PATIENT RIGHTS IN THE EU

ESTONIA

EUROPEAN ETHICAL - LEGAL PAPERS N° 5

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Estonia

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Preferred citation:

H. NYS, et al., "Patient Rights in the EU - Estonia", *European Ethical-Legal Papers N°5,* Leuven, 2007.

ISBN: 978-90-334-6625-0

FOREWORD

Within the Centre for Biomedical Ethics and Law of the Catholic University of Leuven - one of the leading bioethical and legal research centres in Europe - we are involved as coordinator, partner or participant in different European research projects. Biomedical ethics and law are rapidly evolving disciplines. Although there exists already a great number of specialized peer reviewed journals and series of books in both disciplines we felt a growing need for a medium through which the results of our research can directly be presented to the research community and the interested community at large. To meet this need we decided to start the *European Ethical-Legal Papers.* Such papers will also contribute to the transparency we owe to society that finances our research efforts. We also hope that it will contribute to the discussion and the exchange of information and ideas among researchers in Europe and elsewhere.

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I. INTRODUCTION

EuroGentest is a five-year EU funded program that aims to develop the necessary infrastructure, tools, resources, guidelines and procedures that will lead to the establishment of harmonized, quality genetic testing services in Europe. Within EuroGentest we are dealing with the ethical and legal issues of genetic testing. Harmonization of the technical aspects of genetic services in Europe requires a legal and ethical framework that respects the cultural, religious, philosophical and other domestic characteristics of a given country and its population(s), but at the same time conforms to basic and universally accepted human rights. To continuously supervise the legal and ethical developments regarding the promotion and protection of the rights of patients and users of health services and to make the results of our research publicly available is a permanent challenge. This publication in the European Ethical-Legal Papers aims to contribute to it.

Opened for signature 10 years ago (in Oviedo, Spain, on 4 April 1997) the European Convention on Human Rights and Biomedicine is now of growing importance as a standard to evaluate the efforts and the progress made by the Member States of the European Union to promote and protect the rights of patients and users of health services. In this fifth issue we present the results of this evaluation for Estonia, one of the EU member States that have ratified the Convention.

The contents of this publication is as follows.
In an Introductory chapter we describe briefly the Republic of Estonia according to some of its main features related to its political and economic background and its health care system.
This is followed by an encompassing overview of the rights of patients in Estonia. In a first paragraph the legal status of the Biomedicine Convention is situated against the background of Estonian constitutional law. Then we turn to a description of the national legislation on patient rights. There exist many different enumerations of patient rights. Because we are particularly interested in the way the Biomedicine Convention has been received in the

Members States of the European Union we follow the structure of the Convention. The right to informed consent (articles 5, 6, 8 and 9 of the Convention) comes first, followed by different aspects of the right to private life and the right to information (article 10 of the Convention) such as: patient rights regarding the medical file; the right to medical secrecy/confidentiality and the right to privacy and protection of private life. This part of the analysis ends with the right to complain in case of unlawful infringement of a patient right (article 23 of the Convention) and the right to compensation for undue damage (article 24 of the Convention). In the next chapter we look at the rights of patients as users of genetic services: are the rights of patients complemented by more specific rights for users of genetic services? (articles 11 and 12 of the Convention). With some concluding remarks we finish this paper N° 5 of the Ethical-Legal Papers.

Without the help of Mr. Ants Nõmper (adjunct lecturer, Faculty of Law, University of Tartu and attorney-at-law, Law Office Raidla & Partners), Ms Kristi Lõuk and Ms Kadri Simm (Project Managers, Center for Ethics, University of Tartu) and Ms Laine Peedu (Ministry of Social Affairs of Estonia) we could not have accomplished this work. They furnished us valuable information on the status of patient rights in Estonia and answered our repeated questions accurately and patiently. In the footnotes we refer to the information provided by one of them as “personal communication of” .The possible mistakes and wrong interpretations are our responsibility. We are also aware of the limitations of this endeavor not the least because of differences in languages. Nevertheless we hope that this publication will stimulate the discussion on the promotion and protection of patient rights in the Estonia. Therefore we welcome all reactions on www.cbmer.be.

Leuven, 10 June 2007

The research for this publication was supported by the Eurogentest Network of Excellence of the EU, FP6 – 512148 and its co-ordinator Prof.Dr. J.J. CASSIMAN

II. BRIEF DESCRIPTION OF ESTONIA

§ 1. Political and legal system[1]

The Constitution of Estonia came into force in 1992 and is, in a number of ways, a compilation of aspects of Estonia's previous constitutions. It has continued the democratic spirit of the 1920 Constitution, with some added mechanisms to maintain the balance of power of the state.

The legislative body, in which the supreme power of the state is vested, is the Parliament which is elected by proportional representation. It has 101 members and is elected for a period of four years.

The executive power of the state - the Government is responsible to the Parliament. Appointment to the office of the Prime Minister and withdrawal of the Government lies within the competence of the Parliament. The Government also enjoys a stabilizing guarantee - the right to dismiss the Parliament with the consent of the President and to call new elections if the Parliament expresses no confidence in the Government. This has, on several occasions, proved a balancing factor in situations where the wish to dismiss the Government has not been well-founded.

The President has mainly representative functions, although he still retains a number of executive powers. The President may veto a parliamentary bill and sent it back for revision, and his signature is required when appointing the Ministers of the Government. He is also empowered to present the Parliament with the names of several higher officials. The President is also the supreme commander of the armed forces. The President is elected for a 5-year term by the Parliament. If

[1] www.vm.ee/estonia

a sufficient majority of votes is not forthcoming, he is elected by an electoral college which consists of representatives of local governments and members of the Parliament.

