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POPULATION GENETIC DATABASES: A COMPARATIVE ANALYSIS OF THE LAW IN ICELAND, SWEDEN, ESTONIA AND THE UK

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Abstract. The first population genetic database proposed in the world was the Icelandic Health Sector Database in 1998, followed by the Umangenomics proposal in Sweden, the Eesti Geenivaramu in Estonia and the UK Biobank. These genetic databases have been established with the primary goal of carrying out genetic research on populations to determine the functionality of genes, as well as the relationships between genes, lifestyle and environment. Population genetic databases contain DNA samples, personal information from interviews and medical records, as well as genealogies and family histories on whole populations for genetic research. This variety of information and the issues that are raised by its use, such as ownership, consent, feedback, genetic counselling, benefit sharing and access to the database, have caused a heated debate in many countries. This paper compares the way in which the law deals with these issues in each jurisdiction through specialist legislation and how these issues challenge existing legal precedents. The conclusion reached is that these issues are not currently addressed by the law across these jurisdictions in a coherent manner and we are some way from achieving a uniform legal structure for population genetic databases across Europe.

Keywords: Human biobanking, genetic database, legislation, comparative survey, Estonia, Great Britain, Iceland, Sweden

1. Introduction

The first population genetic database proposed in the world was the Icelandic Health Sector Database (HSD) in 1998, followed by the Umangenomics proposal in Sweden, the Eesti Geenivaramu in Estonia and the UK Biobank. It is only in Estonia and Iceland where specific legislation has been enacted to cover these

population genetic databases.[1] These genetic databases have been established with the primary goal of carrying out genetic research on populations to determine the functionality of genes, as well as the relationships between genes, lifestyle and environment. In order to achieve this population genetic databases combine DNA samples, personal information from interviews and medical records, as well as genealogies and family histories. This variety of information and the issues that are raised by its use, such as ownership, consent, feedback, benefit sharing and access to the database, have caused a heated debate in many countries. The purpose of this paper is to discuss the way in which the law in each of these jurisdictions deals with these issues through specialist legislation and how these issues challenge existing legal precedents.

2. Ownership

Ownership is an internationally recognized legal concept that embraces several aspects related to control over a 'thing'. Its historical roots in the Roman law are so strong that the later national developments in various countries have not triggered any international attempt to harmonise the property law or tackle mutual recognition issues, with the exception of intellectual property law.[2] However the European Parliament and the Council of Europe have recently called for research to be undertaken in the fields of tort law and property law in order to determine whether the differences in Member States' legislation constitute obstacles to the proper functioning of the European internal market.[3] The following sections present a short analysis of the ownership of the contents of the population genetic database such as DNA samples, personal information and genealogies, as well as the discoveries or inventions resulting from the research.

The importance of ownership

Along with the growth in biotechnology, genetic resources have taken on an increasing scientific and commercial value for a wide range of stakeholders. In the context of population genetic databases, one could view ownership as:

a) an instrument to grant control over the things – i.e. the institutionalised owner is entitled to determine by whom, when, how and on what purposes the thing is to be used; and

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1 These are the Act on a Health Sector Database 1998 No. 139/1998 (Lög um gagnagrunn á heilbrigðissviði, nr. 139/1998) (Iceland) and the Human Genes Research Act 2000 (Inimgeeniuuringute seadus) (Estonia).

2 For example Paris Convention for the Protection of Industrial Property (1883); WIPO Patent Law Treaty (2000), Berne Convention for the Protection of Literary and Artistic Works (1886); WIPO Copyright Treaty (1996).

3 Communication from the Commission to the European Parliament and the Council – A more coherent European contract law – An action plan *COM/2003/0068 final*.

b) an instrument to make the thing subject to commercial transactions (sales, pawn, rent, licensing etc) and give rise to financial gain.

Although there are differences in the national rules on the transference of property, the substantive differences reveal themselves in careful analysis of the 'new' property that has emerged in relation to genetic databases. These 'new' objects include biological samples such as DNA samples, genealogies and health data from particular individuals as well as the genetic database as a whole. The DNA samples and genealogies are new because traditionally there has been no research 'market' for them i.e. they could not be considered as 'genetic goods'. Health data is used for diagnosis of patients or medical research, but it is the potential of genetic research that requires a second look at the regulations. Population genetic databases are a structured collection of material and discoveries or inventions are already covered by ordinary regulations on data collection and intellectual property. The novel aspect of population genetic databases is the altruistic participation of many people, sharing a common heritage, with the potential for the results of the research to benefit society in a number of ways. There are few examples such as this where there is a mass contribution to a project conducted by a small number of researchers where the intellectual property benefits will be concentrated in the hands of a small number of patent holders (unless this is otherwise agreed by contractual means). As this is a new phenomenon there needs to be clear legal guidance on the rights and obligations regarding ownership of the different aspects of the genetic databases as well as the population genetic database itself. However in each country these issues are dealt with quite differently.

