Carlisle George · Diane Whitehouse
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# eHealth: Legal, Ethical and Governance Challenges

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# Foreword

Progressively and perhaps insidiously, the use of the Internet and the applications linked with ICT in the medical sector, represent more of a revolution than an evolution. Rapid changes are occurring in medical care practices and the self-management by patients of their own health, and the relationships between the various actors of the sector and its governance. Instead of the historical human relationship that had developed between a single health care practitioner and a patient, that included human feelings and confidentiality, eHealth now prioritises medical information that circulates through an indefinite number of flows and is stored at numerous places for multiple purposes.

This information could be used for the delivery to the citizen of medical information, for discussion among patients about their medical problems, for checking or completing a prior diagnosis, for monitoring health care at a distance, for obtaining the reimbursement of medical care, for storage in health records, and for aggregation in the context of medical research. It can also be used to enhance both private and public healthcare systems, not only in terms of their quality and efficiency but also in terms of cost-effectiveness or control of social security expenses. Furthermore, national borders are becoming no longer significant at a moment in time when the Internet can offer all these services at a global level.

So, new issues are becoming crucial in this still evolving context. They can be summarised as legal, ethical and governance challenges. First, the **legal** challenges are pinpointed: Who is the owner of this information? Who has access to it? Which forms of liability have to be supported by traditional actors in health systems and services? What liability has to be committed to by the newer actors like IT applications or products developers? To what extent must medical services or pharmaceutical drugs be viewed as traditional services or products when they could be delivered internationally? Which national law will be applicable to that delivery? **Ethical** issues are definitively associated with certain of these legal issues. How do we consider patient autonomy when ubiquitous surveillance and manipulations of mental attitudes are possible, even at a distance? Are patients' mental perceptions of their health modified by their use of Web 2.0 applications?

How do we solve the delicate problem of balancing cost-effectiveness on the one side with universal access to the best possible care for everyone on the other? How and where do we put into place (and through which mechanisms) those ethical debates on which all stakeholders must be invited to participate? Lastly, these debates lead to the need to examine **how to govern** all these developments at both micro and macro levels: at the micro level involving the organisation that provides the healthcare, and at various macro levels—the national, European and global levels. How do we ensure the assessment of these innovations? How do we guarantee that they will be patient-centred and not measured purely in terms of cost reduction? Which role has any public authority to play in that deployment, especially with regard to the multiple choices implied by it?

As editors, Carlisle George, Diane Whitehouse and Penny Duquenoy have aimed to tackle all these questions together since they are deeply convinced that all the issues are interlinked and must be solved by taking fully into account their mutual interplay and interdependence. In order to nourish this multidisciplinary approach, they have asked, in a very structured way, more than 20 well-known contributors, lawyers, philosophers and social scientists and/or policy-makers to put forward their own specific points of view on each of these major questions. For most of the authors, this has resulted in an interesting prospective approach as regards the future of eHealth. The contributors are not only academics but are also persons in charge of the concrete implementation of eHealth applications or policies. Most of them describe a European approach but others, from outside the European Union, introduce a number of points of comparison as regards the solutions proposed.

To conclude, the result is worthy of praise. The book offers an integrated overview of the challenges raised by the eHealth revolution to all stakeholders: lawyers interested in the development of these new applications, medical information systems designers or producers, members of the various health professions, representatives of civil society and, particularly, patients' associations, data protection authorities, managers of health organisations, whether private or public and, finally, public authorities. Moreover, the book is not only descriptive of existing solutions, it invites the raising of fundamental questions about the ways by which the eHealth revolution might—or has to—be approached, builds bridges, and helps to a create a dialogue based on good faith, respectful of the fundamental values of our society. This is a dialogue which is fundamentally necessary among all the actors in this promising, but at times also distressing, eHealth new world.

Namur, Belgium                                                          Yves Poullet

# Preface

Around the world, information and communication technologies (ICT) play an increasingly integrated role in the provision and management of healthcare and medical services, known as eHealth. In the European Union (EU), the deployment of ICT-enabled healthcare to improve the quality, efficiency and effectiveness of medical and welfare services throughout all the Member States is seen as essential to the development of comprehensive healthcare services and to the promotion of an open and competitive digital economy. Similarly, many other countries continue to promote and implement eHealth as a fundamental part of their national health strategies.

The use of ICT changes many of the characteristics of healthcare and does so in ways that reveal new challenges in terms of legislation, ethics and governance. As technology continues to evolve, and new ICT-enabled tools and techniques become embedded in healthcare products and services, these challenges grow in number and complexity. They pose ever-changing difficulties for administrators, healthcare professionals, ICT professionals, legislators, policy-makers and patients. At the same time, however, these issues also provide opportunities to engage in constructive reflection, analysis and debate on the implications of eHealth in order to find new solutions and to chart new directions.

This book focuses on important challenges affecting eHealth in the EU, North America and other Organisation for Economic Co-operation and Development countries in the three areas of law, ethics and governance. It makes meaningful contributions to the eHealth discourse by suggesting solutions and making recommendations for both good practice and possible ways forward.

The volume starts (Part I) with a general overview, introducing the area of eHealth and discussing the importance, relevance and rich interconnectedness of the themes and topics that are covered in the subsequent chapters. Part II focuses on legal challenges related to electronic medical records, telemedicine, the Internet and pharmaceutical drugs, healthcare information systems and medical liability. Part III addresses ethical challenges such as telehealth and service delivery in the home, Web 2.0 and the Internet, patients' trust and relevant ethical frameworks.

Part IV considers governance challenges, including information technology governance in healthcare, governance and decision-making in acute hospitals, and different models of eHealth governance.

The book provides useful support materials and readings for persons active in developing an understanding of the current legal, ethical and governance challenges that exist in the eHealth context. The legislative and policy landscape affecting various aspects of eHealth is under continual development: it changes with sometimes unsettling frequency around all the various stakeholders even as novel solutions are found for new and existing challenges. We have therefore endeavoured to ensure that the text of the book, particularly with respect to both the law and governance, is up-to-date as of January 2012.

