OMICS A Journal of Integrative Biology
Volume 20, Number 1, 2016

DOI: 10.1089/omi.2015.0123

Biobanks in Oral Health: Promises and Implications of Post-Neoliberal Science and Innovation

Kean Birch,[1] Edward S. Dove,[2] Margaret Chiappetta,[3] and Ulvi K. Gürsoy[4]

Abstract

While biobanks are established explicitly as scientific infrastructures, they are *de facto* political-economic ones too. Many biobanks, particularly population-based biobanks, are framed under the rubric of the bio-economy as national political-economic assets that benefit domestic business, while national populations are framed as a natural resource whose genomics, proteomics, and related biological material and national health data can be exploited. We outline how many biobanks epitomize this 'neoliberal' form of science and innovation in which research is driven by market priorities (e.g., profit, shareholder value) underpinned by state or government policies. As both scientific and political-economic infrastructures, biobanks end up entangled in an array of problems associated with market-driven science and innovation. These include: profit trumping other considerations; rentiership trumping entrepreneurship; and applied research trumping basic research. As a result, there has been a push behind new forms of 'post-neoliberal' science and innovation strategies based on principles of openness and collaboration, especially in relation to biobanks. The proliferation of biobanks and the putative transition in both scientific practice and political economy from neoliberalism to post-neoliberalism demands fresh social scientific analyses, particularly as biobanks become further established in fields such as oral health and personalized dentistry. To the best of our knowledge, this is the first analysis of biobanks with a view to what we can anticipate from biobanks and distributed post-genomics global science in the current era of oral health biomarkers.

Introduction

In many ways, biobanks, which are defined as an organized collection of biological material and associated information stored for one or more research purposes, epitomize the massive shift from the 1990s onwards from small-scale science to large-scale science, and from genetics to genomics (e.g., the shift from the search for single gene traits to genome scanning). The transition by many scientists and other actors to the -omics field, which is replete with big data, necessitated the establishment of repositories for biospecimens, genomic data, *and* associated information; and, hence, the biobank was born.

One of the most famous early examples was deCODE Genetics, a private company based in Iceland and established in 1996, which was allowed to create an Icelandic health database in 1998, after legislation by the Icelandic Parliament (Fortun, 2008). There are now numerous biobanks around the world, although they are primarily concentrated in the Global North, with a range of purposes, institutional structures, and governance arrangements (http://specimencentral.com/biobank-directory/). While they are better known in the medical field (Verlinden et al., 2015), they are increasingly important in other –omics areas such as ecology and agriculture as well (e.g., Misra et al., 2013; Weng et al., 2014).

Concomitantly, many biobanks epitomize a market-driven—or neoliberal—form of science and innovation, in which research is driven by market priorities (e.g., profit, private goods, shareholder value) underpinned by state or government policies. Neoliberalism is a symbiotic relation between market *and* state; in this sense, it does not signify the replacement of states with markets (Mirowski, 2011).

Departments of [1]Social Science, Faculty of Liberal Arts and Professional Studies, and [3]Science and Technology Studies, Faculty of Science, York University, Toronto, Ontario, Canada.
[2]J. Kenyon Mason Institute for Medicine, Life Sciences and the Law, University of Edinburgh School of Law, Edinburgh, United Kingdom.
[4]Department of Periodontology, Institute of Dentistry, University of Turku, Finland.

Although biobanks are inherently and explicitly scientific infrastructures, they are implicitly economic ones too, in that many (particularly population-based biobanks) are presented as national *political-economic* assets. More specifically, they are framed as a national resource—primarily meant to benefit domestic business—and, concurrently, they involve framing national populations as a natural resource whose genomic characteristics and national health data can be exploited (Hinterberger, 2012; Hinterberger and Porter, 2015).

As both scientific and political-economic infrastructures, biobanks can end up entangled in an array of problems associated with market-driven science and innovation and ''academic capitalism'' (Slaughter and Rhoades, 2004). These include: profit trumping other considerations; rentiership trumping entrepreneurship; and applied research trumping basic research. As a result, there has been a push behind new forms of ''post-neoliberal'' science and innovation strategies based on principles of openness and collaboration, especially in relation to biobanks (Hope, 2008).

''Open science'', as it has come to be known, promises to alleviate the problems associated with neoliberal science, leading to a cornucopia of new scientific productions. Whether it meets that promise is another question. What it does do, however, is highlight the importance of considering the role and purpose of biobanks—open or proprietary—and their application to healthcare areas such as oral health, personalized dentistry, and ''dentomics'' (Erciyas et al., 2015).

