

Book Review

Ethical Issues in Governing Biobanks: Global Perspectives **Bernice Elger, Nikola Biller-Andorno, Alexandre Mauron, and** **Alexander M.Capron Ashgate Publishing Ltd, 2010**

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Introduction

On the basis of the title of this book, I expected something other than what I found inside. Rather than another, ethical analysis of the question of how we should collect, store and use genetic and other data in biobanks, the book reports an empirical study that includes the discussion of future scenarios with no fewer than 87 individuals worldwide. These individuals include academics (with a background in medicine, life-sciences, social sciences, humanities and law), people from NGOs, members of national ethics committees, government representatives, independent consultants and employees of international organizations. Most intriguingly, the participants come from all continents, hence the subtitle 'global perspectives'.

Order of the book

Before exploring further the results of this study, a few words about the order of the chapters and the way the book is constructed. The reason I want to pay attention to this aspect is because this is actually very well done in this particular volume (and such is not always the case if a collection of people publish an edited book as the result of their research project). The book starts with an overview of the ethical issues that can be found in the literature and that have shaped discussions on ethics and biobanks over the past few years. This chapter, written by Bartha M. Knoppers and Ma'n H. Abdul-Rahman, covers the major issues related to consent, confidentiality and commercialization. Here, these authors lay the groundwork for the rest of the book, introducing the notions of consent, anonymisation, ownership of data, right to withdrawal and so on. The next chapter, by Effy Vayena and her co-authors, touches upon more or less the same issues but explores how these are being dealt with and defined in international guidelines and recommendations, including those from WHO, HUGO, the OECD and others. The main focus of this chapter is both the (possibility for) emerging consensus and the unresolved controversies. As the reader has learned by this point, controversies prevail when talking about the ethics of biobanks.

The second part, which really is the heart of the book, describes the results of the in-depth interviews with people all over the globe. To structure these interviews, four scenarios were developed which were subsequently discussed with each of the interviewees. These scenarios are not so much *alternative* scenarios to describe different worlds, but rather portray different possible uses of biobanks:

- Scenario A involves the setting up of a *de novo* international biobank with DNA extracted from biological specimens to enable research on colorectal polyps. In

this particular scenario, three countries collectively take the initiative for this biobank, which is overseen both by a steering committee and an independent Ethics Review Board (ERB). Part of this scenario concerns different options to anonymise samples when they are being shipped to other countries; the possibility to withdraw samples; the use of samples for research other than colorectal polyps, and so on.

- Scenario B describes a non-profit organization in country A that wants to set up a population biobank to enable research on the specific genetic characteristics of this population. In this case, samples cannot be transferred out of country A. Questions to the interviewees concern this territorial limitation (is it ethical, useful, possible) and who should profit from the use or exploitation of the data.
- Scenario C describes a commercial company that wants to collect 2000 biological samples from an indigenous population in the country where the firm is based. Several options are presented as to what should be the relationship with and benefit for the members of the indigenous group.
- Scenario D describes a local hospital that routinely asks clinical patients to give their consent to the storage of biological samples for research purposes. The ERB is being asked to choose between different forms of consent. Should patients consent to a general use of their specimen for medical research, for example, or should they be given the opportunity to consent to each research project separately?

Discussion of Scenarios

In subsequent chapters, different authors describe what different interviewees have to say about the ethical issues concerning biobanks as presented in the different scenarios. Chapter four, for example, written by Bernice Elger, uses scenarios A and D to discuss questions regarding the use of samples, in particular the type of consent that is necessary. The chapter discusses under what circumstances interviewees prefer: (a) *informed consent* for each new study; (b) *presumed consent*, meaning that consent is presupposed but information is given about each research project that is being done and participants are given the opportunity to opt out; (c) *general consent* for future studies; or (d) a mixture of the other three. Chapter five, by the same author, focuses on scenario B and discusses consent for the use of samples collected as part of medical care. Agomoni Ganguli-Mitra's chapter uses scenario C to discuss the issue of 'collective consent'. Under what conditions is collective consent relevant and ethically acceptable? Chapter eight deals with the issue of data withdrawal. Again, four options are discussed: (a) no right to withdrawal; (b) right to withdrawal restricted to irreversible anonymisation of samples and information; (c) right to withdrawal includes destruction of samples and information in the biobank; and (d) right to withdrawal includes destruction of samples and information, including samples and information given to researchers.