The court system is divided into three levels: county courts and city courts, circuit courts of appeal and the Supreme Court which also functions as the constitutional court. The Estonian judicial system is based primarily on the German model, especially within the field of civil law with which it has direct historical links. The courts are independent, judges are appointed for life and may not take up any other appointed public offices.

The Constitution provides for a Bank of Estonia, independent of the government, which operates as the bank of issue. It also provides for the office of the Legal Chancellor whose task is also to be Ombudsman. The third office is that of the office of the Auditor General. These three offices are appointed by the Parliament at the proposal of the President, but in their functioning they are independent government officials and cannot be dismissed by the Parliament before serving a full term.

Further the Constitution provides for two types of government with a large degree of autonomy - local governments and cultural self-governments of ethnic minorities. A significant fact is that all permanent residents, regardless of citizenship, are eligible to vote in the local elections.

§ 2. Health care system[2]

Since regaining independence in 1991, the Estonian health system has undergone two major shifts: first, from a centralized, state-controlled system to a decentralized one; and second, from a system funded by the state budget to one funded through social health insurance contributions. At the same time, there has been a growing emphasis on primary care and public health.

[2] M. JESSE, et al., *Health care systems in transition Estonia,* Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004.

The restructuring of the health system has taken place in several phases. The beginning of the 1990s saw the introduction of a social health insurance system operated through the Central Sickness Fund and 22 regional sickness funds. In 1994, responsibility for planning health services was partially decentralized to the county level through the 15 county governors and the county doctors. The current organizational and management principles were established between 1999 and 2002 by acts of the parliament intended to re-centralize some health system functions.
The main bodies responsible for planning, administration, regulation and financing in Estonia are the Ministry of Social Affairs, the Health Care Board, the State Agency of Medicines (SAM), the Health Protection Inspectorate and the Estonian Health Insurance Fund (EHIF).

Through the Ministry of Social Affairs and its agencies, the state is responsible for development and implementation of overall health policy, including public health policy, and for supervision of health service quality and access. Its main function is regulation.
The *Ministry of Social Affairs* was created in 1993 as a result of the merger of three separate ministries of health, social welfare and labour. Consequently, it has three major policy divisions: health care, social services and employment. The health care division is further divided into three policy areas: health care, drugs and public health. Over the last 10 years, the subdivision of these policy areas into separate departments has changed many times, but as of the end of 2003 the health care division has been subdivided into three administrative departments: the Health Care Department, responsible for health care, investment and drug policy; the Public Health Department, responsible for public health policy, prevention programs and health protection legislation; and the Health Information and Analysis Department.

III. GENERAL PATIENT RIGHTS

§ 1. Legal status of the Convention on Human Rights and Biomedicine

Estonia has signed the Convention on Human Rights and Biomedicine on 4 April 1997 and has ratified it on 8 February 2002. The Convention entered into force on 1 June 2002.
Art.123 of the Constitution of the Republic of Estonia provides that if Estonian laws or other acts are in conflict with international treaties ratified by Parliament, the provisions of the international treaty shall apply.[3]

Estonia did not made restrictions on the exercise of rights contained in the Convention.

§ 2. National legislation on patient rights

The first draft of a law on patient rights was already prepared in 1993 (thus before the ratification of the Convention), presented to government in 1994 and then passed on to the Parliament. However, its passage was blocked by the health care professional lobby, which requested the simultaneous preparation of a law on the protection of medical personnel. Several subsequent drafts have been prepared by the Ministry of Social Affairs over the years, in collaboration with representatives from patient organizations and health care professional associations. Some of these drafts made their way to the Parliament, but none have been approved. An example is the draft of the Law of the Protection of the Patient Rights which was completed in the Ministry of Health and Labour of the Republic of Estonia in November 1994. This draft was based on the corresponding law of Finland as well as on the Declaration of the Patient's Rights of the European Region of the World Health Organization of March 30,

[3] T. BIRMONTIENE, "Health Legislation in Eastern European Countries: the Baltic States", *European Journal of Health Law*, 2004, 98, note 3.

1994 served as a basis[4]. Another draft of a Patient Act was submitted to the Parliament in 2002. Its second reading was interrupted on 19 November 2002. After the election of the new Parliament (in March 2003) the draft act was removed from the agenda and has not been re-submitted.[5]

The idea of a specific patient rights law has not been completely abandoned. The position expressed by officials at the Ministry of Social Affairs in 2004 is to observe current regulations under the Law of Obligations (see below) and then to decide on the necessity of a law that specifically regulates patient rights.[6]

Meanwhile medical practice has undergone extensive legal regulation. The principles of informed consent, professional liability etc. have been introduced into Estonian law only in recent years and with great reluctance on the part of physicians who were accustomed to the concept of a community beneficence ethics that governed soviet medicine.[7]

Actually, the rights and obligations of patients are laid down in the Law of Obligations Act 2001 (hereafter: LOA 2001) which entered into force on 1 July 2002.[8] According to our appreciation the articles of this Law of Obligations Act which govern the rights and obligations of patients have clearly been inspired by the Dutch Act on patient rights, the so called Medical Treatment Contract Act. [9] The expression 'contract for provision of health care services', the