DNA samples

DNA samples are the most basic unit of a population genetic database and are usually stored as both a physical substance and as sequence information. Many parties that have an interest in the DNA samples starting with the donating person and ending with researcher or funding institution. As a tangible thing it could theoretically be subject to traditional ownership rules, but various questions rise. First, the general principle in European law is that no part of human body should give rise to financial gain as such.[4] There is also a general presumption in the law of each country that there are no property rights in the body. The parliamentary discussion and investigation preceding the Swedish Transplants Act stated that a body was not considered a thing in legal sense, but not much more has been said.[5] In the UK, the common law has traditionally regarded that the human body cannot

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[4] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biotechnology and Medicine, Article 21.

[5] SOU 1992:16 Kroppen efter döden (SOU 1992:16 The Body After Death), Prop. 1994/95:148 Transplantationer och obduktioner m.m. (Bill 1994/95:148 Transplants and Autopsy etc.). For an account of the Swedish position see also Westerlund L. & Persson A.H., Civil law reflections on the use of human biological material, In Hansson Mats G. (ed), (2001) *The Use of Human Biobanks. Ethical, Social, Economical and Legal Aspects*. Uppsala University.

be the subject of a property right. However in the case of *R v Kelly*[6] the court found that a body part from a dead person could become a property if sufficient 'skill and work' has been exercised over it. This means that once DNA has been isolated from a sample it could be used without further permission from the individual. The court also said that they thought that such issues were best left to the legislature to resolve. The UK Medical Research Council guidelines which do not have any binding legal force, regard that biological samples should be seen as donation or gift to the research institution, because of this uncertainty in the law.[7] Other than these unconnected statements of principle, there is a lack of clear legal intent and the preferred method of protecting donor interests is through privacy law and data protection legislation.

The general approach in the law across the different jurisdictions is that control of the DNA samples rest with the controller of the population genetic database, though this is not clear in all jurisdictions if this is actual ownership. In Estonia, biological samples are expressly made the ownership of the chief processor of the Eesti Geenivaramu, but ownership is not transferable (subject to commercial transactions) and the donating person cannot claim any remuneration for it.[8] However the donor has the right to request the destruction of the sample, if his or her anonymity is illegally disclosed. In Sweden the biological samples are collected and possessed by various medical institutions, the most well known in Umeå. The lawfulness of their collection and storage has not been challenged although it was not until 2003 that legislation was put in place to govern this.[9] However, the legislation has incomplete regulations regarding consent, and different rules apply to the transfer of single biological samples or the transfer of a genetic database or part of the genetic database. There is also a legal distinction between genetic databases operated by public or private entities, which leads to a high degree of uncertainty regarding the ownership of genetic databases in Sweden.

In contrast, the Icelandic Act on Biobanks[10] provides that the biobank operator is not to be considered the owner of the biological samples in the bank. Instead the operator retains limited rights to the usage of biological samples which includes that such samples cannot be sold or used as settlement of claims. The law does not make anybody expressly the owner and thus one might ask, for instance, if the donating person still retains ownership over the sample or not. In the UK the new Human Tissue Act will introduce a licensing system to cover the storage of tissues and organs. However it is unlikely that the UK legislation will address ownership issues. It is more likely to frame such considerations in terms of the rights and responsibilities that attach to the licence as is the Icelandic legislation.

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6 [1998] 3 ALL ER 741.

7 Medical Research Council (2001) *Human Tissue and Biological Samples for Use in Research* MRC:London.

8 Section 15 of the Estonian Human Genes Research Act 2000.

9 Lag om biobanker i hälso- och sjukvården m.m. (2002:297), Biobanks [Health Care] Act 2002:297).

10 Act on Biobanks no 110/2000 (Lög um lífsýnasöfn, nr. 110/2000)

In conclusion the UK, Swedish and Icelandic regulators have left the issue of the ownership of DNA samples in an uncertain state unless this is determined through individual contracts. Another reliable conclusion is that in all four countries the donating individuals would be regarded as having waived proprietary rights in the DNA samples (if they ever had this right to begin with). This conclusion could be legally challenged, except in Estonia and in Iceland (and perhaps in the UK) where DNA samples are explicitly placed under the operator's control, even though this control does not extend to commercial transactions. In the UK and Sweden the tissues are under control of the biobank processors either as situation *de facto* or according to the decision of lower authorities (such as the Medical Research Council) rather than the parliament. The transfer of the samples to any third party, including any commercial entity, is not legally precluded in Sweden and in UK as long as the purpose of the transfer is coherent with the aims of relevant regulations.

