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The Emergence of Biobanks:
Between Ethics, Risks, and Governance

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INTRODUCTION

In the last thirty years, genetic information has been at the centre of biological and medical research due to high expectations about the developments for medicine and society. More than in the past, medical science will be able to inform about the chances of contracting specific diseases in the course of a lifetime. It is expected that a risk oriented, predictive medicine will emerge. Insights in the area of genetics will have implications in diagnostics, treatment and the prevention of diseases, and also in terms of lifestyle, insurance, and the extent to which the individual is held responsible for his health; but it can also affect family ties, labour relationships and overall social perceptions (Vries & Hortsman, 2008). The information that biobanks and genetic science can bring may change the perception of the individual itself and of society as well as the workings of the national and international health systems with profound implications for the management of information systems (Bygrave, 2015; Chen, Mao, & Liu, 2014).

The rapid developments in the field of genetics urge society to deal with potential effects of genetics; they also challenge society, with the uncertainties of this new technology. New perceived risks emerge, together with new potentialities for health benefits, for crime resolution and many other expected benefits in diverse sectors of society. Should new meticulous regulations be designed to channel the developments involved and curtail the undesirable social effects? If the related technical developments are international in scope, is it possible to incorporate different cultures and perspectives of biobanks in the international regulation (Vries & Hortsman, 2008)?

Together with the rise of genetics, traditional relations between the state, professionals and citizens, society and science are being transformed. Moreover, a good way to understand these relations is asking how different institutions and countries frame the biobanks settings (Reardon, 2001). From this perspective, the regulation of biobanks, whether to stimulate innovation or control risk, can give precious information about how communities in particular times and spaces are dealing with changes in their perceived contexts (Jasanoff, 2004).

According to the Centre for Society and Genomic in the Netherlands (Bovenberg, Meulenkamp, Smets, & Gevers, 2009) research on common complex disorders requires large amount of data and a multi-purpose and multidisciplinary research approach. Moreover, they highlight that complex disorders are caused by large numbers of small, often additive effects, representing the outcome of the interplay, at various levels, of genes, lifestyle and the environment. Studying these complex interactions will depend critically on the use of large amounts of information and material from patients and healthy persons,

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collected and made available by biobanks. Over the last decade, in many countries such DNA research databases have developed, sometimes in the form of national, population based biobanks (Bovenberg, Meulenkamp, Smets, & Gevers, 2009) or in other and mixed forms or even networks (Meijer, Molas-Gallart, & Mattsson, 2012).

BACKGROUND

Public health research and planning, and the development of more effective therapies for individuals may take on radical new dimensions with the newly information made available through biobanks. Furthermore, the information that can be disclosed about an individual can also be used, intentionally or unintentionally, for economic and social discrimination, especially in insurance, employment, attribution of bank credits and other access issues (Rose & Novas, 2005).

Alongside the scientific revolution, the European understanding and acceptance of biotechnology evolved. Data protection is an important aspect of medical data and a major condition for the safeguarding of fundamental rights and freedoms of individuals, especially privacy. However, the development of these important safeguards still requires the consideration of many key questions about the meaning of privacy in relation to genetic information and about effective protection of legitimate rights (Taylor & Townend, 2010. Several studies have been devoted to the ethical, regulatory and social challenges associated with biobanks, particularly in relation to consent and privacy.

The increasing numbers of biobanks around the world has led to a rush of policy statements (National Cancer Institute (CI), First-Generation Guidelines for NCI-Supported BioRepositories; Washington DL National Cancer Institute, National Institutes of Health, US Department of Health and Human Services, 2006) (Sleeboom-Faulkner, 2009) and academic commentary debating the nature, form and content of the instruments needed to regulate this activity. In addition, some large-scale biobanks have developed their own governance frameworks, for example, the UK Biobank - Ethics and Governance Framework, Version 3 (Sleeboom-Faulkner, 2009).

Biobanking issues have been extensively debated, but predominantly from European and North American perspectives. Their models of regulation are based on individualistic cultural and legal traditions (Sleeboom-Faulkner, 2009). However, biobanks have also been set up in Japan and Taiwan and biobanking is underway in China, India and Indonesia. These countries have different cultural, welfare, healthcare and regulatory practices and traditions that should frame biobanking in these countries quite differently (Wong, 2004). Considering that biobanks are increasingly more a result of international collaboration, these differences can be a challenge for their governance.

