further contributing to the development of the general biobanking scene of the country.

A large part of the know-how which helps to develop a good sample collection will also help engage with researchers. The success of a project is measured not only in terms of samples collected, but also in terms of samples used. It is at this point that engagement with scientists becomes especially relevant. The more the data is used and then sent back to the biobank, the more valuable the resource become. In addition, the more valuable the data is, the more researchers will want to use it. Because of this, it is important also that researchers acknowledge in their papers the contribution of the biobank, although this task seems not to be especially easy.

Another way of making data more valuable is by strengthening the interoperability between biobanks, so samples from different biobanks can be combined. One of the facilitations strategies in the CCB is a shared sample database. There, biobanks would make public their collections and other biobanks could find them and request them in case of need. Nevertheless, this is not easy as biobanks seems reticent to use this system.

But engagement between biobanks and researchers is not only beneficial for the biobanks. Being associated with a good biobank network with high standards may be useful for researchers when they are looking for funding. Therefore, developing high quality standards can also help to engage more researchers. Finally, another strategy to make data more valuable and, therefore, to engage more scientists, is to improve its quality through what is called "enhancements to the project". Incorporating more data from the same person and linking it to the previous data will increase the value of the resource. Re-engagement with donors seems to attract more resarchers therefore turning into an mediated engagement strategy.

Engagement with donors, as it has been mentioned several times before, has been one of the main worries for the biobanking sector. It seems that, because of the historical background of biobanking in the UK, they have a much more prominent position than in other countries. This may be because of the notable role played by charities and patients' associations in the UK. The objective of engaging patients and donors is quite clear: to get samples. Nevertheless, this task can often be difficult. As put by one of our interviewees, part of their task is "to capitalise on this goodwill and try and creat this (club type) feeling" (Interviewee, 2013). In order to do this, biobanks need to identify donor motivations, which seem to be a rather hard task:

> *But if we could bottle what motivates them, gosh. You'd have something you could sell for a million dollars, because actually, it is slightly different in everybody. Which is, there is that sense of.. of giving back, I think a lot of people, too. A lot of people said about having been treated, and feeling that they ought to, give something back.* (Interviewee, 2013)

One of the main motivations for a donor to engage is her/his connection to a certain disease. It seems that if one self or someone close has suffered from a disease, the motivation to collaborate would be higher. But even in those cases, automatic engagement is rather rare, it is necessary to go and get them. Websites, E-mails or traditional mail are the most common way to get in touch with people. But the balance between too much and enough information is also important. Donors do not want to know every detail, but it is useful that they know that things are proceeding (Snell *et al.* 2012). New technologies provide, not only a possible tool for engagement, but a compulsory one. More traditional engagement strategies include community meetings, where interactive activities with donors are carried out or posters hung in clinics in order to raise awareness. However, engagement with patients and donors is not only unidirectional, in the sense that the biobank emits information that may reach the public or not. A number of governance bodies in biobanks usually include at least one lay member, who takes part in all the decisions concerning the biobank.

All these strategies have two main objectives. One, as we have mentioned before, is to increase the motivation to donate. The second one is trust:

> *We need to be trustworthy. We can't afford to cock up. We can't afford to mess up, we can't afford to lose data. Because then we will lose participant trust. And the thing that we have, and we constantly remind ourselves, currently, is that trust. That's why we go to great lengths to respond to correspondence. I see a lot of correspondence. We write to people. I've written to thousands and thousands of participants about, their worries or concerns or, their support.* (Interviewee, 2013)

There is a strong feeling that trust is a delicate thing. Any faux pas and all the effort to keep donors and patients engaged could go to waste. Without trust, donors will not come and, with loss of trust, donors will not stay engaged (Tarkkala *et al.* 2015).

In this sense, it is also useful for biobanks to keep a good image through the media which, for example, has played a very big role in the development of the UK Biobank public image. Their role is that of secondary engagement agent, i.e. there is no final goal in engaging with media, but engaging with them allows biobanks to engage with other communities, especially with the public. The use of media allows mass engagement. The information is released to different agents and it is hoped that it will reach the target group but, still, it offers the possibility of reaching groups which were not thought to be important, but will still play a role in the development of biobanks. When our interviewees talk about media, they refer to quite a broad range of actors: television, radio, newspapers, websites, social networks or newsletters are some of the examples. Carrying out a successful engagement strategy with media was seen to facilitate the engagement with other stakeholders when approached directly.

Other stakeholders often relevant to biobanks are private companies. Contrary to what happens with public engagement, national policies rarely regulate the interaction between genetic research institutes and the private sector (Kerr 2003; Busby 2006). This is also the case in the biobanking sector. Still, even if policies do not often acknowledge this relationship, biobankers find it not only as something necessary but actually unavoidable. According to one of our interviewees, it is usual that people in academia have connection with industry. Therefore, this makes trying "to disentangle" those connections "in a piece of research" rather hard. But this does not need to be something negative as, in the end, what biobanks want to do is make the resource usable and not to waste "time or money with lawyers. Or trying to disentangle relationships and costs" (Interviewee, 2013). In this context, the public (here represented by academia) and the private collaboration are understood as one entity. This is not because they are the same kind of organization, but because by doing this, the complex landscape of engagement relationships with so many different stakeholders is simplified. By dealing with two different types of stakeholders as if they were one, the process is made simpler for biobank administrations.

In terms of funding, charities have historically played a central role in the history of biobanking in the UK. But engaging with charities not only brings funding to biobanking. Some of those charities focus on specific diseases and they tend to have their own researchers that are able to use the samples. Finally, being associated to a charity gives good commercial image to the biobank, as charities often have a good reputation.

Funding concerns always redirect to the common problem of sustainability, as we have seen already throughout the report. Usually, funding for biobanks is directed at covering a certain period of time. Even if there is no reason for the funding to stop, there is always some uncertainty. Given the fact that they mainly deal with public entities, it is hard to say what are the costs and benefits and often, the latter ones, have an intangible form. It is hoped, nevertheless, that the cost of activities, such as storing or retrieving samples, will become lower in the future. This should help biobanks to become sustainable without having to rely on public funding. Even if then it becomes relatively difficult to develop long term plans in the biobanking sector, it is necessary for biobanks to think of a business and a sustainability plan when founding a biobank. If the sustainability plan does not work efficiently, this may lead to the termination of a project.

A successful future in terms of sustainability necessarily passes through engaging with the international community. Biobanks in the UK look at Europe as an opportunity for European biobanks to collaborate and grow together, to become more competitive through collaboration. Engaging in international ventures will make samples and data more powerful, which will give the chance to have bigger numbers, better analyses and study rarer conditions. The international biobanking scene should have a collaborative character instead of a competitive one. But globality also entails certain problems. It is difficult to coordinate networks that are horizontal and vertical. Therefore, sometimes it is difficult for biobanks to find their place in these international networks and establish upon whom to rely on a certain coordination responsibility. Also, keeping a local or even national entity connected and active in the international community has a cost in terms of time and resources. Sometimes, given the small size of many biobanks in terms of staff, they do not have the time to carry out their daily duties and engage in international ventures.

Biobanks in the UK seem to be well positioned in terms of engagement. They usually have good relationships with charities and public administration. This seems to give them some stability and also independency from private interests. They carry public engagement events when possible and tend to have lay people inside governmental boards. It is not a surprise that being one of the leading countries in biobanking also entails a successful and efficient engagement strategy.

USA

Background and history of biobanking

The inclusion of the US in this report is based on a number of factors which make it of significance for a broader analysis and understanding of global biobanking, engagement and sustainability. Some have argued that much of the European knowledge-based bio-economy (KBBE) and sustainability policy discourse is based on the developments that took place in the US in relation to biotechnology (cf. European Commission 2005). As Gottweis (1998, 157) has noted, "the idea that the industrial application of genetic engineering would lead to the establishment of a new industry, the biotech industry, was born in the United States." Although Europe developed similar biotechnology engineering programs dating back to the 1980s it is not until after the turn of the millenium that biobanks begin the gain momentum as an organizing principle in the US and Europe on the policy level. In addition, much of the discussions surrounding commercialisation of academic research stems from developments that took place in the US during the 1980 (Boyle 1996). Within this context, the role of tissue collections, the acquisition, storage and distribution has come to play an important role for the development and expectations associated with biomedical research in the US, and subsequently elsewhere.