Health data

In all four countries, the collection and use of health data is governed by EU Directive on the Protection of Personal Data and the Free Movement of Such Data 95/46/EC and respective domestic laws.[11] Therefore, many proprietary aspects (including rules on data subject's consent, collection, storage, purposeful use, access) are regulated there without any need to solve ownership issues in traditional manner. The founding principle of the Directive and legislation in all four countries is that the person shall control his or her data, decide upon sharing it with others and determine its use. The questions arise after the first step has been made and the data has been collected in the genetic database. What are the rights and responsibilities of the operator of the genetic database regarding each set of personal data, when the data becomes unidentifiable? In Estonia and within the Icelandic HSD, genetic researchers can only process anonymous data. In Estonia it has been stated expressly that the chief processor of the genetic database is the owner of the health status description (this is a specifically formatted set of data about an individual), i.e. the chief processor can determine its access and use by other persons (with some statutory limitations and rights of gene donors). No third party can claim or establish through use any independent rights upon the health status description, all users will always legally depend on chief processor's authorization to possess and use the data. Other countries have not addressed the ownership of anonymous data issue at a legislative level. Therefore, anonymous health data in any particular format seems to belong to the public domain, provided that initial rules according to the Directive and implementing legislation have been followed.

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[11] Icelandic Act on Protection and Processing of Personal Data, no. 77/2000 (Lög um persónuvernd og meðferð persónuupplýsinga, nr. 77/2000); Swedish Personal Data Act 1998:204 (Personuppgiftslag (1998:204); UK Data Protection Act 1998; Estonian Personal Data Protection Act 1998

Genealogies

Family genealogies are generally seen as personal information if they are provided by the individual and would therefore come under data protection legislation. Although this information has often been provided by an individual it also contains information about other family members and therefore there needs to be a consideration of other people than those providing the information. However it is not clear what the situation will be under data protection principles or whether there is a concept of family privacy that would be protected under the law. Such information can also be obtained through the public record system and in some countries is regarded as being in the public domain. In Estonia the ownership of the genealogy falls to the chief processor of the genetic database and there are statutory limitations to the access and use. In the legislation genealogies can only be used within the population genetic database to structure the contents and shall not be distributed to anyone, not even the gene donor. In Iceland the licensee is entitled to link a genealogical database to other databases under the Act on a Health Sector Database. The ownership of the genealogical database itself will belong to the licensee even though donors may have some interest in the information under data protection legislation. Neither Sweden nor the UK has national genealogies in the same way as Iceland and unlike Estonia there is no specific legislation on this issue.

The Population Genetic Database

Directive 96/9/EC on the legal protection of databases[12] allows copyright as well as *sui generis* protection of the population genetic database design. This copyright protection does not cover the contents of the database but only the database design, the way in which the database is structured and the collection as a bulk (you cannot copy the whole of the contents).[13] This means that a biobank controller could own the database but not necessarily 'own' its contents. Therefore the regulations on database copyright protection do not assist in determining who actually owns the DNA samples and the personal data. It is only in Estonia that this has been expressly stated that both the DNA sample and the health status description as single items belong to the chief processor of the biobank. In the case of the Icelandic HSD the license agreement requires that all data and the software will be returned to the Ministry of Health and Social Security once the license expires.

Intellectual property rights

These derive from the inventions that have developed out of the research that has been conducted on the population genetic database. Each country recognises patent rights over a novel, sufficiently innovative and industrially applicable invention. As a reward, the inventor has the right to authorize or prohibit others

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[12] Directive 96/9/EC of the European Parliament and of the Council of 11 March on legal protection of databases. Official Journal L 077, 27/03/1996 p. 0020–0028

[13] See preamble (7), (12), (13), (15), (17), (26), Article 3 (2).

from using the invention. The owner of the patent is not obliged to share the benefits (license the patent or distribute royalties) with other persons. However none of the laws in each country recognises that the donor of genetic information has any rights over a patent that is based on that information.[14] Much of the arrangements about the division of intellectual property rights based on research on the data in the population genetic database depend on individual contracts. In Estonia, these arrangements have been made explicit, however not on statutory level, as the chief processor is co-owner of any intellectual property created by its private funding partner. In the UK this is still uncertain, and in Iceland, no special legal restrictions were put on the licensee Íslensk erfðagreining ehf.'s freedom to negotiate this for itself.

3. Consent

Informed consent is the internationally recognised standard for any research that is conducted on human beings, although there are exceptions to this requirement in practice. There has been considerable debate as to whether it is possible to fulfil the requirement of informed consent as articulated in the World Medical Association's Declaration of Helsinki,[15] when it comes to population genetic databases. This is because at the time of collection it is not possible to foresee all the research uses of the population genetic database or to know who all the researchers will be. In contrast the Data Protection Directive 95/46/EC bans the processing of sensitive data, as a general rule, but allows a number of exceptions to this requirement on the basis of the public interest, in addition to allowing such processing on the basis of explicit consent. Each country has taken a different interpretation as to how these requirements should apply and there are differences in the approach to DNA samples and personal information.

