CENTRALIZED HEALTH DATABASE IN ICELAND: THE CONTROVERSY

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EXECUTIVE SUMMARY
Population databases are in widespread use throughout the world and have been for many generations. Remember the population census carried out by King David in the Bible? These days information is available on so many aspects of our lives and in such accessible format that it seems there are hardly any areas where privacy and secrecy can be maintained. Medical records have now become the latest fighting ground. No topic is more contended than the notion of having one’s personal, intimate details, stored in digital format for others to see even if they are the medical professionals we claim to trust. The controversy was recently taken to new heights by Iceland’s decision to set up a database containing the medical records of the whole population and granting exclusive rights over the use of the data for commercial purposes to a single company.

Although the majority of Icelanders seem to support the construction of the database there has been very strong opposition from the medical and scientific community. The opponents of the database do not generally question the usefulness of the database but are opposed to its construction without participants’ ‘informed consent’ and because exclusive rights were granted to an “American” company. The opponents of the database also claim that because the society is so small, individuals will be easily identifiable in the database and that it will be dangerous to have large amounts of sensitive information in one place.

In this paper we try to show the evolution of the Icelandic database from conception to ejection of the bill to sanction its implementation was thrown out, with all the surrounding controversy. We put forward the proponents’ ‘pluses’ and critic’s ‘minuses’ and try to conclude with a few suggestions as to how other countries might go about a similar project, but avoiding some of the controversial issues that have scuppered the Iceland project.

INTRODUCTION
In 1996, a company called deCODE Genetics was set up in Iceland where it has all its operations. The company was founded by an Icelandic entrepreneur who convinced venture capitalists to invest a total of $12 M in his idea about a genetics centre in Iceland. The company started operating in 1996, working on research with the goal of finding the genetic causes of selected common and complex genetic disorders. deCODE genetics went public on Nasdaq on July 18th 2000 at US$18 per share, raising US$198.7 M in cash.

In addition to doing genetic research, the company had plans of setting up a health information database. Late in 1998, a bill was passed through the Icelandic congress that gave authorities the rights to provide deCODE Genetics with exclusive rights to set up and use for commercial purposes a database containing health information on the whole population of Iceland. Debates about this database have been extensive, both in and outside of Iceland, as its generation entails a plethora of controversial issues.

It is not only the issues around the database that have been very controversial. The CEO of deCODE Genetics, a dominant albeit charismatic character, has also been the
center of some debate from the beginning as he tends to make comments that may not be as diplomatic as they could be. As an example it can be mentioned that when the chairman of the health law department at Boston University School of Public Health stated in an editorial that the company should have been required to get permission from each individual before including their medical records in the database, the former “Harvard professor turned CEO” responded that “It's easy to sit in a mediocre university in Boston and express a view of how things should be in utopia”…. “but for George to have his way he would have to change medical practice all over the world.” On another occasion he ended his description of the planned database by saying it would be a “great disco-tool”.

Amusing comments aside, this is not the sort of press a serious member of the Icelandic government would wish from the head representative of the company with full rights over the database!

**THE DATABASE**

Ideas about a database like this, were put forward in Iceland around 1975, but were not put into practice due to reasons like lack of funding, lack of information technology and concerns about confidentiality issues.

There are several reasons for the Icelandic population being attractive for scientists working with health and/or genetic data. Iceland's population is relatively small, close to 300,000 people, detailed individual medical records have been maintained by public health services since 1915 and genealogy is an integral part of the culture; 80% of all Icelandic people who have ever lived can be traced on family trees. There is an advantage to having genealogical data when studying a group's DNA, e.g., a list of people with a common disease can be run through the genealogical database to look for clues to genetic and environmental causes for the disease. The country is isolated geographically, with little migration from other places ever since the Vikings and some Celts arrived almost 1200 years ago. In addition, over the centuries, a series of disasters such as plague and famine, have minimized the opportunity for new genetic input into the country's gene pool.

The exclusive rights of deCODE Genetics for the rights to construct, maintain, and use the database for commercial purposes are valid for 12 years after which the “Minister of Health and Social Security receive indefinite use of all software and right required for the maintainance and operation of the database”. The content of the database will be health information that will be obtained from health data records available at these institutions. A consent will not be sought from individuals but people that do not want their information in their database can send a form to health authorities in order to prevent their information from being entered. The database must meet security and privacy standards set by the government's Data Protection Commission.

According to the law, it will be possible to connect the health information database to a genealogical database and a genetic database after having fulfilled a set of criteria set by external parties. Genetic information will only be used when individuals have given informed consent. The database can not be transported out of Iceland and processing of it can only be carried out in Iceland.
BENEFITS

The Health System in Iceland and Elsewhere
The final goal with the construction of the database is to use its health data to develop new or improved methods of achieving better health, prediction, diagnosis and treatment of diseases. In addition, the information in the database may be used to develop more economic ways of operating health services. The knowledge that could possibly be generated by processing the information in the database could in this way be of value not only for Iceland but health systems in general as well.