Although the use of human tissue in biomedical research is not in itself new, some commentators have argued that recent biomedical research practices using tissue sample collections constitute a new object of study within biomedical research (Strong 2000). The US Navy, for example, developed one of its first tissue banks in 1949 to help orthopaedic surgery during that period (Strong 2000) and several commentators have noted that some institutions have archived specimens that are more than 100 years old (Eisemann and Haga 1999). Despite their long history in the US, and elsewhere, the recent push to harness the contents of biobanks into translational research has placed increased attention on their role in biomedical research. It is not until the late 1990s that interests in biobankings begin to emerge in the US in any systematic fashion.

One study has suggested that by the turn of the millenium there were approximately over 300 million biospecimens in the US in both public and private institutions (Eisemann and Haga 1999). According to Maschke (2008, 12), due to the lack of comprehensive regulations in the US concerning the collection, storage and use of tissue samples, there is a confusion about the application and interpretations regarding the laws on research with humans in relation to biospecimens and related data. As a consequence, there has emerged a large body of literature in the US in relation to responsible research and best practices regarding biobanking (see National Cancer Institute 2007). In addition, there have been a number of landmark court cases in which the rights of patients and research subjects have been tested in relation to the use of said samples and information (Hardcastle 2007; Boyle 1996).

In their organisational study of US biobanks, Boyer et al. (2012, 511) identified five general types of biobanks: commercial biobanks, university-based collections, small collections created by individuals or groups, government funded or facilitated collections, and non-profit disease advocacy organisations. Noting that since there is no common definition of what a biobank is, the possibilities of surveying them can be challenging. Despite these limitations they identified 624 biobanks that operated in the US.

A major feature underlining the legitimacy and sustainability of biobanking in the US and concomitant biomedical research rests, however, on the importance of community engagement in relation to population research in general. The history of medical research in the US, particularly as it applies to minorities and vulnerable populations has been marked by major controversies in which individuals and whole groups of people have been mistreated in the course of medical research. Although falling under the more general category of medical research, as opposed to biobanking specifically, the experiences and outcomes of the investigations into these wrongdoings have provided heightened attention to the conditions and regulatory framings in which biobanking in the US operates today. Another salient feature of the US market in bodily tissues relates to its strong emphasis on free markets and the private commercial sector in pushing development (Schepher-Hughes and Wacquant 2002).

Legislation

Although there is no specific set of legislations governing biobanks in the US, the activities related to biobanking and research are governed by a set of laws on related matters such as medical research, informed consent (Deschenes *et al.* 2001), privacy, (OHRP 2004; Lin *et al.* 2004; Annas *et al.* 1995) as well as guidelines concerning the collection and use of biological materials (NBAC 1999). There are a number of Acts that have significant bearing on the way genetic information may be used, such as The Genetic Privacy and Nondiscrimination Act of 1995 (S. 1416 and H.R. 2690, as well as The Medical Records Confidentiality Act of 1995 (S. 1360). In addition a number of organisations have drafted documents which provide guidelines for those conducting research using human tissue samples, such as the Ethical, Legal and Social Implications Working Group of the National Center for Human Genome Research (Grizzle *et al.* 1999; Clayton *et al.* 1995).

A major guiding document in the US has been the Belmont Report (1979) which "is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects." The report is the outcome of the the National Research Act (Pub. L. 93-348) which was signed into law in 1974 which called for the setting up of National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission was charged with exploring various ethical issues, which related to research on human subjects and one of its earliest major contributions to this area was the publication of the Belmont Report.

The regulation of the biomedical collection, storage and use of tissue samples in the US is confounded in many ways by the fact that practices are governed and judged at both the state and federal levels. In relation to the biomedical use of human tissue sample collections, there has emerged a large body of literature and case law in the US that has explored the role of patients, as well as citizens and their rights over samples that have been taken from them (cf. Boyle 1996). As a result, much of the practices, interpretations and understanding in the US related to biobanking and biomedical research using human tissue samples is based on cases in which the merits of various positions are argued through the court system; first at the state level and then through the appeals process which can ultimately lead to the federal level. In the following we will cover some of the major cases that have taken place in the US that have a bearing on biobanking practices either indirectly or directly in the US.

Moore v Regents of the University of California

The case of John Moore, who began treatment for his leukaemia in 1976 at the University of California Medical Center, has been one such landmark case. The doctors treating Moore realized very early on that his particular type of leukaemia and the products that they could produce resulting from it were commercially very valuable. Over the years that Moore received treatment, his doctors collected numerous tissue samples from his body including the removal of his spleen. In 1981 the doctors were able to establish a cell line and consequently the University of California proceeded to patent Moore's T-lymphocytes, whereby his doctors were listed as inventors (see Boyle 1996, 22). Moore felt that he had certain rights to the samples that had been removed from him and proceeded to take legal action against the university.

The significance of the case is reflected in the ensuing US Supreme Court decision whereby it was ruled that Moore did not have property rights in the cells and genetic information that had been removed from his body. The court argued, among other things, that by agreeing to take part in treatment and provide samples, Moore had 'abandoned' his cells. Another major argument put forward by the courts was that the provision of property rights in bodily fragments would in due course hinder scientific research in such a way that it would become prohibitively expensive in the future (see Moore v. The Regents of the University of California 1990).

Greenberg v Miami Children's Hospital

The case in question involved the parents of a child affected by a rare disease called Canavan disease and the researchers and hospital which were involved in finding the genetic causes behind the conditions and subsequent development of a genetic test. The parents had been very active in finding other families affected by the condition and then recruiting them to participate in the research by donating familial information and samples so that a test could be developed. With the assistance of the parents the researchers were able to identify the gene associated with the condition and subsequently sought to patent it and restrict access to it.

The parents felt that the doctor and the hospital had breached their agreement by patenting the mutation and restricting access to it by others, a goal which the parents had held as crucial to their recruitment of other parents and acquisition of research funding. Following the Moore case The Federal District Court of Florida ruled that the donors had no property rights once donation had occurred (Hardcastle 2007). The ruling drew heavily on the language and arguments that had been laid out in the Supreme Court decision made concerning Moore and his cells. Although

the case did not go further in the US court system due to an out of court settlement, it also highlights the legal status of tissue sample in the US once they have been donated.

Washington University v Catalona

The final case we want to highlight relates to the legal status and ownership rights of Washington University and the GU Biorepository collection which had been built and developed to study prostate cancer. The GU Biorepository had samples from approximately 30 000 research participants who had been enrolled in medical research and who were referred to as 'research participants'. The doctor who had been most involved in setting up the collection and had been involved in the treatment of many of the patients moved to a new position at a different hospital and contacted the research participants for permission to transfer their samples to the new institution; over 6000 of the participants consented to this. Washington University objected to this noting that they had property rights to the collection and that the research participants could not decide how the samples would be used and whether the rights could be transferred to another institution (Hardcastle 2007). In the ruling the judge ruled in favour of Washington University noting that if participants could move their samples from one institution to another the integrity of biorepositories would be in serious peril.

Although the first two cases above relate to issues of ownership relating to human tissue samples and subsequent research, and not specifically to biobanking per se, the court cases highlight the process through which rights and duties are negotiated within the US system, as well as the values and expectations that are assigned to researchers and research participants when samples are procured through donation.

Engagement practices and social aspects related to biobanking

As mentioned above, although there is no set of specific legislation governing biobanking in the US, there nonetheless exists a number of policy documents and general guidelines on a multitude of issues which provide ethical guidelines and frameworks for operations related to biobanking, such as informed consent. In relation to the notion of engagement, which we have been exploring in relation to biobanking a seminal text is the text "Principles of Community Engagement" (CDC 2011) that was first published by the Centers for Disease Control in 1997. According to the CDC, community engagement is grounded in the principles of community organization: fairness, justice, empowerment, participation, and self-determination.

