eHealth... but is it legal ? A report on 'Legally eHealth' - A study funded by the European Commission

VAN DOSSELAERE, Céline; WILSON, Petra; SILBER, Denise; Herveg, Jean

Published in:
Eurohealth

Publication date:
2007

Document Version
Publisher's PDF, also known as Version of record

eHealth…… but is it legal?

Celine Van Doosselaere, Petra Wilson, Jean Herveg and Denise Silber

Summary: Unconstrained by familiar points of entry to health care or traditional channels for delivering information or care, the eHealth revolution has as many serious implications for health care regulators and lawyers as for medical professionals. In the context of the Commission's eEurope Action Plan, the "Legally eHealth" study established a baseline report on existing EU level legislation, its impact on the delivery of eHealth and an analysis of the legal and regulatory barriers and gaps that may exist. This article gives an overview of some of the issues studied and key recommendations made.

Keywords: eHealth, Security and Privacy, Liability; Data Protection and Ownership

eHealth is a broad term with many definitions, including health informatics, health telematics, ICT (information and communication technology) for health, connected health, medical computing, or medical informatics, all of which are used to describe the use of a wide range of information technology applications and services in the healthcare setting. For the 'Legally eHealth'* study described in this article we use the term eHealth as defined by the Action Plan for a European eHealth Area: "the application of information and communication technologies across the whole range of functions that affect the health sector".[1]

eHealth is premised on a fundamentally new patient experience unconstrained by familiar points of entry and structures or traditional channels for delivering information or care. Not surprisingly therefore, the eHealth revolution has as many serious implications for health care regulators and lawyers as for medical professionals, including questions about patient and professional identification, maintenance of patient confidentiality in an environment of electronically shared care, as well as questions of liability for care provided in this new environment.

Celine Van Doosselaere is EU Affairs Manager, European Health Management Association, Brussels, Petra Wilson is Director Public Sector Healthcare, Cisco, Jean Herveg is Senior Researcher, Centre de Recherche Informatique et Droit, Faculty of Law, University of Namur, Belgium and Denise Silber is Director and Founder, Basil Strategies. Email: petrwils@cisco.com

In response to the lack of legal certainty about the use of eHealth tools, the European Commission, through its eHealth Action Plan, called for a study to establish a base-line report on existing EU level legislation, its impact on the delivery of eHealth and an analysis of the legal gaps which may exist. The 'Legally eHealth' study, which we present in this article, was completed in response to that call.

The 'Legally eHealth' Framework

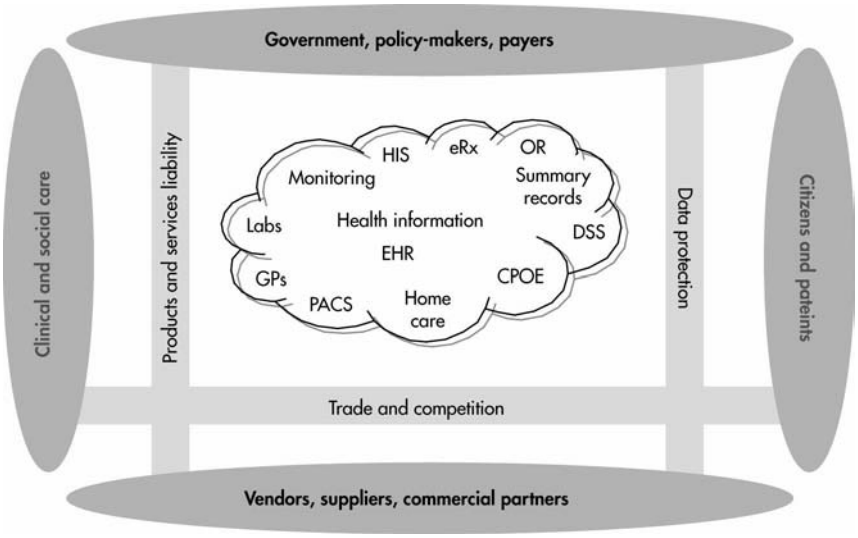
The one year study, completed in May 2007, looked in detail at three particular legal aspects of using information society technologies (IST) in health care: privacy, liability and competition. Although other legal issues arise in the context of providing health care services using eHealth tools, we focussed on these three as the main legal issues with European level implications.

We first looked at the key tools and applications and then the main stakeholders and existing regulations that have an impact on the use of eHealth. These covered a wide range of information technologies found in hospitals and primary care settings, including administrative tools such as hospital information systems (HIS), summary records and discharge letters; clinical applications of a technical nature such as picture archiving and communications systems (PACS), as well as clinical support systems such as operating theatre systems (OR), decision support systems (DSS); and systems linking key health care actors such as General Practitioners Systems, and electronic prescribing systems linking general practitioners (GPs) with pharmacies (eRx).