[4] E. KERGANDBERG, "Patient's autonomy in Estonia?", *Juridica*, X, 1994, 251 (abstract), www.juridica.ee.
[5] V.PARVE, *National Regulations on Ethics and Research in Estonia*, Brussels, European Commission, DG Research, 2003, 10.
[6] A. NÕMPER, "Clinical Ethics Committees in Estonia – first steps on a long way", www.ethicsnetwork.org.uk.
[7] *Ibid.*
[8] P.VARUL, A. AVI and T. KIVISILD, "Restrictions on active legal capacity", *Juridica International*, IX/2004, 99. An English translation is available at www.legaltext.ee.
[9] See however the opinion of Jesse who states that the law was based on German legislation. M. JESSE, et al., *Health care systems in transition Estonia*. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004,121. As there is no patient rights law in Germany this opinion is surprising.

definition of patient, the duty of the patient to pay a fee and his or her duty to provide information to the physician are all examples of the similarities between both acts. According to a privileged witness "the Convention is an inspiration for Estonia to legislate in this field".[10]

According to the LOA 2001, a contractual relationship where both parties have their rights and obligations arises between a doctor and a patient. The LOA 2001 grants the patient clearly defined rights. §758 (1) of LOA 2001 defines the contract for provision of health care services as a contract according to which one person (the provider of health care services) undertakes, in his professional activities, to provide health care services to another person (the patient), particularly by examining the patient in the interests of his or her health and observing the rules of medicine, by consulting and treating the patient or offering obstetrical care to the patient and by informing the patient of his or her state of health and the progress and results of his treatment.[11]

§764 LOA 2001 obliges a patient to inform the provider of health care services of all circumstances which, according to his or her best understanding, are necessary for the provision of health care services and to provide any assistance which the provider of health care services requires to perform the contract. This duty of the patient to provide information to the doctor does not entail that the patient should be able to describe his or her problems precisely in medical terms or establish connections between his or her health problems and other circumstances. A patient must inform the doctor according to his or her best understanding. The task of the doctor is to elicit the necessary information from the patient with clarifying questions.[12]

[10] T. BIRMONTIENE, "Health Legislation in Eastern European Countries: the Baltic States", *European Journal of Health Law* 2004, 80.
[11] SOTSIAALMINISTEERIUM, "Towards a human-centered society, Patients have the right to decide on their treatment", www.sm.ee.
[12] SOTSIAALMINISTEERIUM, "Towards a human-centered society, Whether and how should doctor and patient inform each other", www.sm.ee.

§ 3. Right to informed consent

Article 5 of the Biomedicine Convention:

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.
This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.
The person concerned may freely withdraw consent at any time.

A. Right to informed consent as a basic requirement

§766 (3) LOA 2001 explicitly provides the requirement of informed consent: "A patient may be examined and health care services may be provided to him or her only with his or her consent". §770 (1) of the same act holds liable providers of health care services […] for the violation of the obligation to obtain consent (of the patient).

The Regulation N° 144 of 20 December 2001 of the Minister of Social Affairs on Quality Assurance Requirements for Health Services also contains the requirement of informed consent. This Regulation is based on §56 (1) of the Health Services Organisation Act.[13] §6 (4) of the Regulation N° 144 provides that a patient or a person representing him or her shall grant an informed consent for diagnostic and treatment procedures which may involve risks.

Although not applicable in daily medical practice, reference should be made to §18 of the Constitution of Estonia according to which "Nobody can be subordinated to medical scientific experiments without his or her free consent".[14]

§138 of the Estonian Penal Code which entered into force on 1 September 2002, provides that conducting medical or scientific

[13] www.tervishoiuamet.ee (website of the Estonian Health Care Board).
[14] V.PARVE, *National Regulations on Ethics and Research in Estonia*, Brussels, European Commission, DG Research, 2003, 10.

research on a person who has not granted consent thereto pursuant to the procedure prescribed by law or who before granting such consent was not notified of the essential potential dangers arising from the research is punishable by a pecuniary punishment or up to 3 years' imprisonment.

The practice varies a lot. There are some medical institutions where professionals deeply venerate the patient right to information and consent to treatment, but there are also several medical institutions where provision of information and obtaining a consent is only a formal procedure by signing a consent form in the registration office without having seen a doctor or having obtained information on their health at all.[15]

B. Contents of information preceding informed consent

According to §766 (1) LOA 2001 the doctor shall inform the patient of the results of the examination of the patient, the state of his or her health, any possible illnesses and the development thereof, the nature and purpose of the health care services provided, the risks and consequences associated with the provision of such health care services and of other available and necessary health care services.

§766 (2) LOA 2001 further provides that, as a rule, a doctor shall not promise that a patient will recover or that an operation will be successful.

The LOA 2001 does not prescribe explicitly the duty to inform the patient of the cost of the service, although according to the Ministry of Social Affairs this ought to be done. Such information should relate to the cost of the service, the amount covered by the Health Insurance Fund and what must the patient pay himself or herself. Also the approximate cost of the medicines needed and other services the patient should receive has to be included in this information.[16]

[15] ESTONIAN PATIENT ADVOCACY ASSOCIATION, "Realization of patient rights in Estonia", 12 June, 2006, www. epey.ee.
[16] SOTSIAALMINISTEERIUM, "Towards a human-centered society, Whether and how should doctor and patient inform each other", www.sm.ee.

A patient has to be informed early on before the provision of the service so that he has sufficient time to make up his or her mind.[17]

When informing a patient, the doctor must not be biased: the doctor might prefer one way of treatment, but the patient has to be informed of all the alternatives. The same applies to medicines - the doctor and patient should find together the best price-quality ratio for the patient.