We would like to thank all the chapter authors for their personal contributions, for taking the time and effort to respond to reviewers' comments and suggestions and for helping to review the anonymous chapters of other authors. We would also like to acknowledge and thank several non-author colleagues for undertaking external reviews of some of the chapters: Hugo Agius-Muscat, Marc Griffiths, Georgios Karageorgos, Marc van Lieshout, Karel Neuwirt, Peter Singleton and Chris Zielinski. Our thanks also go to all the attendees at an eHealth workshop held at Middlesex University on 16–17 June 2011, for their contributions to various discussions that helped in developing and fine-tuning some of the overarching issues explored in the introductory chapter. We very much look forward to continuing these discussions in a vigorous and pro-active way in the future.

Technological developments will continue to take place in eHealth. Many of these will become part of new and innovative healthcare products and services not simply in the immediate future but over the next several decades. However, this shift will not be driven exclusively by technology-push. Demand will also play a significant role: healthcare professionals, patients, institutions and industry will all want a share of the benefits that eHealth can bring. Reinforcing the take-up of ICT by the healthcare sector are the trends and pressures from a larger context: slow-growing or stagnant economies, cash-strapped public authorities, and populations that live longer and want to remain active and healthy. While ICT has the potential to make a positive contribution to people's health and well-being, we must begin to look at all of the implications that accompany the introduction of each new ICT-enabled change to healthcare. We shall have to examine these in a context that considers the whole of the globe.

By continuing to question, discuss and debate the challenges that arise, each and every one of us can play a role in ensuring that these new developments occur in the most democratic, egalitarian, sustainable and yet cost-effective manner.

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London, UK                                                                            Penny Duquenoy

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# Part I
# Overview

# Chapter 1
# Assessing Legal, Ethical and Governance Challenges in eHealth

**Carlisle George, Diane Whitehouse, and Penny Duquenoy**

**Abstract**  This chapter offers a brief introduction to the phenomenon of eHealth, and its increasing deployment to improve the quality of healthcare delivery. The chapter also gives an insight into the contents of the book by discussing the various issues raised in its 16 chapters that focus on legal, ethical and governance challenges. It concludes with a set of reflections on the kinds of concerns that have been common to the chapter authors, and that are likely to continue to face eHealth in the near- and mid-term future.

## 1.1  Introduction

eHealth encompasses a wide variety of technologies applied to the provision and management of healthcare.

Early definitions of eHealth focused on the range of technologies included under the umbrella of eHealth, such as health information and communication networks; health portals; electronic medical/health records; telemedicine services; electronic prescribing services; personal wearable and portable communicable systems; and various other information systems used to assist in diagnosing, monitoring and treating patients (European Commission 2004). In line with the European Union's increasing focus on the growth of markets, industry, innovation and sustainability (European Commission 2005, 2010a, b), a definition of eHealth, developed 3 years later, concentrates on the relationship and connections between the data shared

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among institutions and users (European Commission 2007, p. 10) and yet provides a similar list of the applications covered:

> eHealth can thus be said to cover the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals; it can also include health information networks, electronic health records, telemedicine services, and personal wearable and portable communicable systems for monitoring and supporting patients.

This book illustrates various aspects of eHealth. It shows that it aims to improve the quality of healthcare by enhancing the quality, access and use of medical information; enhancing patient safety; reducing medical errors; facilitating the exchange of medical information among medical practitioners; assisting medical practitioners in decision-making and treatment; increasingly involving patients in understanding and managing their own health status; and enabling the efficient and economic management of health care information. Similar to this understanding—although clearly expanded to incorporate the wide-ranging World Health Organization (WHO) notion of health—is the 2005 definition of eHealth (WHA5828 2005, p. 121) as:

> the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research.

The impetus for the need to transform healthcare in Europe has arisen from various major challenges facing healthcare systems such as rising costs, shortages of many different kinds of health-related staff, demographic changes, medical errors, a growing elderly population that potentially needs prolonged medical care, the increasing management costs of chronic diseases and fragmented European Union (EU) healthcare services and solutions. Such challenges continue to need to be faced by Europe and also by many other continents around the world. Indeed, eHealth has become a major priority especially for developed countries, and increasingly for developing countries and emerging economies. Information and communication technologies (ICT) are now being used in almost every aspect of healthcare.

Under the umbrella of the former i2010 strategic framework, a major aim that underpinned the development of eHealth in the EU was to achieve a European healthcare landscape based on a new delivery model founded on preventive (rather than symptom-based) and person-centred (rather than hospital-centred) healthcare systems (European Commission 2006). This delivery model can facilitate personalised care and give patients more independence and autonomy to manage their healthcare needs. The European Commission (EC) has also sought to address the problem of fragmented healthcare systems across Europe by embarking on technical and policy measures to achieve EU cross-border interoperability of electronic health record (EHR) systems[1] (European Commission 2008b).

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[1] See as a pertinent example, the work of the large-scale pilot on Smart Open Services for European Patients (epSOS). http://www.epsos.eu. Accessed 21 December, 2011.

Interoperability of healthcare systems is expected to bring many benefits including supporting cross-border patient mobility, facilitating EU-wide medical research and epidemiological studies, combating chronic diseases and pandemics, and managing healthcare policy more effectively.

An important aspect of the i2010 initiative (which was aimed at promoting an open and competitive digital economy based on ICT as a critical driver) entailed the use of ICT-enabled healthcare to improve the quality, efficiency and effectiveness of medical and welfare services. eHealth continued to be included in the next phase of strategic planning by the EU, the EU2020 Initiative, with its contemporary focus within the Digital Agenda for Europe on the importance of active and healthy ageing (European Commission 2010b).

As in Europe (European Commission 2011a), many other countries continue to promote and implement eHealth policies as an integral part of their national health strategies (World Health Organization 2010).

There are numerous tasks ahead that must be completed to achieve the many promised goals of eHealth. The use of ICT and their accompanying innovative approaches to providing, assisting and managing healthcare, inevitably raise new challenges related to legal, ethical and governance issues. While these challenges can pose difficulties for legislators and policy-makers, they also provide an opportunity to engage in constructive reflections, analyses and debates on critical issues affecting eHealth in order to find new solutions and to chart new directions.