Having established what concepts and tools were included in eHealth, we next classified the stakeholders in eHealth into four groups of actors: citizens and patients; clinicians and care providers; payers, policy-makers and governments; and, vendors, suppliers and commercial partners. All four groups of actors have highly significant but not always equal roles to play in health care. We looked in particular at the tensions that can arise between clinicians and patients with respect to privacy and confidentiality, or between governments and vendors with respect to competition in the health care market.

The study considered the impact of European data protection legislation, European consumer protection and liability legislation, and European competition law. We analysed this legislation in detail, and followed the analysis by a series

* European Commission contract #30-CE-0041734/00-55. Study on Legal and Regulatory Aspects of eHealth, 'Legally eHealth'. Partners in the study include the European Health Management Association, the Centre de Recherche Informatique & Droit (CRID) at the Facultés Universitaires Notre-Dame de la Paix (Namur, Belgium), and Basil Strategies. Special thanks are due also to Cisco Systems Internet Business Solutions Group who gave technical input and writing support. Further details on the Study can be obtained from EHMA (www.ehma.org) or European Commission (http://ec.europa.eu/information_society/activities/health/studies/index_en.htm)



of small case study 'vignettes' which demonstrated the practical implications of the key legal concepts. Key legal aspects studied in the 'vignettes' included:

Electronic Medical Records
- responsibility of the service provider to the physician
- responsibility of the physician to his/her patients

Sale of medical products on line
- responsibility of the manufacturer's website
- responsibility of the consumer

Distance monitoring products
- responsibility of the manufacturer,
- responsibility of the service provider

Using digital records pedagogically
- protecting patient anonymity

eHealth industry
- role of the state versus private sector
- monopoly and competition

We concluded with recommendations to the European Commission on further regulatory activities to support the implementation of eHealth.

In this article we outline the three legal aspects we studied and the key recommendations made.

On data protection

The study looked in detail at the requirements of EU privacy and data protection legislation, providing a thorough examination of the Data Protection Directive (95/46/EC) and the Directive on Privacy in Electronic Communications (2002/58/EC).

We looked carefully at the existing regulations and concluded that while the Directives are probably sufficient to meet the needs of IST in health, further clarification of specific legal duties would be helpful. Data protection legislation is now well established in Europe: while health data is always sensitive and requires special protection, such data may be processed on the basis of patient consent; or in the vital interests of the patient; or for the purpose of medical diagnosis and care provision; or, in certain cases, if there is a substantial public interest in such data processing.

We believe that generally the existing data protection legislation at EU level and its transposition at Member State level are sufficient to allow eHealth tools and applications to be used efficiently in health care. However, we recommended that the European Commission and Member States cooperate, in particular through the Data Protection Working Party set up under Article 29 of the Data Protection Directive, to address uncertainties in the role of consent to the processing of medical data; the necessity to state a finality of purpose for data collection; and technical aspects of data processing and storage security.

There are particular difficulties connected with the concept of 'consent' in health related data processing. A particular problem with consent lies in the fact that, in order to be valid, consent must be freely given. Thus, if the creation of electronic medical records is a necessary and unavoidable aspect of providing good quality health care, then withholding consent may be to the patient's detriment. We argue therefore that it would seem appropriate for the European Commission to coordinate the adoption of specific rules for the processing of health information that allows for proper balancing of patients' and public health interests, without recourse to the concept of consent.

On eHealth and product liability

Traditionally, medical liability is restricted to the relationship between the patient and the health practitioner (usually a doctor). When a patient is a victim of medical negligence or of a medical error, he or she will usually seek to introduce a civil or criminal lawsuit against the doctor. However, the use of eHealth tools, as well as the multiplication of intermediaries in the field of health services, is changing the legal relationships between the various actors, and often makes it more difficult for a patient to know where liability lies if something goes wrong.

Although general legal rules have been agreed to provide consumers with a legal guarantee of high quality products and services, the legal texts do not specifically address health or eHealth. The current EU level law is applied within the general context of service provision and product delivery, whether by traditional or electronic means. As a result it is often difficult to ascertain which EU level legislation applies to an eHealth product: is it considered a medical device, a software package, and does other legislation (for example, on hazardous substances) also apply? In terms of health goods, whether eHealth or traditional, standard contracts for sale of goods will apply. In general therefore in the eHealth arena, the purchaser of an eHealth good will need to make reference to the relevant national legislation based on Directive 1999/44/EC on the Sale of Consumer Goods.

