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eHealth: legal, ethical, and governance challenges – an overview

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***Abstract:* eHealth is moving steadily towards greater deployment and implementation worldwide. Some of its greatest challenges lie in the three fields of law, ethics, and governance. This paper outlines a number of key issues due to be highlighted by contributors to a 2011 book. While the book focuses on the European scene, it is set in the international context.**

Introduction

eHealth, the use of information and communication technologies (ICT) in providing, managing and enhancing healthcare services is an important area of focus around the world. Internationally, many countries promote and implement eHealth as an integral part of their health strategies [1][2]. In the European Union, eHealth has played an important part in the various actions that have related to eHealth since 2000 [3][4][5]. It continues to have a priority role in the most recent European programmes launched in 2010. In the specific arena of active and healthy ageing, eHealth is at the forefront in at least two flagship initiatives of the EU2020 Initiative, the Digital Agenda for Europe [6] and the Innovation Union (see especially its Annex III) [7]. ICT-enabled healthcare is increasingly considered to enhance the access, quality, efficiency and effectiveness, and safety and security, of services related, for example, to health, medicine, welfare, and care [8].

The use of ICT in healthcare raises a number of challenges related to legal, ethical and governance issues [9][10]. These issues pose both concerns and opportunities to academics, industrialists, legislators, policy-makers, and those responsible for implementing both policy and technologies. However, ultimately, they also challenge the people who use and consume these services whether they are carers, families, people and patients, or health professionals in a wide range of occupations.

This paper sets out a three-part approach to law, ethics, and governance in relation to eHealth. It highlights a range of perspectives. The issues are reflected in the book on which the paper is based.

Three eHealth Challenges: law, ethics, and governance

Law as a discipline has a precision that identifies various concepts, differences in context, and norms in relation to eHealth: however, it is often recognised as trailing behind various systemic and organisational developments. It almost constantly plays a game of catch-up with the leaps implicit in technology, particularly those technologies which can be considered as disruptive. Legislation too can take some time to become established and to be successfully applied.

Ethics provides a more familiar foundation from which to explore new concepts and contexts, one that is well understood by many stakeholders in the health arena – especially those which operate in either the clinical/medical field or in the computer sciences.

Governance of good practices, standards, policy and legal implementations, faces a considerable contemporary difficulty. How easy is it to arrive at a common standpoint and perspective on how eHealth should support health systems and services? Such an action is perhaps especially difficult when individual countries have traditionally had a great deal of autonomy in this regard, and when organisations operate using levels of considerable flexibility. Governance – even when a more top down-oriented solution is being developed, as is the case in Europe – is constantly implemented in real-life settings either in umbrella policy or in operational contexts in healthcare and care institutions [11][12].

Several aspects of each of these three challenges to eHealth are explored here in more detail, and are further described in the authors' forthcoming book [10].

Law

The European Commission, in conjunction with the Member States, first stated its desire to see legal clarity in terms of products and services that relate to eHealth in 2004 [5]. There was, and is, no single piece of European legislation which incorporates eHealth. Rather, there is a wide range of both Europe-wide and national sets of legislation which cover its various technologies. Coming to a position of a clear legal understanding on eHealth is by no means, therefore, an easy venture. Translating that understanding into easily understood documentation is even less so. Understanding the privacy and protection of personal health data continues to be of paramount importance to patients, health professionals, and

legislators. This is especially due to the increasing use of electronic health records, and interconnected healthcare technologies, in countries throughout the European Union (including the United Kingdom), as well as the United States. Various other areas or contexts that relate to eHealth such as telemedicine, pharmaceutical sales over the Internet, and the liability of health professionals also bring many legal concerns and challenges [10][13][14].

Each of these legislative contexts may need international, European, national – or even in some cases in certain European countries – regional revision and/or simple clarification and explanation. Such increasing clarity is likely to influence business and commercial confidence in the eHealth sector. Potentially, it could also raise the levels of trust that both health professionals and the public at large experience in terms of their use of equipment and services. As a result, providing and managing eHealth in clinical, organisational, and more commonplace settings should become easier.

Ethics

The European Union has placed increasing emphasis on involving the public in regulatory processes with respect to modern technologies. Some theorists hold the view that the tools needed to take into consideration ethical concerns effectively – and to involve European citizens satisfactorily – are not yet fully developed or described [15]. Attempts in this direction are underway in at least one European eHealth-related large-scale pilot (epSOS <http://www.epsos.eu/>) and its accompanying thematic network (CALLIOPE <http://www.calliope-network.eu/>). Examining the ethical background that underpins eHealth opens up a wide variety of broad-based considerations. Assessing eHealth use in concrete, applied settings – a pertinent example is telecare, and support for care in the home – raises not only classic, clinical concerns [16], but emphasises the growing importance of issues relating to equity and justice [10][17].

Members of the public are increasingly using the Internet for information on health issues, and sharing information through the social network facilities offered by the web. Issues of information integrity and authority of information are therefore key ethical issues [18]. At least one concrete solution for the enhancement the quality of electronic, health-related information has emerged from the European scene: Health on the Net [10].

Governance

European governance of eHealth has taken a number of steps forward since the mid-2000s. At the start of 2011, an eHealth Governance Initiative has been established, after several years in development. It will become a

direct player in the eHealth policy debate, and will report regularly to the appropriate Councils of the European Union. Meanwhile, the European Commission will support the work of the Initiative while it will also continue to fulfil its obligations set out by the Treaty [19] in terms of its right to propose policy and legislative initiatives in the area [10].

At a local or organisational level, information technology (IT) governance ensures that "the organisation's IT supports and enables the achievement of its strategies and objectives" [e.g., 20]. As far as eHealth is concerned, much current work in this field focuses on the secondary and tertiary health sectors. Relatively little data has been available on ICT use in acute healthcare settings outside the United States of America. In 2010, the European Commission commissioned a survey of ICT use in thirty European countries, obtaining feedback from both chief information officers and chief medical officers (the findings that are emerging from this 960 hospital-respondent survey are anticipated to be made public in May 2011 in the context of the eHealth week 2011 in Budapest, Hungary). Several non-American literature surveys are available as well as a set of 2007 European hospital case studies. Alignment between business and IT governance, through eHealth, is perceived as having a positive effect on healthcare performance and effectiveness [10].

However, how would governance operate in a more distributed and less institutionalised setting in which people and patients are themselves involved in even more direct eHealth use? Explorations of the implications of social networking in eHealth are now coming to the fore [10][21].

Next steps

The authors are in the final stages of editing a book manuscript that will contain contributions on eHealth legal, ethical, and governance challenges. The book is anticipated to be published in autumn 2011.

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