

BOOK REVIEW

THE ETHICS AND GOVERNANCE OF HUMAN GENETIC DATABASES: EUROPEAN PERSPECTIVES

By Matti Hayry, Ruth Chadwick, Vilhjalmur Arnason and Gardar Arnason (eds.)
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This book presents the findings of the ELSAGEN (Ethical, Legal and Social Aspects of Human Genetic Databases: A European Comparison) project and provides a unique account of the concerns and issues at stake in the field of Human Genetic Databases (HGDs). The book presents a truly interdisciplinary investigation containing, as it does, input from the disciplines of philosophy, law and sociology. The authors are amongst the most recognised in this research field and the book benefits, as does the reader, from their collective knowledge and expertise.

HGDs typically combine health and genetic data from a large population and may also include genealogical information or lifestyle information. Their purpose is to provide data and samples for research in human genetics and medicine. HGDs have the potential to assist researchers in their aim to improve the prevention, diagnosis and treatment of disease. However, along with this potential comes a raft of legal and ethical questions, including:

- How can participants provide informed consent when future uses of HGDs cannot be predicted from the outset?
- How will a participant's privacy be adequately protected?
- Who should be entrusted to manage an HGD and how will it be governed?
- How will the benefits of the research be shared?

The book sets out to address these questions with reference to four actual, or planned, HGD initiatives: deCODE's databases in Iceland, the Estonian Genome Project, UK Biobank and the Medical Biobank of Umea, Sweden. The book is divided into 27 chapters arranged into six parts: Background; Social concerns; Legal issues; Ethical questions; Political consideration and Conclusions.

Background

The reader is first introduced to the HGDs in question, and specifically their size, purpose, ownership and developmental status (the ELSAGEN project ran from 2002-2004 at a time when most of the HGDs were new or under construction). ELSAGEN's objectives and methods of working are also presented as an introduction to the subsequent chapters.

The reader is also provided by means of background with an analysis of the fundamental concepts of bioethics and their relation to HGDs. Ethical issues that relate to the concepts of consent, privacy, confidentiality, security and public interest are used to test the differences and similarities between American (autonomy, non-maleficence, beneficence and justice) and European (dignity, precaution, subsidiarity

and solidarity) approaches to bioethics. The authors conclude that, depending on definitions, the principles are compatible with radically different practical rules and guidelines. They propose therefore that if people want to know the concrete values to which politicians and legislators are committed the ‘proof is in the pudding’ – in the practical rules they apply to HGDs, not in the words that they use.

The final chapter in this section provides an enlightening focus on the languages of privacy. The author draws on Iceland to investigate the evolution of the term ‘privacy’ as it has changed to better capture the English meaning of the term. As with the chapter on bioethics, this points to the importance of interpretation and the need to be aware that when we translate concepts we are also translating cultural references. Evidently, in any proposed harmonisation of regulations the issue of cultural context becomes pressing.

Social concerns

Chapters 5-9 present empirical evidence about public attitudes to uses of genetic information in Estonia, Iceland, Sweden and the UK. The chapters focus on public perceptions of privacy in relation to personal medical and genetic data and people’s attitudes to the trustworthiness of public and private organisations.

Heeding the call in earlier chapters for due consideration of cultural context, the ELSAGEN team tailored their research to these existing legal and social circumstances in the countries in question (including, for example, utilising different methodologies). This thoughtful investigation is a real strength of the book reflecting, as it does, the different cultural contexts in which the analyses were performed.

As might be expected, the authors find a variation in the attitudes of the surveyed citizens of different nationalities in relation to genetic research. These range from a sense of optimism in Estonia, to a sense of suspicion of scientists in England (accompanied by general support for HGDs as part of the contemporary healthcare system). In Iceland, the authors found some doubts expressed about items that are stored in the Health Sector Database but that the surveyed individuals are technologically motivated. In Sweden the interviewees wanted genetic data handling to be securely under state control, but were otherwise pragmatic. It should be noted that these results may or may not be representative of the broader public in these countries.

Against this backdrop of varying attitudes to genetic research, common themes of concern were found in all countries, including consent, privacy and confidentiality. Despite these concerns, the surveyed members of these countries generally wanted to support HGDs providing that they are run by dependable organisations and only used for good causes (e.g. health research). A number of unacceptable causes were also identified in these chapters including genetic discrimination in employment, insurance and reproduction; science purely for its own sake; and the accumulation of excessive profits.

Legal issues

This part of the book presents comparative analyses of the law and governance in the four countries with respect to consent, third parties’ interests, feedback of health information to participants, genetic counselling, benefit sharing and governance. In

doing this they reflect on the different regulatory environments of the HGDs. For example, Estonia has specific legislation which includes rules concerning many of the issues described above; Iceland has specific legislation which addresses only some of these issues; Sweden and the UK have legislation which addresses medical research but nothing specific to HGDs.