The study concluded that while specific eHealth sale of goods legislation is probably not needed, it might be appropriate to consider the adoption of specific EU level guidelines on the sale of eHealth goods in order to encourage the adoption of EU wide markets in eHealth tools rather than the fragmented national level markets one sees currently.

Beyond the sale of the product, Directive 2001/95/EC on General Product Safety requires that any product put on the market for consumers, or likely to be used by them, is safe. Further it requires that producers provide consumers with the relevant information enabling them to assess the risks inherent in the product, and take appropriate actions to avoid these risks (withdrawal from the market, warning to the market consumers, recall

products already supplied etc).

National authorities have been established to monitor product safety and to take appropriate measures to protect consumers and an information system has been put in place which imposes collaboration not only between distributors, producers and the national authorities but also between Member States and the European Commission (RAPEX).[2] This system has thus far not been used well (if at all) for eHealth products, which are still rather new and for which little legal guidance currently exists. Accordingly, the study recommended that the European Commission should adopt policy tools to encourage the use of the RAPEX system for eHealth products.

We also noted also that some eHealth products are considered medical devices, in the terms of Directive 93/42/EC on Medical Devices. The Directive includes in its definition of medical devices electronic equipment and software manufactured or promoted for medical purpose. Thus, monitoring devices, for example, could be considered as medical devices under the European Medical Device legislation, while eHealth tools used for the administration of general patient data will generally not be considered medical devices unless such a product (for example, a laptop, printer, screen, etc.) has had a specific medical purpose assigned to it.

It is clear that more clarity is needed on the extent to which eHealth products are covered by Medical Devices Legislation. Many of the currently available monitoring devices are covered only by general product liability, not by a specific liability provision. It is suggested that further consultation on the application of medical devices legislation to eHealth tools takes place to establish if special guidelines should be issued.

On competition law

Health services, in most European countries, are provided at least to some extent though direct taxation and compulsory health insurance. However, most eHealth services are offered through private enterprises and businesses and thus eHealth poses difficult questions concerning competition within public and private markets in situations where the distinction between the two is often very hard to establish.

The principles of free trade and free competition are among the most important economic principles supported by the European Community. It is therefore not surprising that the European Community has adopted a wide range of legislation to support free competition through a legal system that prohibits any disloyal practices that restrict competition.

The core of European competition law is found in the rules applying to private firms or 'undertakings' in Articles 81 and 82. Article 81 prohibits agreements and concerted practices with an anticompetitive objective or effect on the market, while Article 82 prohibits abuse of a dominant position. Article 86(2) states that the rules on competition also apply to public undertakings, as long as the "application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them."

The rules of competition law on abuse of dominant position and concerted practices are defined by the Treaty to apply only to those organisations classified as 'undertakings'. The key question for purposes of health care providers is therefore whether any of the parties to an eHealth service are deemed to be undertakings and therefore subject to competition law.

Recent case law at national and EU level[3] has established that publicly funded health bodies may, in certain circumstances, be subject to competition law. However, the case law is unclear and would seem to provide that the same institution may, in some aspects of its conduct, be regarded as an undertaking (if it offers goods or services on the market) but in other aspects (such as contracting out certain care services) will not be considered an undertaking.

This ambiguity in law will be unsettling for both public and private sector health care providers. The study recommended, therefore, that the appropriate committees of the European Commission should be encouraged to examine the recent decisions of the European Court of Justice (ECJ) on the application of Articles 81 and 82 to health care providers, in order to draw up clear guidelines establishing when a health care provider will be regarded as an undertaking and when not. Such guidelines should address the widest possible range of health care providers and suppliers, covering traditional and eHealth care.

Further to Article 86(2), the Treaty provides that an undertaking normally subject to the rules of competition law may be exempted from their application if it has been entrusted by a public body to provide a Service of General Economic Interest (SGEI)[4] and if the application of the rules on competition would obstruct the performance of the particular tasks assigned to them. While it is left up to Member States to define the services they consider as SGEI, considerable lack of clarity still exists at EU level on the designation of health services.

Recognising that many European health systems are provided through public funds, the European Commission has, in a number of communications, suggested that health services are not generally to be regarded as SGEI nor are they to be included in the wider definitions of Services of General Interest (SGI) or Social Services of General Interest (SSGI)*. The Commission has instead proposed that, because health services have such a unique character, special targeted rules on health services of general interest should be established. However, despite first raising this issue in 2001, the European Commission has yet to clarify the position of health services and their possible exemption from competition law.