The Icelandic Health system
After the construction of the database, The Ministry of Health in Iceland and Director General of Public Health, will be entitled to statistical data from the database for the purposes of making health reports, planning, policy-making and other projects. The data contained in the database may make some of these tasks easier and less expensive for authorities, when the information in the database is relevant for the task at hand.

To be able to construct the database, old and new data within hospitals in Iceland will have to be transferred into a digital format. To be able to construct the the database, deCODE Genetics is obliged to perform and pay for the setting up of standardized patient information system in the health institutions with which it collaborates. This would gradually lead to the creation of dispersed databases, that could all be linked together and would be useful for health professionals for the everyday use of patient records and others (e.g. scientists). The estimated cost to build the Icelandic Health Sector Database is between $135 million and $250 million

Commercial benefits to Icelandic Society
The construction and maintainment of the database would help the development of a high-technology industry in Iceland and generate employment. The database could potentially attract business relating to the database to Iceland.

Scientists
The database would be available to scientists in Iceland. Scientists would have to apply to a special committee that can only grant access to the database to scientists for non-commercial uses.

ETHICAL ISSUES

The Right to Privacy
Privacy is today a massively contentious issue in Western society, with heated debates in parliaments and the media about identity cards, tagging of prisoners, etc. Medical records are traditionally sacrosanct. By putting such information on a database critics argue the privacy of patients is automatically violated (even though there is no such thing as absolute secrecy of patient’s records even in dark dingey basements of hospitals). Information filtered from outside, or inside an organisation with access to such records can fall into the wrong hands (ie. insurance companies, the press, etc).
Proponents of medical databases say the information can be made anonymous. But critics of the Iceland database say anonymity is impossible to guarantee in a relatively small community like in Iceland. Encryption technology can be de-scrambled. The Council of EU Conventions has deemed the Icelandic database acceptable from the point of view of International Law (re. Privacy) BUT there is no common agreement on what ‘reasonable safeguards’ means.

**Informed vs presumed Consent**

According to the EU directive information consent is necessary if data is going to be used for purposes other than those for which it was originally gathered. This is not necessary if the information is not personal and in Iceland’s case the database is designed in such a way that individuals are ‘anonymous’. However, critics say, again, that given small country & the vast amount of specific data available it would be possible to personalise the database. All the same Icelanders are allowed to opt out of the database if they choose to. But this is not so easy say critics. People have to get the forms from a pharmacy, health institution, fill them out themselves and post them. This disadvantages the disabled and the semi illiterate. Critics also say that the information that is stored cannot be removed retrospectively, even if the person opts out. The point is the Icelandic case did not involve *fully* informed consent.

A lot of the controversy about consent also centers on the complexity of the issues being presented to patients. How can they make informed choices? As justification, deCODE and the government claim that the Act results from an informed democratic decision. The vast majority of Icelanders actually wanted the database. But only 13% of the nation considered themselves to have a good grasp of the bill according to a Gallup poll in November 1998. The issues can also be framed to aid the agenda of policymakers. The Council of EU Steering Committee on Bioethics states that research for legitimate purposes can use personal data without consent provided that the scientific research is provided for by law and constitutes a necessary measure for reasons of public health. But is the Icelandic database ‘necessary’ for public health? And is national law always ethical (think of the international controversy regarding euthanasia laws in places like Holland)? Not everyone might agree.

**Conflicts of Interest**

According to the Human Genome Project’s Ethical, Legal and Social Committee: “honesty and impartiality are the cornerstones of ethical research.” The problem in Iceland’s case is the money involved with the deCODE project is sizeable relative to Iceland’s GDP and disproportionately large compared with foreign investment. The government granted deCODE 12 year exclusivity rights over the database – tantamount to a monopoly over a resource which arguably belongs to the people. Critics say the government is getting too commercial for its own good and jeopardising the integrity of the Health system. What if deCODE goes bust, or passes into foreign hands? Surely, some claim, money would be better spent tackling social deprivation and environmental problem areas, which would have a more beneficial impact on the nation’s health. Ironically, by placing so much emphasis on the commercial opportunities and balance of payments requirements (attracting foreign investment) the Icelandic government may have put in jeopardy a unique opportunity for improving the health of the nation.
Abuse of individuals’ rights and the spirit of scientific research
Purists claim that pay-as-you-go research damages the spirit of science in which knowledge should be freely shared. By making the database a legal monopoly the government has transgressed this code. If medical records are used as a community resource shouldn’t they be available to ALL researchers within the community? Yet rights have been exclusively granted to deCODE. The debate goes further: can anyone OWN parts of our genome through patents, copyright and the like? To some establishing proprietorship over such sensitive areas is violation of human rights.

