ACTA MEDICA LITUANICA. 2006. VOLUME 13 No. 1. P. 21–22

Digital health record and handling of sensitive data in Estonia

Arvo Tikk

Dept. of Neurology & Neurosurgery,
University of Tartu, 2 Puusepa Street,
51014 Tartu, Estonia
E-mail: Arvo.Tikk@kliinikum.ee

Progress in info technology makes it possible to concentrate medical data of a big number of patients into a central database. In the framework of the Estonian Hospital Master Plan 2015, in Estonia it is planned to create digital health records of the whole population. To analyse this issue from the ethical point of view, a special working group was set up at the Estonian Council on Bioethics. The general principles of digital health record are given. Access of patients and doctors to the data is thoroughly analysed. Some sensitive issues of such databases are given. Possible conflicts of interest are brought forward. The problems are discussed in the framework of relevant international documents. For the implementation of the digital health record in Estonia, a new law regulating collection of medical data is needed.

Key words: digital database, data protection, privacy of patients, international documents concerning data protection

INTRODUCTION

The contemporary society is moving in the direction of evidence-based medicine. In healthcare and in the treatment of individual persons, decisions should be based on the exact data but not on opinions, impressions or indefinite approximate data. Progress in info technology makes it possible to concentrate different data in databases relatively easily. In medicine it is highly necessary to create an optimal system of collecting virtual health records of a large number of patients.

In collecting medical data, the interests of individual persons, society and doctors are intersecting. The interests of different social groups are different. Patients are interested in correct diagnosis and better treatment, as well as in privacy and autonomy. The society is interested in the good health and welfare of citizens and in the optimal use of limited resources. The doctors' interest is to obtain full information about their patients as quickly as possible and to use correct medical statistics.

In the framework of the Estonian Hospital Master Plan 2015 (1) it is planned in Estonia to create digital health records for the whole population. Preparatory work on this project has been going on already for some years. The main idea of the digital health record system is to concentrate general data into a central database, while detailed medical information will be accessible using links to local hospital databases.

In principle, some conflicts of interest are inherent for this system already beforehand. For instance, there exists a conflict between the privacy and autonomy of patients and their interest to receive the correct diagnosis and the best treatment. There can also be a conflict between the interests of patients as individuals and the interest of the same patients as members of society.

MATERIALS AND METHODS

The paper describes and analyses the establishment of Estonian database of digital health records, which is a highly innovative and ambitious project. The paper also addresses the issue of confidentiality in using the digital health records and analyses this issue in the light of international legal instruments, in particular the Directive 95/46/EC of the European Parliament and of the Council.

RESULTS

Medicine involves mainly delicate personal data. Therefore the patient's privacy, welfare and dignity are of importance. In using a database, many relevant issues should be taken into consideration. To analyse these problems from the ethical point of view, a special working group was set up at the Estonian Council on Bioethics (2). The results of the analysis are given below.

The general principles of digital health records are the following:

1. Anonymous data are preferable and can be used for medical statistics. All possible data shall be included.
2. Persons have the right to restrict the access to their data.

3. Different users have a different extent of access to data.

Access to data is thoroughly analyzed, *e.g.*, who has access to data and what is the level of access... Patients themselves shall have direct access to basic data: data identifying the person, the diagnoses and the list of analyses and treatments. The patient has also the right to know who has made a search and when it was made. In the case of suspected misuse of data, patients should have a possibility to inquire about relevant information. We support the opinion (3) that detailed data can be only examined in presence of health professionals.

Health professionals shall have access to data for prevention, treatment and diagnostics, first of all for the period of treatment and in the needed amount. Each enquiry should be recorded. It is important that the information contained in the database cannot be deleted; it can be only corrected or complemented. For better data protection at access, the patient, the doctor and the computer should be simultaneously identified.

One of the issues related to patient's privacy and confidentiality is the right to restrict the use of his / her data. Analysis of this problem shows that blocking of access to data should be prudent. Concealing or withholding of data can significantly influence the quality of treatment and make the health care system inadequate in general. At the same time, every person has the right to the best possible treatment, and insufficient medical care is neither in the interests of patients nor the society or doctors.

A very sensitive issue is psychiatric diseases. Family doctor is the key person in the health care system in Estonia. Our commission has come to the conclusion, that the family doctor should have full access to all collected data, among them psychiatric diagnoses. Unfortunately, this is not yet the case in Estonia.

DISCUSSION

It should be stressed that when a large-scale database of the whole population is created it is important that all kinds of measures guaranteeing protection of the person's privacy and at the same time of the interests of the society as a whole should be taken into consideration. This idea is fixed in many international general documents on human rights and data protection. For instance, Article 29(1) of the United Nations Universal Declaration of Human Rights (1948) stipulates: "Everyone has duties to the community in which alone the free and full development of his personality is possible" (4). Article 10(2) of the European Convention for the Protection of Human Rights and Fundamental Freedoms (1950) also stipulates: "The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, ... for the protection of health or moral …" (5). At these antagonistic interests of individual persons and society some kind of balance should be sought between them. Such a document reflecting trends to equilibrate the different interests is the European Union's Directive 95/46/EC on data protection. Article 8 paragraph 1 of this directive stipulates: "Members states shall prohibit … the processing of data concerning health or sex life", however paragraph 3 of the same article stipulates: "Paragraph 1 shall not apply where processing of data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services".

Discussions on the problems of data protection in general, as well as on patients′ rights and privacy and collection of medical data into different registries and databases and for the purposes of medical statistics have been very heated and emotional in Estonia. For a specialist it is clear that for different forms of medical and population statistics, certain disclosure of health information without individual authorization is inevitable. This conception is also fixed in the EU Directive 95/46/EU. Article 11 paragraph 1 states: "Where the data have not been obtained from the data subject, Member States shall ... provide the data subject with at least the following information …" However, paragraph 2 of the same article stipulates: "Paragraph 1 shall not apply where, in particular, for processing for statistical purposes or for the purposes of historical or scientific research, the provision of such information proves impossible or would involve a disproportionate effort ..."

In conclusion, our working group came to the conclusion that for the implementation of the digital health record in Estonia a new special law regulating collection of medical data is needed. At present, Estonian legal specialists are working at the development of such a law. This will also involve relevant amendments to the existing law on data protection.

Received 10 September 2005
Accepted 13 January 2006

References

1. Estonian Hospital Master Plan 2015. Executive summary. Available from: URL: http://www.sm.ee/eng/HtmlPages/HMP2015/$file/HMP2015.pdf.
2. Report of the working group on ethical aspects of the digital health record (in Estonian). Available from: URL:http://www.sm.ee/est/pages/index.html.
3. Directive 95/46/EC of the European Parliament and of the Council. Official Journal of the European Communities. L281, 23/11/1995: p. 0031–50.
4. UN General Assembly. Universal Declaration of Human Rights. 1948 Dec. Available from: URL: http://web.archive.org/web/20010605034932/www.humanrights.ee/eng/decl/text.htm.
5. Council of Europe. Convention for the Protection of Human Rights and Fundamental Freedoms. European Treaty Series No. 5. 1950 Nov. Available from URL: http://conventions.coe.int.