The genome era has seen the establishment of large-scale population biobanks in many countries for the purpose of facilitating research into major diseases including cancer, cardiovascular disease, mental health and diabetes through genome wide association studies. These biobanks present different models. Sleeboom-Faulkner (2009) studied different biobank models like the Taiwan Biobank case and the issue of public trust, which is widely seen as a fundamental cornerstone in genetic research. Data linkage has become a major concern and a challenge to building public trust in Taiwan. The author argues that this will become a similar concern around the world as different publics become more aware of the extent of data linkages. The essay discusses unique problems like the indigenous Taiwanese populations attitudes towards the recruitment and sampling but returns to common ground with concerns about commercial involvement and benefit sharing. Collaborations between biobanks and drug companies are becoming

more common, all around the world, and there are increasing linkages between existing private and public collections and Taiwan Biobank is similarly considering such collaborations (Sleeboom-Faulkner, 2009).

Several authors explore the relationship between Indigenous communities and genetic research. (Santos, 2008). The author argues that, Native viewpoints are not respected or understood because their concerns often require more time, consideration and effort, and do not fall within the structure of the Euro-American research tradition. Unfortunately, the history has given reason to the Native communities for the sense of mistrust they feel against western research (Jacobs et al, 2010). There is growing recognition that some research involving Aboriginal individuals may also involve the communities or groups to which they belong. In developing ethical standards and practices, Aboriginal peoples have rights and interests that deserve recognition and respect by the research community.

Genetic information has implications that extend beyond the individual since it may reveal facts about biological relatives and others with whom the individual shares genetic ancestry. Researchers may sometimes seek to conduct genetic research with family members or communities to look further into the social and cultural contexts in which participants live. As a result, concerns arise around participant recruitment, the consent process, privacy, and confidentiality.

Biobanks are built mainly for research purposes and with these different types of data it is hoped that risks and cures for many multi factorial diseases could be developed. Risk of getting a disease, risks of becoming ill is influenced not only by genetic disposition, but also environmental factors and life style. Collecting information about these factors becomes more important, and once more, the amount of personal information that is collected with the biological samples can create ethical challenges. On the other hand, there are biobanks that specialize on rare diseases. Biobanks can produce information about risks and risk factors or correlations, among other aspects. In addition, the information is mainly produced on the level of populations – not of individuals. So, in most of the biobanks, feedback for individual participants is limited (Snell, Starkbaum, Lauß, Vermeer, & Helén, 2012).

The concept of biobanking is fairly new and the impact of individual biobanks on health and the economy has yet to be assessed in any detail (Gottweis, Chen, & Starkbaum, 2011; Hewitt & Watson, 2013). Biobanks are essential tools for genetic research, particularly genome-wide association studies (GWAS) and for the pharmaceutical industry for the translation of research findings into new products. Biobanks will also be involved in the development of personalized medicine (Sleeboom-Faulkner, 2009).

The EU is funding biobank research as well as the development of an integrated system for sharing their vast amount of data. Collecting biological information from people with illnesses has a long history, but collecting data from healthy people is relatively novel and key to biobanks. The issues of altruistic duty to contribute to research, the privacy of very sensitive personal data on health, life habits information and genetic profiles, commercialization of the results from research on biobank data and governance issues have been widely debated (Elger, Biller-Andorno, Mauron, & Capron, 2008) (Gottweis & Peterson, 2008). The use of healthy patients is also related to the evolution of statistical analysis, tools, big data and the diffusion of research methods such as randomized controlled trial (RCT).

To accomplish current requirements of the scientific community biobanks face essential challenges including an appropriate design, harmonized and more suitable procedures, and sustainability, all of them in the framework of their ethic, legal and social dimensions. Biobanks are developed in relation to a research question having its own strategy and specific demands on quality and annotation of the collected samples, resulting in a very heterogeneous concept. Even considering exclusively human samples-related banks for research, there are multiple designs according to the different possible goals (Tupasela, et al., 2010).

However, it is the amount of clinical data linked to the sample that determines the availability and biological, medical, economic and social value of the sample (Riegman, Morente, & Betsou, 2008).