Biobanks offer significant potential in oral health—that is, if we can learn from our experiences in other areas of science. Biobanking in oral health has a relatively short history. A PubMed search with keywords ''biobank'' and ''dentistry'' cites the article of Galloway (2011) as the oldest in the field, wherein he describes the UK Biobank project. Since then, there have been successful attempts to collect and organize human oral samples systemically in developed and developing countries; for example, Norwegian primary teeth biobank (Tvinnereim et al., 2012), Malaysian oral cancer biobank (Zain et al., 2013), and Malaysian periodontal disease and biobank system (Vaithilingam et al., 2015). There are, of course, other biobanks, such as UK Biobank (http://www.ukbiobank.ac.uk) or the Finnish Biobank (http://www.nationalbiobanks.fi/), where the aim is to collect several different human samples, including oral samples, such as saliva, from population cohorts.

Though health biobanks differ greatly in characteristics (e.g., adult, pediatric, *de novo* sample collection, legacy sample collection, hospital-based, industry-based, etc.), major concerns relating to biobanks are cross-cutting, and include protection of privacy, standardization of data and sample processing, and long-term stability of markers of interest in the ''banked sample.'' Although clearly important, these issues are nevertheless not the only ones to raise concern. Economic, ethical, and sociopolitical considerations are also important. For example, financial sustainability is one challenge that biobanks will sooner or later have face (Warth and Perren, 2014). An unfortunate example is the Singapore biobank, which was closed due to high maintenance costs and under-utilization of biobank samples (Chan, 2012). Also, questions have to be asked about commercial exploitation and intellectual property (IP) rights; for example, when research outcomes lead to a product with commercial value, who will own it (Dove and Joly, 2012; Pathmasiri et al., 2011)? Will it be possible to send saliva samples to private genomic research and pharmaceutical companies, and what will be the social impact of such an act?

As biobanking moves into further fields such as oral health, we believe that researchers should learn some of the answers to these ''already asked'' questions and benefit from both the experiences of the medical field and the social science analyses of neoliberal science and innovation. In this article, we briefly analyze biobanks with a view to what we can anticipate from biobanks and distributed post-genomics global science in the current era of oral health biomarkers, and consider whether and to what extent a post-neoliberal agenda will emerge in governance and the sociotechnical shaping of biobanks worldwide.

Neoliberal Science and Innovation

Large-scale science and innovation are driven by their funding; the piper calls the tunes in many ways. By this, we do not mean that ''big science'' and innovation are necessarily perverted by the influence of money, undermining the scientific method or regulatory systems, though this has been a past claim (Weinberg, 1961). Rather, the kinds of science and innovation that get done are shaped by their funding context (Tyfield, 2012). The last few decades have been witness to the emergence of something scholars are calling ''neoliberal science and innovation'' (e.g., Abraham, 2007; Biddle, 2011; Mirowski, 2011). When scholars talk about neoliberal science and innovation, what they mean is science and innovation that are *inherently market-oriented*; driven by market priorities, logics, and expectations (Birch, 2006). When it comes to the -omics sciences, this means that a significant driver of research is the promise or expectation of market potential, whether directly through product sales or indirectly through business capitalization. Anything that is not designed for, or does not lead to, profit or earnings ends up under-valued and side-lined.

Why might neoliberal science and innovation be a problem then, if it is not necessarily corrosive? There are always specific issues with the ways in which we organize and configure science and innovation in societies, whether today or in the past. When it comes to neoliberal science and innovation, it revolves around the effects of three main market pressures. First, innovators come to focus on profit and cost over other considerations in their research decisions and priorities; consequently, market potential has increasingly influenced research decisions. For example, in 1990 ''commercial reasons'' represented only 5% of the explanations given for drug development failures; this rose to 30% by 2000 (Birch, 2006). Another example is the emphasis on developing ''me-too'' drugs rather than riskier, more innovative treatments (Joppi et al., 2005).

Second, market competition drives innovators to search for ways to capture value through *rentiership*, as opposed to creating value through entrepreneurship; that is, innovators try to find ways to avoid actually having to compete altogether. To do this, innovators seek to create knowledge monopolies through IP rights (IPRs) in order to extract value (e.g., through licensing), rather than create it through riskier activities (e.g., drug development) (Zeller, 2008).

