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

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