Damaging the trust between doctors & patients
From a Doctor’s point of view the database could lead to a serious breakdown in trust between patient and doctor. If everyone has reason to believe every fact about them will be entered into a database they might withold information. This in turn could give rise to perverse outcomes. For instance, sick people, or people suffering from what they perceive as hereditary illnesses might ‘opt out’ on the irrational belief they were protecting their children. Fear of being singled out as genetic freaks might take precedence over helping prevent them from contracting a genetic disorder. Doctors could be perceived as information gathering bureaucrats operating for the database managers (deCODE) and not acting independently.

Violation of International Codes
Further accusations, mainly by non-Icelanders, focus on Icelanders being treated as ‘guinea pigs’, effectively taking advantage of the fact international standards on ethics subordinate themselves to national law. For instance, one argument goes along the lines of: deCODE should have submitted its plan to institutional review boards affiliated with Harvard University in the Boston area of the USA where majority shareholders are located. Plans analagous to the Icelandic database would never be approved in this case. Neither, they say, should the expatriate activities of deCODE in Iceland. The critics of the Icelandic database argue such matters, including the evaluation of research databases, are not for politicians to decide.

ACCESS BY PARTICIPANTS TO THEIR GENETIC PROFILES
Again there are ethical and legal considerations to do with access to the data. Iceland has disallowed access to the genetic data in the interests of protecting anonymity, thus they will not be able to directly improve their condition as a result of ‘opting in’. Estonia has taken the opposite view allowing participants to see their genetic profiles and providing them with feedback. The project founder, Andres Metspalu, claims the project will give benefits “back to the people”.

Another issue regarding this is what would the public do with their genetic profile. It is not obvious to us, from reading articles on the Estonian database, what is the purpose of giving people their profiles other than that they want to “give something back”. It is important to clarify how and what they plan to give back, which is quite a complex issue. It is debatable if it is such a good idea to give a person, that has no genetic or medical background, genetic data without extensive consultation with a professional on what the information means and what can be done as a result of having this information. For most common diseases, the genetic causes are unknown, although there are known risk factors for some diseases, and advice on actions in response to genetic information are neither simple nor straightforward to dispense.
WHO SHOULD BE PAYING?
A very controversial subject. Many people think private companies shouldn’t be involved, and that the government fund everything. Under deCODE’s 12 year license drug companies can access data for a fee, access would be free to academic researchers for “non-commercial” projects. Icelanders wouldn’t learn the results, the main benefits, supporters argue, are economic. We’ve already examined above the potential pitfalls of such claims especially over conflicts of interest. Perhaps Iceland should have adopted the approach some other countries have taken on this matter so as to diffuse the issue of commercial gains, whilst safeguarding funding.

EXAMPLES OF OTHER DATABASES

Estonia database
In September 2002 the Estonian government funded, non-profit Estonian Genome Foundation began collecting DNA samples from 10,000 volunteers aged 16 and over. This 3 year pilot project funded with $2.5m by Egeen International, a US based company, will rely on a health questionnaire rather than the medical records of patients. The Foundation hopes to enroll 1m of the country’s 1.4m people. Organisers have taken “great pains” to educate the public and allay ethical concerns, we’re told. And as mentioned above, participants will be able to see their genetic profile.

UK (BioBank UK)
Starting in 2004, BioBank UK plans to gather examination and interview data from volunteers aged 45 to 69 years old and then track them for at least 10 years. The volunteers are not (similar to Icelandic case) promised any direct benefits. Researchers expect to see enough cases of specific diseases to verify and quantify links with candidate genes. Access to BioBank will be open to any “bona fide researcher with a good idea.” Funding will come from the UK MRC and the Wellcome Trust (the second largest medical charity in the world after the Bill and Melinda Gates Foundation). In total over GBP60m will be spent on the programme, attracting over 0.5m volunteers. Opponents have argued this is a diversion of urgently needed funds to non-essential areas when social or environmental problems could be tackled instead.

Private Clinics (USA)
In the USA data is more difficult to gather owing to the absence of a national healthcare system. However, genetic information is already being collected by numerous private clinics and research institutes who also have access to patient’s medical records. One example is the Marshfield Clinic which has records on over 1.2m patients and began collecting DNA samples in autumn 2002. Patients will not learn their results, but “they will help advance health care in general” the clinic tells donors. The project is part funded by the State of Wisconsin, contributing $2m of the $3.8m funding. Patents will be filed and profits will be ploughed back into research or donations to medical causes. Companies will not be directly involved. The Mayo Clinic has a similar programme, building on a database of 4m of its patients and
members. None of these projects are regulated by International Conventions on Ethics, or any other similar organisation. All are aware that they tread a legal and ethical minefield.