BIOBANK NETWORKS

The Biobanking and Biomolecular Resources Research Infrastructure (BBMRI-ERIC) project, funded by the EU comes at a time when some of the biggest names in the pharmaceutical industry are recognizing that progress lies in sharing information and resources.

BBMRI-ERIC aims to build a sustainable model for a biobank that works in the interest of researchers, both private and public, offering low-cost access to infrastructure and samples while upholding the highest ethical standards set by the EU and other internationally governing bodies (Meijer, Mattson, Noojsen, Boekholt, & Gallart, 2010). The end result, it is hoped, will be a faster reaction time to epidemics, better availability of research tools for universities and other organizations and for private business, better access to a more succinct and standardized set of research samples – access that could give industry new impetus to conduct research into areas previously thought unachievable (Pharmaceutical-technology website- http://www.pharmaceutical-technology.com/, 2010).

BBMRI-ERIC has received the support of pharma players, large and small, and it is drawing on the expertise of privacy advocates and leading healthcare professionals to solve key issues such a resource will pose, one of the biggest being a shared-access IT (Information technology) system that holds standardized data, which can be extrapolated in many different ways (Meijer, Mattson, Noojsen, Boekholt, & Gallart, 2010). Sixteen Member States and one International Organisation have joined forces in establishing BBMRI-ERIC, which is one of the largest health Research Infrastructure in Europe today and has recently been joined by the United Kingdom.. Today the biobank networks are so extensive that it is difficult to assess the organizational culture of each institution (do they share the same principles, goals, vision and mission?).

One more consideration about the issue of technology and ICT. Biobanks, as new phenomena, is related to a vast array of technological aspects such as big data, digital access, digitalization, data organization and structure, control of access, data encryption, among others. The literature on biobanks is not as wide and deep on those matters and this is an area of future research but some elements can be put forward.

To leverage the potential of biobanks, the frameworks in which they are created, governed and sustain will need to keep advancing. As Harris et al (2012) highlighted, more research and investment should be allocated to the areas of:

1. Networking of multidisciplinary professionals;
2. Development of comprehensive inventories, including listing of extant biobanks, their holdings, and access procedures;
3. Establishment of standardized data-collection protocols governed by appropriate quality management systems;
4. Continued innovation that leads to improved technologies for preservation of biospecimens and pre-analytical processes;
5. Progress in information infrastructure to facilitate data sharing and pooling, including new technical solutions for data management and analysis, as well as for the protection of participant privacy and data confidentiality; and

6. Harmonization of quality management systems to ensure consistency of materials (Harris et al., 2012).

Innovative solutions need to be developed to address issues like the confidentiality and anonymisation that arise from the increased medical information that is being collected along with the biological samples.

From a social and ethical perspective, more research is needed to understand the diverse societal attitudes of participants towards privacy. In addition, the scientific community has to find new ways of engaging research participants into the development of new governance frameworks (Murtagh et al., 2012).

BIOBANKS GOVERNANCE: THE ROLE OF THE STATE (EUROPEAN CONTEXT)

The risks associated with the creation of genetic databases have been the subject of concern in governance, both national and supranational. Indeed, the regulation seeks to safeguard the conditions for access and use of personal genetic information, which, in addition to the humanitarian purposes of scientific research, relates to interests of a personal nature, e.g., in establishment of paternity and kinship relations with missing persons, but also in the fields of criminal investigation and criminal association. The state's role as legislator and regulator is essential to safeguard privacy and personality rights, especially because the risks associated with the DNA databases are amplified by the existence of dozens of databases already created and many others to be implemented (Machado, 2011).

Governance issues concerning DNA databases concern how the accumulation, storage and use of genetic samples and profiles are managed and monitored (Williams & Johnson, 2008, p. 128). In this domain, "the government may be our best hope for privacy protection as we move into the new millennium" (Garfinkel, 2001, p. 6).

In general the risks are many when considering the creation of personal databases, which limits the privacy of the targeted individuals, compromising individual rights, freedoms and guarantees constitutionally protected. The problem involves several issues related to genetic manipulation such as family dimension of genetic diseases. But no less worrying are the unfair terms in insurance contracts and contracts of work predicting future disease, through a genetic test done before you sign the contract, as Miranda stresses (1997, p. 55-63).