According to the CDC the principles of community engagement are founded upon,

> *…the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people It is a powerful vehicle for bringing about environmental and behavioral changes that will improve the health of the community and its members It often involves partnerships and coalitions that help mobilize resources and influence systems, change relationships among partners, and serve as catalysts for changing policies, programs, and practices.* (CDC 1997, 9)

The idea behind community engagement is that the uptake and success of interventions is based primarily on the social conditions in which interventions are implemented and practiced. As a consequence it is believed that through community engagement the impact and benefits of any research and possible interventions will be greatly improved. A large number of surveys, focus groups and engagement activities have been performed in relation to many US biobanks to understand the expectations and motivations of biobank participants and their relatives (Kaufman *et al.* 2008; Halverson and Friedman Ross 2012; Brothers *et al.* 2011)

Much of the ideas surrounding community engagement in medical research are an outcome of the sometime problematic experiences that many groups of people – especially minorities – have experienced at the hand of medical research in the US. Some examples of these include the Tuskeegee study of untreated syphilis in the black males where treatment was withheld from men who were afflicted with syphilis (Epstein 2007). A similar study has come to light that took place in Guatemala between 1946 and 1948 where US doctors deliberately infected people with sexually transmitted diseases. According to a US study on the issue "subjects were exposed to syphilis, gonorrhea, and chancroid, and included prisoners, soldiers from several parts of the army, patients in a state-run psychiatric hospital, and commercial sex workers" (Presidential Commission for the Study of Bioethical Issues 2011, 2). Such tragedies have led over the years towards policies which emphasise transparency, accountability, as well as ongoing community engagement with those communities that researchers have sought to study.

Putting aside the scandals that have helped to shape policies in the US that emphasise community engagement, a number of recent developments surrounding the decreased costs of genomic tests need to be examined to understand some of the more important changes that have been taking place within the commercial sector. During the

past decade there have emerged a multitude of companies offering personal genetic testing services to consumers (Hogarth *et al.* 2008). Based on the idea that genetic tests are becoming more accurate and information and understanding about the role and function in genes in predicting disease has improved greatly, a number of commercial companies have sought to provide services to consumers who are interested in such services.

One of the most notable US-based companies has been 23andMe (www.23andme.com) which offers a genetic test that can be ordered online. Customers are sent a test kit where they are asked to provide a sample of saliva and send it back to the company. A few weeks later the customer will be notified of their test results, which they can view online. The service also provides a number of other services, such as genetic ancestry and drug response results, as well as the possibility of linking up with possible genetic relatives who have taken the test as well. The purpose of these online tests is not to provide consumers with clinical tests or diagnostics, but rather the test is intended for research and educational purposes only (Lee 2013).

What makes the services provided by 23andMe of interest is the style and form of engagement they articulate in attracting customers to purchase their services. Much of the online service is geared towards developing an online community through which customers can discuss questions, gain support and meet others who might have similar conditions. The site provides a similar experience to that of Patients like me (www.patientslikeme.com) which provides an online peer support network for people who are seeking support from others with the same medical conditions as themselves. Recently, however, the FDA has prevented 23andMe from continuing to provide its services under its current remit, noting that its services are considered diagnostic in nature, but the validity of their findings have not been sufficiently validated. The FDA has been concerned that the consumer is being mislead as to the trustworthiness of the information. Interestingly, 23AndMe has simply moved its service provisions to other countries where the regulatory landscape has not yet prevented it from offering its services.

Finland

Background and history of biobanking

Finland has a long tradition in collecting biological samples and connected lifestyle and health information for research purposes. Large collections from population research done at the National Institute of Health and Welfare (THL), diagnostics samples in hospitals, and samples from different research projects conducted at the universities form a basis of Finnish tissue collections. The Finnish biobanking sector has been regarded as a national asset because of these long traditions, and also because of a relatively homogeneous population, positive attitudes towards science, possibilities in combining register data and the existence of personal social security number (Carpén and Launis 2014, Kallioniemi *et al.* 1020).

Finland has been conducting research into national health risk factors since the 1950s and collecting DNA-samples for such purposes since the beginning of 1980s (Aromaa *et al.* 2002, 7; see also Anttonen *et al.* 2004). The research has produced a wealth of tissue samples in different form, as well as important information on health risks in the Finnish population. In the European context, Finnish collections have gained importance in that they are of high standard and have been conducted on a number of important common diseases, such as diabetes and heart disease and that unlike more notable efforts, such as the UK Biobank, these collections already exist and have been followed meticulously over the years through longitudinal studies, especially at the National Institute of Health and Welfare.

Automated sample handling and processing. Photo credit: Aaro Tupasela

According to a study in 2004 funded by the Finnish National Technology Agency Tekes, Finland had over 190 000 samples within ten of its most significant epidemiological cohort studies (Technomedicum 2004). This represents about 3.6% of the country's population, which in comparison to the UK Biobank's 500 000 samples from a population of over 60 million represents only under 1% sample of the population. According to the report, these samples and the related health information could be used far more efficiently in the study of the human genome, diseases, as well in the development of pharmaceuticals and treatment. The report also sees genome research as uniting science and industry in a way that will give Finland an edge over similar competing projects elsewhere in the world. In addition to the epidemiological cohort collections, Finland has pathology collections that amount to well over 2 million samples. These sample collections are used routinely in medical practice for teaching and research, as well as for comparative purposes if patients are re-diagnosed with a new condition. Together these sample collections are seen by both researchers and policy makers as a significant national resource that should be organised to facilitate the development of new innovations and scientific discoveries (see Academy of Finland 2003, TEM 2014).

Some notable examples of important population based studies include Finrisk -97, -02, -07 and -12 that has looked especially at cardiovascular disease and is made up of over 15 000 samples with informed consent; the Finnish twin cohort study has over 170 000 samples of twin pairs and the Northern Finland cohort has 20 000 samples with informed consent. All studies include carefully documented lifestyle information that can be compared and utilised in new studies as well. The importance of these studies has increased in that, not only can they be used to study other diseases than what they were originally collected for, but they can also be combined with other similar studies to gain a larger population sample, either within Finland or internationally.

Legislation

The last couple of years have, however, created a new situation for biobank research in Finland. A new Biobank Act (Act 688/2012) came to force in September 2013. The act is one of its kind in Europe as it regulates directly and only biobanks of all types – from population to clinical and disease based biobanks and public as well as private biobanks (Soini 2013). The Biobank Act defines criteria for biobanking and its passing has resulted in a situation where all research infrastructures that called themselves biobanks prior to the enactment of the Biobank Act have to apply for permit to function as a biobank as defined by the act. This has created lots of activities in the field and most old tissue collections will be or have already started the process of transferring to biobanks.

The two first biobanks – as defined in the act – got their permissions to start operation in early 2014 from Valvira, the National Supervisory Authority for Health and Welfare that supervises biobanks. Before Valvira's authorisation, the biobanks have to first get an ethical approval from TUKIJA, The National Committee on Medical Research Ethics. The first two new biobanks are Auria Biobank (a clinical biobank in the Turku area) and THL Biobank (a national population-based biobank, to which it transfers its major longitudinal cohorts). Auria Biobank's goal is to get new samples from every patient enrolled in the hospital. During the retrieval of a diagnostic sample a surplus sample will be given to the biobank after receiving consent from the patient. In addition it is transferring old sample collections of the hospitals as well as research project samples to the biobank. About 80% of the samples in Auria Biobank are cancer samples. Other biobanks that have already gotten TUKIJA's approval are Helsinki Urological Biobank (HUB) and Finnish Hematology Register and Biobank (FHRB). These two biobanks are dedicated to specific disease groups (urological diseases and haematological diseases) and both have a strong orientation towards combining research and care. Academic Medical Center Helsinki Biobank (AMCH) - which is a clinical biobank of the Helsinki area - has submitted its application to TUKIJA. AMCH differs from Auria, as it does not aim at such a comprehensive recruitment, but it is basically a similar clinical biobank that has close links to the local university. HUB will be merged to AMCH in the future. It is important t note that changes in the biobank structures, host organisations and actors behind the biobanks can have a considerable effect on public opinion (Snell *et al.* 2012). In the planning stages there are at least four other biobanks located in different parts of Finland: Tampere, Kuopio, Central Finland and Northern Finland.

