

COMMENTARY

GENOMICS

An Icelandic saga on a centralized healthcare database and democratic decision making

Jeff Gulcher and Kari Stefansson

The May issue of *Nature Biotechnology* contained a commentary by two expatriate Icelanders entitled "Decoding Iceland." The commentary focused on deCODE genetics and a centralized health care database, but ended with a reference to a new biotechnology company the authors have founded in Iceland. The authors stated they have lived outside of Iceland for over 20 years, and perhaps because of this, their commentary suggests that they have lost touch with the local scene, although it is clear that they have warm feelings toward their old country. The following account was put together to correct some of their misunderstandings.

In 1997 deCODE genetics suggested to the Icelandic Ministry of Health that a centralized database on health care in Iceland could become a powerful instrument with which to generate new knowledge on the nature of common diseases as well as a unique tool to use for modeling in health care. The Ministry of Health drafted a bill to create its legal framework. The bill was placed on the homepage of the Ministry of Health for comments. This was followed by a vigorous debate that included 700 articles in the three Icelandic newspapers, numerous radio and television programs, and town meetings all across the country. The database bill was debated more than any other bill in the history of the republic.

On the eve of the parliamentary vote on the bill, a public poll taken showed that 75% of those who took a stand supported the passage of the bill. Parliament passed it in December 1998 with approximately the same margin. Three months later, another poll showed that support for the legislation had risen to 88%. The debate resulted in fundamental changes in the bill, which in its final form was in keeping with the highest standards of scientific ethics and EU directives on protection of privacy and the use of medical information.

The law provides the Minister of Health with the authority to grant a single party an exclusive license to construct a centralized database on health care and to market it for 12 years. The database will be overseen by an

independent ethics committee, the Data Protection Commission of Iceland, and an operations committee appointed by the Ministry of Health.

Both the supporters and critics of the database bill focused on five issues during the debate, which are discussed in what follows.¹

Community consent

One of the conditions that the international bioethics community sets for research on populations is consent from the communities. It is, however, not easy to find definitions of what community consent is. We believe the way in which Icelanders handled the database idea provides a reasonable definition of the concept of community consent.

Partnership with the community

One of the reasons for broad-based support for the database is that the people of Iceland are already enjoying benefits from a partnership with deCODE on individual disease-based projects the company engages in. These include repatriation of a large number of scientists, financial support for research done outside of the company that far exceeds the total support of governmental agencies for biomedical research, opportunities for Icelandic scientists to do front-line genetics research, tax revenue, and the beginning of a new industry in a country that still lives almost by fish alone.

The company will triple the number of jobs for highly educated people to construct the database. Since the company is majority-owned by Icelanders, most of the value that accrues to the company directly benefits Icelanders. The database will be a powerful instrument to use in the running of the Icelandic health care system. The database law stipulates that the Ministry of Health should negotiate for a share of any profit that may result from the database.

Consent of individuals

The database law allows the gathering of medical information from the entire Icelandic health care system into a centralized database without requiring the consent of individuals. This is in keeping with tradition in epidemiological research, allowing the utilization of information that is generated in the process of delivering health care, without consent from individuals, to create new knowledge in medicine. The database

law stipulates that individuals can request that information about them not be deposited in the database. The law allows the cross-referencing of medical information with molecular genetics information but only from individuals who have consented to the use of genetics information for this purpose.

Protection of privacy

The database will be continuously monitored by the Data Protection Commission of Iceland. All personal identifiers will be encrypted in the institutions where the information is generated and again before the data arrive at the database. Users will access it through a query layer designed such that it will only yield data on a group of 10 or more people. Furthermore, repetitive questions to narrow the group will not be allowed.

All medical data will come from the institutions of health care, where it is easily accessible to allow for its use to benefit patients. Hence, for those who would seek to illegally obtain medical information about individuals or the entire Icelandic nation, it would be orders of magnitude easier to break into the health care institutions themselves than into the database. The collection of medical data into a centralized database in Iceland is not unprecedented; there are nationwide, centralized databases containing medical information in Sweden, Denmark, and New Zealand.

Freedom of science

All original data in the centralized database will continue to reside in the institutions where they are generated, accessible to scientists to use as they do now. Furthermore, the licensee will not have an exclusive right to the use of the database. The Icelandic health care authorities will have free access to the database, as will academic scientists in Iceland who use it for noncommercial research.

The integration of medical information with genealogy and molecular genetic information in the Icelandic Healthcare Database provides Icelanders and the world with a powerful tool to answer fundamental questions about disease. It provides a model for how similar databases will be constructed in other countries in the future as well as how a nation can democratically come to terms with the complex ethical issues surrounding them.

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1. www.database.is