

CONFIDENTIALITY IN INTERNATIONAL CONTEXT EUROPEAN EXPERIENCE

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Introduction

It has become quite normal that genetic data are collected for medical purposes. Typically during prenatal genetic screening, genetic tests of parents, seeking for genes influencing certain diseases. Such data are then stored. Several international documents have recognized that human genetic data have a special status on account of their sensitive nature. Data may contain information which significance is not necessarily known at the time of the collection of the biological sample or of data.¹

Sometimes it happens that data are needed for different purposes than for those they were collected. We will discuss to what extent international (especially European) documents cover such situations and under which conditions data can be used for different purposes.

If we think about common usage of genetic data different from medical reasons, we can find at least following purposes:

- Research,
- Identification of persons,
- Criminal investigation,
- Historical purposes,
- Statistical purposes,
- Public health purposes,
- Parentage testing,
- Public interest purposes².

We can see that purposes for which data can be used are quite broad. Research purposes enable to improve our knowledge of genetics, help us to prevent various diseases. Similarly statistical collection of data makes further research easier. On the other hand, influence of identification of persons, criminal investigation or historical purposes is more disputable, benefit for public can be questionable.

What we want to clarify is to what extent genetic data can be used under the regulation given by international documents. Purpose of this paper is not to investigate single national legal documents.

United Nations

United Nations documents clearly must be very general. United Nations bodies, especially UNESCO, have recently elaborated various documents on genetic data.

¹ See e.g. Article 4 para a/iii of the International Declaration of Human Genetic Data

² Public interest is not precisely defined. It can cover variety of purposes.

In 1997 it was **Declaration on the Human Genom and Human Rights**. But the most important one is the **International Declaration of Human Genetic Data** adopted in 2003, in which especially Article 14 requires our attention.

Article 14 reads as follows:

“(a) States should endeavour to protect the privacy of individuals and the confidentiality of human genetic data linked to an identifiable person, family or, where appropriate, group, in accordance with domestic law consistent with the international law of human rights.

*(b) **Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights.** The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected and the data should be treated as confidential.*

(c) Human genetic data, human proteomic data and biological samples collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples.

*(d) **Human genetic data, human proteomic data and biological samples collected for medical and scientific research purposes can remain linked to an identifiable person, only if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law.***

*(e) **Human genetic data and human proteomic data should not be kept in a form which allows the data subject to be identified for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed.**“*

The aim of the Declaration is to promote single states to adopt legislation ensuring adequate protection of human genetic data when public interest is at stake. The whole Declaration including its preamble defines fundamental boundaries in which national legislations have to be kept. Restrictions are imposed on using of data for different purposes than for those they were collected. On one hand, it allows data disclosure for important public interest reasons (clearly and restrictively provided for by domestic law) but on the other hand it restricts storing of data linked to identifiable person longer than is necessary for achieving the purposes for which they were collected or subsequently processed.

Reading the Article 14 of the International Declaration of Human Genetic Data we can easily imagine that domestic law will define statistical, scientific and historical purposes and need to identify a person as public interest purposes. Defining criminal investigation as public interest will be more complex for having troubles to say that any collected genetic data can be used for tracing offender of crime. UNESCO beard in mind complexity of criminal investigation purposes and therefore the International Declaration of Human Genetic Data sets it in its Article 1 (c) that **provisions of Declaration do not apply to the**

collection, processing, use and storage of human genetic data, human proteomic data and biological samples, in the investigation, detection and prosecution of criminal offences and in parentage testing. These purposes are subject to domestic law that is consistent with the international law of human rights. More precisely it is expressed in the Article 12 stating **when human genetic data or human proteomic data are collected for the purposes of forensic medicine or in civil, criminal and other legal proceedings, including parentage testing, the collection of biological samples, in vivo or post-mortem, should be made only in accordance with domestic law consistent with the international law of human rights.** UN calls for clear domestic legal boundaries for using genetic data for mentioned purposes but domestic legislation must be in accordance with ethical framework set by the Declaration. There appears explanatory problem since the Declaration in Article 1 (c) states that it does not cover investigation, detection and prosecution of criminal offences and in parentage testing but Article 12 sets obligations of states in this field. It should be understood that the Declaration codifies minimal standard that must be followed in any treatment of genetic data.

Article 6 (d) of the Declaration imposes duty to provide clear, balanced, adequate and appropriate information to the person whose prior, free, informed and express consent is sought. Such information shall, alongside with providing other necessary details, specify the purpose for which human genetic data and human proteomic data are being derived from biological samples, and are used and stored. So, the person must be clearly informed about all the purposes for which data are collected and he/she has to give his/her informed consent to all procedures with biological samples and genetic data derived from those samples.

We can not find any *ex lege* exceptions in the Declaration which enables usage of genetic data or biological samples for purposes different from those they were collected. The Declaration only takes into account that need of such usage may occur and asks for clear domestic legal regulation of this field.

