Digital Personalized Health and Medicine
L.B. Pape-Haugaard et al. (Eds.)

doi:10.3233/SHTI200340

Legal and Ethical Issues in Secondary Use of Administrative Health Data: The Case of Latvian Healthcare Monitoring Datalink

Signe MEZINSKA[a], Arnis BUKA[b], Agnese BANKAVA[b], Juris BARZDINS[a1]
[a] *University of Latvia, Faculty of Medicine*
[b] *University of Latvia, Faculty of Law*

Abstract. The paper presents analysis of the legal and ethical issues surrounding establishment of the Latvian Healthcare Monitoring Datalink. The paper covers three interconnected issues in the context of the use of administrative health data for research purposes – anonymization of data, concept of 'public interest' and involvement of research ethics committees. The analysis has been put into broader context of interaction between General Data Protection Regulation (GDPR), national legislative measures and practical needs of researchers. Neither GDPR, nor Latvian legal framework regulate the particularities on the use of potentially identifiable health data in research. Also, the practical use of 'public interest' as a basis for lawful processing of personal data concerning health for research purposes is not clear. More extended involvement of research ethics committees might serve as useful tool for determination the 'public interest' and for the evaluation of proportionality when balancing the aims of the research and the personal data protection

Keywords. Personal data, data concerning health, secondary use, anonymization, informed consent, public interest

1. Introduction

To perform their functions, several state institutions in Latvia (the National Health Service, the Centre for Disease Prevention and Control, the State Emergency Medical Service and the Health Inspectorate) are collecting personalized patient level data. The primary use of these data does not require that the personalized data stored in one institution is linked to the data of the same person in another institution. Linking these data sets through a unique identifier for each person may ensure that the data can be used more broadly, e.g. for monitoring the quality and effectiveness of health care and for research. Joint initiative of the University of Latvia and the Ministry of Health of Latvia has resulted in development of a unique Latvian Healthcare Monitoring Datalink (Datalink) of unidentifiable persons and identifiable service providers [1].

The Datalink is controlled by the Centre for Disease Prevention and Control, and it includes healthcare process-related and outcome-related data of the population. The currently available data (2014-2018) includes information (health care provider, dates

[1] Corresponding author, Faculty of Medicine, University of Latvia, Jelgavas iela 3, LV-1004, Riga, Latvia; E-mail: juris.barzdins@lu.lv

of provided services, manipulations, primary and secondary diagnoses, costs etc.) about more than 65 million ambulatory and 3,5 million stationary treatment episodes as well as over 250 million units of medicines dispensed at pharmacies (including formulation, strength, quantity, and price). The demographic file provides information on patient's age, sex, place of residence. Additionally, the Datalink includes data from national Causes of Death Registry and from registries for particular diseases (e.g. diabetes, cancer) and conditions (e.g. trauma). The Datalink is updated once a year. To ensure protection of personal data, the direct identifiers of persons are irreversibly anonymized to exclude the possibility for either party to store and reuse the encryption key. Thus, to add data each year, the Datalink is re-created.

While the use of the Datalink for the monitoring of healthcare system performance by governmental institutions is regulated by the Cabinet decree assigning this function to the Centre for Disease Prevention and Control, the use of the Datalink for research is not clearly regulated by the existing regulatory framework leading to several legal and ethical problems. The present article addresses three of these issues – anonymization of data, concept of 'public interest' and involvement of research ethics committees.

2. Anonymized or potentially identifiable?

The data stored in the Datalink provides opportunity for researchers to analyse highly valuable administrative health data. However, due to gaps in legal regulation and due to ethical considerations, the secondary use of such anonymized but still potentially identifiable data is complicated. Some uncertainties arise also from the fact that the data originally have been collected for administrative purposes therefore there is no informed consent obtained for secondary use of the data in research.

The main scientific value of the Datalink is a possibility to track an anonymous patient's journey through the healthcare system knowing basic information about his/her health status, healthcare interventions and outcomes. The value of research data in many cases depends on keeping details regarded also as possible indirect identifiers as patient age, sex, place of residence, service provider, diagnosis, dates and codes for interventions. At the same time, the anonymization after linking independent datasets ensure privacy and confidentiality of persons concerned only if an indirect identification is not possible. It leads to the trade-off between the public interest justifying procession of such data for research and the small, but still existing risk of identification of persons.