Another important player in Finnish biobanking is the BBMRI.fi network. The network is one of the daughter networks of the European BBMRI. The goal of the BBMRI.fi is to enhance cooperation between Finnish biobanks and linking them to their European counterparts. The network is also aiming at developing a cooperation and discussion forum between biobank actors, financiers, state administration and research subjects/citizens.

The new legislation is in many ways in key position in defining the functioning and future of Finnish biobanking. The Biobank Act had been in preparation already since 2007, and was finally passed by the parliament in spring 2013. Some of the arguments for drafting the Biobank Act were based on securing the use of samples by defining consent practices, enhancing the quality of samples and making the sample collections more attractive for commercial

use (Kere 2007). The drafting process was long and complicated with two governments, disagreements with the content and a belief that the system was working already rather well (see Kääriäinen 2009).

> *We started with biobank issues rather late. We have a lot and only now the legislation is coming. In Sweden they have had for long. But we have a strong tradition in clinical research and these bio centres that have cooperated… long tradition in research in genetics, population samples in THL, lots of contacts… I think we are doing well even though we had a late start, because of the old working systems.* (Interviewee, 2013)

The passing of the act was received mainly positively by the actors involved with biobanking because this meant that they could finally proceed with biobanking activities without wondering whether their activities will comply with the legislation. Even though after the passing of the law the main question is how the act will be interpreted by biobanks and civil servants in Ministry of Social Affairs and Health and Valvira. Biobank staff interviewed described the situation:

> *Drama.. And here we don't know at all how it will go, for example what kind of decree it will be about the consent… But when the act was heavily criticised, we were the only ones that went to the Ministry and said that we don't see any problems in it.* (Interviewee, 2013)
>
> *We have got stuck in it, that first it took so long to get the act, and they assigned the steering group, and the working group of civil servants that should give the recommendations, the statues and possible recommendations. So we cannot do very much. We cannot say that let's do this kind of consent forms because we have to wait that the working group would say what they will require.* (Interviewee, 2013)

Not all were happy with the content and formulations in the act and how difficult the implementation period seemed to be. Many concrete parts of the act have received criticism (i.e. returning of research results, neglection of the idea of combining research and care), but the main target of disapproval was the complexity of the Act and uncertainty of how the Act should be interpreted. Some still questioned whether it is a relevant act at all – especially in relation to population and cohort based biobanks.

> *It is of course the act and how the act is interpreted. For example how far the control of the consent goes for example. Can the person deny the use of his samples in an ongoing research project …* (Interviewee, 2013)
>
> *When I looked at the first version [of the Act], and I said that we don't need this kind of act at all. I thought it was totally unnecessary, and still almost do. It's a kind of a "me too" legislation. Because everyone else has a biobank act we had to have one too... But perhaps it is needed today. Because it seems that everyone is fixated on the idea that you can't ask for a broad consent without that biobank act. And let it be so then.* (Interviewee, 2013)

During the preparation process the act draft was commented on two occasions (2007 and 2010) by the stakeholders and finally also discussed in the parliament, but the law and biobanks in general have created very little public discussion. The enforcement of the Act and the establishment of the first two biobanks have created some media attention though, which has been mainly positive. Some of the biobank actors have hailed the Act on Biobanks as the "best biobank law in the world" that enables research and secures the position of sample donors through wide consent and good control by the authorities. The act is also seen as a means to enhance public trust towards biobanking.

> *And it [the Biobank Act] clearly, definitely increases trust because we have this legal frame and a specific model of operation that is being controlled. And it is good that there will be quality standards for specimen and information and of course information security and all… What is bad, is that the law is very complicated.* (Interviewee, 2013)

Our study findings seem to suggest that the biobanking community in Finland, draws a great deal of legitimacy and authority from official legislation in relation to their operations. Unlike the UK, where legitimacy and trust was drawn from extensive public consultation and engagement, trust in Finland tends to operate through somewhat different channels.

Engagement practices and social aspects related to biobanking

The Biobank Act serves also as an official basis for the engagement practices of biobanks and has in many other respects a large role in defining the governance of biobank research. The Act has some specific requirements for biobanks dealing with engagement of the public or donors, but it is worth to note that public engagement in the law is perceived more or less synonymous with informed consent. The Act states that all biobank research is based on informed consent. The consent has been defined as wide but the participants can cancel their consent, or make restrictions to it.

The informed consent was seen as a cornerstone of biobanks also in our interviews. First, broad consent backed

by the legislation enables the operation of biobanks and the use of tissue samples and information. Without samples and related information, biobanking would not be possible. Second, it serves as a legitimation for action. If consent procedure has been done correctly, the samples and information can be used for research purposes.

> *I personally think that if it is explained well and you go through the consent process, that it would be strange the something couldn't be done.* (Interviewee, 2013)

Third, consent can be perceived as a way to inform people about where they are possibly participating. A general view among our interviewees was that Finnish people do usually give their consent and if the consent is clear enough and participation is made easy there are rarely any problems afterwards i.e. withdrawing the consent.

> *When the people show up, there is the question if they show up. so When they show up, they agree to almost anything.* (Interviewee, 2013)

Consent can be seen as a form of contract for the use of participants' samples and information. Sometimes it was also regarded as a possibility for face to-face contact that brings people closer to the research. This view was supported by researchers who are heavily involved also in clinical work and encounter patients on weekly basis. They also tend to see participants more as stakeholders than people only involved with the research side of biobanks.

The act has been on one hand criticized by some because it focuses more on the operation logic of population biobanks than on clinical or disease specific biobanks. On the other hand, the passage dealing with returning of research results is seen to be very problematic from the viewpoint of population or cohort biobanks. The act states that all biobank research is based on informed consent. The consent has been defined as broad but the participants can cancel their consent, or make restrictions it. The participants have according to the act also the right to get information about where their samples and information are being stored, where it has been gathered from and for what purposes they have been used and in addition the participants have a right to ask information determined about their health, and also the meaning of such information.

The insufficiency of informed consent as the only form of engagement or the suitable engagement for biobanking became also apparent. The consent model for biobanks is wide, and as it covers such a vast amount of research. Relying on consent can also weaken the other types of engagement practices. Other actions are needed and the most prominent in Finnish interviews was the need for communication and public relations.

> *I have been thinking that as the consent is so broad and vague, we have to have, our operation ends that day when the trust of citizens runs out, or the willingness to support this activity. We have to communicate with them. We have to have this kind of active communications.* (Interviewee, 2013)
>
> *The meaning is, it really is, that we have some person all the time at the end of a phone line. If for example people can take contact and ask whatever issues. And the aim is to transparently inform all the time, where we are going and what we are doing.* (Interviewee, 2013)

One of the most notable ways of enhancing public acceptance or knowledge is seen to be good communication. Many of those interviewed stressed the importance of developing a communication strategy or otherwise being active in communication. Others pondered the timing of communication in order not to create too many expectations. The AMCH biobank has chosen not to be active in communication before it receives the final approval from Valvira to start the operation.

Auria has been forerunner in many issues. It has also been active in developing many types of communication and media schemes. They have hired a consultant firm to deal with public relations and communication. Auria Biobank has developed a game about biobanks to involve young people and has been active in arranging public lectures about biobanking. They have also made a deal with Taltioni – a platform service provider – through which Auria and the hospital district aim to communicate with the patients and biobank participants. Participants can follow through the service:

> *"how your biobanks samples are used in biobank research. You will receive information on the research of your sample, research results and on whther you can expect personal health benefots from the research"* (www.auriabiopankki.fi)

This is in lain with the Biobank Act where it is stated that the participants have a right to ask information determined about their health, and also the meaning of such information. The Act was heavily criticized by some because it focuses more on the operation logic of population biobanks than on clinical or disease specific biobanks, but the passage dealing with returning of research results is seen to be very problematic from the viewpoint of population or cohort biobanks. The passage transforms the one dimensional engagement of people that is visible in the other parts of the Act – providing samples and information to unspecified research that potentially benefits the population as a whole – to engagement where personal information to the participant should be provided on request of the participant. The criticism of returing research results to participants has been based on two main arguments. First,

population biobanks do not use clinical standards in their analysis. Therefore the results are not reliable from the viewpoint of an individual. Second, population biobanks do not have a channel through which the information would be given to the individual. Interentingly, in the drafting process the Act was criticised particularly by those involved with disease based and clinical biobanks, because it was unclear whether the biobanks had a right to inform their participants (and in this case the patients) about their individual research results.