Explicit consent

The Estonian Human Genome Research Act (HGRA) requires a donor's OKAYconsent to be explicit, without exception. This is different in Sweden where the Biobank [Health Care] Act (BBA) requires consent for collection of biological samples to be explicit – the same does not apply to genetic data. Important exceptions from the requirement of explicit consent are made in the Swedish Personal Data Act, including permission for sensitive personal data to be processed for health and hospital care purposes, without the consent of the data subject. This exception makes almost all unconsentual processing of personal data in biobanks and genetic databases lawful. The Icelandic Act on Protection and Processing of

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[14] Recitial 26 of the Directive 98/44/EC on Biotechnological Inventions stresses that the informed consent of gene donors as a precondition to patent protection.

[15] World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects, 52nd WMA General Assembly, Edinburgh, Scotland, October 2000 (http://www.wma.net/e/policy/b3.htm Accessed 16/10/03).

Personal Data holds similar provisions, stemming from the EU Directive 95/46[16]. These clauses have so far not been interpreted as being quite as wide as in Sweden. However, explicit consent is not the rule in Iceland, since the Act on a Health Sector Database is not based on explicit consent, and the Act on Biobanks requires explicit consent only in cases where biological samples are harvested for the purposes of storing in a biobank. In the UK following the Directive 95/46/EC the general requirement is that there should be explicit consent for the processing of health data, but there are exceptions to this rule for research purposes and in the public interest. Where the UK differs slightly is that data that has already been collected for research can be used for related secondary research purposes as long as this is not used to support decision-making about the individual, nor should it cause the individual substantial distress or damage. In the UK conditions are attached to the research exemption. Exemptions will also be allowed in the public interest by the Secretary of State[17]. The new Human Tissue Act will govern the collection and storage of biological samples but the requirements for consent have yet to be finalised.

Should the consent be specific?

One of the contentious issues around population genetic databases is whether consent must be limited to a particular processing, e.g. a particular type of medical research, or if it can be more vaguely defined, for example by only giving a broad description of the purpose for the processing such as to 'research health for the public benefit'. In legislation that has been especially drafted for genetic databases it has been seen as sufficient that a broad description of the purpose is allowed. For example in Iceland where consent for the processing of health related data, including genetic data, is required by law, the Act on Protection and Processing of Personal Data requires such consent to be specific. This is the same in the Act on the Rights of Patients, when a patient's participation is solicited in a particular medical research. However neither the Act on Biobanks, nor the Act on a Health Sector Database, which apply to genetic databases stipulate that a specific consent needs to be given. The same applies in Sweden, with the added exception that if biological samples are to be used for a different purpose, then the donors' consent will need to be renewed. The Estonian Genome Research Project is based on a very broad description of the project as a basis for consent. In the UK the legal requirements are uncertain regarding biological samples because of the impending introduction of the new Human Tissue Act. The Data Protection Act would require explicit consent for the initial collection of the data, even though 'explicit' is not defined in the Act. The medical guidelines in the UK also require informed consent for research purposes.

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[16] Directive 95/46/EC of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data. See Article 8, Paragraph 3 of the Directive, and Articles 33 and 34 of the preamble to the Directive.

[17] s.60 Health and Social Care Act 2001

Must the consent be voluntary?

While the requirement, that consent be given freely and without constrain or under duress, is an underlying principle in Swedish law, it is not expressly put forth in the national legislation. In Iceland, it is also considered to be a general principle and is also stipulated in a number of acts. Estonia provides the clearest enactment of this requirement, making it criminal to induce a person to donate organs or tissue, or to become a gene donor. The same applies to conducting medical research that is not based on valid consent. This principle underpins the common law principles and medical guidelines that exist in the UK, but it is not explicitly stated as in the Estonian legislation.

Must the consent be written?

The general principle is that consent must be written, though this is not always explicit in the law. This is the preferred mode in practice and there has been little consideration if consent could be given electronically. No special form of consent is generally prescribed, either in Iceland or in Sweden, although the requirement that consent be 'formal', in the Icelandic Regulation on Scientific Research in the Health Sector, must probably be interpreted as a stipulation that consent for such research be given in written form. Also in Sweden the consent has to be documented and public authorities generally 'recommend' consent to be given in written form. In Estonia, a written consent is required by law for participation in the project. The UK medical guidelines generally require written consent and this is the norm in research practice.

Can there be group consent?