Finally, innovators end up abandoning or defunding basic research, either because it is unprofitable or because it cannot

be captured by IPRs. Some of the most important research (e.g., the diagnostic groundwork, regulatory research, or cross-cutting science) simply does not get done, leaving governments to take over or coordinate multi-institutional efforts; examples here would include the US FDA's *Critical Path Initiative* and the EU's *Innovative Medicines Initiative* (IMI).

The effect of these problems inherent to neoliberal science and innovation is what legal scholars Michael Heller and Rebecca Eisenberg (1998) call the ''tragedy of the anti-commons.'' By this, they mean the blockages or bottlenecks created by market-driven decisions, such as patenting and licensing, on the development of new science and innovation. For example, as knowledge—basic and/or applied—becomes increasingly commodified and therefore valuable as IPRs, it becomes increasingly difficult to coordinate projects and collaborate across diverse and different sites. Negotiating around the growing number of property rights become prohibitive, and ends in ''gridlock'' (Heller, 2008). As a result, there has been growing interest and investment in forms of open science and innovation, especially when it comes to biobanks and other bioscientific repositories (Hope, 2008).

Open Science and Innovation: Beyond the Market?

The -omics sciences are significantly altering the landscape of science and innovation in the biosciences. -Omics fields are characterized by a broader focus on systems (e.g., the genome, the proteome) rather than objects (e.g., the gene, the protein), and this focus is, more often than not, data-accelerated, internationally collaborative, and interdisciplinary by nature. However, this creates problems when science and innovation are dominated by neoliberal principles.

For example, the development of sequence data (e.g., gene, protein, or other transcript sequences) is primarily a collaborative endeavor wherein researchers rely heavily on communally available biobank databases to interrogate nucleotide sequences of interest, compare protein sequences, and search for sequence data in particular disease contexts. Given that inquiry in these fields often relies upon the availability of and access to vast networks of biological samples and data (stored in biobanks), duplicating research is costly and prohibitive, and traditional means of IP protection may, in fact, hinder innovation. Consequently, free and collective access to data and information is paramount for science and innovation. This has led to the emergence of *open science* as a new, potentially ''post-neoliberal'' paradigm.

Open science has its origins in the *open source* movement, which is a software movement based on *open access* to source code, and the freedom to share, adapt and reconfigure that code as desired (Hope, 2008). The open source model is generally characterized by voluntary participation and voluntary task selection—a freedom made possible by ''transparency, exploitation of peer review and feedback loops, low cost and ease of engagement, and a mixture of formal and informal governance mechanisms built around a shared set of technical goals'' (Gitter, 2013). In the context of biomedical research, open science refers to open access to publications and the release of reusable scientific data into the public domain, in addition to methodological transparency and interdisciplinary collaboration (Gitter, 2013).

Access to data and information within the open science model is facilitated by the prevalence of open access journals, where traditionally costly user fees are either non-existent or minimal, and publications are made freely available to readers (Wellen, 2013). As well, the issue of ownership is solved by licensing arrangements such as *copyleft* or *Creative Commons* licenses, where, contrary to their proprietary counterparts, users are granted the right to freely access and distribute data or information and subsequent modified work on the condition that its derivatives are distributed under similar conditions (Hope, 2008; Rhoten and Powell, 2007).

Open science is connected with biobanks. As mentioned, biobanks have a diverse taxonomy, ranging from population-based biobanks to disease-based and tissue-based ones to clinical trial-based biobanks (Verlinden et al., 2015). Examples include the International HapMap Project, the Human Genome Project, and the EuroBioBank, Open access to biobank data (or depending on the sensitivity of the data, ''controlled access'' to data) is integral to current -omics science and innovation, particularly given the potential for data-sharing across countries and research groups, which would reduce the inefficiencies entailed by research duplication and the prohibitive costs from data collection and sample management (Fortin et al., 2011).

The advantages of open data sharing in the context of biobanks have not gone unrecognized. For example, the UK Biobank has implemented a grant-back policy, requiring users to ''put results from all analyses made on participants' data and samples, and any relevant supporting information, in the UK Biobank database'' such that researchers conducting similar projects may have access, and further that users ''place all research findings using its data into the public domain after a limited period of exclusivity'' (Gitter, 2013).

In terms of ownership of data and material submitted to open access biobanks, both the US National Institutes of Health and the UK's Medical Research Council have established policies allowing contributing researchers ''some period of exclusivity during which they will have the sole right to publish analyses of the data,'' often for a 12-month period, while users of this data may not submit publications prior to the end of this period (Gitter, 2013). As examples of open science, biobanks represent an opportunity to promote open collaboration and, thereby, avoid the stifling effects of rising commercialization and proprietary IP rights restrictions on science and innovation (Dove and Joly, 2012). But one should be careful about praising too one-sidedly the virtues of open science and innovation.