> *But the biobank law does not say that is will come back to care, instead in my opinion it prohibits it. It is a biobank as a biobank, they have thought about creating preconditions for research… it has been seen as a closed bucket for research.* (Interviewee, 2013)

Another aspect that has been heavily criticised in the Act on Biobanks, especially by hospital biobanks and biobanks aiming at translation of research result is that the Act does not take a strong enough stance on how to combine research and care.

> *We are of course ready to bring the information to patients care. That has been the big problem that translational medicine is trying to repair, that research and care are so far from each other at the moment. They should be brought closer to each other so that results can be used as fast as possible in patient care.* (Interviewee, 2013)

The aspect of translation and how research and care can be combined has however become an acute polcy question for esample through the drafting of the national genome strategy. Engagement with different stakeholders seems to be in many ways even more important than engagement with the public. This type of engagement is not discussed as much in the literature or in the web pages of the biobanks for example, but it is crucial for the operation of biobanks. Engagement of different stakeholders is extremely important especially in the phase where a new biobank is being constructed. For example Auria has already signed contracts with many industrial partners. Other important stakeholders include the regulatory authorities and other biobanks. The Finnish biobanks have been actively networking to form unifed standards and operation practices to ensure usability of samples and data. Especially in the establsishment of the new biobanks good connections to Valvira and TUKIJA – the regulatory authorities – have been essential. The relationships are also important in the phase were both the Biobank Act and biobank practices are being implemented.

Canada

Background and history of biobanking

There are dozens of biobanks in Canada ranging from disease based to population biobanks. According to an estimate of Canadian Tumor Repository Network, there are about 10 000 collections of samples in Canada of which most are only for single purposes for only the use of one researcher or research group and around 80 large-scale biobanks with multiple users and uses of the data and samples (CTRNet 2013). Two of the most notable efforts in recent years have been in the field of population biobanks: the launching of Canadian Longitudinal Study of Ageing (CLSA) and Canadian Partnership for Tomorrow Project (CPTP). CLSA states its goal is "to mobilize experts in the community to generate the scientific content for a longitudinal research platform that will enable interdisciplinary, population-based research and evidence-based decision-making that will lead to better health and quality of life for Canadians." There are currently about 50 000 participants in the Study with 30 000 participating in "CLSA Comprehensive" where they provide more comprehensive health and lifestyle information and have the option also to donate a blood sample. Canadian Partnership for Tomorrow Project (CPTP) is a multimillion dollar research platform with currently almost 300 000 participants from different parts of Canada largely funded by the Canadian Partnership Against Cancer. The core of the platform is comprised of five regional biobanks: CARTaGENE (Quebec), Ontario Health Study (Ontario), Tomorrow Project (Alberta), Atlantic Path (Atlantic provinces), and BC Generations Project (British Columbia). In this report the main emphasis is on two of these: CARTaGENE and The Tomorrow Project.

CARTaGENE is a scientific project originally based at the Université de Montreal and then transferred to the CHU Sainte-Justine. CARTaGENE is composed of a health database which is based on health and environmental questionnaires, a bank of biological samples (blood, urine and saliva) as well as range of physiological measures. There is also a genealogical database that is run by BALSAC project where people can participate in addition to the health related databases. CARTaGENE is a prospective health study where the research cohort has been targeted to the population most at risk of developing chronic diseases: men and women of 40–69 years in Quebec. CARTaGENE defines its mission as follows:

> *CARTaGENE's mission is to create and maintain in the long term a bank of data and samples that represent the genomic identity of Quebec and are competitive on an international scale, thus facilitating the emergence of new research projects and knowledge regarding health care for Quebec, Canada, and the international community.*
> (www.cartagene. qc.ca/en)

The participants are recruited from four metropolitan areas in order to facilitate translation into health promoting policies and interventions. (Awadalla *et al.* 2012) CARTaGENE has received lots of attention in the literature as an example of a biobank project that has introduced engagement of participants and the community into its operation. The engagement model has been labelled as "partnership approach" instead of "communication approach" adopted by many other biobanks (Godard *et al.* 2004).

The Tomorrow Project has been launched as a local study in Alberta in 2000 with aim of recruiting 30 000 participants starting in 2002. In the study participants were recruited to fill in "pencil and paper" questionnaires and they also consented to getting a possible invitation to give a blood sample. From 2009 a new phase of recruiting has started in accordance with the launching of Canadian Partnership for Tomorrow Project - the Canadian wide biobank network. Currently there are 36 000 Albertans who have participated in the project. The Tomorrow project's primary focus is on cancer research, but also on heart disease and other long-term health conditions.

> *... primary goal is to discover more about what causes cancer, so that it may be prevented in the future.*
> (www.in4tomorrow.ca/)

The cohort consists of men and women of 35-69 years of age. In the current phase participants are asked to complete health questionnaires and invited to consider providing urine, blood or saliva samples, and to have various physical measurements taken. Participants' health will be tracked for up to 50 years through cancer registries and other health records.

The Canadian population is not homogenous, but has many different ethnic origins, therefore, the scope of cohorts is in many cases to achieve population representativity. Considerable amounts of public funding both in the federal and

regional level have been made to biobanking and health research infrastructures. This has enabled research projects such as the Tomorrow Project to transform into modern biobanks – although in Canada these kinds of infrastructures are rarely called biobanks. In addition to significant funding, another success factor named for Canadian biobanks is the strongly supportive citizens who support both public health research and the public healthcare system (Caulfield *et al.* 2012).

Legislation

Canada has no specific federal law on biobanks. The regulative framework varies also between the different provinces. The provinces themselves do not have direct regulation on biobanks but some of them have legislation dealing for example with consent to research (Allen *et al.* 2013). The need for more specific biobank regulation both on the federal and on the provincial level has been argued for (i.e. Advisory group 2006). An important document that sets the ethical framework for biobank research is the Tri-council policy statement: Ethical conduct for Research involving humans (TCPS 2, 2010/2014). It is a document made by three primary federal funding agencies in Canada. Caulfield and Knoppers (2010) call it as the "de facto research ethics policy" in Canada. The document defines fore mostly the practices of informed consent. Most Canadian ethical guidelines propose rather strict requirements for consent, for example many of them argue for no secondary use without re-consent (Allen *et al.* 2013) which is in contradiction to broad consent practices wanted and used by most biobanks.

Canadian law and ethics policies are built on a tradition of specific research projects and informed consent. But their application to biobanks is not clear (Caulfield and Knoppers 2010). Informed consent is a highly discussed topic in Canada and forms the bases for many ethical debates. This fits well with the idea that autonomy and privacy are regarded as important values for Canadians (Caulfield 2007). Canada has a rich legal tradition in the area of consent and not with biobanks or even medical research have many examples in the Canadian consent case law. (Caulfield and Knoppers 2010).

In addition to informed consent, guidelines for disclosure of incidental findings are formulated in the TCPS 2 where it is stated that researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of the research and an appropriate plan is in place for managing information that may be revealed through their research. This passage has proven to be problematic as there are no guidelines to how to do this in practise. A Statement of Principles has been developed by a group of researchers from Quebec to bridge the gap between what is recommended in the TCPS 2 and the practical application (Sénécal *et al.* 2013).

> *Because of the nature and quantity of the information analyzed, genetic or genomic research is especially likely to generate material individual results and material incidental findings compared to other research domains. Consequently, in almost all cases, genetics researchers should develop a plan for managing this type of information.* (Sénécal *et al.* 2013)

Still many Canadian biobanks, such as CARTaGENE and the Tomorrow Project were not disclosing any research results to the participants during the time of the interviews. The TCPS 2 was revised in 2014 and it introduced exceptions to the obligation to disclose material incidental findings. The return of research results is one of the key ethical, legal and practical issues currently in biobanking.