This publication focuses on a set of important challenges affecting eHealth in the EU and North America in the three areas of law, ethics and governance. It intends to make a meaningful contribution to the dialogue about eHealth.

"Law as a discipline has a precision that identifies various concepts, differences in context, and norms in relation to eHealth" (Whitehouse et al. 2011, p. 424). "It is often recognised as trailing behind various systemic and organisational developments" and "almost constantly plays a game of catch-up with the leaps implicit in technology, particularly those technologies which can be considered as disruptive" (Ibid 2011, p. 424). Hence, legislation can take years of development to be established and to be applied with success. However, it is anticipated that, in Europe, proposals for laws that are related to eHealth and address a number of the legal challenges raised in this volume will be put forward in the immediate future.

Ethics is based on a foundation that involves the exploration of new concepts and contexts. It is a field that is understood well, and supported, by many of the stakeholders in the health arena, whether patients or health professionals. It is given comprehensive coverage in this volume.

Today, there are difficulties facing the governance of good practices, standards, policy and legal implementations in Europe. There is generally agreement on the common fundamentals underpinning eHealth in its support of health systems and services (European Commission 2010a, b). On the one hand, a more top-down oriented solution is being developed in Europe through the eHealth Governance

Initiative.[2] Yet directions highlighted at the apex of the political hierarchy are always applied actively in real-life settings and in operational contexts in institutions, such as healthcare and care organisations (Mintzberg and Waters 1985; Mintzberg 2012). Hence, in Europe today, there is also an increased focus on stakeholder engagement in eHealth.

## 1.2 Law

The possibilities that exist for using technology in healthcare, both within the borders of nation states and across groups of states, such as the EU, have given rise to many legal concerns and challenges (for example, see Duquenoy et al. 2008; European Commission 2008a; and George 2009). These legal concerns and challenges are considerable, and relate to many different aspects of implementing and managing eHealth. They arise in many contexts, including: implementing ICT in a clinical setting; providing and managing eHealth in organisations; providing medical products and services across borders; and developing policy decisions for eHealth that have regional, national, or international legal implications. In many cases, existing national and supranational legislation do not adequately address concerns related to recent forms of technology use, and new capabilities offered by technology (e.g., the use of EHRs). In other areas, such as the application of electronic commerce in healthcare (e.g., telemedicine), there is a need to ascertain how existing laws can be properly applied and harmonised especially to facilitate cross-border activities.

The widespread application of information technology (IT) as an enabler of economic and social development in the EU, including in public health, has meant that there is a need for greater legal clarity and harmonisation of laws related to eHealth. In 2008, a study report by the European Commission on the legal and regulatory aspects of eHealth identified three main areas of law that are difficult to interpret in the context of eHealth (European Commission 2008a). The first area is data protection and privacy laws, in light of the increased collection and sharing of patient data. The second is laws on liability for goods and services when using eHealth tools. The third is trade and competition laws which face the nascent emergence of the eHealth industry.

As the EU moves towards greater integration, new cross-border capabilities offered by interconnected technologies that enable the sharing of patient records and integration of IT healthcare systems or provide medical goods and services at a distance (e.g., cross-border electronic commerce) have led to increasing demands for eHealth tools and services. However, the implementation of eHealth, both within and across Member States, raises legal concerns and challenges especially

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[2] http://ec.europa.eu/information_society/activities/health/policy/ehealth_governance_initiative/index_en.htm. Accessed 21 December, 2011.

regarding patients' rights (e.g., in relation to privacy and data protection) and liability.

Currently there is no single body of EU legislation that covers eHealth. Rather, there are various bodies of both national and EU legislation that address aspects of technology use in healthcare. In some cases, the differences in implementation of EU legislation in Member States, such as on data protection, have raised concerns about the law, especially in protecting the individual rights of patients. The tasks ahead for the EU to implement legal clarity and greater harmonisation of laws affecting eHealth, will be difficult, particularly in view of the right of Member States to decide on matters of public health in their own territories. However, it is necessary that citizens understand and are assured that their rights are protected in view of the increasing use of interconnected technologies in eHealth and greater patient mobility across the EU (supported by the 2011 Directive on patients' rights in cross-border healthcare).[3] It is also important that health professionals, as well as other providers of medical products and services, know and understand their professional and legal responsibilities in order to maintain high standards in their practices especially if they continue to expand their use of ICT. Legal clarity in healthcare and its associated confidence-building is therefore needed for a variety of stakeholders in the eHealth domain including citizens as a whole, medical consumers (e.g., patients), professionals (e.g., doctors, nurses, and pharmacists) and commercial entities (e.g., medical service providers, manufacturers, and suppliers).

The six chapters in Part II of this book explore the legal aspects of the many challenges that eHealth technologies bring. They touch on issues relating to privacy, data protection, human rights, interoperability, jurisdiction, the freedom to provide electronic services across the EU and liability for eHealth goods and services. In Chap. 2, Jos Dumortier and Griet Verhenneman, offer a critical and comparative analysis of the legal and regulatory frameworks for EHRs in Europe and the United States (US) of America. They begin with an in-depth discussion of traditional patient regulations, focusing on the bipolar tradition of regulation in Europe (of laws on data protection and patient rights) and contrasting this with the consumer protection approach taken in the US. They then discuss how the introduction of shared EHRs brought a new layer of regulation to the traditional legal frameworks in both jurisdictions. With regard to EHRs in Europe, the authors identify and discuss three distinct EHR models, and the legal issues associated with them. With regard to the US, they focus on legislation aimed at standardisation and enhancement of the rights of the individual. They foresee further legislative reform in both jurisdictions to address new challenges such as an EU-US cross-border eHealth market.

The focus on EHRs continues in Chap. 3 in which Elizabeth Wicks examines privacy interests in relation to EHRs in the context of the English experience.

