Special Section: International Voices 2004

The Estonian Healthcare System and the Genetic Database Project: From Limited Resources to Big Hopes

MARGIT SUTROP and KADRI SIMM

This article focuses on healthcare ethics discussions in Estonia. We begin with an overview of the reform policies that the healthcare institutions have undergone since the region regained independence from the Soviet Union in 1991. The principles of distributing healthcare services and questions regarding just what ethical healthcare should look like have received abundant coverage in the national media. An example of this is the exceptionally public case of V—a woman with leukemia whose expensive drugs the national health insurance fund refused to compensate. In our subsequent discussion, we focus on a grand-scale local healthcare and research project—the Estonian Genome Project—that attempts to include 1 million DNA samples into one database.

General Background of the Healthcare System

Estonia is a small country (with a population of 1.4 million) situated in northeastern Europe, just south of Finland, west of Russia, and north of Latvia, sharing a sea border with Sweden to the west. Independence from the Soviet Union was regained in 1991, and the following decade has been a turbulent and difficult time of drastic reforms and rapid developments in all areas of life. The Soviet legacy in the healthcare sector included huge hospitals, subsidized drugs, centralized planning, and an abundance of educated medical staff. Clearly, important changes were needed to adjust the system to the new conditions of a market economy.

The first years of independence were difficult in terms of public health: increased mortality (the crude death rate rose from 11.8% in 1990 to 14.8% in 1994, leveling in 1996 to around 12.9%)[1] with clear consequences for the average life expectancy (from 71 years in the second half of the 1980s to 66.9 years in 1994).[2] Also, health has increasingly been linked to socioeconomic indicators, and the social inequality in healthcare utilization and morbidity has increased throughout the 1990s.[3] The birth rate has been below the rate required for population renewal since 1990 (e.g., −4.1% in 1999).[4] Clearly, the reasons for such changes are manifold, ranging from severe disruptions in the social sphere to increased poverty and overall economic difficulties. Similar

---

The following article has benefited from the participation in the projects "The Ethical, Legal and Social Aspects of Human Genetic Databases: A European Comparison," financed between 2002 and 2004 by the European Commission's Fifth Framework Programme (#QLG6-CT-2001-00062), and "The Ethics of Genetic and Medical Information," financed between 2002 and 2004 by the Nordic Academy for Advanced Study (NorFa). We gratefully acknowledge their support.

Cambridge Quarterly of Healthcare Ethics (2004), **13**, 254–262. Printed in the USA.

tendencies exist in terms of both statistics and the causes of these numbers with other ex-Soviet Baltic countries. On the other hand, there are obvious positive trends related to the availability of better medical equipment and improved facilities. Infant mortality rates have decreased considerably since Soviet times, and healthcare expenditure has risen from 4.5% of GDP in 1992 to 6.1% in 2000.[5]

A number of new laws have been passed by the Parliament, the most relevant to healthcare being the health insurance law, the law on the management of healthcare services, the law on human gene research, the law on organ and tissue transplantation, the law on artificial insemination and the protection of the embryo, and the law on the protection of personal data.

In January 1992, a compulsory health insurance tax of 13% was enforced, and approximately 578,000 people are currently contributing, with the tax money being used to cover the medical costs of 1.3 million[6] (in 1999, an estimated 5–8% of the population was without health insurance). This means that, like other European countries, healthcare in Estonia is based on the solidarity principle, providing needed services to all members of the Health Insurance Fund regardless of their actual contributions. Private insurance is allowed, but only in addition to national health insurance. The number of private clinics is rising, mostly offering dental care and outpatient care (e.g., gynecology, ophthalmology).

The Estonian healthcare reform was launched during the first half of the 1990s. The project boasts an array of desirable objectives, ranging from improved healthcare services to better public health records. A novel family-practitioner system should be fully implemented by 2003 but is still ardently discussed and has created additional controversies. The radical changes suggested by the invited Swedish experts to reform the healthcare sector include the restructuring of the Estonian hospital system by decreasing the number of hospitals from 27 to 13 by 2015 and concentrating the specialists in more highly populated centers.