All and all, the ethical, legal and social (ELSI) questions of biobanking from the Canadian perspective have been relatively visible in Canada and internationally as some of the fields prominent experts come from Canada and have been working in cooperation with Canadian and international biobank projects. The experts include such persons as Bartha M Knoppers and Timothy Caulfield. The Canadian ELSI research field has received ample funding and the experts have been publishing vast amount of publications. A notable part of Canadian ELSI research is funded by Genome Canada through the GE3LS initiative. The funding decisions and strategies have received also some criticism as it has been argued that only some big efforts lead by the established experts get funding and different opinions do not get heard. As a result of Canadian biobanking and ELSI efforts many best practices and guidelines have been developed through for example CARTaGENE and P3G, which is a Canadian led "international consortium dedicated to the development and management of a multi-disciplinary infrastructure that can compare and merge results from studies, biobanks, research databases and other similar health and social research infrastructures conducted around the world" (p3g.org).

Engagement practices and social aspects related to biobanking

As stated before, Canadian biobanks such as CARTaGENE have been used as benchmark cases or examples of a "partnership approach" to engagement (Godard *et al.* 2004). This approach means that the public is not perceived only as donors but as stakeholders who have opportunities to voice their opinions and perhaps even influence decision-making.

> *In fact, community consultations are becoming an increasingly common adjunct to genomics research. For instance, the UK Biobank as well as the Quebec Cartagene project adopted a "partnership approach" meant to involve the public in decision-making processes* (Godard *et al.* 2010)

Before the launching of CARTaGENE community consultations around Quebec were performed by market research organisations to identify the social and ethical concerns of the public by using focus group research. Also a phone survey among Quebecers was conducted. In addition, stakeholder consultations were arranged prior to the launching of CARTaGENE. Important stakeholders such as professionals in ethics, law, decision and policy-making were consulted. (Godard *et al.* 2010)

> *There was some sort of public consultation before the beginning of the project. But they had targeted selected groups of stakeholders and experts to sort of define the roles of the project and the main objectives of the project. It wasn't a public, it wasn't open to the public per se. It wasn't about only looking at, that society in general was ready to accept the project with such a large public funding.* (Interviewee, 2014)

Setting up a partnership model during the beginning phases of CARTaGENE may have been the goal and a strategy adopted, but as a representative of CARTaGENE stated:

> *I have to say we haven't been really strong at working with the community. So there's not a big bridge between what we do and what the public has to say.* (Interviewee, 2013)

The "partnership approach" has been part of the CARTaGENE strategy, but practical work of biobanks, allocation of resources and transformations in the biobanking sector have transformed the focus and practices of engagement from public consultation to communication, mundane encounters and involvement of other stakeholders than the public. The prevailing mantra in biobanking has been to transform the donors as participants of biobanks. But the practical constraints and forms of biobank operation do not necessarily support this type of "partnership approach".

Both CARTaGENE and the Tomorrow Project have, however, used multiple methods of stakeholder and public engagement. The main incentive for engaging the public has been to recruit participants. This has been primarily done by providing information to participants and potential participants about the functioning of the biobanks and how one can participate in them. The biobanks have made press releases, posters, information leaflets and newsletters. And for example when the mobile study center of the Tomorrow Project arrives at a location in Alberta, the people from Tomorrow Project have been promoting their cause actively in local media. The media coverage of biobanks was regarded to be mainly positive in Canada.

> *They've [the media] been very supportive. I think we've used them mainly for public awareness.* (Interviewee, 2014)

In addition to media, the Tomorrow Project uses also special ambassadors for recruitment.

> *We have also identified people, ambassadors, who are committed to the cause, to help to recruit participants.* (Interviewee, 2014)

The ambassadors give out leaflets in various happenings, arrange "lunch and learns" and recruit friends and relatives to the Tomorrow Project. There are currently over 800 ambassadors. This could be interpreted as some sort of one-way community involvement. Community involvement is a form of engagement that has been acknowledged to be important also in Canada. There have been studies for example of how ethnocultural community leaders view biobanking activities. The leaders believed that biobanks could have positive impacts provided that their community members are not only informed but are also involved in deliberation, development and decision-making (Godard *et al.* 2010). On the other hand the communal and social aspects of biobanking are used in the communication of biobanks to the public. In the communication material it is often referred to the willingness to help the community.

> *Many of the Albertans involved in our study have an innate desire to help out in their community.* (www.in4tomorrow.ca/)
>
> *I'm making a difference… for the future of my children.* (www.cartagene.qc.ca/e)

In practice, the Canadian biobanks we have studied have not adopted strict community involvement as a form of engagement. It seems that in the beginning stages of CARTaGENE partnership model was promoted, but in reality it has not been materialized but resembles more of the "communication approach". Both biobanks under our scrutiny acknowledged that they could do more with public engagement. The Tomorrow project is planning to develop a participant engagement strategy and CARTaGENE is planning to build a communication platform to participants.

> *And what we're going to try to do in the next year provided that we have funding, is try to develop somewhat of a platform that would help us to have a good communication channel with our participants.* (Interviewee, 2014)

It is interesting to note that in the article from 2004 where Godard *et al.* promoted the partnership approach of CARTaGENE stated that "part three of the community consultation plan consists of a deliberative electronic forum" which had not yet been developed in early 2014.

One of the reasons for not engaging more with the public is that Canadians in general have a positive attitude

towards research, genetics and biobanking (Caulfield et al. 2012). Knopper's has noted that the government officials were more apprehensive and critical towards biobanks than the people they represent. But one of the negative issues that have come about from the public is related to the return of individual research results. Even though the ethical guidelines by the TCPS 2 recommend the disclosure of material incidental findings most of the biobanks are not communicating individual result back to the participants.

> *One of the expectations we need to manage is that people are not going to get anything in return for doing such a, taking so much time to fill out the questionnaires and providing blood and doing the physical assessment. A lot of the participants,... they would be very interested in getting return of results. So, we, apart from the return of results that they get from the clinical assessment centres at the time of the assessment, we don't return anything to the participants. So we don't provide, you know, a risk based on genetic analysis or anything of that sort. So that I think, that would have been, if it would be possible, would be interesting for participants. A lot of them have asked us to provide such information.* (Interviewee, 2014)

For example in a survey of Albertans (Caulfield *et al.* 2012) most respondents were in the opinion that the researcher should contact the person or a doctor if something about the individual's health is discovered. Also the Tomorrow Project has had a strategy not to return individual research results. But due to a new research project that uses MRI scanning the TP has opted to re-consent participants and there are five abnormalities that in case found will be communicated to the participant and family doctor.

The engagement with the public happens also through channels that are not publicly visible or constitute from mundane practices. Talking with participants during sample taking, calling them for survey information and other personal contacts are highly important channels of communication for biobanks.

> *A lot of the information I have is from the participants directly, so people who are interested in taking part in the study and people who have already participated in the study. So what we've done with the participants is send out a questionnaire asking them what their impression of the project was in general… I do rely on feedback from participants because, it gives you a direction, if something is really wrong, you'll know about it.* (Interviewee, 2014)
>
> *We do follow up on questionnaires, we follow up on missing information or unclear answers. It is to quality control. We do a lot of phoning, quality checks on data. If we hear a concern, we have regular meeting about them.* (Interviewee, 2014)

An important aspect related to the sustainability of biobanks and engagement of people is related to the transformations of institutions responsible of the biobanks and how biobanks become networked and incorporated into larger entities of biobanks. In the second phase of recruitment of the Tomorrow Project, people who had participated in the first wave were asked a re-consent as the second wave recruitment coincided with the Tomorrow Project becoming part of the large Canadian consortium of CPTP - Canadian Partnership for Tomorrow Project. A significant part of the people declined to participate in the second wave. A common reason stated was that they had participated in an Albertan project. A similar local nationalistic attitude can be found in Quebec:

> *I mean, I think that, the way the project was sort of marketed to the population in the beginning was saying that, we will construct the genetic map of Quebec. So, people who are part of this heritage are very proud to be part of this very Quebec, this very much Quebec project. And I think that, this is a big incentive for participants...that we need to be careful because obviously for how people understand the project, they have to know that we are CARTaGENE and it is a Quebec project but we are part of a larger initiative. And the data that they are providing and the specimens that they are providing may be used not only for researchers in Quebec that are using CARTaGENE but also for researchers across Canada and even internationally.* (Interviewee, 2014)

The tendency in Canada is to form larger networks and entities of biobanks. Cooperation requires common strategies for data sharing, standardisation of sample taking, storage and analysis as well as merging of ethical principles. One of the projects aiming at this is the P3G-IPAC project that has devised together with other international partners a "Framework for Responsible Sharing of Genomic and Health-Related Data" (2014). This framework is used in CPTP to enhance data sharing between the different Canadian biobanks.