As the research in a population genetic database concerns the whole population there has been a debate as to whether the community should give consent to the establishment of the population genetic database. In Iceland this was the subject of much debate. It could be argued that the Icelandic HSD project may be considered to be based on group consent. The rationale for such a conclusion is built on the premise that the project is based on presumed consent.[18] If that is the case, considering presumed consent to be individually 'given', would imply that individuals would have expected to have consented, if they had been approached in person. In fact, the grounds for considering the project based on presumed consent are quite different. The justification there is that the overwhelming support by the Icelandic

[18] This assumption is also debatable. If a project is to be said to be based on presumed consent, some trace of an actual assumption will need to be evident. There would need to be arguments present, laying the foundation for expectation that if the data subjects in question were to be asked, they would most likely give their consent. In the case of the Act on a HSD, although the strong support of the Icelandic population for the project was discussed in the Icelandic Parliament when the legislation was being debated, no provisions of the act, nor its underlying bill, provide the basis for such a presumption. Instead, the act focuses on methods for individuals to withdraw from the project. It is of questionable value to say that the project is based on presumed consent, solely because it provides for an effective way for individuals to exit from the project.

people justifies the presumption of consent. Therefore, this presumption relates to the group, or a large majority of it, instead of its individuals. Consequently, if the Health Sector Database is to be thought of as being based on presumed consent, then that consent can be thought of as being group consent in nature. This issue has not been addressed in any of the other countries and there is no international or national legal requirement for community consent. However the Convention on Human Rights and Biomedicine which has been signed by all countries except the UK requires that there must be public discussion and consultation, rather than consent, on the developments in biology and medicine.[19]

4. Feedback

Population genetic databases which will be used to conduct unspecified research in many years into the future, challenge not only the classical concept of informed consent but also have raised the issue as to whether participants should be informed of the results of conducted research. The main arguments in this discussion are the duty of confidentiality, duty of care and the right not to know. The central question is whether the operator of a genetic database has the moral obligation or a duty to inform participants about the results of research conducted many years after collection? The question is even more acute in cases where a project has not been designed as pure research undertaking[20] but also involves elements of a clinical relationship.[21]

A comparison of current laws in Iceland, Sweden and Estonia shows considerable differences even though the above mentioned rights and duties are internationally recognized.[22] The Estonian Human Gene Research Act explicitly recognizes participant's right not to know his/her data which has been entered into the genetic database, whereas the Swedish Act on Biobanks[23] does not set forth such a right and the participants can rely only on general principles of medical law. In Iceland the right not to know can be found in the Act on Rights of Patients.[24] However individuals are not always given the option of a right to know. For instance the informed consent form used within the framework of the Estonian

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19 Convention on the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine of 4th April 1997 ETS No 164 art 28.

20 Like the contemplated UK Biobank. UK Biobank Ethics and Governance Framework. Version 1, Section I B 3. http://www.wellcome.ac.uk/en/images/ukgene bank_egf_comments2_7439.doc Accessed on 2 October 2003.

21 For instance in Estonia, doctors are conducting data and tissue collection as well as carrying out treatment and so their role is one of a clinician as well as a researcher.

22 Even 'the right not to know' as the most recent concept has already been included into international documents. See Article 10 (2) of the Convention on Human Rights and Biomedicine of the Council of Europe. Adopted in Oviedo on 04/04/1997. European Treaty Series No. 164.

23 Lag om biobanker i hälso- och sjukvården m.m.(2002:297).

24 Lög um réttindi sjúklinga nr. 74/1997.

Genome Project does not provide for an opportunity for participants to make a decision on whether or not they want results to be fed back to them.[25] There is also the issue that is being discussed in the UK Biobank as to whether an individual can give informed consent not to be informed about individual results when at the time of consenting they do not know the results or what the implications might be.

In such cases, there seems to be a gap in national laws, which allow different interpretations. The Medical Research Council of the UK has taken the approach that in case of new (though incidental) findings where treatment is required 'the clinician involved has a clear duty of care to inform the research participant.'[26] This approach can be linked with good clinical practice and research policy, which suggests there maybe a moral obligation to feedback even though there is not always a legal obligation. Time will show whether the courts in Iceland, Sweden, UK and Estonia will accept this approach. This duty of care does not currently extend to affected family members in Estonia, Sweden, Iceland or the UK.

5. Genetic counselling

There is little doubt in modern literature concerning genetic testing or biomedical research that due to amount and complexity of information which such testing or research can reveal about a person, proper (pre and post) genetic counselling should be available to persons undergoing genetic testing or participating in biomedical research. Genetic counselling itself is not a modern 'thing' as it made its first appearance already before the Second World War as 'genetic advice'. To relieve it from the burden of eugenics, the term 'genetic counselling' was introduced in 1947.[27] Nowadays, genetic counselling has been defined and understood as a procedure to explain the possible implications of the genetic testing or biomedical research, its advantages and risks and, where applicable, to assist the individual in the long-term handling of the consequences.[28]

This commonly accepted need for genetic counselling has found its way also into different legal instruments, most influential of which is probably the Convention on Human Rights and Biomedicine. Article 12 of the Convention underlines the importance of appropriate genetic counselling within the context of predictive genetic tests adding it as a supplementary condition for performing such

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[25] Translation of the informed consent form is available in Internet at http://www.geenivaramu.ee/index.php?lang=eng&sub=74 Accessed on 2 October 2003.

