

eHealth – making clear the legal context

eHealth services promise to improve the quality and provision of care while reducing costs. However questions exist over the legal and regulatory implications for particular eHealth services. One initiative, 'Legally eHealth', aims to help remove those doubts.

There is little current information available about the legal implications of eHealth. However growing interest in and implementation of eHealth systems is certain to bring this topic to the fore. Hence the interest in the [Legally eHealth](#) study.



Take electronic health records. They can reduce enormously the administrative burden of managing patients, while simultaneously improving reliability and accuracy, and establishing a record of a patient's medical history. Ultimately, they become the medical biography of an individual over the course of his or her lifetime.

That is the compelling logic of eHealth services, which leverage information technologies to create enormous efficiencies in an expensive but vital health service. It's a logic that doctors, engineers and policymakers are eager to apply to Europe's health systems.

It's none too soon, either. Europe's population is ageing rapidly, at a rate that will almost inevitably multiply the demand for health services, both preventative and in terms of long-term treatment, particularly for chronic diseases.

eHealth – what are the challenges?

eHealth poses some major challenges. Patients have different rights to confidentiality and privacy in the different EU member states. Some patients are the owners of their own data – in other countries it is their clinicians or general practitioners who have this right. If electronic information is easy to share and update, it can also be easy to acquire. What is the burden of responsibility of each actor and each link in the European health service chain?

Electronic health management systems can also have other implications. An online pharmacy in one country might be allowed to supply a drug as an over-the-counter medicine. But what happens if the drug is a prescription medicine in another country, and a patient orders it there?

Similarly, services monitoring the blood glucose of diabetics or the heart rate of cardiac patients need to have a quality of service guarantee. But who is responsible for that guarantee; the health centre or the monitoring service provider?

"It's impossible to say categorically who is responsible for what in a particular instance, every case needs to be assessed individually," warns project coordinator Céline Van Doosselaere of EHMA (European Health Management Association) in Brussels. Therein lies a big part of the dilemma.

"eHealth is huge, it's such an enormous area, that we often prefer to call it 'connected health'. The services and liabilities are essentially the same as traditional healthcare delivery, but there are a lot more intermediaries, a lot more actors providing the service. It's very complex," Van Doosselaere cautions.

Establishing the legal antecedents

The Legally eHealth team plans to bring the information on both European laws and their precedents up-to-date as they currently apply to eHealth systems, creating a simple way to get to grips with the complexity.

To this end the study's participants have catalogued and analysed the legal aspects of eHealth at EU level, using traditional legal research methods including review of standard European legal



and regulation databases, the records of the European Court of Justice, and selected national databases.

"Our study focuses on three legal clusters – data protection and privacy; product liability and consumer protection; competition and trade law. This research won't provide all the answers, but it will equip stakeholders with all the appropriate questions," says Van Doosselaere.

For example, what happens if a device fails and the patient suffers as a result? Who is responsible for guarantee of service: the equipment manufacturer, the service provider or the hospital administration providing the service?

"It depends on the situation and contract that's agreed, but these are exactly the sorts of questions that stakeholders need to ask if they launch an eHealth service," says Van Doosselaere.

How the eHealth service is provided can also matter. Is the service provided by a centralised health authority like the UK's national health service or by a particular local hospital? How a service is chosen and tenders managed are important. Similarly, if a single provider offers a unique technology, patents and intellectual property are important issues.

The legal clusters developed by Legally eHealth provide an overview of the legislative situation. Yet the study will go further, by producing a series of real-life case studies which will illustrate the complex character of key legal concepts in the three clusters. The project team will publish the information in a book after the close of the study in April 2007.

The law for non-lawyers

"Our study will use vignettes [case studies] as a way of illustrating complex legal references through simple narratives. Readers can refer to these for each of the three clusters of legal eHealth issues," says Van Doosselaere.

The project is developing a structured, searchable online knowledge base which will cover, at EU level, all the legal, regulatory and policy issues which can be explored through practical cases. Users can consult the database directly, or use the case studies as a launch pad to explore the relevant legislation.

"These vignettes illustrate the salient legal issues," notes Van Doosselaere. "Our audience is comprised mainly of non-lawyers. We therefore realise the need to make these documents readable, understandable and user-friendly to the various different stakeholders involved in eHealth."

The study will also highlight whether current EU legislation is sufficient to regulate eHealth, emphasising any issues that may need new legislative or regulatory considerations. Finally the study will develop a series of recommendations that meets those needs.

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