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[3] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

She focuses on the introduction of the Summary Care Record to England. Wicks argues that EHRs pose significant new risks for the privacy and security of personal health information. She also suggests that technologies associated with EHRs move the organisation of healthcare beyond the traditional doctor-patient relationship. She identifies and discusses challenges that need to be dealt with when using EHRs: they include patient consent, confidentiality, data protection and the security of information. Wicks appears to take a cautious and critical view of EHRs: she is of the opinion that, although they bring many advantages, the challenges and concerns associated with EHRs have not been satisfactorily addressed. One of her main concerns is the potential for unnecessary access by persons other than the medical staff who care for the patient directly. She argues for more specific regulation to address storage and access to EHRs. She also identifies the need to address obstacles related to the sharing of patient information, especially to facilitate the goal of patients travelling between EU Member States to receive medical treatment.

The concept of privacy in eHealth and, in particular, health information systems is considered further in Chap. 4 by Concetta Tania Di Iorio and Fabrizio Carinci. They focus on the broader goals that can be fulfilled by public health information systems, and discuss whether the current European legislative framework provides an optimal balance between the privacy of the individual and public health interests. Using conclusions drawn from two EC co-financed projects, BIRO[4] and EUBIROD,[5] they discuss the concept of privacy by design as a way forward to meet legal and ethical requirements especially for cross-border information exchange (i.e., embedding privacy and data protection throughout the entire life cycle of technologies). Di Iorio and Carinci argue that practical solutions can be successfully implemented to enhance privacy protection in health information systems (e.g., the implementation of privacy by design, and the use of privacy-enhancing technologies). Among other issues, they also identify the need for a homogeneous application of EU data protection legislation across the Member States.

An increasingly popular application of eHealth technologies is in the provision of healthcare services at a distance (e.g., telemedicine), especially to people in remote geographic areas and to those who may not have access to certain medical specialisms in their locality. In Chap. 5, Cătălina Ionescu-Dima analyses several problematic legal aspects in the provision of cross-border telemedicine services in the EU. She first examines the phenomenon of telemedicine indicating its importance and the lack of EU legislation targeted specifically at telemedicine services. She then identifies and discusses the legal implications of: licensing; accreditation and registration of providers; reimbursement of the costs of telemedicine services; data protection; jurisdiction, and the potential conflict among differing laws. In an attempt to show how legal clarity for telemedicine can be provided in the EU, Ionescu-Dima takes a detailed look at EU case law and legislation including

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[4] http://www.biro-project.eu/. Accessed 21 December, 2011.

[5] http://www.eubirod.eu/. Accessed 21 December, 2011.

Directive 2011/24/EU (on the application of patients' rights in cross-border healthcare), Directive 2000/31/EC (on electronic commerce), and Directive 95/46/EC (on Data Protection).

In addition to facilitating services like telemedicine, the Internet and associated technologies have facilitated the widespread uptake of electronic commerce in every area of commercial activity, including the sale of medical goods and services. Electronic commerce is now a global phenomenon, crossing traditional national boundaries, and generally enabling access to many online medical goods and services by anyone from any location. This has lead to challenges to national governments, especially regarding the control of activities within their jurisdiction. It has become difficult to control the online access to medical goods and services, and also the access to information about drugs, treatments and other medical information.

In Chap. 6, Carlisle George therefore focuses on the use of the Internet as a medium for pharmaceutical drug sales. He discusses the increasing use of the Internet by EU citizens to obtain pharmaceutical drugs, and the attendant potential risks posed to these citizens especially due to the rising levels of counterfeit drugs sold online by rogue Internet Pharmacies. He examines the legal framework that impacts on EU cross-border Internet pharmaceutical sales, and discusses the relevant legislation and case law. He questions whether the legal framework is desirable and sustainable, and explores how concerns that gave rise to it may be addressed by new technologies and recent EU legislation. George argues for a rethinking of the status quo regarding cross-border prescription drug sales in light of emerging realities and technical and legal developments in the EU.

Use of recent and existing technologies in eHealth, the practice of medicine, and the provision of medical goods and services bring various risks, many of which can result in fatal consequences. Medical professionals and providers of medical goods or services are therefore expected to know of risks associated with their practice or trade, exercise diligence and high standards in the provision of medical care, services or goods, and also take responsibility, i.e., be liable for their actions. In light of the introduction of innovative eHealth tools and services into the traditional health care environment, it is necessary to develop legal clarity regarding the legal framework for liability.

In the final chapter of the legal section, Chap. 7, Isabelle Andoulsi and Petra Wilson focus on civil liability issues in relation to eHealth. They examine the extent to which EU-level liability legislation addresses with sufficient adequacy civil liability related to the use of eHealth tools and services. They discuss the EU legislative frameworks for eHealth product liability and eHealth services liability. In particular they mainly focus on Directive 2001/95 on General Product Safety, Directive 93/42 on Medical Devices, legislation on internal market services, and Directive 2011/24/EU (on the application of patients' rights in cross-border healthcare). They note the lack of a fully worked-out EU-level framework for addressing liability in the provision of eHealth, and argue that the EU needs to further address problems regarding responsibilities for eHealth goods, products and services.

While many of the issues in the chapters in Part II are related, they also vary in terms of areas of law covered, perspectives taken, geographical coverage and approaches used. The chapters therefore provide a rich ensemble of different legal issues, analyses and recommendations. With regard to the general areas of law and regulation covered, Chaps. 2–4 concentrate on privacy and data protection, Chaps. 5 and 6 focus on electronic commerce, and Chap. 7 covers liability. Even where some authors have written about similar areas of the law, they approach the subject from different perspectives. Chapter 2 is more concerned with how EHRs are regulated generally, Chap. 3 looks specifically at individual privacy interests when using EHRs, and Chap. 4 has a concern for the broader issue of public health. Similarly, while Chaps. 5 and 6 both tackle electronic commerce from a pan-European perspective, Chap. 5 is oriented towards telemedicine and Chap. 6 examines the online sale of pharmaceutical drugs. With regard to geographical coverage, in some cases chapters have mainly focused on a single country (Chap. 3), whereas others have taken a pan-European view (Chaps. 4–7), or a more international perspective (Chap. 2). Different approaches to discussing and analysing legal issues can also be seen. Chapters 3, 5, 6 and 7 approach their subject from an academic perspective in comparison to the empirical approach taken in Chaps. 2 and 4.