In European region we have to check two formally different approaches. First one has its basis in Council of Europe and second one in European Union.

Council of Europe

Council of Europe made an important step in information protection by adopting **Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine.** Up to date it has been ratified by 19 states. Article 10 (1) stipulates that everyone has the right to respect for private life in relation to information about his or her health. This provision covers also genetic data information and sets minimal standard for collecting and further using of genetic data.

Data protection is specifically regulated by the **Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data** (ETS No. 108). According to Article 3 para 2c this it is up to the Member States to apply this Convention also to personal data files that are not processed automatically. The Convention prohibits preservation of data in form that permits identification of the data subjects for longer than is required for the purpose for which those data are stored. Such principle has to be applied also for genetic data. Member States may derogate from this provision in the interest of protecting

state security, public safety, the monetary interests of the state or the suppression of criminal offences. Derogation must be provided for by the law and has to constitute a necessary measure in a democratic society.

More detail provisions are given in the **Recommendation No. R (97) 5 of the Committee of Ministers to Member States on the Protection of Medical Data**. According to Article 1 of the Recommendation it applies also to genetic data and Articles 4.7., 4.8. and 4.9. contain special provisions concerning treatment of genetic data. Similarly as in the International Declaration on Human Genetic Data Article 4.7. asks for informed consent of data subject concerning purpose for which data are collected. It sets in 4.7 that “*genetic data collected and processed for preventive treatment, diagnosis or treatment of the data subject or for scientific research should only be used for these purposes or to allow the data subject to take a free and informed decision on the matters*”. But Recommendation No. R (97) 5 has also more specific provisions concerning processing of genetic data for purposes different from those they were collected. As other international documents it requires clear domestic legal regulations especially when data are used for the purposes of judicial procedure or criminal investigation. *Expressis verbis* it allows these data to establish whether there is a genetic link in the framework of adducing evidence **to prevent a real danger or to suppress a specific criminal offence**. During such procedure they should not be used to determine other characteristics which may be linked genetically. We can conclude that the Recommendation admits usage of once collected data for different purpose (prevent real danger, suppress a specific offence). On the other hand, we can not find adequate conditions for conservation of data. Generally, data can be conserved no longer than necessary to achieve the purpose for which they were collected and processed. *When, in the legitimate interest of public health, medical science, the person in charge of the medical treatment or the controller of the file, in order to enable him/her to defend or exercise a legal claim, or for historical or statistical reasons, it proves necessary to conserve medical data that no longer serve their original purpose, technical arrangements shall be made to ensure their correct conservation and security, taking into account the privacy of the patient* (Article 10.2). This article does not enable data controller to keep data for prevention of real danger or to suppress a specific offence.

Under the Article 4.9. of the Recommendation for other than medical, research, judicial and criminal investigation purposes, collection and processing of genetic data should only be permitted for health reasons and in particular to avoid any serious prejudice to the health of the data subject or third parties.

Under the Article 7.3. of the Recommendation, *medical data (including genetic data) can be communicated if they are relevant and:*

a. if the communication is provided for by law and constitutes a necessary measure in a democratic society for:

- i. public health reasons; or*
- ii. the prevention of a real danger or the suppression of a specific criminal offence;*
or
- iii. another important public interest; or*
- iv. the protection of the rights and freedoms of others; or*

b. if the communication is permitted by law for the purpose of:

- i. the protection of the data subject or a relative in the genetic line;*
- ii. safeguarding the vital interest of the data subject or a third person; or*

- iii. *the fulfilment of specific contractual obligations; or*
- iv. *establishment, exercising or defending a legal claim; or*
- c. *if the data subject or his/her legal representative, or an authority, or any person or body provided for by law has given his/her **consent** for one or more purposes, and in so far as domestic law does not provide otherwise; or*
- d. *provided that the data subject or his/her legal representative, or an authority, or any person or body provided for by law **has not explicitly objected** to any non-mandatory communication, if the data have been collected in a freely chosen preventive, diagnostic or therapeutic context, and if the purpose of the communication, in particular the provision of care to the patient or the management of a medical service operating in the interest of the patient, is not incompatible with the purpose of the processing for which they were collected.*

Under conditions given in the Article 8.2., there can be refused, limited or delayed access to medical data by data subject. Such refusal, limitation or delay does not constitute opposite right, i.e. to make data accessible for purpose different from that they were collected.

Similarly as in the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data, medical data cannot be kept longer than necessary to achieve the purpose for which they were collected and processed. Article 10.2. says that “*when, in the **legitimate interest of public health, medical science, the person in charge of the medical treatment or the controller of the file**, in order to enable him/her to defend or exercise a legal claim, or for historical or statistical reasons, it proves necessary to conserve medical data that no longer serve their original purpose, technical arrangements shall be made to ensure their correct conservation and security, taking into account the privacy of the patient.*”.