ANTS NÕMPER has outlined a number of principles to be followed when informing a patient:
"1. The greater the risks entailed in the health care service are, the more thoroughly a patient has to be informed.
2. The more serious the consequences of the health care service are (e.g. amputation), the more thoroughly a patient has to be informed.
3. The less important the service is from a medical aspect (e.g. cosmetic surgery), the more thoroughly a patient has to be informed.
4. In a situation where a doctor has only one option - either to treat or to inform - treatment must come first.
5. A doctor should provide only such amount of information which the patient is able to take in and reasonably analyze.
6. The more a patient knows about the recommended health care service, the less he or she has to be informed. Where a doctor realizes that a patient is aware of the service to be provided (e.g. the patient is a doctor or has undergone such treatment before), the doctor does not need to inform the patient of what he or she already knows.
7. The less known the health care service is, the more thoroughly a patient has to be informed."[18]

C. Form of informed consent

According to §766 (3) LOA 2001 the doctor may ask that consent is confirmed in writing.

[17] SOTSIAALMINISTEERIUM, Towards a human-centered society, "Whether and how should doctor and patient inform each other" www.sm.ee.
[18] See the medical journal *Lege Artis* , October 2002, cited in SOTSIAALMINISTEERIUM, Towards a human-centered society, "Whether and how should doctor and patient inform each other" www.sm.ee.

§6 (4) of Regulation N°144 on Quality Assurance Requirements for Health Services requires that the consent of the patient in case of procedures which may involve risks has to be documented and signed by the patient or the person representing him or her and has to be preserved together with the health card or medical history of the patient.

No other general provisions exist regarding the form of consent. However, some specific rules have been approved. For instance, §16 (1) of the Artificial Insemination and Embryo Protection Act of 11 June 1997 requires that artificial insemination of a woman shall be carried out with the written consent of this woman.[19]

D. Exceptions to the requirement of informed consent

Article 8 Biomedicine Convention

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

§766 (6) LOA 2001 provides in general terms that "in the cases and to the extent provided for by law, the consent of a patient or his or her legal representative is not required for the provision of health care services".[20] More specifically §767 (1) LOA 2001 provides that if a patient is unconscious or incapable of exercising his or her will for any reason and if he or she does not have a legal representative or his or her legal representative cannot be reached, the provision of health care services is permitted without the consent of the patient if this is in

[19] J.SOOTAK and M.KURM, "A wish to have a baby and the dignity of the child and embryo: about the law on artificial insemination and embryo protection of the Republic of Estonia", *European Journal of Health Law*, 1998, 191-201.

[20] Article 11 of the Act on psychiatric aid recognizes non-consensual psychiatric aid while article 4 of the Communicable diseases prevention and control Act sets out the conditions for non-consensual treatment of such diseases.
Personal Communication of A.NÕMPER. See regarding the latter Act also SOTSIAALMINISTEERIUM, "Towards a human-centered society, Those refusing treatment can now be forced to undergo treatment against their will", www.sm.ee.

the interests of the patient and corresponds to the intentions expressed by him or her earlier or to his or her presumed intentions and if the failure to provide health care services promptly would put the life of the patient at risk or significantly damage his or her health.

E. Refusal and withdrawal of consent

According to §766 (3) LOA 2001 a patient may withdraw his or her consent within a reasonable period[21] of time after granting consent. At the request of a provider of health care services, an application to withdraw such consent shall be in a format which can be reproduced in writing.

§766 (2) LOA 2001 provides that a patient may cancel a contract for the provision of health care services at any time without giving a reason.

F. Previously expressed wishes

Article 9 Biomedicine Convention

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

According to §767 (1) LOA 2001 the provision of health care services is permitted without the consent of the patient if this is in the interests of the patient and corresponds to the intentions expressed by him or her earlier. This seems to imply the binding character of a previously expressed negative wish. The form of such an expression of will is not regulated. Neither exists a register of previously expressed wishes.

Regarding a previously expressed positive wish article 9 of the Biomedicine Convention is applicable.

[21] According to article 5 of the Biomedicine Convention the withdrawal of the consent is possible “at any time”.

G. Informed consent in case of minor patients[22]

According to §8 (2) of the General Part of the Civil Code Act persons who are under 18 years of age have so called restricted active legal capacity.[23]

With respect to the legal position of minors in relation to the provision of health care, §766 (4) LOA 2001 stipulates: "In the case of a patient with restricted active legal capacity, the legal representative of the patient has the rights specified in subsections (1) and (3) of this section in so far as the patient is unable to consider the pros and cons responsibly".
Apparently it should be evaluated on a case-by-case basis whether a minor patient is capable of understanding the information provided and giving consent to treatment. In case the legal representative is entitled to receive information regarding the health status of the minor patient, this patient "shall be informed of the circumstances and information specified in subsection (1) of this section to a reasonable extent" [§766 (4) LOA 2001].
In case a minor patient is considered not to be capable of taking health care decisions and his or her legal representative is acting on his or her behalf, a health care provider "shall not comply with the decision of the legal representative if this decision appears to damage the interest of the patient" [§766 (4) LOA 2001]. This seems to imply an obligation to deviate.[24]
Although no provision of the LOA 2001 relates to the obligation to take the opinion of the minor into consideration when taking health care decisions related to him or her, this should be done in accordance with article 6 §2 of the Convention.[25] §91 (2) of the Medicinal Products Act of 16 December 2004 provides that the consent of a minor who is between 7 (!) and 17 years old is necessary in case