## 1.3   Ethics

In 1999, the European Group on Ethics in Science and New Technologies[6] (EGE) adopted for the first time an Opinion on the ethical aspects of the information society and, more specifically, on ethical issues of healthcare within it (European Commission 1999a). The EGE noted the explosion of ICT in healthcare and the consequent impact on personal health data which they viewed as being "the most sensitive data about an individual. They not only concern an individual's medical history, but also behavioral patterns and possibly sexual life" (European Commission 1999b). The list of ethical principles that the EGE considered relevant in this context are wide-ranging. They include:

- Respect for private life;
- Confidentiality;
- Trustworthiness (of healthcare systems);
- Legitimate purpose for collection of data;
- Explicit informed consent for use of data by the patient;
- Respect for the security of personal health data;
- Transparency of standards (which embody value-related choices);
- Access of the patient to an EHR;

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[6] The European Group on Ethics advises the European Commission on ethical issues, and its findings can also be drawn on by both the Council and Parliament.

- The right of citizens to participate in the design of ICT systems in healthcare; and
- Citizen education that includes the ethical implications of ICT as a pre-condition of European democracy.

Identifying these ethical principles lays the foundation for thinking about the ethical implications of eHealth in Europe. Determining these principles is, however, merely a start: for them to have meaning, we should consider how the principles might operate in practice.

Around the same time as the original work of the EGE, a column appeared in a US journal representing the nursing profession. It pointed out the changing expectations and behaviour that will result from eHealth, both socially and professionally (Maddox 2002). The Internet, of course, forms part of the eHealth concept. According to Maddox, it will influence eHealth activities "including how consumers and healthcare providers:

- Purchase health-related products and services over the Internet;
- Access health records via the Internet;
- Manage personal health information on the world wide web;
- Communicate between consumers/patients and providers, benefits managers, insurers and so forth via e-mail and other Internet means (e.g., chat rooms); and
- Participate in consumer-initiated communities of support that foster information exchange and through which new "virtual" relationships are formed."

Since this column and list of activities first appeared, much has changed. All these activities have either taken place or have been the subject of discussion, debate, and research. New applications for ICT have also appeared. For example, chat rooms have emerged in social media and social networks. However, although the technologies that enable communication—and in many cases drive social and professional communications—have been adapted or have altered, the basic behaviours listed remain valid in broad terms.

In this book, the contributors address the issues raised above in contemporary settings. They explore the underlying ethical principles at stake in the health field in terms of personal health information, and the activities of consumers and healthcare providers with regard to products and services provided on the Internet, access to health records, management of health information on the world wide web, and communications between people and their healthcare providers, including through the use of social media (Web 2.0).

The five chapters in Part III of this book adopt different perspectives that offer insights into the ways by which the introduction of ICT to healthcare can challenge the ethical principles that form the basis of healthcare, such as those put forward by the EGE: privacy, confidentiality, trustworthiness and access. The perspectives have a broad range: how these ethical principles can be applied to different technological contexts in order to see which of them might be compromised by the technology; how ICT impacts on a patient's relationship with healthcare; the uses of specific types of technologies (such as social media or Internet searches)

that provide a much greater opportunity for people to find their own information on health matters; and finally, the impact on the patient who is faced with a new healthcare paradigm based on ICT.

This part of the book on ethics begins by offering practical help in assessing ethical issues that could arise from the use of ICT to support healthcare. Chapter 8 analyses the tools currently available for ethics assessment in the health area, including the "four principles approach" offered by Beauchamp and Childress (2001), and current standards that are in use for medical professionals and for health websites. The authors, Kush Wadhwa and David Wright, then look at other ethics assessment tools that are in use outside of the health domain (in business and research, for example) to provide an overview of the approaches used in different domains. These approaches vary. They include sets of ethics keywords or prompts, the gathering of a wider range of views from stakeholders in focus groups, and scenario-building that can offer a more practical and accessible method to recognise potential ethics trigger-points. From this assessment of existing tools and their benefits and disadvantages, Wadhwa and Wright turn to the ethical issues specific to eHealth. They comment in-depth on the challenges raised by technology, access to technology, and ethical principles relevant to using ICT for health. They finally bring all these elements together in a case study. This presents a hypothetical scenario which they analyse using a preliminary framework developed out of the different approaches discussed in the chapter. The case study provides a useful example of how such a framework could be implemented and how ethical issues can be drawn out in a practical way.

Chapter 9 addresses what might be called a precondition of ethics. It is the notion of autonomy, i.e., the ability of a person to exercise choice. In this case, autonomy refers to the ability of a person to make choices regarding the provision of telehealth technologies and services. Malcolm Fisk and Drago Rudel argue that the provision of telehealth services currently follows the medical model of healthcare which sees patients as recipients of care. For the principle of autonomy to be applied, a social model needs to be introduced which would conceive of people as making choices (or at least, in case of any degree of limited ability, acting as partners in the decision process). In making this argument, the authors explore the notion of care and the reciprocal benefits of caring: "acts of caring are crucial to both forging and maintaining relationships within families and communities and between its givers and receivers. We recognise that these acts of care are often reciprocal in nature—with, arguably, their greatest value lying in this reciprocity." They note that, over time, caring has been appropriated by institutions. Certain conditions have begun to apply to the receipt of care—i.e., the limiting of individual autonomy.

The need for care is particularly relevant to older people. Today, we can see how the members of this social group are perceived as beneficiaries of healthcare provision (which is often framed in terms of tasks rather than relationships). Fisk and Rudel proceed to explain their position by looking at the specific case of telehealth provision. They bring out ethical issues relating to monitoring technologies and information gathering, whether in the home or outside (i.e., mobile monitoring), especially for older people. In promoting a more social

model of care, where the environment is designed to include the patient, the authors conclude the chapter with recommendations for good practice. The recommendations include technology design. As an example, the European Commission co-financed project, ICT for all,[7] which is concerned with social inclusion and citizenship is cited.

