Do the Legal Systems of Europe and its Member States Meet the Needs of eHealth?

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The term "eHealth" is used in this special edition of the European Journal of Biomedical Informatics to describe the use of information and communication technology (ICT) in the delivery of healthcare. It encompasses the use of a wide range of ICT applications including *eHealth tools*, such as Electronic Health Records; *eHealth services*, such as the Electronic Prescriptions; and *eHealth devices*, such as the remote monitoring software. The use of these tools, services and devices in the delivery of healthcare is widely acknowledged to be beneficial. They allow for accurate, timely and safe sharing of information so that patients may be better treated and supported.

Core to the efficient functioning of eHealth tools, services and devices is interoperability. Achieving interoperability in eHealth involves a complex set of operations, including *technical interoperability*, which ensures data integrity and authenticity in sharing data between different end points; *semantic interoperability*, so that information may be understood by the end user regardless of the natural language or physical environment in which it is being accessed; *organisational interoperability*, which allows healthcare providers to share information across different internal structures and processes; and *legal interoperability* which allows different jurisdictions to enable secured access to and processing of patient information transferred electronically.

In this special edition four papers are dedicated to different aspects of the legal interoperability which is fundamental to the adoption and implementation of eHealth in Europe. Stroetman [1] and colleagues provide an overview of the state of the art in legal and policy interoperability based in part on the work they undertook within the framework of a European Commission funded study which examined the progress EU Member States had made on the journey towards national eHealth Infrastructures [2].

Stroetman et al examine the current legal frameworks in place in a range of European countries for three core eHealth applications: EHRs, ePrescriptions and telehealth. They conclude that while many countries have made considerable advances in building or adapting legal frameworks for the use of EHRs, much less has been achieved in developing robust legal frameworks for ePrescriptions or telemedicine. They note that most of the legislation currently applied to the use of ICT in healthcare focuses significantly on issues of data protection, measures for ensuring patient consent to the creation and access of records, and administrative measures for ensuring appropriate security in the storage and management of EHRs.

The richness of the legal frameworks necessary to allow the smooth functioning of EHRs within and across healthcare systems is made clear by the two detailed examinations offered in this volume of the legislation on EHRs in Austria and in the Czech Republic. Reimer [3] offers a comprehensive analysis of the wide range of legislation which underpins the use of ICT in healthcare in Austria. His comprehensive paper makes clear that while Austria is still waiting for the enactment of the ELGA legislation which will establish the legal framework for the EHR itself, much of the other necessary legislation is already in place. Austria has for example already established the necessary data security requirements and the information governance framework. Reimer's analysis is significant therefore in underlining that while the EHR is a core element of a functioning eHealth system, it is not the whole story. This will serve as a useful reminder to those who still see the EHR as the Holy Grail which will solve all eHealth problems.

Dostál and Šárek [4] examine the legislation applicable to EHRs in the Czech Republic. Their thorough paper notes that while the Care for Health of the People Act n. 20/1966 Sb Health Record Order provides a good base line for the use of the EHR including guidelines on which data is to be collected, how patients' interests in confidentiality and access are to be guaranteed and how records are archived for future reference. The authors note, however, that the existing legal framework provides very little guidance on technical interoperability issues, and argue that the Czech Republic could do well to follow the model adopted in the USA of appointing an official body that co-ordinate health IT standards.

The fourth paper in this collection broadens the scope of the discussion of legal issues in eHealth away from the EHR to look at the fast evolving range of eHealth devices and eHealth services. Vollebregt [5] examines in careful detail the way in which the Ker-Optika case [5] decided by the ECJ in 2010 begins to clarify the way in which European law will apply to eHealth devices and to the provision of eHealth services on-line. Vollebregt begins by examining the facts in Ker-Optika case and draws clear conclusions that because medical devices are not excluded from the eCommerce Directive, Member States may not prohibit outright the sale of a medical device via on-line retail. However, since that same directive does not cover the modalities of sale, any rules a Member State may wish to impose for public safety or other

reasons must be examined in the light of the general EU internal market rules, which require that any restrictions on the free movement of goods in the internal market must be strictly proportionate to the harm that is to be avoided.

Vollebregt's paper goes on to look beyond the immediate impact of the Ker-Optika case on the on-line sale of medical devices (in that case contact lens were the subject matter) to extrapolate how the reasoning of the court would impact on eHealth software as a service - notably eHealth apps. Here he draws the reader's attention to the 2007 amendment of the Medical Devices Directive (which clarifies that standalone software can be a medical device, which must be duly CE marked) and concludes that "eHealth service providers are fully subject to the internal market clause in article 3 of the e-Commerce Directive".

While Vollebregt's paper looks into the future role of the EU legal framework in regulating eHealth services and eHealth devices, all four papers serve to underline the enduring importance of one of the core principles of medical ethics - that of autonomy. Beauchamp and Childress, in their textbook Principles of biomedical ethics [6], which has for many years been the touchstone of understanding medical ethics around the world, reduce all medical ethics into four core principles: autonomy, beneficence, non-maleficence and justice. Of these the concept of autonomy is most relevant to legal frameworks for eHealth as it is based on the right of every competent adult to make decisions for him or herself.

In health law, a key aspect of respecting the autonomy of the patient is usually upheld by reference to the concepts of consent and privacy. Thus most legislation on health records includes the requirement to seek a patient's consent before collecting, processing, or sharing health related information, and a duty to ensure that the privacy of the record will be maintained. It is not surprising therefore that of the legislative tools most developed in response to eHealth around the world make reference to core legal texts on privacy. The second WHO Global eHealth Observatory Survey [7] completed in 2010 established that most legal systems have enacted legal mechanisms for protecting privacy of medical information. As reported "some 70% of the 113 responding countries reported having legislation providing a basic right to privacy, and the remaining 30% anticipate that such legislation would be adopted by 2015" [8]. The report of the survey noted however that while legislation protecting medical confidentiality was widespread, far fewer countries had adopted specific legislation to protect privacy in EHRs.: only 30% globally reported having such legislation in place. Further analysis of the responses on the use of legislation to ensure privacy in sharing EHRs for treatment or research purposes revealed that very few countries have established comprehensive legal frameworks on EHRs (e.g. only 10% of countries reported having legislation which covers cross-border EHR sharing).

An important contribution towards addressing the paucity of legislative tools addressing EHRs and more particularly the sharing of EHRs across EU borders is made by the epSOS project [9] which establishes a technical and legal framework for sharing Summary Patient Records and ePresciptions between participating nations in the EU. The project provides not only a technical specification for building and sharing such records, but also established the concept of a "circle of trust" based on a common legal framework agreement to create a legal environment in which records can be shared across borders. Stroetman et al, as well as Reimer, make reference to the epSOS project and conclude that the tools and guidelines it develops will greatly assist Europe in developing a more robust legal framework for eHealth.

While the four papers in this collection make clear that Europe still has some way to go in establishing a full legal framework for eHealth, it is worth noting that it is not only the legal framework but also the organisational framework which requires further development. Indicative of this is the fact that the label "eHealth" is used to describe the use of information and communication technology (ICT) based tools in the delivery of healthcare. The very fact that we still use a special label to describe the wide range of ICT applications in healthcare is symptomatic of the fact that we do not yet see it as a core element of healthcare delivery in the twenty-first century, and until it is seen as such a core element it is unlikely that the legislation will be developed to ensure that it can function as such.

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