[22] L. STULTIËNS, et al., "Minors and informed consent: a comparative approach", *European Journal of Health Law*, 2007, 26-27.
[23] P.VARUL, A. AVI and T. KIVISILD, "Restrictions on active legal capacity", *Juridica International*, IX/2004, 101.
[24] See in this regard A.NÕMPER, "Criminal prosecution of doctors of a child of Jehovah's witnesses", *Juridica*, IV, 2000, abstract.
[25] §766 (4) LOA 2001 only stipulates that *information* must be provided to the minor patient to a reasonable extent. It does not state that the *opinion* of the minor patient should be taken into consideration.

he/she participates in a clinical trial.[26] Whether this rule also applies in case of daily medical practice is not known.

H. Informed consent in case of incapacitated adults

Article 6 Biomedicine Convention

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.
3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorisation procedure.

There is no regulation in Estonian law about proxy decision-making for incapacitated adults. The practice varies a lot: most of the times the treating physician takes the decision on behalf of the patient or in more rare cases a relative of the patient.[27]

Reference to the role of the relatives of the incapacitated patients is made in §767 (1) LOA 2001 in case of an emergency: "the intentions expressed earlier by a patient or his or her presumed intentions shall, if possible, be ascertained using the help of his or her immediate family. The immediate family of the patient shall be informed of his or her state of health, the provision of health services and the associated risks if this is possible in the circumstances". According to §767 (2) LOA 2001, immediate family means the spouse, parents,

[26] This rule already existed before 2004. see V.PARVE, *National Regulations on Ethics and Research in Estonia*, Brussels, European Commission, DG Research, 2003, 12.
[27] ESTONIAN PATIENT ADVOCACY ASSOCIATION, "Realization of patient rights in Estonia", 12 June, 2006, www.epey.ee.

children, sisters and brothers of the patient. Other persons who are close to the patient may also be deemed to be immediate family if this can be concluded from the way of life of the patient.

§ 4. Right to information about his or her health

Article 10 Biomedicine Convention

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.
3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

A. Right to information about his or her health as a basic requirement

According to §766 (1) LOA 2001 the provider of health services shall inform the patient of the results of the examination of the patient, the state of his or her health and any possible illness and the development thereof.
§6 (3) of the Regulation N° 144 on the Quality Assurance Requirements for Health Services provides that a patient or a person representing him or her shall be informed of the state of health of the patient, the results of tests and treatment and the complications involved.

B. Right not to know

§766 (5) LOA 2001 stipulates that a provider of health care services shall not disclose information regarding the results of the examination of the patient, the state of his or her health and any possible illness and the development thereof to a patient if the patient refuses to be given such information and if his or her legitimate interests or the legitimate interests of other persons are not damaged thereby.

C. Therapeutic exception

There is no provision in Estonian law regarding the therapeutic exception.

§ 5. Patient rights regarding the medical file

Article 10 Biomedicine Convention

1. *Everyone has the right to respect for private life in relation to information about his or her health.*
2. *Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.*

A. Right to a medical file

§769 LOA 2001 obliges a provider of health care services to document the provision of health services to each patient pursuant to the requirements (contained in §768: confidentiality- see below) and to preserve the corresponding documents.

§770 (3) LOA 2001 states that the burden of proof regarding circumstances which are the basis for the liability of the provider of health care services shall lie with the patient unless the provision of health services to the patient is not documented as required.

B. Contents of the medical file

There are no legal provisions regarding the contents of the medical file.

C. Right to access and copy the medical file

i. Right to access the medical file

§769 LOA 2001 grants the patient the right to examine his or her medical file […] unless otherwise provided by law.

ii. Right to copy the medical file

§769 LOA 2001 also grants the patient the right to obtain copies of his or her medical file at his or her own expense, unless otherwise provided for by law.

iii. Post mortem access by relatives

Not regulated

D. Right to correction, erasure and/ or demolition

Not regulated

§ 6. Right to medical secrecy/ confidentiality

Article 10 Biomedicine Convention

1. Everyone has the right to respect for private life in relation to information about his or her health.

The obligation to respect medical secrecy is laid down in §157 of the Criminal Code :"Disclosure of information obtained in the course of professional activities and relating to the health, private life or commercial activities of another person by a person who is required by law to maintain the confidentiality of such information is punishable by a pecuniary punishment".

§768 (1) LOA 2001 contains the obligation to respect the confidentiality : providers of health care services and persons participating in the provision of health care services shall maintain the confidentiality of information regarding the identity of patients and their state of health which has become known to them in the course of providing health care services or performing their official duties and they shall ensure that the information contained in the patient's medical file does not become known to other persons unless otherwise prescribed by law or by agreement with the patient. According to §768 (2) LOA 2001 it is permitted to deviate from this duty to a reasonable extent if failure to disclose the information could result in the patient significantly damaging himself or herself or other persons.

§14 (5) of the Personal Data Protection Act provides that data relating to the state of health of a data subject who is in hospital may be transmitted or may be accessed by those closest to him or her except if the data subject has prohibited such access or transmission.

According to the Estonian Patient Advocacy Association health care providers are often not able to fulfill all the requirements to protect health records and archives. Usually there is access to health records to all staff members of the hospital or policlinic and the health records are badly protected.[28]

§ 7. Right to privacy/ protection of private life

Article 10 Biomedicine Convention

1. Everyone has the right to respect for private life in relation to information about his or her health.

Articles 42, 43 and 44 of the 1992 Estonian Constitution recognize the right of privacy, secrecy of communications, and data protection.