The V Case: Justice and the Healthcare System

Setting up the national healthcare system has, understandably, been a very rough road for both the medical establishment as well as the public. Arguably, there has been a discrepancy between the rather harsh (neo)liberal political ideology pursued by most Estonian governments and the installed solidarity-based health insurance system that should cater to the needs of all without regard to their individual contributions. Although this has been to the benefit of public and private health, the situation has also created tensions around the distribution of scarce resources.

In April 2002, the national papers published articles describing the frightening case of V, a 44-year-old woman diagnosed with chronic myeloid leukemia. Her condition was alleviated when she started using the new drug Glivec. The costs of the drug were, however, huge—a price tag of a monthly supply being 44,000 EEK (about €2,800), whereas the average monthly income is approximately €450. The financially struggling Estonian Health Insurance Fund, after supplying her with a few months of Glivec, decided to discontinue the payment, referring to pecuniary difficulties (10,000 EEK or €637 annually were set aside for the treatment of all patients with such diagnoses in Estonia[7]). There was no money available; the only option offered by the fund seemed to insist on taking it from the funds earmarked for other patients.

Discussions around the justification for such an expensive drug abound, although it was clear that Glivec had improved the situation of the patient. Some doctors referred to uncertainties in the long-term usage of the new drug and suggested bone marrow transplant. Nevertheless, the core of the issue involved the difficult questions of social justice and the rights and responsibilities of the state and of the people. The patient(s) demanded the taxpayer's right to medical treatment, and in the ensuing court case V referred to several paragraphs of the constitution where, for example, section 16 states that everyone has the right to life, and section 28 also states everyone's right to the protection of health. As a rather well-earning professional, V had paid a lot of taxes over the years and was now being denied the treatment she needed and had even "earned" through taxpaying. Of course, being a solidarity-based health insurance, arguments based on someone's wealth should not be important. Nevertheless, the pitch of discussions on the necessity of private health insurance soared.

Although the state had taken on the responsibility of providing necessary healthcare, it seemed to have failed in action. Of course, for many people the main issue was not lack of resources (as put forward by the Health Insurance Fund) but rather their unjust distribution. The case also illustrates the problems faced by poorer countries flooded with the new, expensive medical drugs, equipment, and technologies (although obviously the same issues are problematic in more affluent countries as well). As is so often the case, the financial difficulties of struggling economies are decisive in providing for the possible ways of reforming the healthcare system and providing services. The enforcement of social rights still largely depends on the financial capabilities of the state. The V case was clearly only the tip of the iceberg but exceptionally to the point in positioning health insurance providers (the fund, the Minister of Social Affaires, and ultimately the state) as the Godlike decisionmakers in questions of human life and death. This case brought the tensions to the fore and initiated public discussions on the ethical principles of providing healthcare. One leader of the insurance fund summarized the situation by admitting that it was simply unfortunate to be born in Estonia.

Still, a more informed, transparent, and wider discussion needs to accompany these issues. The public discourse on social issues is currently slow to waken from the decade of heavy silence, an understandable although regrettable reaction to 50 years of forced socialism. Currently, many still perceive the Soviet time as rather generous in making healthcare services available and accessible to all, although in reality grave inequalities existed in ways that healthcare was provided to functionaries and the rest. Thus, the ways of thinking from the Soviet past clash with the new individual-centered discourse of the liberal political and economic thinking.

The Estonian Genome Project

Background Information

The most renowned and visible Estonian healthcare ethics issue concerns the planned Estonian Genome Project (EGP), which aims to collect the data of up to 1 million people (out of the population of 1.4 million). During the past few years, numerous countries have followed Iceland's lead in combining the health, genealogical, and genetic data of large populations (similar proposed gene banks are to be located in Iceland, the United Kingdom, Latvia, Sweden, Singapore, Canada, and the Kingdom of Tonga). One could speak about a boom in population databases.

