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Education And Debate

The Icelandic database—do modern times need modern sagas?

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- [The Icelandic database: do modern times need modern sagas? - January 22, 2000](#)

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On 17 December 1998, as a result of legislation instigated by deCODE genetics, a Delaware biotechnology company working in Reykjavik, the Icelandic parliament adopted a law making it legal for a private company to construct an electronic database of the country's health records.¹ deCODE has received an exclusive licence to build a database of Iceland's medical records (including diagnoses and test results, treatments and side effects) and will be able to combine and analyse these with genetic and genealogical data. The act also grants deCODE exclusive rights to commercial exploitation of the database for 12 years. Accordingly, deCODE has entered into a (non-exclusive) arrangement with Hoffmann-La Roche which gives the latter company access to the database for the purpose of researching the genetic origins of 12 common diseases.

Summary points

The government of Iceland has granted an exclusive licence to deCODE genetics to construct a database of the country's health records

Debate about issues of informed consent, privacy, scientific freedom, benefit, and commercial monopoly is vigorous

The question at issue is whether the rules being applied to the database can deal with the issues raised

A debate that focuses on traditional principles risks ignoring new challenges brought about by advances in medical technology

If the role of commercialism is to be assessed and defined appropriately, benefits to the individual and to public health need to be articulated clearly

Are the rules out of date?

The debate before and after the bill on Iceland's proposed database has been vigorous. Sigurdur Gudmundsson, Iceland's surgeon general, was quoted in the *New Yorker* as saying, "I don't think this country can just sit here and say, 'Nope, sorry, we are going to stand on rules that existed in a different era for a different world.'"² But are the rules being applied to the database able to address adequately the issues that have been raised? It is striking that both proponents and opponents have classified the ethical and human rights issues similarly, into five main areas: informed consent, privacy, scientific freedom, benefit to Iceland, and commercial monopoly (sometimes included under scientific freedom or benefit).^{3 4} These concerns can be grouped under two broad headings—matters of medical ethics and the question of scientific freedom versus commercial interests. The ethical issues are clearly important and relevant to international conventions and policies concerned with human rights. However, the way we categorise issues in a debate can sometimes obscure other aspects that need to be considered and prevent us from questioning whether traditional distinctions need to be revised.

Better, cheaper health care?

The database will not help directly any individual patient with the management of his or her condition, say those who are in favour of the database. Rather, it will be a tool in the development of new or improved methods of achieving better health, prediction, diagnosis, and treatment of disease and in establishing more cost efficient ways of operating health services.⁵ The database can help to achieve the first aim by providing information—for example, on genetic and environmental risk factors in common diseases and statistical data on disease and treatment. The health economics aim is a secondary one, but it is still important. Although the average health status and the life expectancy of the population are high, Iceland's health insurance system is sixth in the Organisation for Economic Cooperation and Development's league table of expenditure on health care in relation to gross national product.⁵

Making use of a valuable asset

Iceland's population of approximately 270 000 has a genetic history that makes it particularly valuable for genetic research into common diseases (box).² Furthermore, the extent to which the new genetics will affect the delivery of health care remains unclear, and Iceland, say the proponents of the database, provides a unique opportunity for testing this. It has also been argued that since the data in the records have been paid for out of public funds they are not owned by individuals or institutions and should be used for the public benefit.^{5 6}

Importance of the Icelandic database

- Meticulous medical records on every Icelander have been kept since the second world war
- Since the second world war, tissue samples have been taken from a large proportion of the population and have been stored
- Family trees have been drawn up for most of the population

- There has been no immigration for a thousand years
- The population's standard of living is uniformly good

There will of course also be “spin offs” in terms of advantages for particular people or organisations. The pharmaceutical companies who deal with deCODE will be able to develop and test new products. It is the position of the licensee and the licensee's arrangement with Hoffmann-La Roche that have given rise to some of the major criticisms. The fear is that these companies will benefit while Icelanders as whole, and scientists in particular, may be subject to “harm.”