[28] ESTONIAN PATIENT ADVOCACY ASSOCIATION, "Realization of patient rights in Estonia", 12 June, 2006, www.epey.ee.

The presence of another person during the provision of health care services is permitted only with the consent of the patient unless it is impossible to provide the health care services without the presence of the other person, it is impossible to obtain the consent of the patient and failure to provide the health services would significantly damage the health of the patient (§765 LOA 2001).

A. Processing of data concerning health

Processing of personal data is regulated by the Personal Data Protection Act of 12 February 2003.[29] §11 (1) provides that personal data may be processed only with the permission of the data subject (the person whose personal data are processed), unless otherwise provided by law. According to §14 (1) 2) and §14 (2) 2) the processing and transmission of personal data without the consent of the data subject is allowed "for protection of the life, health or freedom of the data subject or other person". According to §14 (3) 2) and (4) 2) the processing and transmission of sensitive personal data is permitted without the consent of the data subject "for the protection of the life, health or freedom of the data subject or other person". Sensitive personal data are data relating to the state of health or disability and data relating to genetic information [§4 (3), 3) and 4)]. A recent amendment of the Personal Data Protection Act considers a person's biometrical data, such as fingerprints and DNA also as sensitive personal data.[30]

The obligation to notify the data subject cannot be found clearly in the Personal Data Protection Act (§15 provides for an obligation of notification in case the data subject is not the source of personal data) but may be deduced from the following excerpt:

"A significant omission is not performing the obligation of notifying the data subjects. For example, in the medical sector each health care service provider must have developed and made available to data subjects a client service standard, which must contain at least the

[29] For the consolidated text of this Act see www.dp.gov.ee (website of the data protection inspectorate).
[30] MINISTRY OF JUSTICE, News 2007, February: "New act to improve protection of personal data", www.just.ee.

following: 1) method for the registration of complaints, their resolution and providing of feedback to patients; 2) patient's rights and obligations; 3) communication with the patient and their family; 4) process for the informing of patients regarding the provision of health care service; 5) the on time notification of patients in registering for the waiting list, their direction between health care service providers and in the substitution of health care professionals".[31]

B. Right to access and right to receive a copy

§29 (1) 1) of the Personal Data Protection Act provides that at the request of a data subject, the chief processor and the authorized processor shall notify him or her of the personal data relating to him or her.
§29 (2) provides that a data subject has the right to receive copies of personal data relating to him or her against the payment of 3 kroons[32] per page for copies on paper starting from the 21st page. A fee for the release of personal data may be charged also for the repeated release of the same personal data.
According to §29 (3) the information has to be provided within 5 working days after the date of receipt of an application.

§30 (1) 1) restricts the right of a data subject to receive information and personal data relating to him or her if this may prejudice the rights and freedoms of other persons.

C. Right to correction, erasure and/ or demolition

If processing is contrary to the Personal Data Protection Act, other Acts or legislation established on the basis thereof, a chief processor or an authorized processor is, at the request of the data subject, required to terminate the processing of personal data relating to him or

[31] DATA PROTECTION INSPECTORATE *Report concerning the performance of the Personal Data Protection Act and the Public Information Act 2006*, 9, www.dp.gov.ee.
[32] 1 Estonian kroon = 0.0639111277 Euros.

her; to rectify inaccurate personal data and to block or erase the collected personal data [§31 (1) Personal Data Protection Act].

§ 8. Right to complain and to compensation

A. Right to complain

Article 23 Biomedicine Convention

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

§6 (1) of the Regulation N° 144 on Quality Assurance Requirements for Health Services obliges physicians to analyse and assess the satisfaction of patients and to register and settle complaints of patients and provide feedback to patients.
§6 (2) requires health care providers to develop the procedure for the registration and settlement of complaints and inform their patients of the right to file complaints against the activities of health care professionals with a regional unit of the health insurance fund, the Health Care Board or a county governor.
§6 (6) requires health care providers to prepare summaries and analyses of and conduct discussions on the satisfaction and complaints of patients and to record the results at least once a year.

According to the Estonian Consumer Centre health services users are in general satisfied with the health care services rendered. However, there may be situations when they are disappointed with the services as they don't give the expected results or cause complications. The first step to be made in the event of problems is to approach the service provider to try to find a solution satisfactory for both parties. If the patient and the health care service provider fail to come to an understanding, the patient may file a written complaint with the Supervision Department of the Health Care Board. If a more accurate establishment of the circumstances is required, the case will be handled by the standing expert Committee on the quality of health care services of the Health Care Board. The patient has to file a

written complaint with the expert Committee, setting out the reasons for his dissatisfaction and complete it with information regarding the medical institution/doctors and the time of the event, as accurately as possible. If the patient holds relevant medical documents that are not in the possession of doctors or medical institutions (X-rays, for example), these should be also attached to the complaint. The expert Committee is a standing advisory committee that provides independent expert opinion regarding the quality of health care services rendered to the patient. Proceedings conducted by the Committee are document-based: the decision is made on the basis of documents, which detail the provision of the health care services, explanations given by health care workers and the expert opinion requested from a specialist. The decision of the Committee represents an expert opinion and will not give rise to any rights or responsibilities to either the patient or the doctor; the patient can't contest the decision. Nevertheless, the Health Care Board may use the decision of the Committee to initiate a proceeding in the disputed case.[33]

The statistics of complaints submitted to the expert Committee indicate that approximately half of the complaints arise out of the communication problems between doctors and patients. A closer look into the stories that have made newspaper headlines reveals that the dissatisfaction of a patient is the consequence of the patient and the doctor misunderstanding each other.[34]

The Estonian Patient Advocacy Association also refers to the Health Care Board as a possible channel where patients can complain but "as the board consists only from medical professionals it cannot be considered as independent review".[35] According to the Association there is no possibility to present a complaint to an independent review board other than the Court.