'Social' is the key word in Chap. 10, since it investigates social media ("Web 2.0") as a tool for eHealth. It discusses the challenges that social media raises for the health profession. The discussion is around information asymmetry, the imbalance of information between two parties. In the healthcare context, this asymmetry relates to the differences in knowledge between a doctor and a patient. Peter Winkelstein brings a perspective from the US of a healthcare system that is financed by various sources (in contrast to the "single payer" model that is common in many European countries). He draws attention to the significance of "regulated reimbursement and competition for patients" and, from the patients' side, financial incentives (or disincentives). In this environment, social media can offer patients the opportunity for a two-way interaction which contrasts with the primarily one-way interaction previously common in Web 1.0 (where patients could browse health websites for information that were not likely to offer unbiased information). With the rise of social media, individuals have more opportunity to share information with each other on health conditions and healthcare providers. Another recent development of which patients can take advantage is a personal health record (PHR) that is accessible online via a patient portal. Although these portals allow patients to have access to their health record and, combined with social media, to share information, the information security risks are increased. Another information security issue related to social media is the potential for medical students to post inappropriate comments about patients or breach patient privacy.

Overall, the benefits to patients include more autonomy as well as greater ability to find their way around the healthcare system and to manage their own health. Among the risks are breaches in the confidentiality of personal health information, and confusion or damage with regard to the doctor-patient relationship, as well as, on the academic side, to the integrity of medical research and medical education.

The opportunities offered by Web 2.0, in particular for people to search for, and to post, health information on the Internet, is the topic of Chap. 11. This chapter is concerned with the quality of health information, and the protection of users' private data. The uncontrolled development of medical content is of particular concern as it can have "important repercussions on people's decisions concerning their health". This observation also applies to users' sharing information with others on health therapies, drugs, side effects and their own experiences. Celia Boyer presents an overview of the regulations that currently exist in terms of the responsibilities of website operators, and the lack of regulation on information content or quality which is a cause for concern. She then presents strategies that have emerged

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[7] http://www.ictforall.net/. Accessed 21 December, 2011.

to address the matter of quality assurance in respect of health information, such as codes of conduct, self-applied codes, user guidance tools, certificates for quality, dedicated search engines for health information, users' collaboration-generated content, and third-party certification. She has concerns regarding the privacy of users' personal information submitted to health information websites that are similar to the concerns referred to by Winkelstein. Boyer provides some detail on the issues and the regulations in place in the EU and US that can apply in these cases. The conclusions of the chapter relate to both the user and to governance mechanisms. Patient empowerment has to be strengthened through the development of critical skills. These can be expanded by the initiatives discussed in the chapter, together with regulation (whether law or self-regulation as offered by codes of conduct, for example). Tools and training can make a valuable contribution in offering guidance to developers of health websites.

The last chapter in this section, Chap. 12, brings many of the themes in this section together by taking the patient perspective in the eHealth context. It covers what eHealth might mean to patients in practical terms and what needs to be in place to encourage their use of it. The authors (Penny Duquenoy, Nermeen M. Mekawie and Mark Springett) argue that trust and confidence are key factors when it comes to eHealth adoption, and that these two factors are challenged when ICT is brought into the health domain. The role that ICT plays in eHealth, often as a mediator of the healthcare practitioner and patient relationship, has a number of implications. People would need to have trust and confidence in the technology that supports this relationship, and in the institutions and staff that use the technology. At the heart of the discussion is the question of privacy—in terms of traditional medical notions of patient confidentiality and, more specifically, patient health information (i.e., patient data in ICT terminology). The authors note the challenges to privacy already faced by Internet users. There is a consequent implication for online commercial enterprises and online government initiatives to address these challenges, for example, by introducing privacy policies and assurances regarding the collection of user information and the security of personal data. In the case of eHealth, these issues need to be addressed not only to encourage trust and confidence, and therefore patient adoption, but also to meet the ethical requirements of healthcare.

Confidentiality, informed consent, and patient autonomy are fundamental ethical principles in professional healthcare, and ICT raises challenges for each of them. In this context, the chapter questions the various roles and professional responsibilities of the healthcare practitioner and the technology developer or provider, and also the role and responsibilities of the patient. Of significant relevance to the patient in this situation is the feasibility, and indeed fairness, of assigning responsibilities relevant to the management of health information to people who may not have a reasonable understanding of the technology, the processes of information collection and movement, or—most importantly—the capability of using or understanding the technologies involved. The confidentiality of patient information may be particularly at stake. Consequently, much needs to be done to put in place procedures directed at maintaining patient confidentiality in an ICT-mediated environment,

including: education and awareness of the issues raised by technology on the part of the healthcare practitioner; specific training for the information technology professional working in the healthcare domain; attention to the competences of the patient as the user of the technology (i.e., understanding of the devices, and physical and cognitive capabilities); technical and financial support for the patient as user; and clear guidance on boundaries regarding the allocation of responsibilities in the healthcare practitioner/technology provider/patient chain.

The key themes that emerge from these chapters are that eHealth has the potential to bring benefits to the people delivering and receiving healthcare, by offering timely and easy access to information. However, how and by whom the information is used and understood can present problems. The chapters in this section take different approaches to identifying the problems: Chap. 8 offers a set of ethical values as a framework combined with a scenario that gives a practical application; Chap. 9 refers to the conceptually different medical and social models of healthcare to illustrate degrees of autonomy; Chaps. 10 and 11 discuss the potential of web technologies to both empower people by access to information or mislead them—depending on the quality of the information provided; and Chap. 12 takes the perspective of those receiving healthcare services to consider the effect of changes on the relationship between the patient and the professional.

Underlying the discussions is the occasionally unequal relationship that exists between the healthcare provider and people receiving care. New technologies to support vulnerable people and encourage independence such as, for example, technologies that monitor health status or mobility, are considered in Chaps. 8 and 9. The collection of personal information given by people accessing health information on the Internet by third parties, often without the consent of the person concerned, is addressed in Chaps. 10 and 11. Other concerns raised in Chap. 12 relate to the level of understanding by many people of today's technologies, which could have significant implications for autonomy and consent.