A Panacea? Implications of Open Science and Innovation

While open science and innovation offer a solution to certain forms of monopoly rent-seeking, or rentiership, represented by proprietary IP rights, it also raises new, challenging questions. On the one hand, certain forms of open licensing (e.g., *Creative Commons*, *copyleft*) can simply close down the commercial incentive to undertake science and innovation (Deibel, 2014). For example, Verlinden et al. (2015) argue that proprietary IP rights (e.g., patents) can provide an incentive to innovate since they provide a mechanism to reap financial rewards from costly research and development. All of this obviously raises a critical issue around who would then develop new products if there were no proprietary IP rights—genomic, dental/oral, or otherwise.

On the other hand, building on the open source software movement, open science does nothing to challenge the traditional expert control of scientists, innovators, and clinicians over science and innovation priorities. Participant and patient involvement may be treated as secondary or irrelevant. Theoretically, anyone could contribute to open science, but largely it remains policed and controlled by professional scientists; it is not, therefore, inherently open to *everyone* (Hope, 2008).

A final issue, and one that is only really being raised recently, is the extent to which open science might simply be another attempt to create a ''knowledge commons'' that can then be enclosed through new property rights or technical arrangements (Tyfield, 2012). It could, in this sense, represent another form of rentiership in which everyone's freely-given labor is subsequently exploited as part of an intensified neoliberalization of science and innovation.

Thus, while open science and innovation *may* overcome certain forms of monopoly rent-seeking and can potentially provide benefit sharing and promote broad social benefits, it is *not* an unalloyed good. Indeed, this ''post-neoliberal'' way of doing science and producing knowledge can raise complex legal and ethical challenges. In addition to the usual concerns that open science may conflict with well-established, restrictive IP rights, and discourage (traditional) incentives to innovate, there are pressing concerns about informed consent and privacy. Namely, any ''more open'' form of sharing data must respect the interests and preferences of those who contributed their data to a biobank.

If participants stated a desire to not have their data shared for secondary uses, or only shared for certain purposes, that desire should be respected (and the inverse should also hold true). Similarly, if a consent form did not clearly document potential secondary uses of the data, it cannot be said that the data can be freely shared with all third parties for any purpose. As for privacy, open science and innovation must not mean the exploitation of personally identifiable data in ways that offend the privacy interests of individuals and groups.

As a result, in the biobank context, ''open science'' is more nuanced. Personally identifiable data is often made available on a ''controlled access'' basis, which means data access through some modality of control; for example, through application to a data access committee (after first possibly obtaining research ethics committee approval), who decides whether the applicant has a scientific basis for needing the data and through formal agreement, assures that the applicant will use the data in an ethically and scientifically robust manner.

This privacy concern is acute in health contexts, where genomic information is seen as inherently individuating (Lowrance, 2012). Researchers are making increasing use of vast datasets containing personal information, such as genomic and health data. Individuals and communities have a legitimate interest in safeguarding their privacy by avoiding their personal data being used to exploit, stigmatize, or discriminate against them or to infringe on their personal autonomy (Royal Society, 2012). Open science and innovation must not include the freely open, public marketing of data where it could result in the unwanted identification of individuals or lead to stigmatization of individuals or communities. Researchers and policymakers are advised instead to adopt proportionate and responsible approaches to sharing, compilation, and linkage of datasets containing personal data (Council of Canadian Academies, 2015; Sethi and Laurie, 2013).

Moreover, and as noted elsewhere (Ahmed et al., 2014; Dandara et al., 2014; Dove et al., 2012; Günther et al. 2014), it is critical to anticipate and address the panoply of sociopolitical, economic, legal, and ethical issues that may yet still emerge as hot topics in open science and innovation. Such issues may include disclosure of metadata, data integration, creating knowledge translation platforms in the developing world, public trust, inequities in access to innovations, accountability, dual use, and data security (as distinct from privacy).

Foresight may help to reduce friction between open models and extant laws and policies regulating biomedical research, diagnostics, and therapeutics based on the classic research governance model (e.g., specific consent, data protection measures potentially incompatible with open access, etc.). The anticipatory lens should be as global and broadly framed as possible (Petersen, 2013), as open science and innovation may not provide adequate protection from exploitation of publicly-funded basic science and some people or entities may have more ability to participate in open science and innovation than others simply because of their market power.