According to the definition of the HUGO Ethics Committee, a genomic database is

> a collection of data arranged in a systematic way so as to be searchable. Genomic data can include inter alia, sequences, mutations, alleles, polymorphic haplotypes, SNP's, and polymorphisms. The work associated with a database includes collecting, annotating, curating, storing, validating and preparing specific sets for transmission.[8]

The characteristics of the genetic database projects vary, but most intend to map genes for common diseases and promise to deliver "personalized" medicine.

Several important factors distinguish the Estonian case from other database projects. As in Iceland, the planned database is population based, but it is based on an opt-in system. Contrary to the Icelandic project, explicit voluntary consent is obtained from participants, and the blood sample, together with health and genealogical information, is collected by family practitioners. Second, and more important, the Estonian Genome Foundation has publicly promised to all participants the possibility to know their genetic data—that is, to be informed of their potential or present genetic risks. This important population-wide aspect, together with the potentiality of almost everybody actually knowing his or her genetic constitution (providing the project is successful), forms the background for several healthcare ethics issues.

The aim of the EGP is to establish a database (Gene Bank) that would include the health, genealogical, and genetic data of the majority of the Estonian population. The Gene Bank will permit the implementation of studies to identify genes causing and influencing the development of common diseases (the database will include information on both phenotypes and genotypes). A long-term goal of the project is the practical implementation of gene-based medicine to public health on a massive scale. A special law, the Human Genes Research Act, was passed by the Parliament in December 2000 to govern the setup and management of the Foundation. The act determines the rights of gene donors, data processing, and protection in the bank as well as prohibits discrimination in employment and insurance relationships or any other discrimination based on the structure of person's DNA and his or her genetic risks.[9]

The Estonian Genome Project Foundation (EGPF) is the chief processor of the Gene Bank. The EGPF was established on March 26, 2001, by the Estonian government with the aim of coordinating the EGP. It has the right to organize the taking of DNA samples, to prepare, code, decode, destroy, and issue descriptions of state of health and genealogies, to perform genetic research, and to collect, store, destroy, and issue genetic data.

The costs of implementing the project are estimated at $150 million. The project is characterized as the public-private partnership between a nonprofit body of the Estonian Genome Foundation as an owner of the data and a public limited company EGeen, as the exclusive commercial licensee of the database for 25 years. EGeen was established by the Estonian Genome Foundation to incorporate the investments and mediate financing of the project.

In the Gene Bank Agreement, signed by the EGPF and EGeen on September 19, 2001, EGPF grants EGeen the right to commercialize the data stored in the Gene Bank. The EGPF has the right to conduct genetic research for scientific purposes and to transfer Gene Bank data, free of charge, to gene donors, physicians of gene donors, state agencies responsible for the organization of healthcare in Estonia, and research institutions. For its right to commercialize the data, EGeen is obligated to pay indexed annual payment of €300,000 and additional fees depending on its financial success (unlimited annual profit payment of 0.5%; 3% of the turnover of the created IP rights). In comparison to the Icelandic project, the conditions seem favorable.[10] Originally, EGeen was 100% owned by EGPF. According to the agreement between the EGPF and EGeen, the EGPF's shareholding in EGeen diminished to 2.5% after the end of the Pilot Project.[11]

Data collection began in October 2002 with a special six-month Pilot Project that had the goals of ensuring technical and organizational readiness for the main project and also collecting tissue samples and health information from 10,000 volunteers in three Estonian counties. In reality, fewer than 1,000 samples were collected during the Pilot Project.

Public Perception of the Project

Although the international press has referred to the Estonian project as an ethical time bomb,[12] there has been very little substantial discussion in the Estonian media. The project itself has organized series on television as well as regular radio broadcasts, but critical reflection is rare, and the argumentation on ethical risks mostly unheard of or hurriedly dismissed. Important background information to such a situation is the general positive and trusting attitude toward scientists and strong belief in scientific progress—a trend that sharply differs from Western countries. One possible explanation for this tendency suggests that an answer lies in the Soviet past.[13] Although Soviet modernity had applauded the rationalization of technology and the application of scientific achievements in practice, it had suppressed the parallel process of emancipation and critical reflection that characterized Western modernization. Science and scientists continue to enjoy uncontested status and a highly positive reputation in Estonian society, and the traditions of critical thinking are yet to be established.