[33] www.consumer.ee.
[34] SOTSIAALMINISTEERIUM, "Towards a human-centered society, Whether and how should doctor and patient inform each other", www.sm.ee.
[35] Realization of patient rights in Estonia, www.epey.ee.

B. Right to compensation

Article 24 Biomedicine Convention

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

§770 LOA 2001 contains the following rules regarding the liability of providers of health care services:
(1) Providers of health care services are liable only for the wrongful violation of their own obligations, particularly for errors in diagnosis and treatment and for violation of the obligation to inform patients and obtain their consent.
(2) Providers of health care services are also liable for the activities of persons assisting them and for any defects in the equipment used upon provision of health care services.
(3) The burden of proof regarding circumstances which are the bases for the liability of the provider of health care services lies with the patient unless the provision of health care services to the patient is not documented as required.
(4) If there is an error in diagnosis or treatment and a patient develops a health disorder which could probably have been avoided by ordinary treatment, the damage is presumed to have resulted from the error. In this case, the burden of proof regarding the damage resulting from the health disorder also lies with the patient.

§771 LOA 2001 provides that the limitation period for a claim of a patient concerning compensation for damage is five years as of the time when the patient becomes aware that a provider of health care services has violated an obligation or caused damage.

There is no state mechanism to get a compensation for damage of malpractice. The only possibility to get compensation is through the court system, but that is expensive, time consuming and demands a

patient to provide evidence. Due to these reasons there are only very few malpractice cases in Estonia.[36]

[36] www.epey.ee.

IV. RIGHTS OF USERS OF GENETIC SERVICES

§ 1. Introductory remark

Estonia is world wide known because of the Estonian Genome Project. One of the corner stones of this project is the Human Genes Research Act (HRGA) of 13 December 2000 that entered into force on 8 January 2001. However, this act does not apply on genetic testing. Genetic testing has been intentionally left unregulated by that Act.[37] §6 (2) HRGA provides that its Chapter 2 (Rights of gene donors), Chapter 3 (Processing of Gene Bank) and Chapter 4 (Data Protection) are not applicable to genetic testing. It also stipulates that genetic testing may be performed pursuant to the procedure and for the purposes provided by law. Until now a specific law on genetic testing does not exist. As a consequence the provisions of the Law of Obligations (LOA) 2001 which have been discussed in the previous part have to be applied.

Following §766 (3) LOA 2001 genetic testing always requires informed consent of the user. Informed consent means consent based on appropriate information provided by a health care professional. The health care provider responsible for the genetic test may request written consent but an oral consent is also valid.
The right not to know has to be respected. Not informing the user because this could damage his or her health (the so called therapeutic exception) is not provided for in Estonian law.
It should be evaluated on a case-by-case basis whether a minor patient is capable of understanding the information provided and giving consent to genetic testing.

Under Estonian law users of genetic services have several rights regarding their medical file, such as the right to a medical file, the

[37] A. NÕMPER, "Legal regulation of genetic testing" *Juridica*, II, 2001, 113-123 (only the English abstract available at www.juridica.ee).

right to access the medical file, the right to copy the medical file and the rights to correction, erasure and/or demolition.
The right to medical secrecy and confidentiality of medical information is protected by different provisions.

The rights to privacy and protection of private life in relation to information about his or her health are protected by the Personal Data Protection Act.

Estonian law provides for several channels through which patients can complain when their rights have not been respected such as the Supervision Department of the Health Care Board. There is no state mechanism to get a compensation for damage of malpractice. The only possibility to get compensation is through the court system.

§ 2. Prohibition of discrimination on grounds of genetic heritage

Article 11 Biomedicine Convention

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited

§25 of the Human Genes Research Act 2000 prohibits to restrict the rights and opportunities of a person or to confer advantages on a person on the basis of the structure of the person's DNA and the genetic risks resulting thereof. Is also prohibits to discriminate against a person on the basis of the person being or not being a gene donor.

§26 of the Human Genes Research Act 2000 prohibits employers from collecting genetic data on employees or job applicants and from requiring employees or job applicants to provide tissue samples or descriptions of DNA. Employers are also prohibited from imposing discriminatory working and wages conditions for people with different genetic risks.

§27 of the Human Genes Research Act 2000 prohibits insurers from collecting genetic data on insured persons or persons applying for

insurance cover and from requiring insured persons or persons applying for insurance coverage to provide tissue samples or descriptions of DNA. Insurers are also prohibited from establishing different insurance conditions for people with different genetic risks and from establishing preferential tariff rates and determining insured events restrictively.[38]

According to §30 (1) of the Human Genes Research Act 2000 complaints concerning discrimination occurring in employment relationships due to genetic risks shall be adjudicated by the Labour Inspectorate, if necessary with the assistance of the chief processor or experts from the data protection supervision authority in investigating and deciding the matter. According to §30 (2) complaints concerning discrimination occurring in insurance relationships due to genetic risks shall be adjudicated by the Insurance Supervisory Authority, if necessary with the assistance of the chief processor or experts from the data protection supervision authority in investigating and deciding the matter.