Some, but not all aspects of this problem are regulated by the General Data Protection Regulation (GDPR) which does not apply to fully anonymized data concerning health but applies to pseudonymized and potentially identifiable data. Article 9 of the GDPR includes data concerning health into *"special categories of personal data"* for which there is a presumption that its processing is prohibited, at the same time, part 2 of the Article 9 provides a long list of exceptions on when the processing of special categories of personal data is permitted [2]. Mostly those exceptions are related to the consent of data subject or to the overriding public interest justifying procession of special categories of personal data. However, also in these exceptional cases, data processing must be legitimized by EU or national legislation and must be proportionate, including the duty of the data processor to take *"suitable and specific measures to safeguard the rights and freedoms of the data subject"* [2]. Article 9 (2) (j) of the GDPR includes a reference to the Article 89 explaining further

how to apply the above-mentioned conditions to processing special categories of personal data. Among other, Article 89 refers to the principle of data minimization explained in the Article 5, namely, that the data must be adequate, relevant and only include what is necessary for the purposes of the processing. The preamble of the GDPR also clarifies the processing of data concerning health for research purposes in several recitals. Recital 56 of the preamble refers to the main objective that justifies the processing of special categories of personal data, including data concerning health – it must be in the public interest. Recital 159 states that the processing of personal data for scientific research purposes should be interpreted in a broad manner including, for example, technological development and demonstration, fundamental research, applied research and privately funded research. While outlining the basic principles of data protection, the GDPR at various places points out to the responsibility of Member States to adopt further legislation, providing *"an unusually wide margin of maneuver for Member States"* [3].

In 2018 Latvia adopted the Personal Data Processing Law. Article 2 of this law puts forward the aim of the law *"to create legal preconditions for the establishment of the system of protection of personal data at the national level"* [4]. Regrettably, the new law is overly brief regarding regulation of scientific research. Although the law contains Article 31 on the processing of data for scientific or historical research purposes, in substance this article is just a blanket norm referring to the GDPR and copying Article 89 (2) of the GDPR.

Neither GDPR, nor Latvian legal framework directly regulates the use of anonymous or potentially identifiable health data in research. However, both the conditions for processing fully anonymous data and data anonymized but still potentially identifiable applies to the research use of the Datalink data.

3. Public interest as a basis for secondary use of administrative health data in research

One of the possible solutions is to use public interest as a basis for secondary use of administrative health data in research. The Article 9(2) of GDPR in listing possible grounds for processing of personal data not only includes a point (j) with specific reference to the *"scientific or historical research purposes"*, but also more general point (g) that allows processing of personal data *"for reasons of substantial public interest"*. The interrelation between those two grounds in the general scheme of the GDPR is rather unclear, especially considering recital 159 which states that *"scientific research purposes should also include studies conducted in the public interest in the area of public health"*. Yet, in any case, it should be possible to use public interest as a basis for secondary use of administrative health data in research, if all the preconditions on the proportionality, mentioned in the Article 9(2)(g) of the GDPR are fulfilled.

The problematical aspects of seeking the balance between public interest in research and privacy rights of individuals have already been analysed by several authors [5]. There are particular problems regarding application of proportionality test in cases when public interest serves as a basis for conducting the research, for example: how to define and assess public interest in the context of particular research protocol?

Assessment of the social value of the research study before it has been started is one of the main requirements in international documents defining the principles of research ethics for biomedical research involving human subjects. Human subject

research as defined in these documents is not only research where a person is directly involved in a study (e.g. clinical studies of medicinal products), but also research studies on identifiable human biological material and personal data.

Article 16 (iii) of the Council of Europe Convention on the Protection of Human Rights and Dignity in Biology and Medicine states that studies involving human subjects may be carried out only if *"the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability"* [6]. A detailed requirement to assess the social value of the study is included in the International Ethical Guidelines for Health-related Research Involving Humans issued by the Council for International Organizations of Medical Sciences (CIOMS) (2016). It states that *"[t]he ethical justification for undertaking health-related research involving humans is its scientific and social value: the prospect of generating the knowledge and the means necessary to protect and promote people's health"* [7]. In Latvia, the Law on the Rights of Patients (Section 9, paragraph 8) allows research use of patient data recorded in medical documents without informed consent if several requirements are met, including the requirement that *"the study is carried out in the public interest"* [8].