To provide knowledge about the public attitudes toward the EGP as well as toward the developments of genetics and biotechnology in general, the Centre for Ethics at the University of Tartu commissioned a poll in December 2002.[14] The survey results demonstrated that, although the general attitude toward the project is very positive, individual readiness to participate in the project is rather low.[15] The least trusted information sources about the database project were politicians and journalists. The fact that the most trusted sources of information about the project were geneticists and employees of the EGP surely raises questions. In addition to the generalized positive attitude toward science and scientists mentioned previously, another explanation for this phenomenon is that the database project carries a double meaning for Estonian people. On the one hand, people perceive it as a national project that is expected to have positive effects on the Estonian economy, science, and healthcare, as well as the overall image of Estonia. As a national project, the EGP is a symbol of Estonia's successful transition from a former socialist country into a Western one. Amy Fletcher has shown how the EGP effectively moved forward, despite opposition, because "the initiators successfully situated the EGP not only within the issue of public health, but also within the more resonant identity narrative of Estonia's historical and contemporary contributions to the field of molecular biology."[16]

On the other hand, a large number of people fear that their data may be misused. For example, they think it is quite likely that insurance companies and employers may start to discriminate against people on the basis of their genetic data, despite the existing law forbidding such discrimination.[17]

The attitudes are ambiguous: On the one hand, there is trust that the EGP will make Estonia rich and famous or at least an equal partner in the world of science and biotechnology. On the other hand, there is mistrust in the institutions that store and handle personal data.

Some Ethical Issues of the EGP

Can Open Consent Be Informed?

The initiators of the EGP have repeatedly stressed that the project has been designed taking into consideration the critical points of the Icelandic project. The Estonian project has an opt-in system, participation is voluntary, and one has to give valid consent to become a gene donor. The consent given by the gene donors is open (as in many database projects), which means they will consent to "scientific research in the fields of health of people and genetics."[18] This is a general problem of databases: because data will be collected for indefinable future uses, one cannot speak about the informed consent in the traditional sense, where the detailed objectives of the research are specified in the research protocol.

Confidentiality of Data

Participants in the project will be informed that their data will be kept confidential and that they have the right to withdraw their consent until their tissue samples or the description of their state of health are coded (afterward, donors can only require the destruction of the key enabling decoding). This means that the personal data of the gene donor will be separated from genetic data, and each blood sample and set of health data will be given a unique 16-digit code. But according to the Human Genes Research Act, data decoding is permitted for the following purposes:

- issuance of the data to the gene donor
- issuance of the data to the doctor of the gene donor
- renewal, supplementation, and verification of data
- asking the gene donor for new data on the consent of Ethics Committee
- taking a new tissue sample on the consent of the gene donor
- supplementation of genealogy
- destruction of data entered into the Gene Bank

The gene donors will have the right to prohibit the supplementation, updating, and verification of descriptions of their state of health stored in the Gene Bank. However, it is presumed that participants will agree to the supplementation and updating because extra effort is needed to prohibit this (there is no box to tick; the participant has to write a specific letter to the Gene Bank). There is currently no information available on how the renewal, supplementation, and verification of data will take place. Little is said about the kind of risks that the process of renewal and supplementation will bring along when additional information about the health of the gene donor will be collected from other databases, hospitals, and doctors.

The most common breaches of confidentiality in healthcare in Estonia happened in similar circumstances; for example, the histories of the patients were sent electronically by the doctors to the health insurance fund, and accidentally these were accessible for some days from the fund's website. The general level of security of sensitive personal data in Estonia is rather low, and most often the breaches are not caused by hackers or thieves but by malevolent or negligent employees of the relevant institutions.

Ethics Committee of the EGPF

The setup of the ethics committee of the EGPF is characterized by ethical ambiguity. Formally independent and impartial, it can only make suggestions to the supervisory board (according to the Human Genes Research Act), meaning that (with one exception[19]) its assessments are not binding. Furthermore, any member of the ethics committee may be removed by the Foundation's supervisory board "with good reason," meaning, among other things, as a result of "causing of significant damage to the interests of the chief processor" (i.e., the Foundation).[20] Needless to say, such an arrangement raises serious doubts as to the freedom of action of the ethics committee.