CURRENT SITUATION OF THE DECODE DATABASE
Four years after the laws were passed the database still remains empty. The main reasons for this are delays in obtaining necessary government approval, continuing opposition from doctors. The Icelandic Data Protection Commission (DPC) and deCODE have not reached an agreement on the adequacy of security measures for the HSD. Moreover, negotiations between deCODE and the National-University Hospital in Reykjavík, the largest hospital in Iceland, leading to the construction of the HSD have been postponed indefinitely according to a letter from Dr Kári Stefánsson, CEO of deCODE, to the Director of the National-University Hospital (14 October 2002). Earlier this year a commissioner of the data protection commission commented that the commission has received and evaluated about half of the material it will want to examine to determine whether deCODE’s database design adequately protects Icelanders' private records and that the problem of personal identification of information from the database remained the most challenging issue.

In addition, many of Iceland's doctors are resistant to the Health Sector Database, even though the Icelandic Medical Association won a concession in August 2001, when deCODE promised to find a way to make data entry reversible at a patient’s request. The opposition group “Mannvernd” claims that the database will only become reality when informed consent will be sought from every individual and when individuals will be informed about what happens to their information after it has been put into the database.

CONCLUSION
From the beginning of this discussion in Iceland there has been a lot of debate and strong opposition from both the scientific community and the political parties in the opposition. In the beginning authorities intended to get the bill passed without much discussion but the opposition of the ruling party was able to prevent authorities from forcing the bill through parlament on record time and discussions on the topic, both in parlament and the media, preceded the passing of the bill.

As the opposition of the plan of a database have been very forceful, some misconceptions have been created, willingly or not, in the minds of the public in Iceland. The most common is that the exclusive rights are on the data itself, meaning that scientists and others wanting to use the data would not be able to after it had been entered into the database. This is not so: the data would still be available in its current form in its current location and the generation of a database would not change the access policy to the data. Only if scientists want to access all the data from one place, i.e. the database, they would have to apply for a permission from a special committee to do so. Another important misunderstanding has to do with genetical information and informed consent. Opposite to what many people believe, genetic data will only be entered into the database given an informed consent from the individual.
Although it is difficult to say, it might have been better to introduce the bill to the nation and parliament with less “force”, i.e. to try to generate some kind of consensus among stakeholders before proceeding with this important issue. The government has tended to over-emphasize the commercial benefits to Iceland without framing the issue in terms of long-term health benefits to Icelanders. The task was made all the more difficult by the huge publicity the database generated in world media and scientific journals. Not all of the attention was balanced. Some of it has been plain misleading, i.e. linking Roche’s $200m injection into deCODE with the database (even though it happened a year before the bill was announced). Other countries contemplating setting up a similar databases will undoubtedly do well to take note of these controversies. For instance, communication of how anonymity would be preserved was poorly handled. The experts could have diffused this issue by limiting queries into the database to groups of people. This way it would be impossible to call up all data for individuals meaning that their identification is protected.

We would conclude that it is preferable to get a consensus on an issue like this and that to give private companies exclusive rights to use health information for a whole nation for commercial purposes is politically very tricky.

Four years have passed since the bill on the centralized health information database in Iceland became law and the database is still empty. It will be interesting to follow this matter in the coming few years. Will deCODE construct the database in the end? If not, will anyone be able to generate support, expertise and funds to extract value from health data in Iceland? It would be sad to think a valuable opportunity has gone to waste both for Iceland and for potential beneficiaries elsewhere.

TOPICS DESERVING FURTHER RESEARCH
A question that comes to mind when reviewing the “database” history, is if it would have been more feasible after all, to take on the cost and the logistical work of obtaining informed consent from everyone for every project? If that had been the path chosen would the opposition within the health system have been less than it turned out to be? Would enough individuals provide informed consent in order for the database to be useful, since a critical mass of data is necessary for the database to be useful? Would obtaining informed consent for every individual for every study, like some opponents of the database propose, make the construction of the database unattractive? These are all difficult questions to answer.
LINKS AND BIBLIOGRAPHY

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(Web site of Mannvernd, a group fighting against the database)

http://www.opendemocracy.net/debates/article-9-79-1344.jsp

http://www.landlaeknir.is/Uploads/FileGallery/Heilbrigdistolfraedi/Gagnagr_isl.pdf
(Website of national health authorities in Iceland)


http://www.opendemocracy.net/debates/article.jsp?id=9&debateId=79&articleId=1024

http://www.actionbioscience.org/genomic/hlodan.html

Ruth Chadwick, prof. Of moral philosophy, Center for Ethics, University of Central Lancashire, Preston, UK
and various others

Other interesting links:

http://www.opendemocracy.net/debates/article-9-79-1344.jsp

http://www.opendemocracy.net/debates/article.jsp?id=9&debateId=79&articleId=1250