

Ethical, Legal and Social Issues related to the health data-warehouses: re-using health data in the research and public health research

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Abstract. Research derived from the application of information and communication technologies in medicine operates in a context involving the globalization of collecting, sharing, storage, transfer and re-use of personal health data. Health data computerization within Clinical Information Systems (as Electronic Healthcare Records) should allow the re-use of health data for clinical research and public health purposes. One of the objects allowing the integration of healthcare and research information systems is the health data-warehouse (DWH). However, ethical-legal frameworks in force are not adapted to these DWHs because they were not conceived for re-using data in a different context than the one of their acquisition. For that matter, access modalities to data-warehouses must ensure the respect of patients' rights: information to the patient, as well as confidentiality and security. Through a bibliography research, some Ethical, legal and Social Issues (ELSI) have been identified: Patients' rights Modalities of implementation of the DWs; Solidarity and common good; Transparency and Trust. Comparative analysis between the Directive 95/46/CE and the "Proposal for regulation on protection of individuals with regard to the processing of personal data" shows that this regulation pretends allowing the re-use of key-coded data when aimed at a scientific purpose. However, since this new regulation does not align with the ethical and legal requirements at an operational level, a Code of practice on secondary use of Medical Data in scientific Research Projects has been developed at the European Level. This Code provides guidance for Innovative Medicine Initiative (IMI) and will help to propose practical solutions to overcome the issue of the re-use of data for research purposes.

Keywords. Ethics, Privacy, Security, Data

Introduction

Electronic Healthcare Records (EHR), the Systems of hospital information, and the databases have allowed the reuse of these personal health data for medical research and public health. One of the tools that has allowed the integration of information systems

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of healthcare and research is the health data-warehouse (DWH). We have witnessed, thus, the arrival of the health DWH as a new object; into the medical research's landscape.

There are several initiatives, at a national and international level, aiming at the establishment of health DWHs and the integration of Clinical Information Systems within clinical research and public health systems. This development of implementation comes from a large consensus amongst health providers, physicians and researchers that sharing health data is crucial for the development of public health and clinical research. These initiatives aim to overcome technical issues, for instance, the lack of standardization and interoperability between Clinical Information Health Systems. They do so by establishing a cross-institutional health DWH and guarantying an efficient reuse of personal health data for medical research [1, 2, 3]. Even so, the modalities of the integration of Information Systems for healthcare and research raises new ethical, legal and social issues (ELSI) regarding the development of shared personal health data and the reuse of computerized personal data for research purposes. Indeed, the ethical-legal frameworks in force in the European Union (EU) are not adapted to these health DWHs because they have not been conceived for reusing data in a different context than the one of their acquisition. The large diversity of cultures, laws, regulations and operational implementations regarding personal health data processes within the EU, reflects the obsolescence and heterogeneity of current regulations. The differences in the interpretation of these regulations are even noticed at the local level, within a single country. Thus, the lack of a common and adequate new ethical-legal framework impedes the full promises of health data re-use, and compromises the respect of patients' rights to privacy and security of their data [4]. On the one hand, the implementation of the health DWH lies in the core of many translational research projects such as Innovative Medicines Initiatives (IMI), and their establishment must be conceived in a way that respects both patients' rights and the protection of their data. On the other, the modalities of access to the health DWH must ensure transparency, trust and security. Therefore, these new ELSI need to be studied in the context of the re-use of data for research purpose and will address the following notions: Patients' rights (information and consent) and those of health care providers (agreement on data sharing); Access modalities to data-warehouses – right of access – tutelage (depository institution); Optimization of data confidentiality (possibilities of data-crossing extension to other sources of information, data sharing); Solidarity and common good (shared infrastructures); Transparency and Trust.

The purpose of this work was to firstly identify these above-mentioned ELSI and analyze the different initiatives and studies that have sought to overcome the lack of a common ethical and legal framework regarding the secondary use of health data. And in particular, notions and components required to build up a trustworthy system for the re-use of health data in a transnational perspective [5] underlined by the white paper "Trustworthily Reuses of Health Data". Then, a comparative analysis between the "Proposal of the General Regulation on data protection" [6] and the Data Protection Directive (95/46/EC) [7] in force was made in order to evaluate if this new regulation responds to the ethical and legal requirements in the re-use of health data that have been pointed out. Finally, we will discuss about the Code of Practice on secondary Use of Medical data in Scientific Research Projects[8] being the first attempt the give guidance for IMI projects, developed by privacy experts participating in those projects.

1. Methods

Through a bibliography and documentary research, a personal participation in conferences and meetings, enabled the identification and analysis of the ELSI in the context of re-use health data. The documents that have been analyzed, belong to different categories: Laws and regulations, opinions, recommendations, the article “Trustworthy Reuse of Health Data” (2013), documents derived from work packages named “Data protection and privacy” within European Projects in the field of health research, such as (IMI), the Code to re-use health data in collaborative scientific research project (document derived from the Convergence Initiative, Brussels, Mars 2013). Furthermore a comparative analysis between Directive 95/46/CE and “Proposal for a regulation of the European parliament and of the council on the protection of individuals with regards to the processing of personal data and on the free movement of such data has been made.