Disclosure of the Genetic Data

According to the Human Genes Research Act, the chief processor is permitted to decode data "in order to enable access to data on a gene donor stored in the Gene Bank, except genealogies, at the written request of the gene donor." The consent form states that "data on hereditary characteristics and genetic risks obtained as a result of genetic research may be unpleasant for me. I have the right to not know my genetic data." The initiators of the project have insisted that allowing decoding of genetic data will give donors the possibility of directly profiting from the project, as they can take preventive measures according to revealed risks. The gene donors have been promised a personal "gene card" giving them an opportunity to make use of individualized medicine. Our sociological study showed that the main motivation for people who have decided to participate in the project is the wish to get a personal gene card.[21] As of yet, however, it is quite problematic what kind of information a personal gene card is able to provide besides raising anxieties about potential problems.

Currently, for example, the U.S. National Bioethics Advisory Commission guidelines suggest caution in disclosing genetic information, especially when treatment or prevention is not available or possible.[22] Professor Bartha Maria

Knoppers, chair of the HUGO Ethics Committee, who also advised the EGP, has supported limits on reporting back.[23] At the same time, if predictive medicine is ever to be practiced on a considerable scale, the disclosure of genetic information to persons must take place. As the NBAC indicates, the information must be "scientifically valid and confirmed" and "findings must have significant implications for the subject's health concerns."[24]

At the moment, there exist no specific procedures on how (or even when) genetic data will be disclosed to donors by the EGP. The gene-donor consent form states that the donor has the right to know his or her genetic data free of charge and has the right to genetic counseling. But who will be providing genetic counseling to 1 million people? Who will pay for it? The responsibilities have not been specified, and the Estonian Heath Insurance Fund only has limited resources. As the V case demonstrated, the new "smart" drugs (such as Glivec and Herceptin) are already proving to be too much of a burden. The processes of delivering on the given promises have not been thoroughly considered. Certainly, no one has anything against simply altruistic activities toward improving medicine, but the current project has been largely popularized under the personal-gain banner.

It follows that such a population-wide project also has important social aspects. For example, if genetic information is available to a considerable part of the population, most likely in reality only its affluent sectors will be able to afford the personalized medicine of the future, the preventive lifestyle requirements, and the treatments that should be followed to avoid a potential disease. Individualized medicine is certainly not going to be a cheap affair. Put differently, what will be the social significance of the choice of not knowing your data in these circumstances? The right not to know is not respected when health is increasingly considered a personal responsibility (the narrative that genetics has so much contributed to through its emphasis on prevention)—a "choice" that must be taken. How will the situation affect solidarity in national health insurance, and how will the system cope with such an all-encompassing move to preventive medicine?

The EGP has placed Estonia in a novel position. There are multiple risks but at least as many promises. Genetic research is clearly a vital necessity. Estonia is, in a sense, marching in the forefront and will have to deal directly with the issues and problems that are only theoretical to other database projects and bioethicists. Greater public discussion in Estonia is needed, as many of those risks have not been acknowledged, whereas the benefits are eagerly awaited. Few are suggesting a Luddite stance on advances in genetic research and biotechnology, but it is important to acknowledge the necessity of balancing harms and benefits. Internationally, the possible impact of individualized and preventive medicine on countries with different economic, as well as cultural and social, capabilities should be recognized.

Notes

1. Kiivet R, Harro J, eds. *Health in Estonia 1991–2000*. Tartu: Paar OÜ; 2002:11.
2. See note 1, Kiivet, Harro 2002:12.
3. Kunst A, Leinsalu M, Kasmel A, Habicht J. Social inequalities in health in Estonia. Tallinn: Ministry of Social Affairs of Estonia; 2002.