Besides taking stance on the public engagement, the framework serves the need of other stakeholders of biobanking. Clear frameworks and policies of access, data sharing and dissemination are highly relevant for the researchers, institutions and companies using biobank data. Some of the biobanks are already sharing the data but biobanks such as the Tomorrow Project in Alberta is more or less still compiling data and has not in any ways marketed the biobank to companies for example. Some of the most important stakeholders have been local research ethical boards and represnatatives from local governments and funding institutions.

Discussion

Sample storage. Photo credit: Aaro Tupasela

The focus of this research has been on engagement practices associated with biobanking around the world. More specifically, we have sought to understand some of the factors which may contribute to the long-term sustainability of these operations. A number of recent commentators have noted, that the life cycle of biobanks is tenuous and subject to external and internal pressures which may, ultimately, lead to the collapse of such operations (Tupasela and Stephens 2013; Stephens 2011). Although biobank failure is rare, these findings indicate that biobanks go through a type of life cycle in which the cessation of activities is a distinct possibility if the multiple needs of biobanking are not adequately met. In addition, biobanks may transform over time and become associated to other institutions, become networked or merged to other biobank entities or re-align their function and focus. Related to this, biobanking activities may come under close and intense public scrutiny whereby their activities, legitimacy and operating procedures may come under public criticisms. In relation to long term sustainability, such crises of legitimacy and criticisms may have a significant impact on the operation of a biobank in particular, but also broader societal consequences regarding levels of trust and legitimacy that may be associated with biomedical research in general.

Given these circumstances, we have sought to examine the engagement practices of different biobanks in six countries to identify important aspects related to the operation of biobanks and the governance structures in which they operate. A short analysis of these practices has been presented above. As a qualitative study we have identified

important themes which have presented themselves within the empirical material we have collected. These themes do not necessarily present themselves in all the cases, but we believe that they contribute in a substantive manner to the ways in which biobanking activities can be approached from a policy and governance level. Since the countries we have examined have very different histories, capacities, as well as governance and regulatory frameworks, and the biobanks examined represent population and clinical biobanks of various kinds, we do not take as our starting point, that the approach and subsequent analysis speaks to some definitive answer as to how biobanks ought to be governed or the ways in which they should manage their engagement strategies. But rather we see these as important beacons or threads that can help illustrate the way biobank managers and personnel conceptualise their operations and activities in the long run, as well as facilitate broader understanding among policy makers and funding organisations as to some of the challenges that relate to the long term sustainability of biobanking not just in Finland, but elsewhere as well.

Given this broader contextualisation we would like to suggest three important themes through which we feel the discussions regarding long term sustainability of biobanking could be approached: *broadening the concept of engagement, engagement as dynamic and types of engagement*.

Broadening the concept of engagement

Some scholars have noted that engagement is not a singular concept, but rather there are levels and styles in relation to the type of engagement that can be practiced (Thiel *et al.* 2014). In our empirical material, we found, however, that engagement is not only related to levels and styles, but should be conceptualised in a broader sense in relation to the object of engagement as well. By this we mean to broaden the somewhat traditional notion of engagement, whereby the target or object of engagement is with patients or the public in general. This conceptualization of engagement has had it roots in particular forms of political aspirations and policy programmes which have sought to close the gap between science and society. Although we do not question the legitimacy and usefulness of such efforts, the findings in our study indicate that biobanks tend to engage much more with actors other than patients and the public. According to Cañada et al (forthcoming) biobanks engage with a broad spectrum of actors many of whom do not fall into the traditional category of the public. Instead some of the most notable engagement targets include funding agencies, regulatory actors, as well as the research and clinical community from which samples are sourced. Many of these engagement targets have a profound impact on the wasy in which biobanks organize their activities, as well as the ethical, lecal and social context in which biobanking takes place. In this sens, it might be argued that the overemphasis in focus on public engagement has perhaps overshadowed the role that other actors play in the ways that biobanks operate and organize their day-to-day activities.

From a policy perspective this has important implications in terms of identifying the social role and significance of biobanks in general. Given the broad societal networks that biobanks need to maintain in order to make sure that their activities continue in the long-term, biobanks need to engage with a broad range of stakeholders. The public, research participants and patients are only part of this stakeholder group. In the day-to-day activities of biobanks, broader engagement with the public becomes often of secondary importance as the engagement with funders, research ethics boards, companies and other biobanks takes up all the time and resources. From a public policy perspective, however, the public still maintains a special profile as a target of engagement since much of the public trust and legitimacy in relation to long-term sustainability is drawn from that group. In relation to short-term goals, however, other engagement groups represent and require significant resources and efforts from biobanks to maintain various forms of engagement.

Engagement as dynamic

In addition to broadening the concept of engagement to include a larger set of actors with whom biobanks engage with, the study also identified important elements which relate to the dynamics of engagement in relation to time and temporality. A number of the biobanks and tissue collections that we have examined in our study indicate that current biobanking activities often build upon existing activities which were derived from previous projects, collections, samples or information. This is the case of Iceland's deCode, which was founded and based on earlier research, as well as smaller sample collections (see section on Iceland) or the Auria biobank in Turku, which is based on moving diagnostic samples that the Pirkanmaan hospital disctrict has collected for decades into an institutional entity (called a biobank) and which is governed by the new law on biobanking in Finland (see section on Finland). Following this line, Spanish biobanks saw their dynamics and activity changed at a very specific point in time marked by the creation of the Biomedical Research Law. All previous activities and collected samples had to therefore adapt to fit the requirements stated by the law. These changes over time point to a salient feature regarding biobanks, namely that they tend to have a type of life cycle which is dynamic in relation to time and temporality. By dynamic we simply mean that biobanking is not necessarily a set of stable practices in which tissue samples and information are collected

and circulate, but rather they are in a more or less constant state of flux whereby their practices and governance structures are continually 'evolving' to meet new needs by the research community, funding organisations, regulators, as well as participants and the public. In this dynamic model of biobanking, the public and patients represent only one, albeit important, aspect of biobanking.

The notion that biobanking and its activities are dynamic has a number of important consequences when we consider it in relation to the broadened notion of engagement. ***First***, as biobanks go through transformative processes, so do the requirements and expectations that are associated with their activities. The operational and practical requirements that are necessary for managing small research collections can be vastly different than those that are associated with larger collections. As collection go through transformative processes they may encounter tensions and frictions as to the definitions of their purpose and function, as well as contention over control and management of the samples and information themselves (cf. Hoeyer 2004). Furthermore, the changes that collections undergo may have significant consequnces in relation to institutional identity and roles as it relates to the practices that take place with biobanking. This can be seen particularly in the clinical setting in hospitals where biobanking activities become embedded in everyday clinical care. The intergration of such activities has been show to have significant impact on the expectations associated with the delivery of healthcare results deriving from genetic research and clinical practice (Pullman and Hodgkins 2006).

Second, the dynamics associated with biobanks also relate to the ways in which biobanks positions themselves within the broader markets for tissue collections and their availability. Biobanking is increasingly premised on networks of biobanks, such as BBMRI, which suggests that the dynamics of engagement are also elaborated within broader social and technical networks through which standards and best practices emerge and become codified in various ways (Mayerhofer and Prainsack 2009). The dynamics of moving from a singular entity into a broader global market of biobanks also entails a necessary broadening of actors with whom to engage with. It is also important to note that there are numerous different biobank networks that biobanks may belong to the dynamics related to the competition and cooperation among those networks can also have a significant impact on the ways in which biobanks develop their activities.