[26] Medical Research Council. Human Tissue and Biological Samples for use in Research – Operational and Ethical Guidelines (2001). Section 8.3. http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf Accessed on 2 October 2003.

[27] Hellman D. 'What Makes Genetic Discrimination Exceptional?' (2003) 29 American Journal of Law and Medicine 77, 107.

[28] Article 2 xiii of the UNESCO Draft International Declaration on Human Genetic Data. http://portal.unesco.org/shs/en/file_download.php/1b8d8630ceb3d61f913300bce73e3a6adraft_international_declaration_eng.pdf (Accessed on 2 October 2003).

testing.[29] Although the UNESCO's Universal Declaration on the Human Genome and Human Rights[30] does not address this issue, Article 11 of the UNESCO's Draft International Declaration of Human Genetic Data clearly emphasizes the role of genetic counselling calling it as 'ethically imperative at all stages'.[31]

Research conducted within the framework of ELSAGEN project has shown that the internationally recognized right to genetic counselling is not always supported by domestic law. For instance neither the Swedish Biobanks [Health Care] Act[32] nor the Icelandic Act on Biobanks[33] furnishes participants with such right. It is also not certain whether there is legal obligation under the UK common law. The UK Biobank has decided that feedback will not be given to participants and therefore no genetic counselling shall be offered. The argument behind such a decision is clearly connected to practical considerations – high number of participants, need to interpret genetic information together with clinical information and the fact that the research will be conducted long after collection of samples and is mainly of epidemiological nature.[34] No feedback will be given in Iceland as the software does not allow the licensee to link the identifiers with the names of individuals. This mechanism is designed to protect individual privacy. Although under Article 11 (4) of the Estonian HGRA every participant has the right to genetic counselling upon accessing his/her data stored in the genetic database, the official home page of the operator of the genetic database announces that at least at the beginning the operator will not provide personal genetic counselling at all.[35] Thus, none of these countries have ensured that genetic counselling will be made available – a solution which could be justifiable only in respect of Iceland and the UK since in these countries the participants will not receive feedback from the database.[36]

6. Benefit sharing

The issue of benefit sharing in genetic research has been constantly in the spotlight of discussions since UNESCO adopted the Universal Declaration of

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29 So also Section 88 of the Explanatory Report to the Convention on Human Rights and Biomedicine. Available in Internet at http://conventions.coe.int/treaty/EN/cadreprincipal.htm (Accessed on 2 October 2003).

30 ESCO Draft International Declaration on Human Genetic Data. http://portal.unesco.org/shs/en/file_download.php/ff5d05e93eee3fc45659c0cf9d368112Declaration+text-+english.pdf (Accessed on 2 October 2003).

31 Ibid.

32 Lag om biobanker i hälso- och sjukvården m.m. (2002:297).

33 Lög um lífsýnasöfn nr. 110/2000.

34 UK Biobank Ethics And Governance Framework Version 1, Section I B 3. http://www.wellcome.ac.uk/en/images/ukgene bank_egf_comments2_7439.doc (Accessed on 2 October 2003).

35 See http://www.geenivaramu.ee/index.php?lang=eng&show=kkk Accessed on 2 October 2003.

36 UK Biobank Ethics And Governance Framework Version 1, Section I B 3. http://www.wellcome.ac.uk/en/images/ukgene bank_egf_comments2_7439.doc (Accessed on 2 October 2003).

Human Genome and Human Rights in 1997. The concept of benefit sharing encapsulates the sharing of the benefits of the research at a community level. Reimbursements made to participants to cover their direct expenses and income forgone cannot be viewed as benefit sharing but will usually be dealt with within the context of prohibiting financial gain from participation in biomedical research.[37]

During these discussions, the concept of benefit sharing has significantly developed and changed from simply addressing the issue[38] through just proposing exact numbers for distribution of profits[39] to a more sophisticated recommendations ending with the Article 19 of the Draft International Declaration on Human Genetic Data which requires that there should be:

– special assistance to the persons and groups that have taken part in the research;

– access to medical care;

– provision of facilities for new treatments or drugs stemming from the research;

– support for health services;

– capacity-building facilities for research purposes;

– development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems;

– any other form consistent with the principles set out in the declaration.

There is no mention of benefit sharing in the Icelandic Act on Biobanks and the Act on a Health Sector Database, the Swedish Biobanks [Health Care] Act and the Estonian Human Gene Research Act. There is also no provision in UK law though this has been discussed in relation to the UK Biobank. Thus, all these states would have to take steps to introduce benefit sharing principles into domestic law. However, it would be improper to assume that no benefit sharing whatsoever has been foreseen in genetic research conducted in these countries. Agreements entered into between public or at least publicly controlled authorities (such as the Minister for Health and Social Security in Iceland; County Council of Västerbotten in Sweden and Estonian Genome Project Foundation) and commercial entities (Íslensk erfðagreining ehf., UmanGenomics and AS EGeen respectively)[40] provide for a set of payments.