4. Health Information Unit of the WHO Regional Office for Europe. *Highlights on Health in Estonia*. Brussels: European Commission and the WHO; 2001:7.
5. See note 1, Kiivet, Harro 2002:64.
6. Additionally, 20% is paid toward pension systems. All social taxes are paid for by the employers, with the exception of the self-employed.
7. According to Toomas Palu, member of the Board of the Health Insurance Fund, reported in the daily newspaper *Postimees* 14 Apr 2003.
8. HUGO Ethics Committee. *Statement on Human Genomic Databases*. Dec 2002. [Accessed 29 Aug 2003.] Available at: http://www.gene.ucl.ac.uk/hugo/HEC_Dec02.html.
9. Human Genes Research Act (Inimgeeniuuringute seadus). *Riigi Teataja* 2000;104:685.
10. In Iceland, the annuity is fixed at €900,000; annual profit payment is 6% but no more than €900,000. No payments on commercialization of IP rights are foreseen, neither does the government hold any shares in the project.
11. This 2.5% is based on an antidilution clause. This means that, despite the additional investments or company market value, the EGPF minimally holds 2.5% of the shares. The new majority owner of the EGeen is EGeen International (EGI). EGI unites venture capital funds and individual investors investing in the project. (The authors thank Riivo Anton for additional information on this.)
12. Gross M. Estonia sells its gene pool. *Guardian* 9 Nov 2000. See also, e.g., MacWilliams B. Estonia's genetic database promises medical advances—maybe. *Chronicle of Higher Education* 25 Apr 2003; Weber A. Das verkaufte Volk. *Süddeutsche Zeitung Magazin* 2001:(47); Hille S. Die Ersten werden die Esten sein. *Die Weltwoche* 2002:(32); Schümer D. The genetic gold mine. *Frankfurter Allgemeine Zeitung* 26 Nov 2000.
13. Thanks to sociologist Külliki Korts for drawing our attention to this.
14. This nationally representative survey had 914 respondents ages 18–74 in face-to-face interviews. Two main goals of the survey were to explore attitudes toward scientific and gene research in general and to investigate the specific issues of the EGP. The sociological survey is part of an international project called ELSAGEN (Ethical, Legal, and Social Aspects of Human Genetic Databases), financed by the European Commission within the Fifth Framework Programme.
15. Sixty-two percent of the respondents claim to have heard of the EGP, and 7% regard themselves as well informed. Twenty-four percent of those who have heard of the EGP plan to participate, 37% have not made up their mind, and 39% say they will not participate.
16. Fletcher AL. Mapping its future: the Estonian Genome Project and the politics of identity. In: Delener N, Chao C, eds. *Beyond Boundaries: Challenges of Leadership, Innovation, Integration, and Technology*. New York: Global Business and Technology Association; 2002:371.
17. Sixty-four percent of the population perceive it as quite likely that genetic data might be used against them by insurance companies and employers.
18. Estonian Genome Project. *Information about the Gene Donor Consent Form*. [Accessed 5 Sep 2003.] Available at: http://www.geenivaramu.ee/index.php?lang=eng&sub=75.
19. See section 24, 2 (4) of the Human Genes Research Act (on decoding donor information):

    > The chief processor is permitted to decode data only in the following cases and for the following purposes . . . (4) in order to identify a gene donor on the proposal of the chief processor and with the consent of the Ethics Committee, to contact the gene donor and to renew, supplement or verify a description of his or her state of health with his or her written consent.

20. Human Genes Research Act, sect. 29, 5. Passed 13 Dec 2000. Entered into force 8 Jan 2001. Available at: http://www.geenivaramu.ee/index.php?lang=eng&sub=18&eetika=1.
21. Of those people who have decided to participate in the EGP, 83% want to receive their own gene card (i.e., know their own genetic risks).
22. National Bioethics Advisory Commission. Research Involving Human Biological Materials: Ethical Issues and Policy Guidance. [Accessed 30 Aug 2003.] Available at: http://www.georgetown.edu/research/nrcbl/nbac/pubs.html.
23. Knoppers BM. DNA banking: a retrospective-prospective. In: Burley J, Harris J, eds. A Companion to Genethics. Oxford: Blackwell; 2002:384.
24. See note 22, NBAC 2003:recommendation 14.