Lessons for Oral Health

We now turn to the implications of biobanks and post-neoliberal science and innovation for oral health. Two of the most prevalent oral diseases are caries and periodontal diseases. Both are infectious diseases, yet their initiation and especially progression are highly dependent on the host's genotype and environmental factors. Research has already demonstrated that evaluating the dental patient as a whole, not limiting the interest to the oral cavity alone, will uniquely bring distinct diseases together; examples include Crohn's disease and periodontitis (Keskin et al., 2015) and coronary artery disease and periodontitis (Schaefer et al., 2015). Oral pathologies are not limited to caries and periodontitis, however. There are other severe diseases and conditions like oral cancers, dysplasia, cleft lip-palates, and soft and hard tissue anomalies. Taking into account all of these problems, the integration of the potential benefits from biobanks driven by open science principles and an ethically and legally robust governance framework will likely increase the chance of developing new diagnostic and therapeutic modalities.

Yet caution is in order. On the one hand, constructing new oral health or dental biobanks and integrating molecular pathways of distinct diseases to reach multiple clinical endpoints is a highly tempting approach. On the other hand, as the saying goes, nothing is free—there is always a price to pay. Accepting oral-biobanks solely as value-free scientific infrastructures and ignoring the legal, ethical, and economic context around them will most probably lead to significant issues with detrimental impact, as we discussed above.

The economic points that need to be considered are not only related to the sustainability of the biobanks themselves; open science can enable researchers and innovators from around the world to analyze vast amounts of data without even running wet-lab analysis. A question then arises: who will own the IP? There is a conflict here

between the jurisdiction or institution that invested in the construction of the biobank and the researcher who analyzed the bioinformatics. The ''Montreal statement'' on research integrity and cross-boundary research collaborations might represent one starting point to resolve this issue (Lancet, 2013), although further mechanisms will be likely in the long run.

Other questions arise when it comes to legal and ethical issues. How eager will any jurisdiction be to expose the genome characteristics of its citizens, given the legitimate concerns around identifiability and even with the (remote) risk of biological and chemical wars? For example, researchers have already demonstrated that the DNA of a person can be isolated from salivary samples (Cuevas-Córdoba and Santiago-García, 2015). Researchers of oral medicine need to understand that a drop of saliva, which may let them understand the pathogenesis of periodontal diseases, can also be the source for a dual use technology. Therefore, it is advised that well-written guidelines, such as the National Research Council (US) guidelines (National Research Council 2004), be followed to minimize the unexpected risks.

Conclusions

In this article, we have suggested that many biobanks are established not only as scientific infrastructures, but also often as *de facto* political-economic ones. They epitomize a neoliberal form of science and innovation, in which research is driven by market priorities, logics, and expectations (e.g., profit, property enclosure, private goods, shareholder value) underpinned by state or government policies. As biobanks become established in fields such as oral health, it is incumbent on scholars in the -omics community to confront the array of problems associated with market-driven science and innovation, including profit trumping other considerations; rentiership trumping entrepreneurship; and applied research trumping basic research.

We suggest that a more promising avenue for biobanking in the 21st century—if we take concerns seriously about exploitation and loss of trust and solidarity—is a turn towards new forms of ''post-neoliberal'' science and innovation. Biobanks and the governance framework steering them have the capacity for reflecting values of citizenry, reflexivity, adaptation, solidarity, and reciprocity. Post-neoliberal science and innovation rests on the principles of openness, blue skies thinking, entrepreneurship, and collaboration. While openness and collaboration are more sustainable, socially just principles of science and innovation than profit and exploitation, this post-neoliberal turn must also be watched carefully, as it may raise questions regarding power, inequity, expertise, consent, privacy, robust incentives to innovate, and even disguised forms of rentiership.

In short, open science and innovation are not an unalloyed good. It is thus further incumbent on scholars in the -omics community to address these and other issues that may yet still emerge in open science and innovation. The post-neoliberal moment has arrived in the biosciences. Time will tell whether biobanks embrace a turn towards open science and innovation, what forms it will take, who will be able to contribute, and whether the master market logic will dissipate, but undoubtedly the issues raised herein will intensify in the coming years.

Acknowledgments

No funding was received in support of this article. The authors thank Vural Özdemir for his encouragement and suggestions.

Author Disclosure Statement

No conflicting financial interests exist.

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Address correspondence to:
Kean Birch, PhD
Department of Social Science
Faculty of Liberal Arts and Professional Studies
York University
4700 Keele Street
Toronto M3J 1P3
Ontario
Canada

E-mail: kean@yorku.ca