Third, as repositories which seek to preserve and maintain samples and information for later use, the temporality of biobanks and their need to stabilize or freeze samples in time poses a subsequent challenge in relation to dynamics. Given the transformative changes that collections sometimes need to go through, a considerable amount of work goes into negotiating the space and time between the fixed/preserved/frozen samples and the dynamic of the engagement processes involved in transformations. Within this tenuous process, samples and information exit and enter new 'zones' of governance where a broader set of engaged actors and practices are needed in order to assure sustainability (from small to large; public to private or a hybrid etc…). Samples collected today and which may be developed into cell lines in 10 or 20 years may meet the ethical and legal governance frameowkrs of today, but the landscape that they enter into when activated or revitalized may be significantly different than that of today. In this sense biobanks are continually positioning themselves in a way that is rooted in the past, but which must also consider the future.

Fourth, dynamics is linked very much to the expectations, attitudes and opinions of the public towards biobanking. Research among publics in different countries has shown that people are interested, worried and enthusiastic about future prospects of biobanking (Snell *et al.* 2012). Instead of worrying about how their personal information is being handled currently, many people expressed concerns about the future governance of biobanks: Who gets to use the samples and information in the future? What happens to the samples if a publicly funded biobank becomes privatized? What kind of a world are we creating with biobank research? Thus many of the public's concerns are related to the sustainability of biobanks.

Types of Public Engagement

In conceptualising engagement practices in different countries and between various biobanks we have developed a typology of public engagement in which we have sought to classify various types of public engagement (Snell *et al.* 2012). Our research shows that in addition to large public communication events and involving the public in decision-making, engagement takes place in mundane practices and private situations, such as face-to-face contacts with donors and sample takers, as well as patients' visits to the clinic. Engagement happens also outside the official protocols and strategies in either unexpected or routine situations that may be out of control of the biobanks.

Our starting point for analysis has been the typology of public engagement developed by Rowe and Frewer (2005) that distinguishes between *public communication, public consultation* and *public participation*. In their typology, they focus on the flow and nature of information that is mediated and the effectiveness of different types of public engagement. Consequently they identify variables that help to maximise information transfer or the number of participants in public engagement. According to them, in public communication, information is conveyed from the initiators of the communication to the public. Thus the Information flow is a one-way process and public feedback

is not required or even sought unlike with public consultation, where information is conveyed from members of the public. As regards to public participation, information is exchanged between members of the public and the initiators of the discussions so that there is some degree of dialogue. Participation aims at dialogue and negotiation that serves to transform opinions in the members of both parties.

Within this framework we have added three dimensions which further elaborate on the nature of biobank engagement. These dimensions are open *vs private/restricted* engagement, *official vs unofficial* forms of engagement and finally *direct vs mediated* forms of engagement. Below we have constructed a table (Table 4) where we describe the wasy in which our three categories complement Rowe and Frewers (2005) original conceptualisatin of engagement practices.

With *open vs private* engagement we seek to distinguish between the type of engagement one tends to be able to observe and recount through publically accessible information, such as webpages, versus the often quite and behind the scenes type of engagement which is more personal and often is mediated through tacit forms of knowledge transfer between, for example, clinicians and patients.

Our categorisations of *official vs unofficial* forms of engagement relate to the ways in which engagement is structured through various governance and social interaction frameworks. Official forms of engagement include the processes of gaining informed consent, information dissemination to participants, as well as the protocols which may have been put in place to ensure that biobanks meet some level of minimum requirement in terms of engaging with the research population. Unofficial forms of governance, however, can be seen as forms of engagemernt which biobanks may undertake to increase trust and legitimacy, but which may not be required by ethical and legal norms and standards. These forms of engagement may include a broad range of activities ranging from sending out newsletters to organizing patient evenings and open house events for the public.

Finally, the notions of *direct vs mediated* forms of engagement relate to the distance between the biobank itself and its source of sample and information. Often information is mediated through various types of media. Some biobanks engage directly with their research population, collecting samples and information themselves, while others operate through clinicians or hospitals which mediate the process as well as the information that patients or donors receive regarding the biobanks and what is done with samples. As we noted above, for some biobanks, maintaining some distance to the research population is an explicit strategy through which the organization seeks to maintain independence and organizational clarity, whereas with other biobanks, such as deCode, the process of collecting samples and information may form an important part of their organizational identity and responsibility towards the research population.

Table 4. Engagement matrix.

	Public Communication	**Public consultation**	**Public participation**
Official Forms of engagement that are regulated, standardised or use a specific protocol	1. Informed consent, registry information & official documents	2. Informed consent, Sample and health data collection	3. Lay representation in biobank boards
Unofficial Unregulated or sporadic encounters	4. Media coverage, mobile games, newsletters	5. Social media, personal enquiries	6. Open seminars and discussions
Open Forms that are open or available to all, or information about engagement is available openly	7. Web pages, newsletters, posters, registry information & official documents, media coverage	8. Open feedback through i.e. web pages, social media	9. Open public seminars and discussions
Private/restricted Personal encounters, or engagement that is not publicly available or manifested	10. Re-contact, return of research results, platforms	11. Surveys and focus groups Personal enquiries, doctors' appointments	12. Personal encounters with biobank, medical or research staff Lay representation in boards
Direct Biobanks engage directly with the public	13. Informed consent, re-contact, newsletters,	14. Feedback to biobanks, social media, phone calls to participants	15. Public stakeholder seminars of biobanks
Mediated Facilitated through another actor, mediator, intermediary	16. Legislation, media coverage, doctors & nurses 'Biobank ambassadors'	17. Visits to the recruitment centers Social research and opinion surveys	18. Biobank evenings in the media Lay representation in biobank boards

This study has sought to study and explore engagement practices undertaken by biobanks in six different countries. The biobanks we have examined represent a very broad spectrum of actors with very different types of inditutional setting, as well as histories relating to their conceptions. Our findings indicate that engagement is not a singular concept or activity; there are levels and styles in relation to the type of engagement that can be practiced. Our empirical material has shown that engagement is not only related to levels and styles, but should be conceptualized in a broader sense in relation to the object of engagement as well. By this we mean to broaden the notion of engagement, where the target or object of engagement is with patients or the public in general. This conceptualization of engagement has had it roots in particular forms of political aspirations and policy programs which have sought to close the gap between science and society. We recognize public engagement as being a highly relevant aspect of biobank engagmenet, but highlighting the other types of engagement provides understanding of how public engagement fits into the practices of biobanking and what are the priorities of different biobanks. In order to secure the long-term sustainability of biobanking a broader understanding of conditions for engagement is needed - wether it is public engagement or engagement with other stakeholders.

Our study has also identified important elements which relate to the dynamics of engagement as they relate to time and temporality. Over time, biobanks go through transformative processes where collections may encounter tensions and frictions as to the definitions of their purpose and function. The dynamics associated with biobank networks impact engagement practices, whereby moving from a singular entity into a broader global market of biobanks, for example, entails a necessary broadening of actors with whom to engage with. When repositories preserve and maintain samples and information for later use, a considerable amount of work goes into negotiating the space and time between the fixed/preserved/frozen samples and the dynamic of the engagement processes involved in transformations. Within this tenuous process, samples and information exit and enter new 'zones' of governance where a broader set of engaged actors (regulators, ethics committees) and practices are needed in order to assure long-term sustainability. We see these findings as providing important insight into the development of long-term sustainable practices in Finnish biobanking.

Although our study did not find clear evidence as to the relationship between engagement strategy and long-term sustainability, there appears none-the-less to be a trend within the field of biobanking towards policies which encourage the development of engagement strategies. Furthermore, it is important to note that within the commercial biobanking sector, there is a strong push to develop activities which draw on social media and other technologies to provide increased levels of feedback to participants. This general trend may place increased pressure on public research organisations to provide and develop competing forms of engagement strategies and practices in order to compete with private industry, as well as retain and maintain a trusting and happy research population. Although it is unlikely that private industry will be able to gain access or create biobanking collections which are as extensive as those produced by the public sector (hospitals and research insitutions for example), they are able to provide proof of concept like practices which may have an impact on the expectations that the general public, as well as patients in general may have in relation to participation and contribution to biobanking activities in the future. It would therefore be prudent for biobanks operating in the public sector to develop strategies which seek to develop engagement practices with their research populations. These strategies may be very different depending on the type of biobanking activity that is involved. The key, however, is to work towards opening and maintaining different lines of communication to and from the public.

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