The legal analyses tell us that the current laws and governance of HGDs contains many gaps and contradictions which may inhibit the co-operation of scientists and the sharing of samples across national borders. Issues are not addressed in the same way across all jurisdictions: there is a lack of clarity with regards to who owns the samples; requirements of the consent processes are not uniform (in particular with regards to the future uses of the data and samples); different legal systems allow and indeed require different degrees of feedback of health information to participants; and the rules and processes for access to samples and data are unclear in some cases.

The research of the ELSAGEN team concludes that it is only with a specific legal instrument, such as in Estonia, that the issues raised by HGDs will be dealt with in a comprehensive, coherent and consistent way. However, the team's research has shown that such a uniform governance system across Europe may not be feasible – as indicated by the lack of agreement on the definition of the term “HGD.” The team suggests that further research should be undertaken including the elucidation of a full typology of the different features of HGDs (including content; purpose and use; procedures regarding management and access; and public, not-for-profit and commercial status). This is a very constructive suggestion as such a typology would hopefully bring greater clarity as to the different types of HGDs which are in existence and in turn inform the development of an appropriate governance regime.

The ELSAGEN team's work focused on the European context. We should not forget that HGDs are in operation globally with significant initiatives in a wide range of countries, for example Australian, Canada, China, Japan and Taiwan. The typologies mentioned above, and the outcomes of the ELSAGEN team's research, have the potential to have a global significance beyond Europe with regards to the harmonisation of HGDs.

Ethical issues

A range of ethical investigations are presented in this part of the book including: social justice; benefit-sharing; genetic discrimination; informational privacy; trust in science and consent.

The theme of social justice is investigated in the chapters on the notion of global public goods (GPGs) and benefit-sharing. In the chapter on GPGs the authors conclude that in the current social and political realities, it seems problematic to claim HGDs as GPGs, when it is primarily developed countries that will benefit from the technologies and treatments developed. The chapter on benefit sharing argues that the very scale and scope of HGD have introduced new concerns for fairness and justice that call for a different justification for benefit-sharing. The author concludes that it is an open question as to whether HGDs follow traditional reciprocal forms of benefit-sharing (for example as found in Estonia where participants are promised individual feedback) or whether more inclusive arrangements based on solidarity are taken up (for example UK Biobank where participants are explicitly informed that they are not expected to benefit but that the benefit will be for future generations).

With regards to the subject of both of these chapters, this reader would have welcomed a complimentary investigation concerning the actual practices of the HGDs of Iceland, Estonia, Sweden and the UK. For example, to what extent do the HGDs draw on the language of the public good and how does this concept affect the management of the HGDs? What benefit sharing options do the HGDs in question support? These may be interesting avenues for further research.

The chapter on genetic discrimination asks whether genetic discrimination and the regulation of it can be given a reasonable foundation in philosophy and on what grounds we can identify instances of discrimination. An account is put forward which sets discrimination firmly in the relations found in an institutional culture of asymmetric power where certain characteristics can be used as a basis for discrimination. It is proposed that genetic discrimination can be regulated either through the provision of public health insurance or through restrictions on private health insurance (e.g. moratoria on the use of genetic test results). However, in any event, the author of the chapter remains unconvinced that genetic medical information should be treated in a way different to non-medical information and that genetic information is exceptional.

Privacy and trust are two central themes of the book and each has a dedicated chapter in this section. The chapter on privacy proposes a definition of privacy that rests on control over personal information. It is asserted that the nature of HGDs frustrates the possibility of such individual control, for example, if a participant is not able to control the future research uses of his/her data. In light of this the author suggests that the focus on privacy protection should be to prevent misuse and stigmatisation and that a balance should be found between the limited individual control of personal information in a HGD and 'trustworthy institutions' working in the public sphere to protect participants' privacy.

The chapter on trust also asserts that 'trustworthy institutions' would help protect participants' privacy. The following aspects are explored: the concept of trust; what trust relationships might exist in terms of HGD research and what kind of trust is needed for the successful operation of HGDs. The author concludes that to create trust it is necessary to show goodwill and competence. Authentic, reflective trust should be sought and blind trust or irrational mistrust should be avoided. Authentic trust should involve rational thought about the nature of the trust, including the risks associated with it. In this way, the author concludes, thinking about trust helps us to maintain trust and to equip us against possible breaches of trust.