At the same time, several questions arise in the context of these requirements, like: who and how should assess the social value of a research study? what exactly makes the study socially valuable? The practice shows that there is a need for criteria for assessing the social value of a study that could be used by research ethics committees and other bodies involved in the evaluation process. CIOMS guidelines state that *"The scientific and social value of research can be difficult to quantify, but it is generally grounded in three factors: the quality of the information to be produced, its relevance to significant health problems, and its contribution to the creation or evaluation of interventions, policies, or practices that promote individual or public health"* [7]. Ethicist Ezekiel Emanuel and colleagues have defined the social value of the study as the instrumental value of the new knowledge for improving human health. They clarify that the two main reasons for assessing the social value of a study by ethics committees are the prevention of harming study participants (including breaches of privacy) and the waste of limited research resources [9]. The accessibility and dissemination of the study results, including publication of negative results also is an essential pre-condition for ensuring the social value of the study.

4. New role for research ethics committees?

The GDPR in the Article 40 as well as in the Recital 98 encourages *"the drawing up of codes of conduct intended to contribute to the proper application of this Regulation"*. It leads to the role that research ethics committees might play in evaluation of public interest and protection of research participants. Currently in Latvia, the ethics approval for research protocols is clearly required by law only in few specific cases: clinical trials of medicinal products, clinical trials of medical devices and human genome research. For clinical trials and studies using data from medical documents mentioned in the Law on Patient Rights there is no legal requirement for ethics committee review.

This demonstrates the need for re-definition of the role of ethics committees in Latvia. The scope of research requiring review by research ethics committee must be broadened, because the current approach does not meet the requirements of

international documents on research ethics, as well as it does not ensure assessing of public benefit and protection of research participants for all types of medical and health research.

5. Conclusions

There are several ambiguities and problems in the context of establishing and use of the Datalink for the research purposes, which are not fully addressed by the existing legal framework in Latvia. First, it is not completely clear how to define and evaluate the public interest in the context of health research. Second, the line between fully anonymized and potentially identifiable data, as well as evaluation of risk of identification needs further clarifications. Third, there is a need to increase a role and involvement of research ethics committees in the review of secondary use of data concerning health.

The GDPR was one of the most important and most massive legal developments in the EU law of 21st century, ambiguities in the context of research in the field of data concerning health being only one small fraction of challenges that follows the GDPR. One can only hope that future case-law of the Court of Justice of the EU as well as additional national legislative measures will help to deal with those challenges.

Acknowledgement

This study is a part of the UL/CDPC joint project "Transparency and healthcare data - towards public monitoring for quality and efficiency".

References

[1] University of Latvia & Centre for Disease Prevention and Control, *Health Personalised Data Guidebook for Health Care Monitoring Datalink*, 2019. Retrieved October 1, 2019, from http://med.oranzais.lumii.lv/in_english.html

[2] Regulation (EU) 2016/679 of the European Parliament and of the Council of Europe 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), 2016

[3] V. Chico, The impact of the General Data Protection Regulation on health research, *British Medical Bulletin,* 128(1) (2018), 109-118.

[4] Republic of Latvia, Personal Data Processing Law, 2018. Retrieved October 1, 2019, from https://likumi.lv/ta/en/en/id/300099-personal-data-processing-law

[5] J. Bell, S. Aidinlis, H. Smith, M. Mourby, H. Gowans, S. Wallace, J. Kaye, Balancing Data Subjects' Rights and Public Interest Research: Examining the Interplay between UK Law, EU Human Rights Law and the GDPR, *European Data Protection Law Review* 5(1) (2019), 43-53.

[6] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (2019)

[7] CIOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2016)

[8] Republic of Latvia, Law on the Rights of Patients, 2009. Retrieved October 1, 2019, from https://likumi.lv/ta/en/en/id/203008-law-on-the-rights-of-patients

[9] E.J. Emanuel, D. Wendler, Ch. Grady, An Ethical Framework for Biomedical Research. In *The Oxford Textbook of Clinical Research Ethics*. Edited by E.J. Emanuel and Ch. Grady. Oxford University Press. New York, 2008.