In many ways, ICT has the capability to redress the power imbalance and, in others, increase it. These oppositions or conflicts are of course characteristic of ethics discussions. It is only by investigating further, taking into account the circumstances, the people affected, the ethical principles at stake and, finally, prioritising values, that options can be proposed for an ethical outcome. The chapters in Part III of this book achieve this in different ways that are both thought-provoking and practical.

## 1.4  Governance

The governance of eHealth has taken a number of steps forward since the early-2000s as has the notion of governance in general (European Commission 2001). Awareness of governance has grown throughout Europe—and more widely—over the ensuing time-period. It is now much more commonly recognised that eHealth,

and health policy, need to be aligned more effectively in much the same way that investment in eHealth should be based more accurately on actual health needs.

Developments on the European scene, for example, indicate that there is now sufficient political leadership to ensure EU-level eHealth governance. A strong political mandate for eHealth cooperation in several specific areas has been created at the level of the Union, with agreement among all the Member States: it is intended to boost the deployment of eHealth services. Hence, an eHealth Governance Initiative was formally launched at the beginning of 2011, although based on many years of previous, informal interaction.[8] The Initiative will be an active participant in the debate on eHealth policy directions, and it will report regularly to the Councils of the EU. Meanwhile, the European Commission will support the work of the Initiative, while it will also continue its right to propose policy and legislative reforms so as to fulfil its obligations set out in the 2008 Treaty of the Union (C115/47-199 2008).

eHealth governance in Europe is being addressed at three levels: policy, strategy and co-operation. There has been considerable progress in eHealth since the first Action Plan of 2004 (European Commission 2004; Kotsiopoulos and Whitehouse 2011). Practically speaking, a European eHealth Roadmap or Action Plan is likely to be developed out of the interaction of these three levels during the course of 2012. A road mapping exercise will ultimately lay out the priorities and required actions at the level of the EU in order to support the individual eHealth implementation plans of the different Member States.

Positive effects on healthcare performance and effectiveness are seen as emerging through the alignment between business and IT governance. However, it is uncertain how governance would 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 (for example, Miah and Rich 2008), and are also tackled in this volume.

IT governance is considered to be of considerable importance in a political and financial context in which a focus on health for growth is to the fore (European Commission 2010a; European Commission 2010b; European Commission 2011b).

IT governance is described in several ways. For example, at a local or organisational level, IT governance ensures that "the organisation's IT supports and enables the achievement of its strategies and objectives" (Brand and Boonen 2005). It is also described as covering "the decision rights and accountability framework for encouraging desirable behaviours in the use of IT" (Weill and Ross 2004, p. 8) or as being "a framework for the leadership, organisational structures and business processes, standards and compliance to these standards, which ensure that the organisation's IT supports and enables the achievement of its strategies and objectives" (British Standards Institute 2008).

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[8] http://ec.europa.eu/information_society/activities/health/policy/ehealth_governance_initiative/index_en.htm. Accessed 21 December, 2011.

Contemporary work in the governance of eHealth has tended to concentrate on the IT aspects in the hospital sector. Most data available have been obtained from the US as well as from other Organisation for Economic Co-operation and Development (OECD) countries, as Part IV of this volume illustrates. A survey of ICT use in the hospitals of 30 European countries that obtained input from both chief information officers and chief medical officers has more recently provided statistics related to this context (Codagnone and Lupiañez-Villanueva 2011; Deloitte and Ipsos Belgium 2011).

The final part of this book (Part IV) consists of four chapters that focus on different aspects of governance in eHealth. In Chap. 13, Elena Beratarbide and Tom Kelsey support the proposition that alignment between business and IT through eHealth governance has a positive effect on healthcare performance and effectiveness. They use as their starting-point the case of the National Health Service Board in Scotland. The country is subject to a number of pressures, as are other UK home countries and also—more widely—states throughout Europe and around the globe. These pressures include the need to achieve efficiencies in terms of access, quality of care, organisation and financing. The authors investigate what might be the kinds of outcomes from which lessons can be learned with regard to IT governance. They do so in the health sector and in a number of other economic sectors. They draw on studies done in individual European Member States, as well as those carried out in Switzerland, Latin America and South Africa. Overall, their investigation permits them to make some 17 recommendations that tackle both governance and organisation. Fundamental to many of their suggestions is the work of chief executive officers and chief information officers.

In Chap. 14, Magda Rosenmöller asserts that the governance of IT is critical to how eHealth is deployed and taken up. A clearly defined IT strategy ensures more successful use of IT in hospitals. Five elements are fundamental to this model of IT governance: the overall strategy; leadership; bridging the IT and the clinical domains; user involvement; and revision or monitoring of the IT strategy. Evidence from the literature shows that better introduction of IT in the health sector allows it to achieve its full potential. In exploring the general meaning of IT governance, Rosenmöller also draws on findings from hospital case studies undertaken in Germany, Spain and Switzerland. Each shows quite different approaches to IT governance and diverse forms of support from its healthcare providers and IT providers. Crucial elements in the IT governance in hospitals, and in IT implementation, involve both chief information officers and chief medical information officers. Twelve key success factors are identified as a result of these cases. In this chapter, however, the author identifies not simply the responsibilities of the senior levels of IT and clinical staff but also the potential for wider stakeholder involvement, including patients through social networking.

Malcolm Thatcher, whose work features in Chap. 15, argues that IT plays a key role in driving organisational efficiency in a great many areas of commerce worldwide. The healthcare sector has yet to take IT on board in an intensive manner. In the acute healthcare sector of hospitals, IT can proceed further in its delivery of clinical care to patients. IT governance provides a framework that is

able to improve the adoption of IT in organisations. This chapter lays out a comprehensive overview of literature involving IT adoption—and its importance—in acute care delivery. This is a wide-ranging, and critical, review of international documentation: among the sources of the literature are various European countries and a number of OECD countries. This broad survey is then used for two purposes: to support the argument that the design of IT governance is dependent on organisational factors; and to show that the specific organisational factors inherent in the acute healthcare sector—hospitals—impact on IT governance. Overall, Thatcher urges further research into this field.