This part of the book concludes with a chapter on informed consent. This will be a familiar discussion to those readers with a prior knowledge of this field, addressing as it does issues and arguments that have been well rehearsed elsewhere. However, no book on the ethics and governance of HGDs would be complete without at least one chapter on consent and the authors provide a very thorough discussion of what constitutes informed consent, the moral importance of informed consent, and the types of consent that might be employed to satisfy the moral requirements of protecting or promoting the well-being of individuals and respecting their autonomy. The authors conclude that an authorisation, which implies consent based on information about conditions for use of data in the HGD, meets with the moral requirements for genetic epidemiological research.

It was a shame not to see the feedback of health information to participants as a discrete chapter in this section. As the legal analysis described, the provisions for the

feedback of health information to participants vary considerably between the HGDs. In Estonia participants have a right to access data (including genomic data) whereas in the UK Biobank only limited feedback of measurements taken during recruitment is provided. Given the quality of the other chapters in this section, this reader is sure that the ELSAGEN team could have constructively contributed to the ethical debate on this issue.

Political considerations

The three chapters that constitute this part of the book help us to take a step back from the detailed issues around HGDs to take a look at three broader aspects: the impact of HGDs on ethical frameworks; the rhetoric surrounding genetics and, finally, governance. The first and third chapters provide a welcome reflection on the development of the term ‘governance’ and how well governance can deliver responsible biotechnology. They also address the questions HGDs have raised regarding harmonisation of ethics and the impact of HGDs on both the discussion of governance and the practical models being proposed.

It is argued that governance demands a highly competent public sector and that HGDs should steer away from entering into exclusive commercialisation agreements (as otherwise projects initiated in the public interest may no longer reflect the public interest but the interests of a private company). Three of the four HGDs in question (Iceland, Estonia and Sweden) have, or have had, explicit and exclusive agreements with private companies in return for significant funding by those companies. Serious problems have subsequently occurred in all three HGDs. This chapter raises, but does not investigate, the important issue of how a HGD is funded. HGDs are long term ventures requiring considerable and sustained funding. The chapter recommends no exclusive commercialisation agreements, but will this result in a funding gap for some HGDs? Will this gap be filled by the public sector? It would be interesting to look in more detail at the funding of various HGD initiatives and to assess the implications of funding on the governance of the project (including the pros and cons of public funding and the influence of the political climate).

In the second chapter in this part, titled ‘Genetics, rhetoric and policy’, the author calls for a more balanced and accurate account of genetics in media and policy discussion arguing against a deterministic view of genes. The chapter has a very broad focus, drawing heavily on the media discourse surrounding the Human Genome Project (HGP) but unfortunately drawing little on discourse surrounding HGDs. The author points out that the HGP gave rise to stronger rhetoric than HGDs. It would have been interesting if this chapter had addressed HGDs more directly, for example by providing more quotation associated with HGD research or by investigating the possible reasons behind the differences in the amount of rhetoric that the HGP and HGDs have generated. Nonetheless, the author concludes that when it comes to policy issues regarding genetics, rhetoric should be avoided. We are also warned against the temptation to use this rhetoric to present HGDs as promising revolutionary solutions to medical problems.

The reviewer’s conclusions

This book provides a comprehensive account of the key issues at stake with regards to the ethics and governance of HGDs. Privacy and trust come across as the two most

pervasive themes, both of which the authors state should be clearly addressed in the governance arrangements adopted by a HGD. In turn, the governance arrangements will need to be sympathetic to the cultural context in which the HGD is established. Another clear message is that HGD research is challenging traditional understandings of concepts like privacy, consent and benefit sharing and that the regulatory environment governing HGDs is fragmented and lacking. The reader is left with a strong sense that there is much work to be done in terms of developing coherent ethical and governance frameworks at a European level. This book provides an excellent foundation from which these issues can be addressed.

Certain issues are mentioned in the book which this reader considers to warrant further investigation. For example, a study of the complex notion of public interest and public good and how these should be construed in relation to HGDs, and where the appropriate boundary between public good and private profit should rest. It is interesting to note that Jane Kaye, who in the book argues for a typology of HGDs to encourage the formation of European-wide regulation, is currently working on the 'Governing Genetic Databases' (GGD) project. This project aims to elucidate a full typology of the different features of HGDs. Where this book has pointed to the difficulties in harmonising regulation this reader eagerly awaits the outcomes of the GGD project to see what practical suggestions might arise with respect to standardisation and harmonisation of HGDs.

A major strength of the book is that it reflects on actual or proposed HGD initiatives, providing a 'real life' dimension to most of the discussions. However, there has been much progress in the world of HGD's since the ELSAGEN team conducted their study in 2002- 2004. For example, UK Biobank has since launched recruitment and, at the time of writing, has 75 000 participants. Nevertheless the investigations in this book are informative and still relevant to the issues being discussed today. The book will be of general interest to scholars and of practical value to practitioners. It is a welcome addition to the HGD literature.

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