European Union

Basic standard for collecting and processing of genetic data is given by **Directive 95/46/EC on the protection of individuals with regard to the procession of personal data and on the free movement of such data** (hereinafter “the Directive”). Directive is concerned, as is all the work of the European Union, primarily in creating single economic market across Europe. The Directive facilitates this through creating conditions of protection of the fundamental rights and freedoms of individuals and especially the right to privacy, thus enabling the free transfer and use of personal data between Member States within an environment of assured minimum acceptable protection.³

It is commonly accepted that genetic data must be treated as sensitive personal data. In the member states of European Union, both legal and ethical requirements for medical confidentiality and data protection requirements of sensitive health data apply if genetic data are collected by health care personnel for health care purposes. If genetic data are collected by health care personnel for other than health care purposes, than at least on

³ Townend, D.: Overriding Data Subjects’ Rights in the Public Interest. In: Beyleveld, D.-Townend, D.-Rouillé-Mirza, S.-Wright, J. (eds.): *The Data Protection Directive and Medical Research Across Europe*. Ashgate Publishing Limited, Aldershot. 2004. p. 93.

medical confidentiality requirements apply, but the applicability of the restrictions on processing sensitive data under the Directive 95/46/EC is less clear.⁴

According to definition of personal data given in the Article 2 of the Directive, it is applicable also on genetic data since they can be understood as information related to identified or identifiable natural person (data subject). Directive does not apply to the processing of personal data in the course of an activity which falls **outside the scope of Community law and in any case to processing operations concerning public security, defence, state security and the activities of the state in areas of criminal law.**

Basic criteria for processing of personal data are similar as those described above. But special conditions are given *inter alia* to data concerning health (Article 8 para 1), their processing has to be, generally, prohibited by member states. These conditions meet also genetic data originally collected for medical purposes. Prohibition of processing does not apply where processing of the data is required for the **purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services**, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy. Processing of data relating to **offences, criminal convictions or security measures** may be carried out only under the control of official authority, or if suitable specific safeguards are provided under national law, subject to derogations which may be granted by the Member State under national provisions providing suitable specific safeguards (Article 8 para 5).

Additionally, Member States of the European Union may adopt legislative measures to restrict certain rights (*inter alia* duty to inform data subject about purpose of data processing, recipients of the data) when such restrictions constitutes a necessary measures to safeguard:

- a) **national security**,
- b) defence,
- c) **public security**,
- d) **the prevention, investigation, detection and prosecution of criminal offences, or of breaches of ethics for regulated professions**,
- e) an important economic or financial interest of a Member State or of the European Union, including monetary, budgetary and taxation matters,
- f) a monitoring, inspection or regulatory function connected, even occasionally, with the exercise of official authority in cases referred to in (c) , (d) and (e),
- g) the protection of the data subject or of the rights and freedoms of others.

⁴ Lehtonen, L.A.: Genetic Information and the Data Protection Directive of the European Union. In: Beyleveld, D.-Townend, D.-Rouillé-Mirza, S.-Wright, J. (eds.): The Data Protection Directive and Medical Research Across Europe. Ashgate Publishing Limited, Aldershot. 2004. p. 107.

Conclusions

Reading above mentioned international documents, especially those adopted in Council of Europe and European Union we can come to following conclusions:

- 1) They set up basic principles for collecting, storing and using of data. These documents are applicable also on genetic data since they fall into the scope of definition of data.
- 2) As basic principle these documents require to inform data subject about the purpose of collecting of data, about the following usage and about the conditions under which they can be used for different purposes.
- 3) As basic principle data cannot be stored longer than it is necessary for fulfilment of purpose for which they were collected. At least they cannot be stored in the form that enables identification of data subject or privacy of data subject must be safeguarded.
- 4) International documents try to enable promote research in the field of genetics and health care protection, try to enable improvement of public health. Such public interest must be accompanied by adequate protection of rights of data subject. Confidentiality of data must be safeguarded or/and identification of data subject has to be disabled.
- 5) International documents admit that there may be reasons to use data for different purposes for which they were originally collected. When data have to be used for purpose different from the purpose they were collected, such usage must be clearly regulated by law, giving appropriate safeguards to protect rights and freedoms of data subject. International documents concerning data protection admit that special measures can be adopted in the cases of national security, public security, defence, prevention, investigation, detection and prosecution of criminal offences.

Discussion

We can see that within the boundaries given by international documents there is a quite broad space left for national legal measures to regulate usage of genetic data. It would be useful to, step by step, adopt international documents giving standards for every single usage of data collected for one purpose and then used for different purpose. Personally, I am convinced that such standards have to be primarily elaborated for public health purposes (especially medical research) and for investigation of crimes. In both these fields international exchange of data is more and more needed and unified legal measures would make such exchange easier.