§153 of the Criminal Code provides as follows:

"(1) Unlawful restriction of the rights of a person or granting of unlawful preferences to a person on the basis of his or her genetic risks is punishable by a fine or by detention.
(2)The same act, if committed,

i. at least twice, or

ii. significant damage is thereby caused to the rights or interests of another person protected by law or to public interests, is punishable by a pecuniary punishment or up to one year of imprisonment".

[38] According to RAIDLA and NÕMPER such absolute prohibition is in the interests of persons but may lead to abuse (for example insurance fraud). Therefore, in order to prevent abuse, it may be considered reasonable to provide employers and life insurers with the right to require the submission of genetic data in strictly restricted cases. J. RAIDLA and A. NÕMPER, "The Estonian Genome project and the Human Gene Research Act", in I. ZIEMELE (ed.), *Baltic Yearbook of International Law*, 2002, The Hague, Kluwer Law International, 57, note 19. But the Estonian law does not provide for such an exception until now.

§ 3. Use of predictive genetic tests

Article 12 Biomedicine Convention

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

According to A. HALLER it is correct and justified that the Law on Obligations Act 2001 regards predictive testing as an object of a contract concluded by a doctor and a patient. However, the Health Services Organisation Act defines a health service as an activity of doctors to improve the health of patients. Several diseases detected by predictive tests are incurable. For this reason, predictive testing gives rise to the question whether it is ethical, permissible and legal.[39]

With regard to the requirement of appropriate genetic counseling, §11 (4) of the Human Genetic Research Act 2000 provides that gene donors have the right to genetic counseling on accessing their data stored in the Gene Bank. According to RAIDLA and NÕMPER it is therefore not necessary to carry out genetic counseling of a gene donor when the person becomes a gene donor, but only when the gene donor addresses the Gene Bank once again and receives their genetic information.[40] In order for this right to genetic counseling to be enforceable, resources must be allocated and providers must hire a

[39] A. HALLER, "Predictive test as an object of a contract between a doctor and a patient in the Estonian law", *Juridica,* III, 2002 (only abstract in English available on www.juridica.ee).
[40] J. RAIDLA and A. NÕMPER, "The Estonian Genome project and the Human Gene Research Act", in I. ZIEMELE (ed), *Baltic Yearbook of International Law,* 2002, The Hague, Kluwer Law International, 55.

sufficient number of suitable qualified professionals. In this respect, the situation in Estonia still seems to be unsatisfactory.[41]

[41] S.M.C. GIBBONS et al., "Lessons from European Population Genetic Databases comparing the law in Estonia, Iceland, Sweden and the United Kingdom", *European Journal of Health Law*, 2005, 125.

V. CONCLUDING REMARKS

1. Estonia has signed and ratified the Convention which entered into force on 1 June 2002.

2. Estonia belongs to three Central-East EU Member States Member States where the Biomedicine Convention already had a significant impact upon patient rights legislation and policies before the ratification: Estonia, Hungary and Lithuania.[42] The first attempts to legislate on patient rights date back to 1993. These attempts failed but in 2001 the rights and obligations of patients have been incorporated in the Law of Obligations Act. A privileged witness has testified that the Convention was already before its ratification "an inspiration for Estonia to legislate in this field".[43]

3. Compared to other EU Member States the available information in English on the status of the rights of patients and users of genetic services is rather limited. Nonetheless we may conclude that Estonian law on the protection of patient rights is in general in concordance to the Biomedicine Convention. This is not a surprise given that the Law of Obligations Act has been inspired by the Dutch Medical treatment Contract Act.

4. A serious deficiency in Estonian law exists regarding the protection of incapacitated adults. There is no regulation about proxy decision-making for these adults. The practice varies a lot: most of the times the treating physician takes the decision on behalf of the patient. In more rare cases a relative of the patient intervenes.

5. Estonian law does not regulate the right to information about his or her health as a separate right. The right to receive information

[42] H.NYS, et al., "Patient rights in EU member States after the ratification of the Convention on Human Rights and Biomedicine", *Health Policy*, 2007, www.elsevier.com/locate/healthpol.
[43] T. BIRMONTIENE, "Health Legislation in Eastern European Countries: the Baltic States", *European Journal of Health Law*, 2004, 80.

regarding one's state of health is mentioned in §766(1) of the Law of Obligations Act 2001 as part of the right to informed consent. There is no provision in Estonian law regarding the therapeutic exception.

6. Independent review of complaints of patients and compensation for damage due to malpractice is only possible through the court system which is expensive and time consuming.

7. Estonia has no specific law on genetic testing. The Human Genes Research Act of 2000 intentionally left genetic testing unregulated. The Law on Obligations Act and its provisions on the rights of patients are *mutatis mutandis* applicable to users of genetic services.

8. The Human Genes Research Act explicitly prohibits employers and insurers from collecting genetic data on employees, job applicants, insured persons or persons applying for insurance cover and from requiring employees, job applicants, insured persons or persons applying for insurance to provide tissue samples or descriptions of DNA. Employers are also prohibited from imposing discriminatory working and wages conditions for people with different genetic risks while insurers are prohibited from establishing different insurance conditions for people with different genetic risks and from establishing preferential tariff rates and determining insured events restrictively.

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