Subsequent chapters follow suit and use different (parts of the) scenarios to discuss: anonymisation and coding; informing participants about research results; territorial restrictions using samples beyond national boundaries; public domain data sharing,

patents and fees; benefit-sharing and remuneration; and transfer of samples and sharing of results.

Rich material

The strength of the book is the rich and detailed exploration of the moral reasoning concerning a large number of controversial issues surrounding the development of new biobanks and the maintenance of existing biobanks. The book offers an excellent overview not only of the different issues involved but also of the controversies and questions that need to be considered. The interviews with professionals who are engaged with biobanks illustrate very vividly the many ways in which one could approach issues of consent, anonymisation, autonomy, privacy etc.

The authors have managed to present their material in a very lively, compelling fashion, making use of a combination of ethical literature, international reports and guidelines and the statements and questions that have been raised during the in-depth interviews. Since the researchers use very realistic scenarios to explore the moral issues that are connected to biobanks, questions and controversies really come to life, clearly illustrated by well-chosen quotes. Interviews are analysed in a comparative manner, showing similarities as well as differences between experts representing different professions and organisations and between different geographical places.

International comparison

In a number of cases it is clear that interviewees have very different views concerning the use and storage of genetic and other data in biobanks. An interesting issue is the degree of trust that interviewees have in different arrangements. These differences are often linked to geographical places, to where interviewees are situated in the world. With respect to the issue of consent and the use of samples, for example, the authors report that their data indicates “a greater fear of abuse outside Europe and North America, in particular among members of indigenous groups” (p.83). What the researchers describe here is not only a general mistrust among interviewees outside Europe and North America, but also a different appreciation of existing institutions. Ethics committees, for example, have a different role and status in Europe and North-America from that in other parts of the world:

In Europe and North-America respondents seemed to identify the decision of an ethics committee with a form of collective permission, also referred to as custodianship of the samples, whereas respondents from developing countries and indigenous groups outside these regions made a clear difference between the decisions of ethics boards and the genuine instances of collective consent such as ancestor councils or other forms of tribal authorities. (p.118)

Likewise, different regions in the world have a different attitude towards the question of what constitutes an individual. In some parts of the world this is related to families and tribes, which strongly shapes how people see bodily material and who is to decide about uses of this material.

Differences between regions do not always play a role, however. With respect to the withdrawal of data from a biobank, for example, the researchers “did not find any significant differences in the attitudes of respondents from different regions” (p.161). On a number of occasions, differences seem to be determined rather by the professional background of respondents or the experiences they had with biobanks.

Another finding is the difference between interviewees who do and do not have experience with storing samples. This difference is observed most strongly with respect to the issue of consent and the use of data for research purposes. Interviewees who have experiences with data storage themselves are more likely to opt for general informed consent, as opposed to new informed consent, than interviewees who have no personal experience with data storage.

These findings can be explained in several ways: On the one hand respondents who used samples are in a better position to know about burdens they may have experienced themselves. On the other hand, as admitted by several respondents, researchers’ attitudes reflect their own interests to avoid inconvenience for research, and they may see the balance with patients right somewhat differently. (p.84)