2. Results/Discussion

When the data is reused in one or several research projects, the major issue resides in the manner in which the information to the patient is given, the informed consent obtained and the right of withdrawal guaranteed. The research context in which the health data is collected, processed has to be brought to knowledge to the patient to guarantee a free and informed consent. However, when the data is reused in one or several posterior research projects questions arise on how the consent can be obtained again. Should patients be asked to give broad consent? How should the request for the consent be expressed (opt-in/opt out)? How should the absence of consent be notified and taken into account? How can the patient withdraw his consent? How should the guarantee of data confidentiality be worded and implemented? What about the management of traces? [4]. Some studies [1,2,3,4] have given an overview on research, regulatory and ethical requirements for re-use health data. The authors pointed out, that the legal basis for data processing of non-anonymous data outside the treatment context is the consent of the patient. On the other hand, the patient needs to be informed in an understandable way about the purpose of the data processing, as well as the right to inspect and to request that the authority delete his data. In order to reach these requirements there is a need to implement a consent management solution within the DWH. They proposed organizational solutions compatible with the protection of privacy and data security.[3]. In the case of Biobanks, where the biological samples are associated to the data, IT solutions for privacy protection in biobanks have been proposed. They aim to guarantee the respect of the data donor’s rights. IT solutions are based in the new concept, disclosure filters that reconciles 2 objectives: individualization of informed consents on one hand, and increasing efficiency of the quest for material and data for research, on the other, disclosure filters allow donors to individualize the informed consent, that is, to constrain the purposes for which their material and data can be used [2]. Within the context of IMI type projects in different countries, practical solutions have been adopted by some centers where information is given to patients via posters, notebooks recording, etc. Despite all of these initiatives, the problem remains unsolved, that’s why the enforcement of the Code of Practice in Secondary use allow to the compliance between the protection of health data and the research innovation.

The limited applicability of specific informed consent and the limited opportunities of using anonymized data, within the use of DWH in research projects, have caused much discussed ethical and legal dilemmas for research. It has been highlighted that there is a real need to define the modalities of establishment and regulation of the health DWH. The depository institution who wishes to share data from this health DWH must ensure that its implementation and its purpose fulfill legal requirements. Our study, in translational research projects, such as the IMI projects, shows that the legal requirements regarding personal health data differ from a country to another. The differences in the interpretation and operational implementation of these regulations are even noticed at the local level within a single country. Indeed, the legal requirements are very heterogeneous across countries and/or regions, between a depository institution or another, having to make in some cases a statement or ask permission to a local legal authority and not in others. The diversity of European regulations in force makes it difficult to get permission "ad hoc" for the development of DWH in the context of the IMI-type projects. In some countries a single statement is sufficient to establish a health DWH and participate in such projects, in others, an authorization is required. The result of this analysis clearly reveals a legal and ethical loophole regarding the regulation of the re-use of health data from DWHs in the field of medical research. Various initiatives at a European level, have tried to remedy and fulfill this legal emptiness one of these initiatives is the white paper of "Trustworthy Reuses of Health Data: A transnational perspective, includes the concepts that should be taken into account to build up a new framework.[7]

The "European Summit on Trustworthy Reuses of Health Data" brought together 100 stakeholders: delegates representing national governments, academia, patient groups, industry, and the European Commission. The stakeholders participated in the breakout sessions where three scenarios involving the re-use of the health data were discussed. They debated key aspects associated with these three scenarios and a question set for the re-use of health data. The results of breakout sessions show that all groups agreed that the "government" should provide oversight; that the re-use should be "fully" regulated; and the patient "fully informed". These results have been summarized in the trustworthy system which is composed by a technological component, a research component and an exploitation component. The last component of a trustworthy system is related to the goals of data reuse, which may include a variety of purposes, from clinical research, epidemiology and surveillance, to post-marketing analysis. The type of purposes of data reuse has implications that belong to the realm of policies and regulations, which are essential aspects for the establishment of trust. The management of informed consent is a central part of this issue. In fact, the current regulations in many EU countries, similar to the US with the HIPAA act, assume that the consent (implied or explicit) for use of data is strictly limited to the purpose for which the data were collected. This subject needs to be reconsidered in the light of the existence of a proper trustworthy system based on an agreement between citizens and health care organizations [7]. This trustworthy system would lead to the development of necessary conditions among EU organizations to enable large-scale sharing of data, methods and expertise in the meaningful reuse of care records for research, and healthcare service development.

The comparative analysis between Directive 95/46/CE and Proposal for a regulation of the European parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data shows that this new regulation aims at allowing the re-use of key-coded data

when aimed at scientific purpose. In the new proposal the General Regulation on data protection are introduced the following articles: -Article 6 (on the basis of Article 7 of Directive 95/46/EC, which defines the criteria for lawful processing of data (balance of interest), - Article 81 «requires Member States to provide, in addition to the conditions applicable to particular categories of data, specific guarantees in case of processing of health data." - Article 83 «establishes specific conditions for treatment of personal data for historical, statistical and scientific research" It should be noted that the most striking difference between the European Directive 95/46/EC in force and the new regulation, is that the latter is binding for all EU states. Thus, the adoption of it by the Parliament and the Council should contribute to the development of research in the field of e-health of research projects such as retrospective studies, science projects aimed at collecting data from different providers, such as IMI projects, while respecting the ethical and regulatory framework ensures the protection of health data.

Nevertheless, the new regulation will not clarify certain grey zones that appear when conducting international research projects. For instance, it will not clarify what should be considered a new purpose when reusing research data. Neither will it define what kind of treatment and security measures must be applied on health data to consider them anonymised and secured for secondary use. To overcome this "gap", a Code of practice on Secondary use of medical data in scientific projects was originated from collaboration across several IMI projects seeking common rules regarding protection of the data needed in research projects. To conclude, this Code addresses several practical aspects including, for example, basic information and consent for prospective data collection, incidental finding, and others. This Code will, thus, contribute to the development of research innovation projects.

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