Sources of possible harm

Privacy and confidentiality

The main concern is the threat to privacy and confidentiality. Although privacy and confidentiality are different concepts, the issues have not been clearly distinguished in the debate. The central issue is the security of the information in the database. There is concern that information identifying individuals could fall into the hands of groups who might use it for their own purposes: insurers or employers, for example, might use the information to discriminate against some people. Two aspects of this issue need to be addressed—the extent (if any) to which a trade-off between privacy and other benefits is reasonable, and whether the security measures adopted by the Icelandic database afford adequate protection to individuals.

From an ethical point of view, the balancing of privacy and confidentiality against other considerations is not new. The security of data on identifiable parties has long been one consideration, and public health interests form another, though more controversial, issue. These days individual privacy is under attack on many fronts—not only in health care—and widespread surveillance of people's lives is as common in Iceland as elsewhere.² However, the dangers inherent in modern technology and science are judged to be considerable,⁵ and this has led to attempts to ensure protection through various international policy documents and legislation.^{7–10}

One view is that the aims of genetic research, in particular, should not prevail over respect for the rights of individuals.¹¹ Whether the database is compatible with such rights as are protected by Council of Europe Conventions has been examined by the council's steering committee on bioethics.⁵ In considering what is reasonable, this body concluded that identification of the Iceland data “cannot be regarded as reasonably possible without substantial effort” and that the data are therefore anonymous according to the criteria of international law. This is so despite the inclusion of genetic information in the database and the controversy over whether genetic information should be regarded in the same way as other medical data. The act includes measures “to ensure protection of confidentiality in connecting information from the health sector database with the databases of genealogical and genetic information” (article 10). Though the original bill allowed for a decoding key, this was removed in the final version. Article 11 further provides that employees of the licensee must sign an oath of confidentiality.

Although the Council of Europe Steering Committee on Bioethics considers that the database is acceptable from the perspective of international law, the critics are not reassured about the protection afforded. With regard to the dangers to privacy, at least, they are concerned to have an absolute guarantee rather than one based on a criterion of reasonableness such as is used by the Committee.¹²

Informed consent

According to the European Directive 95/46, informed consent is necessary if personal data are to be used

for purposes other than those for which they were originally gathered, but consent is not required if the data are not personal.⁸ Iceland chose to establish a database of information that was not personally identifiable. Icelanders have been offered the opportunity to opt out of the database and will be informed continuously about their right to withdraw from the database at any time.¹



(Credit: CAROLINE THOMSON)

Do these provisions protect sufficiently the interests of individual Icelanders? Once again there are different areas of disagreement. There are concerns about the adequacy of an opting out system for rights protection, as compared with fully informed consent, which is considered to be at the heart of ethical medical practice and research. Against this, the requirement for informed consent is generally viewed to be less for epidemiological research on medical records—especially where these are anonymous.¹³ Autonomy is upheld to some degree at least by the opting out provisions included in the Icelandic act. On the other hand the claim that some people might be in favour of research in general, while objecting to particular kinds of research that they might be unable to foresee, has some force.¹⁴

The debate about the rival merits of opting out and informed consent, however, is undermined by a deeper problem about understanding of what is involved. At one level it is suggested that individual Icelanders mistakenly think they will not have information about them entered on the database until they next visit the doctor (J Eyfjord, personal communication); at another there is concern that informed consent would not even be possible in principle, because doctors are not in a position to explain the risks. Although invasion of privacy is one possible source of harm, the possible future uses of the database are potentially too broad to be foreseen and explained.¹² So even if a system of informed consent was seen to be implemented, it could not provide genuine protection. In fact a requirement for informed consent has not been chosen on the grounds that it would be likely to reduce participation and thus the usefulness of the database.¹²

In genome research, different levels of consent have been recognised.¹³ The Council of Europe Steering Committee on Bioethics has concluded that relevant Council of Europe recommendations allow research for legitimate purposes to use personal data without obtaining informed consent, provided that the scientific research is provided for by law and constitutes a necessary measure for reasons of public health.⁵ This is one of the main points at issue. The Icelandic database is considered to constitute a measure in the interest of public health—but is it “necessary” for public health? This question needs to be answered, but if one of the justifications of the database is to test the extent to which the new genetics can deliver, it is not clear how it can be answered in the affirmative beforehand and thus provide a clear public health justification for overriding considerations of informed consent.