A European overview of an exciting era in eHealth in which dramatic political momentum is being created is introduced by Flora Giorgio. This period is likely to lead not only to the eventual stronger implementation of eHealth strategies at both European and national levels but also to the broader deployment of eHealth in the European health space. Chapter 16 begins with a review of the growth that has taken place in eHealth in Europe over more than 30 years, and it later highlights increasing EU-US collaboration. It covers a number of innovative endeavours that are currently underway: among them, the epSOS large-scale pilot[9] and the first of the European Innovation Partnerships on active and healthy ageing.[10] It also refers to support offered by the Competitiveness and Innovation Framework Programme,[11] and other large-scale pilot activities that can support eHealth in an indirect manner such as STORK on eIdentity.[12] The chapter focuses in particular on the European eHealth Governance Initiative the objective of which is to support the Member States in the wider deployment of eHealth and to ensure eHealth interoperability.

The scale of the coverage of the notion of governance, and particularly IT governance, on the part of the authors ranges from that of the institution to the nation to the political context of an entire continent. In Chap. 13, the level of analysis is that of the national healthcare board. The case investigated is a single illustration of a country—Scotland. However, the literature studied to reach the specific recommendations is extremely wide-ranging in terms of both countries and economic sectors. The focus tends to be on the roles of the chief executive officer and the chief information officer at the national or institutional level. Chapter 14 examines IT governance at the institutional level of the hospital and introduces evidence gathered from four separate European case studies. It covers a set of recommendations that are targeted towards the roles of two of the senior positions in hospitals, the chief information officer and the chief medical information officer. However, attention is drawn to the part to be played by patients, particularly in

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[9] See footnote 1.

[10] http://ec.europa.eu/research/innovation-union/index_en.cfm?section=active-healthy-ageing. Accessed 21 December 2011.

[11] http://ec.europa.eu/cip/. Accessed 21 December, 2011.

[12] A European eIdentity Interoperability Platform. http://www.eid-stork.eu. Accessed 21 December, 2011.

terms of social networking, and the types of technology innovation involved. In Chap. 15, the landscape of the literature studied is particularly large: it is completely international, and indicates that further research in this field is still required. Last but not least, the final chapter of this book, Chap. 16, widens the scope of governance to include not only an entire continent but also EU-US collaboration.

The domain of eHealth is, like many other sectors of modern society and economy, a complex ecosystem. Not only does it require strategy at the very highest level, but it will also benefit from the involvement in consultation and decision-making of the range of all stakeholders throughout its value chain: these constituents are generally well-known and widely identified (and include health professionals (professional bodies and trade unions), citizens, patients, healthcare managers, hospitals, health insurers, eHealth experts, public health organisations as well as industry with a direct interest and core activities in ICT for health).[13] In this volume, the added-value of the involvement of ethicists and legal experts to the debate is also clearly laid out.

## 1.5  Conclusions

The scope of the topics and issues covered in this book provide an in-depth contribution to the eHealth discourse. The use of ICT in healthcare raises questions about the kinds of challenges that manifest themselves in legal, ethical and governance issues (as did the subject-matter of a similar volume (Duquenoy et al. 2008)). 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.

Useful support materials and readings are provided in this volume for persons active in developing current understandings of the legal, ethical and governance challenges currently operating in the eHealth context whether this is in north America, OECD[14] countries generally, or in the different concepts of Europe (such as the EU, the European Economic Area, and/or the larger World Health Organization community of Europe). Its other readers are likely to include theorists and the advanced students whom they teach as well as practitioners.

eHealth developments need to progress in ways that are legally appropriate for the different legal jurisdictions, that recognise the ethics of the diverse cultural and

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[13] http://ec.europa.eu/information_society/activities/health/docs/policy/stakeholders/20111219 ehealth-expert-group-call_interest.pdf. Accessed 21 December, 2011.

[14] Organisation for Economic Co-operation and Development. See: http://www.oecd.org/. Accessed 21 December, 2011.

geographic areas where eHealth is being used, and that can be adequately governed. Many of the book's legal reflections are timely in view of expectations for imminent proposals on data privacy and data protection to be put forward in early 2012 on the part of the European Commission, and anticipations of other legal advances. At the same time as there are indications of progress in the law, there needs to be debate and dialogue that involve other advances in eHealth change management.

The publication explores different eHealth policy developments and routes, the parts to be played by a wide variety of stakeholders and institutions, and the benefits and new roles that this approach can bring to Europe's citizens, including its patients. It considers the implications of eHealth delivery from the perspective of the traditional ethical values inherent in medical practice, and presents useful insights for future development projects.

Just like the technologies that support other forms of service provided to citizens, such as eGovernment and eInclusion, eHealth is increasingly no longer likely to be considered in terms of individual, institutional "silos" but in the context of the wider societal needs in Europe and the globe. Increasing, stakeholder dialogue will bring together not only policy-makers and civil servants but also health professionals, payers and providers, families, carers and patients. To give but one example, concentration may be less on individual personal electronic health records than on the sharing of data for wider possible purposes (such as the cost-effective development of health systems and services; public health; and research).

Ultimately, at least in Europe, it can probably be anticipated that governance considerations will emerge with an agreement to issue and adopt a commonly-agreed EU Information Governance that enables the Member States of the Union to conform to requirements for cross-border health data exchanges (European Commission 2011b). Under these circumstances, and in the context of an ever-changing technology infrastructure, it is becoming critically important to consider where we are today in terms of the challenges to law, ethics and governance in eHealth and to reflect on how future eHealth progress will address those challenges.

The issues raised in this volume can be abstracted from specific instances to inform eHealth and health-related governance policy, technology design and deployment, and legal mechanisms. We cannot predict, of course, what ICT will bring next. However, finding common foundations and principles of health provision and translating them into practical and beneficial outcomes through dialogue, research and professional expertise will set the stage for increasingly supportive ICT.

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