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[37] Stipulations on prohibiting financial gain can be found, for instance, in the Universal Declaration on the Human Genome and Human Rights (Article 4) and in the Convention of Human Rights and Biomedicine (Article 22).

[38] See Article 12 a) of the Universal Declaration on the Human Genome and Human Rights.

[39] HUGO Ethics Committee Statement on Benefit Sharing proposes, among other suggestions, dedication of 1–3% of annual net-profit to healthcare infrastructure and/or to humanitarian efforts. Available at http://www.hugo-international.org/hugo/benefit.html Accessed on 2 October 2003.

[40] Currently, only the agreement concerning the Icelandic Health Sector Database is publicly available at http://government.is/interpro/htr/htr.nsf/Files/oplic/$file/oplic.pdf Accessed on 2 October 2003.

7. Third party access

Family

The most dominant principle that underpins the legal frameworks in each of the four countries is that of individual rights. In the UK and Sweden this is particularly the case as all regulation targets individuals and the only rights that may be attributed to family members are derived from the original individual donor, as providers for proxy consent for example. There have been no measures introduced to recognise that genetic information also has implications for other family members. This is despite the fact that information within the population genetic database will contain DNA samples, family histories and genealogies that place the individual within a network of relationships. It is only in Estonia and Iceland where these issues have been specifically addressed.

In Iceland the National Bioethics Committee may decide that the views of relatives can be solicited, if the use of biological samples is deemed to '*impact important interests*' of the relatives'.[41] The content of this concept has yet to be interpreted by the Icelandic courts. In contrast the Estonian legislation recognises the familial nature of genetic information and provides a way to protect individual interests at the same time. The Estonian population genetic database contains the names, dates of birth and blood relationships of the ascendants and descendants of a gene donor. These genealogies may only be used within the genetic database for organising biological samples, descriptions of DNA and descriptions of state of health on the basis of blood relationships. Family members have no right to access this information or any other information about the gene donor. Gene donor's rights cannot be transferred either. The Estonian legislation also prohibits asking gene donor questions about her or his particular family members.[42] Only general questions about diseases that have appeared in the family, without specifying particular relative or even class of relatives, are allowed. This legal solution might provide some protection for the privacy of the donor and her or his family and also safeguard the right not to know. It might still be argued that general questions about diseases in the family might pin-point family members, especially if reported diseases are very rare.

Scientific community

Regulations regarding medical research seem to provide the scientific community as a whole with many opportunities to access material for research purposes. Underpinning this is a general view that medical research is a public good that should be encouraged as much as possible. An example of this is Estonia where the scientists of Estonian public research institutions may use the descriptions of DNA or parts thereof without charge. In Iceland the development of the Health Sector Database was seen as having scientific benefits for human kind but

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41 Ibid.

42 Human Gene Research Act 2001.

also benefits for Iceland in terms of employment generation, stimulating the economy and providing a centralised health record system. These reasons have been the driving force for plans to establish many population genetic databases. In the UK the primary purpose behind the project is to establish a national resource that can be used by many scientists for many new research projects well into the future. Therefore protecting and controlling access to the resource in order to ensure its perpetuity becomes a very important consideration.

The way that this is balanced is by giving scientists access to the DNA samples and data if approval has been given by a scientific ethics committee. However in each country there also needs to be some negotiation with the controller of the population genetic database. For instance, in the UK Biobank access will have to be approved by both an ethics committee through the normal system, as well as the biobanks scientific committee. In Sweden the ultimate decision on whether to make the DNA samples available for a research project rests with the controller of the genetic database. There is no legal right to appeal a negative decision by the controller. It makes no difference if the research project is publicly financed or approved by a Board for Research Ethics.[43] In Iceland users of the Health Sector Database will initially approach the licensee and then seek research approval from a specially constituted scientific ethics committee. Such decisions can be reviewed by the National Bioethics Research Committee. In Estonia, approval is also needed by a scientific research committee before research can commence. The law in each country allows considerable freedom of access to individual samples and information for scientific purposes on the basis of the public interest. However access by scientists to population genetic databases, which are regarded as national resources, are carefully controlled.

Police

All four countries practice a clear legal distinction between criminal and clinical genetic databases. In Iceland and Sweden special legislation that clearly targets the police authorities' independent work with DNA-material has been issued.[44] In Estonia forensic databases are not regulated at all, however access to the genetic database is prohibited by the police, prosecutors and courts under the Human Genes Research Act. In UK the police have gained access to research samples by means of a search warrant.[45] This has raised some concerns and the UK Human Genetics Commission has considered providing legal means of pre-

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[43] The Biobanks [Health Care] Act 2002:297. See also Rynning, Elisabeth, 'Public law aspects of the use of biobank samples – privacy versus the interest of research.' In: Hansson, Mats G. & Levin, Marianne (eds) *Biobanks as resources for health*, Uppsala 2003.