Methodology

As mentioned earlier, from the title but also the list of authors – who come mainly from the field of ethics and law - I had not expected such a rich empirical study. To me, the book reads like a social scientist’s approach to ethics. However, I wonder whether the authors would describe their work in these terms. My impression is that the authors seem to consider the scenarios and interviews as more or less an *instrument* to explore ethical issues rather than a methodology/approach that deserves attention in its own right. The reader learns little about the actual method and approach that the authors have used to collect their (interview) data. I would have liked to read more about the construction of the scenarios, for example. The authors claim these were developed “following an extensive review of the existing literature and through discussions with experts in the field” (p.41). I am curious to know *how* this construction came about, what happened in the pilot runs and what were the experiences of the researchers in using the scenarios. Scenarios, in my experience, only work well if they are well defined, understandable and seem realistic to those who are presented with them. To develop a good scenario is anything but an easy task, but my impression is that the scenarios presented in this study were very well developed. That the reader cannot learn more about the development of these scenarios and the researchers’ experiences in using them seems to be a missed opportunity.

Governing biobanks?

After finishing the book I was left with one important question: whether it is possible to ‘govern’ biobanks, as the title implies, and if so, how this governance should be organised. The authors claim they want to improve the ethical and regulatory frameworks of biobanks (p.7) but it is unclear what improvement means. The book balances between two opposed conclusions. On the one hand, the story hinges upon

the notion that governance of biobanks is something that can and should be achieved. On the other hand, the different chapters illustrate that biobanks are shaped by controversies and issues that are not easily managed or solved by regulation, harmonisation and standardisation.

In parts of the book the reader is confronted with the difficulties of governance of biobanks. On a number of occasions the authors suggest that it is hard to draw conclusions, let alone make firm recommendations: "Our study does not provide an answer, but it demonstrates how important it is that these questions are raised and more openly discussed." (p.163) In other chapters, we read that from the interviews some consensus or common ground has been observed. However, this does not necessarily lead to recommendations, and there is no overall conclusion or set of recommendations in the concluding chapter.

Other parts of the book suggest that governing biobanks in an ethical way is both necessary and do-able. In several chapters, authors talk about the need for uniform international guidelines, harmonisation and standardisation and make recommendations about the conditions that allow for such uniformity: "The first step towards uniform international guidelines could be the implementation of trustworthy control mechanisms that fulfil local expectations of community representations." (p.119) And, "If there is enough evidence that trustworthy ethics committees and feasible data security techniques exist to protect research participants even in developing countries and in indigenous populations, this could increase trust and make a moderate version of general consent acceptable."(p.87).

The interesting thing is that the empirical study indicates there are very few issues that seem to lend themselves to uniform guidelines, standardisation and regulation. Take the issue of commercialisation. Commercialisation is an issue that is often addressed in relation to biobanks and which most actors agree is a tricky issue. After all, when people donate bodily material and personal information freely, is it acceptable that biobanks somehow profit from this free donation later on? At what cost and under what conditions could this be acceptable? The question is certainly relevant since many biobanks foresee that in the future commercialisation of data and information is the only way to organise a return on their investments. Although most individuals and official bodies agree that commercialisation should not lead to misuse and abuse of data and information that is donated voluntarily, even this topic does not lend itself for easy harmonisation and regulations.

To some, scientific research is undermined if sustained by the profit motive. Scientific research is meant to advance knowledge in the public interest, and commercial interests undermines its basic nature. By contract, others noted that having commercial interests per se is ethically neutral and often provides the necessary incentives. (p.213)

One may argue that the lack of recommendations and solutions is a weakness of the current study. Alternatively, however, one may also argue it is actually one of its strengths as it shows that 'biobanks' are perhaps not one single topic or theme.

Rather, biobanks bring together a variety of issues, technologies and common practices. These are both old and new technologies brought together in a different fashion and a different format. Time will tell how these new formations will help shape our social reality and how social realities will help shape what we call biobanks. Perhaps, if there is one conclusion that can be justified on the basis of this book, it is that we should stop using the combination of “biobanks” and “governance” as this suggests a more homogenous, controllable and foreseeable future than we really have.

I strongly recommend this book to anyone who is interested in the topic of biobanks and who would like to understand more of the complicated discussions concerning them.

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