Scientific freedom

Scientific freedom is a more complex issue. The value of the free flow of information and the importance of free scientific inquiry is widely recognised.^{11 13} The scientific community in Iceland has been angered

by the database proposals, arguing that scientists who want to undertake genetic research will find it harder to raise research funds for their work. However, deCODE's answer is that the database will increase the research opportunities for scientists in Iceland in relation to funding, access to patients, and access to patients' records. The supporters of the database have also argued that this initiative will attract funding and scientists back to Iceland and that the amount of funding provided by deCODE is greater than the medical research funding offered by the Icelandic agency that grants research funding.

However, for scientists wishing to use the database there are necessary conditions such as not using or divulging information in a way that will adversely affect deCODE's business interests. Applications from scientists working outside the licensee's business have to be addressed to the access committee.¹ However, any research carried out in the public domain (for example, by universities) is likely to have an adverse effect on the licensee's commercial interests.¹⁴

Once again different aspects of the debate need to be considered. One concern is the extent to which scientists will be enabled or hampered by this development. Another, more difficult, question is whether the database poses a new kind of threat to scientific freedom or whether it simply presents, under the guise of commercialisation, a new twist to an old problem. Inquiry itself is not to be prevented, but commercial interests will affect who does what. However, this is becoming a widespread feature of contemporary scientific work—for example, work on the genome. What is unclear is the specification of the principles to be defended on both sides—what counts as scientific freedom in this context, and what are the purported benefits that justify the level of control that will exist?

Defining benefit

Proponents of the database consider that it will lead to a reverse brain drain as well as the better management of Icelandic health care.³ Sceptics argue that this benefit will accrue to only a few Icelanders, and that it will take the form of highly paid jobs. The government's annual licence fee will not prove to be a net benefit to the country as a whole.

We need to determine what is understood by the word “benefit,” and this will become increasingly important in the context of population based genetic research. Does it mean financial and health gains (for example, free medicines from Hoffmann-La Roche) or does it also include more intangible benefits such as prestige to the country? Those who believe that the Icelandic population is being turned into a commodity criticise the definition of benefit in financial terms. Lewontin says that Iceland is carrying the “commodification” of people “to its final conclusion by making its entire population into a captive biomedical commodity.”¹⁵ He points to the irony of this in the light of the individualism of the Icelandic sagas. Perhaps this is an example of the value impact of new technology: the environmental impact of technologies is frequently discussed, but a value impact assessment is also required, which would include a consideration of the ways in which we are forced to reconsider, reinterpret, or enrich our understanding of cherished values and principles.

Identifying real issues?

What is interesting about this classification of the ethical issues discussed above is the way in which it centres on very traditional issues in medical ethics (informed consent and privacy) and in scientific research (scientific freedom versus commercial interests). What has not been highlighted so much in the ethical discussion is the relevance of genetics and the phenomenon of “geneticisation,” although this is a constant background presence in the debate. deCODE says that “it may be argued that the database will

save lives, improve health, and cure disease.”³ This is analogous to the rhetoric of progress associated with the human genome project. As in that case, it is challenged by arguments concerning another shadowy presence—the history of abuse of genetic information. Both sides of the database debate, however, seem to agree about the value of the science; they disagree about commercialisation and access. The prevailing model of health here is one that makes genetics central.

In the debates about informed consent and privacy there is also widespread agreement on the value of these traditional ways of looking at things. There is little scope for considering the challenges to traditional principles that result from advances in medical technology. Are these data really individual or national resources? If they are a national resource then the logic of the case might suggest that even opting out should not be offered. The disagreements over whether and to what extent informed consent and privacy will be adequately protected have not been resolved. Whether these approaches need reconsideration or supplementation in the present context should be addressed in the context of clear criteria of what would count as a public health success.

The case for the database has so far failed to convince—and this is because there has been an insufficient attempt to provide an articulation of benefit, or of what “benefit” might mean. A sharper critique of the “why?” as well as the “why not?” is required. Who will benefit, and in what way? If these questions are not answered, commercialisation will understandably be met with absolutist support for traditional principles and frameworks in forms that may no longer be entirely appropriate.

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Footnotes

- Competing interests None declared.

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