However, the mere possibility of affecting family relationships - that would find that between five to fifteen percent of the children are adulterous (Miranda, 1997, p.68) - should receive from the state a leading role in containment of investigations, safeguarding the core of privacy, in the sphere of family intimacy. Risks of population segregation have been appointed by the European Parliament in 1990, both in terms of hiring workers, in terms of carrying out contracts of insurance (European Parliament, 1990).

It should be noted that the risk of invasion of privacy in their intimate sphere, stem not only private but also public officials. The first, in general, is for selfish reasons of pursuing economic interests with lucrative and illegitimate access. The second allegedly is for reasons of public interest in collective security against the fear rooted in activities organized transnationally and the need to combat crime, supported knowledge. However, those factors should not mean an automatic and progressive decrease of the fundamental rights of citizens, which are "rights and freedoms" (ICPD, 2007). Therefore, it is necessary that the governance structure determines the balance of conflicting interests, with adequate regulation; managing them and supervising them.

In this sense, the creation of databases of DNA profiles containing matters of particular sensitivity to allow the exchange of information between Member States of the European Union, has been repeatedly

stressed by Community institutions. In particular the Council resolutions for exchange of results of DNA analysis of 9 June 1997 (97 / C 193/02) and July 25, 2001 (2001 / C 187/01). In the same sense it has to pronounce the Council of Europe, since Recommendation (92) 1, of February 10, 1992, its Committee of Ministers on the use of results of DNA analysis in the context of the criminal justice system and more recently by Recommendation (97) 5 of February13 1997.

However, those resolutions and recommendations leave to the Member States a wide margin of conformation with its internal rules. The first (97 / C 193/02) determines that it is up to each Member State to decide on what terms and in relation to what type of offenses may be stored analysis results of a national DNA database, with this freedom is accompanied by safeguards for the protection of the physical integrity of the persons concerned. The most recent resolution (2001 / C 187/01) allows bilateral agreements between member states with regard to the exchange of specific DNA markers, concluded in accordance with its national legislation.

There is a wide margin for the national delimitation of the essential legal principles of the constitution of DNA databases. In this respect it should be noted that the role of the state as a single entity or regulator, whether through the management or control of personal databases, must support the need for self-restraint, largely because the public official has a relevant role in matters of possible violation of human right to privacy. According to Delgado (2005, p. 239) "the state continues to be the subject that has greater potential to damage or fragile the right to privacy, or more generally, which produces the largest number of conflicts." The example of the National DNA Database (NDNAD) in the UK with millions of records "that contain data from many minorities, with the consent being voluntary irrevocable; the great powers of the police to harvest samples and their preservation even after proof of innocence of the suspects, and the fact that the number of blacks and other ethnic minorities are over-represented, are the source of much discussion and concern on the part of ethics groups and civil rights organizations", as the CNECV (2007, p.14), citing POST, 2006, argues. It is, nevertheless, evident that the great vulnerability stems from public performance.

So either the law is insufficient given the need to attend to other aspects that are beyond the requirements and established balance between the public interest (especially security) and private interests (protecting individual privacy), or the violation is unnecessary attentive to security purposes.

In the confrontation between those two vectors of governance - State legislature vs. State actor, agent in pursuit of the public interest, but also possible (and sometimes effective) offender - what one finds is that legislative restraint, by the necessity of conformity to public opinion does not confer the action elements that are used in practice.

It is however noted that the normative context of the European Union - the possibility of formation of DNA databases - seems preferable to its absence. Indeed, the collection of personal data and the creation of databases for research purposes, especially criminal, have been around for decades in several countries in Europe and the United States of America, being held in addition to collecting personal data often against the will of the alleged offender, as demonstrated by the case law of many countries. In such a case, the role of governance is positive; that is, regulation can take effect with the parameterization of internal and international standardization, contributing to greater individual security at two levels. A thorough knowledge of the constitution of the underlying standards of databases of DNA, to allow citizens to know that although they are subjects simultaneously protected by these and knowing the scope of that protection. Another, because the absence of a regulatory framework appeared to be more permissive view of the need of privacy protection in general law, while these laws are devoted, in particular, the duty of confidentiality of all those engaging with a database of DNA profiles, typifying her rape as a crime. This element has a preventive function that did not exist before.