The study recommended that the Commission adopt a communication or guidelines setting out clearly the circumstances under which a health service provider may make use of the provisions on SGEI in the Treaty and thus be exempted from competition law. Such guidelines should address the changing nature of health services, recognising that a wide range of actors from both public and

* For the evolution of the definition on Services of General Interest, see Green and White Papers at http://europa.eu/eur-lex/en/com/gpr/2003/com2003_0270en01.pdf (COM(2003) 270 final, May 2003) and http://europa.eu/eur-lex/en/com/wpr/2004/com2004_0374en01.pdf (COM(2004) 374 final, May 2004), announcing a more systematic approach in the field of social and health services of general interest. This systematic approach is proposed by a Communication from the Commission 'Implementing the Community Lisbon programme: Social services of general interest in the European Union' (COM(2006)177, April 2006), available at http://ec.europa.eu/employment_social/social_protection/docs/com_2006_177_en.pdf. For more information, see http://ec.europa.eu/employment_social/social_protection/questionnaire_en.htm.)

private enterprises will be involved in the provision of both traditional and eHealth services. In order to encourage adequate investment in eHealth services, both public and private enterprises must have legal certainty on their position with respect to competition law.

Conclusion

eHealth is important for Europe, it can drive up service quality, improve patient safety, contain costs and facilitate access to health care. The 'Legally eHealth' study has examined aspects of European law related to data protection, liability and consumer protection, and competition law. It has identified that a significant body of European law already addresses a number of the key legal issues in eHealth. However, there is still great uncertainty in the eHealth actors, ranging across public bodies, big industry and small enterprises about the full legal implication of using and offering eHealth services.

It is notable that despite the large numbers of communications on Services of General Interest, the Lisbon agenda and long-term care, as well as heated debates on health services with the Services Directive, little emphasis has been given to an impact assessment of the proposed legislative responses to health services in general. Moreover, none have considered in depth their impact on eHealth services. Given however, that the development of eHealth markets is considered to have major economic potential for Europe,[5] further legal clarifications are necessary both to encourage the development of these markets in optimal conditions, all the while respecting the unique nature of health services. Therefore, in addition to the specific recommendations made on each of the three clusters of legal issues, the study calls for a mainstreaming of eHealth impact assessment across all European policy initiatives.

References

1. Commission of the European Communities. *eHealth: Making Health Care Better for European Citizens – An Action Plan for a European eHealth Area*. Brussels: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, COM(2004)356, 2004.

2. See http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm

3. Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental (FENIN) v Commission of the European Communities. Court of First Instance (EC), Case T-319/99, Court of Justice of the European Communities, Case C-205/03.

4. Commission of the European Communities. Services of General Economic Interest, summaries of legislation. Available at http://europa.eu/scadplus/leg/en/lvb/l26087.htm

5. Independent Expert Group on R&D and Innovation. (Esko Aho chair). *Creating an Innovative Europe*. Luxembourg: Office for Official Publications of the European Communities, 2006. Available at http://ec.europa.eu/invest-in-research/pdf/download_en/aho_report.pdf

Regulating nanotechnology: new legal challenges?

Jean V McHale

Summary: The development of nanotechnology has huge potential for medical science. However at the same time it gives rise to a range of legal and ethical regulatory challenges for the EU and Member States. This paper explores first what is meant by nanotechnology and its use in medicine. Secondly, it considers some of the ethical and regulatory challenges discussed by the European Group on Ethics in Science and New Technologies in their recent Opinion on the ethical aspects of nanomedicine. It suggests that there are many legal and ethical issues which will need to be further explored at both EU and Member State level, including the diversity of current regulatory structures applicable in this area, issues of consent, privacy and the regulation of risk.

Key words: Nanotechnology, Medicine, Health, Law, European Union

The rise of nanotechnology in general and nanomedicine in particular has led to considerable debate and controversy.[1] 'Nanotechnology' can enable us to better understand how the body functions at molecular level. 'Nano' itself refers to 'one billionth' and originates from the Greek word meaning 'dwarf'. As the European Technology Platform Report comments:

"It is an extremely large field ranging from in vivo and in vitro diagnostics to therapy including targeted delivery and regenerative medicine. It has to interface nanomaterials (surfaces, particles or analytical instruments) with 'living' human material (cells, tissues and body fluids). It creates new tools and methods that impact significantly on existing conservative practices".[2]

The development of this technology may

Jean V McHale is Professor, Faculty of Law, University of Leicester, United Kingdom. Email: jvm5@leicester.ac.uk