[44] Iceland – Act on a Police Department's Genetic Database, No. 88/2001, and Sweden – Police Data Registers Act (1998:622).

[45] *Her Majesty's Advocate v. Stephan Robert Kelly* [2001] ScotHC 7(20th February, 2001).

venting access to biomedical genetic databases by police and other law enforcement agencies.[46]

Employers and insurers

The legislation in Estonia is the only one among the four countries that has clearly implemented the safeguards regarding genetic information in the European Convention on Human Rights and Biomedicine.[47] According to the Estonian Human Gene Research Act employers are prohibited from collecting genetic data on employees or job applicants and from requiring employees or job applicants to provide biological samples or descriptions of DNA. Employers are furthermore prohibited from imposing discriminatory working and wages conditions for people with different genetic risks. Insurers are prohibited from collecting genetic data on insured persons or persons applying for insurance cover and from requiring insured persons or persons applying for insurance cover to provide biological samples or descriptions of DNA. Insurers are also prohibited from establishing different insurance conditions for people with genetic risks and from establishing preferential tariff rates and determining insured events restrictively.

The regulation regarding the interests of employers and insurers regarding genetic information are currently under investigation in UK and Sweden. At the moment employers' possibilities to ask for or use genetic information exist in a grey zone. The question is whether the interest the employer wants to protect is proportionate to the violation of the integrity of the employees or not. In the UK, the Human Genetics Commission has found no evidence that employers so far are using genetic data for recruitment or occupational health purposes.[48] The interest in the information may grow as the usefulness of such material increases. In the UK the Government is planning a wider review of policy in this area by 2005. In Sweden a parliamentary Committee is expected to propose some legislative amendments by the end of 2003.[49] In Iceland specific legislation regarding employers' and insurers' interests in the area has not been enacted so far.

Sweden and the UK have also chosen similar strategies regarding insurance. The Swedish government has entered an agreement with the Swedish Insurers Association regarding genetic examinations.[50] According to the agreement the members of the association will not ask for a genetic examination or the results of such examinations from the insured or applicants for insurance. In the UK use of genetic information by insurers is currently subject to a voluntary moratorium agreed with the Association of British Insurers (ABI) until November 2006. DNA

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46 Human Genetics Commission *Inside Information – Balancing interests in the use of personal genetic data* (London May 2002), 5.3

47 See article 11 and 12 in particular.

48 Human Genetics Commission *Inside Information – Balancing interests in the use of personal genetic data* (London May 2002), 7.1

49 Dir. 2001:20 Genetiska undersökningar m.m. (Genetic examinations etc.).

50 Avtal mellan staten och Sveriges Försäkringsförbund avseende genetiska undersökningar av den 31 maj 1999.

genetic test results will not be used by ABI members except where the tests have been authorised by the government's Genetics and Insurance Committee.[51] Since both agreements have limited applications they cannot be considered satisfactory in regard to the Convention on Human Rights and Biomedicine. In Sweden the prohibition on asking for genetic examinations or information does not apply if the sum insured exceeds certain amounts. It also does not apply to child insurance or occupational group life insurance or collectively agreed group health insurance. In Sweden the occupational collectively agreed insurance makes up a considerable part of the total amount of health and life insurance.

8. In conclusion

This paper has attempted to demonstrate the different ways that the law in each of the four jurisdictions – Estonia, Iceland, Sweden and the UK applies to some of the contentious issues around the establishment of population genetic databases. The issue over ownership of DNA samples and information seems to be uncertain across all the jurisdictions, except perhaps in Estonia where there is specific legislation. In all countries consent for the use of personal information follows the requirements laid down in the Data Protection Directive 95/46/EC. However there are variations between these countries as to how wide the exemptions from the ban on the processing of sensitive personal data can be interpreted. Common to all jurisdictions, except Estonia, is a difference in the law that applies to biological samples and personal information and this can result in inconsistent outcomes. Genetic counselling is only provided for in the law in Estonia, but currently this requirement has not been implemented. None of the jurisdictions recognise a legal right to benefit sharing or to individual feedback based on the research on the genetic database. Estonia is the only country that recognises individual as well as familial interests in genetic information through special legislation. It is evident that although these countries endorse the same Council of Europe Conventions and EU Directives there can still be considerable differences between the laws in each country. The issues raised by population genetic databases are not currently addressed by the law across all jurisdictions in a coherent manner and we are some way from achieving a uniform legal structure for population genetic databases across Europe. We would recommend that further research is carried out so that there is greater harmony and uniformity in the law that applies to population genetic databases across these jurisdictions.

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[51] Human Genetics Commission (2002) Inside Information – Balancing interests in the use of personal genetic data HGC:London.

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