CONCLUSION

Whether or not the biobanks promise to improve radically human health remains unclear. Regardless of the eventual outcome of biobanks networks, the analyses of the attempts to organize it and the questions it has stirred provides an important resource for understanding contemporary problems and issues raised by proposals to study human genetic information. These issues and problems increase in importance as human genetic research, and the personal data attached, rises to the top of agendas at private and public research institutions around the globe. Thus, it is an important time to discern and understand the conditions and processes that generate them.

Furthermore, at this moment it is unclear if there will be an international consensus about ethical questions, or even if there is a European core system of values towards biobanks. Some groups of populations deserve special attention, like the Aboriginal communities, since they raise very specific cultural concerns regarding the use of genetic information. Some Indigenous groups believe that genetic research into human population history threatens their cultural beliefs, for example, regarding their evolutionary history. Much of the criticism directed towards research involving Aboriginal populations relates to the loss of control over data or biological samples collected from Aboriginal people. In addition, serious concern has been raised over the inappropriate use of stored biological samples, including DNA and cell lines, for unauthorized research. It is crucial for researchers to understand that ownership of traditional and sacred knowledge should always remain with the community.

Before any research can be conducted, the bio-materials and the necessary associated data must first be collected, while research specific factors (number of samples required, the pathology being studied) can influence the duration of the collection process. In addition, with the scientific developments there is a risk, that over time new scientific insights emerge, causing the foreseen experiments to change in their set-up that, in the worst-case, result in a shift in the desired end product, which presents a challenge for today legislators (Bovenberg, Meulenkamp, Smets, & Gevers, 2009).

Therefore, biobank managers and legislators need to monitor the latest developments in favor of harmonization and make an effort in joining networks, establishing a common ground of norms and standards. Especially when the involved biobanks have adhered to internationally accepted procedures, standardization and quality control, the materials can be exchanged between or among institutes, to be used in a high variety of experimental designs, whereas the origin of the samples is expected not to influence significantly the end results (Zika & Paci, 2010).

Safeguards protecting the privacy and confidentiality of data and biological samples should be specified in a research agreement. If there is to be a transfer of the data or biological samples to a third party, consent must be obtained by researchers from the individual participants and community, such as the Portuguese National Commission for the Protection of Data (ICPD, 2007) refers, and as such a condition of freedom of citizens. Thus, the State's role as legislator and regulator - which assumes that the control and management of the system is also a duty of the State - is essential to safeguard privacy and personality.

By the PRIVILEGED study results in each country on the legislation related to biobanks, it is possible to understand the differences among countries on the way they perceived the threats and benefits of this new technology. It is expected that the present legislation will evolve integrating the balance of rights that can be in conflict, like individual right to privacy, to public health interest (Taylor & Townend, 2010).

What about the future? Several avenues of research are salient and one is the systematic review of the phenomenon of biobanks and its ethical, legal, technological, governance and management issues. Another area of research for the time to come is the integration of different dimensions in an interdisci-

plinary framework so knowledge of biobanks and responses to challenges can be better prepared. Other areas of future research are related to local implementation of biobanks and the local or indigenous communities participation as well as the global trends in technology, interconnection between national and regional institutions and practices and their relation to legal, managerial, legal and ethical problems.

In the end, the way that biobanks emerge and grow, the introduced legislation and the way citizens experience the benefits of this new technology reflects the intricate forces that shape society and technology, against a unique historical, economic and cultural national background. Even the choice made by populations on the institutions they trust to control the biobanks and defend public interest are different and can only be understood under a historical background that shapes each nation.

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KEY TERMS AND DEFINITIONS

Biobanks: Collections of biological samples (that can be used to acquire DNA) and different types of information (medical records and medical history, life style information and other personal data).

Ethics: Well-founded standards that prescribe what humans ought to do, usually in terms of rights and obligations. Ethics are cultural, time and context sensitive.

Governance: The *process* by which authority is conferred on rulers, by which they make the rules, and by which those rules are enforced and modified (World Bank).

Network: Series of institutions and/or research centers interconnected by communication paths that share common interests.

Privacy: Right to control who, when, how and to what extent personal information is communicated to others.

Risk: Risk is a threat, a source of uncertainty, a combination of danger and opportunity. It is perceived in a specific cultural and time context.

Society: Group of people that share common values, embed by culture, tradition and beliefs, involved in persistent interpersonal relationships.