Chapter 19
Designing Enabling Regulatory Frameworks to Facilitate the Diffusion of Wireless Technology Solutions in Healthcare

Indrit Troshani, Steve Goldberg, and Nilmini Wickramasinghe

Abstract Pervasive e-health solutions are emerging as a solution to address key challenges faced in healthcare delivery including escalating costs and the exponential increase of chronic diseases. However, existing regulatory regimes appear to be one of the key stumbling blocks in trying to successfully diffuse these proven superior technology solutions. This is largely due to the fact that they are ill-equipped for dealing with them. The following exploratory study serves to investigate institutional regulatory factors that can impact the adoption of such pervasive solutions. These factors are important as they can shape both the nature of these solutions and their diffusion trajectory. In particular it is argued that co-regulation, a mixture of direct monitoring and intervention of regulators through legislation and complete industry self-regulation, can be an effective approach especially in view of the complex and dynamic nature of this industry. Co-regulation can minimize monitoring costs and enhance compliance. A case vignette is provided to illustrate these points.

Keywords e-Health • Pervasive healthcare • Wireless in healthcare • Regulation • Co-regulation

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I. Troshani (✉)
University of Adelaide Business School, 10 Pulteney Street Level,
Adelaide, SA 5005, Australia
e-mail: indrit.troshani@adelaide.edu.au

S. Goldberg
INET International Canada, 131 Glen Crescent, Thornhill, ON, Canada L4J 4W4
e-mail: sgoldberg@inet-international.com

N. Wickramasinghe, Ph.D., MBA
Epworth HealthCare & Department of BITL & HIRi, RMIT University,
GPO Box 2476, Melbourne, VIC 3001, Australia
e-mail: nilmini.wickramasinghe@rmit.edu.au

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19.1 Introduction

Pervasive e-health constitutes the use of digitally enabled technologies to facilitate and enhance the exchange of clinical, administrative, informational, educational, and transactional data ubiquitously in healthcare settings (Holliday and Tam 2004). Examples of pervasive e-health solutions include telemedicine and telecare services, virtual reality, computer-assisted surgery, mobile monitoring systems (e.g., for the electronic management of chronic diseases), electronic medical records management, including digital imaging and archiving systems, and electronic prescribing (Ferraud-Ciandet 2010). Taken together, pervasive e-health solutions have the potential to generate enormous efficiencies and services quality as well as to reduce medical errors (Anderson 2007).

Delivering pervasive e-health solutions effectively requires the integration of diverse technological and organizational resources which typically cannot be found within individual organizations. The knowledge necessary for developing and deploying these solutions may involve several heterogeneous stakeholders that are often embedded in various technological, economic, and social settings (Holliday and Tam 2004). To succeed, these stakeholders must interact with each other while complying with institutional requirements including legal and societal requirements that balance their diverging interests, motivations, and needs (Kluge 2007; Troshani and Rao Hill 2009). These requirements constitute a regulatory regime which can operate at industrial, national, or international levels and can influence, direct, limit, or prohibit any activity undertaken by stakeholders operating in the pervasive e-health solutions industry (Holliday and Tam 2004; Ooijevaar 2010).

Given the nature of healthcare and the sensitivity of healthcare information, it is typically incumbent upon regulatory and legislative government authorities to set up regulatory regimes and mandate their use (Huang et al. 2010). Generally, these regimes can facilitate the exchange of healthcare data and information amongst various healthcare stakeholders while also providing protection of patient rights including privacy. Credible and transparent regulatory rules can boost much needed investments in the pervasive e-health solutions industry, promote public confidence and the development of innovative and affordable pervasive e-health solutions, and stimulate industry research and development efforts (Kluge 2007). However, regulation can also impact the industry in a negative way. Increasing the regulatory compliance burden for stakeholders can increase the overall cost of operation which can impede the development and deployment of pervasive e-health solutions by acting as a barrier, and thus hampering pervasive e-health innovations (Ooijevaar 2010).

It is not until particular pervasive e-health solutions have been commercialized that their originators realize the problems that they pose to patients in particular and more broadly to society (MacInnes 2005). Therefore, "one needs to be concerned with societal, legal, and general economic factors" (MacInnes 2005, p. 7) when a service technology has reached a minimum standard of performance and reliability. This is a stage that is generally overlooked. That is, answers are needed for potential

legal, societal, and general economic concerns that pervasive e-health solutions may introduce (Goggin and Spurgeon 2005; MacInnes 2005; Parente 2000).

Even though regulation has been attracting the attention of policy makers as e-health matures, regulatory regimes around the globe are ill-equipped and moving slowly for dealing with these technologies (Ooijevaar 2010). In fact, there are growing concerns in extant literature that regulatory agencies have failed to keep abreast with developments in the pervasive e-health realm (Goldsmith 2000). Yet, extant research also shows that regulatory issues including legal barriers have been identified as a major force in the development and deployment of pervasive e-health solutions (Holliday and Tam 2004; Min et al. 2007). In fact, because extant policy frameworks that are inherited from specific national and international settings are "not well-placed to deal with contemporary communications technologies that blur the boundaries among these" (Goggin and Spurgeon 2005, p. 181), pervasive e-health solutions may not always fit within traditional healthcare regulation models (Ooijevaar 2010). For example, while in some regulatory regimes there may be legal obstacles that influence the reimbursement structures and payments when treatments are carried out in the e-health realm, in others there are limitations that mandate physical face-to-face physician–patient consultation thereby restricting the use of corresponding emerging e-health opportunities (Holliday and Tam 2004). These examples suggest that regulation can shape the form pervasive e-health solutions will (or will not) take (Ooijevaar 2010; Parente 2000).

This chapter attempts to answer the key research question "why do current regulatory regimens fail to facilitate e-health solution adoption and what can/should be done to address such barriers?" To address this we first leverage extant literature by using the institution-based view as a tool to investigate how regulation can affect the adoption of pervasive e-health solutions. Then, we illustrate with a case vignette and finally present an institutional regulatory framework that we argue is suitable to facilitate the adoption of the plethora of pervasive e-health solutions today.

19.2 Institution-Based View

The institution-based view suggests that institutions interact with organizations or networks of organizations by indicating which choices can be acceptable and supportable; that is, institutions reflect "humanly devised constraints that structure human interaction" (North 1990, p. 3). These constraints take the shape of "regulative, normative, and cognitive structures and activities that provide stability and meaning to social behavior" (Scott 1995, p. 33). In providing constraints and establishing the "rules of the game" (Peng et al. 2009, p. 64) institutional frameworks can help minimize uncertainty in the environment in which organizations operate. Institutional frameworks can comprise both formal and informal constraints. While formal constraints are regulatory, and thus coercive in nature, and include laws (e.g., economic liberalization), regulations (e.g., regulatory regime), and political rules (e.g., transparency and/or corruption), informal constraints include socially accepted

norms of behaviors that are entrenched in culture, ethical standards, and ideology (North 1990; Peng et al. 2009; Scott 1995).

In healthcare all stakeholders operate within the boundaries of a regulated environment (Peng et al. 2008, 2009). In extant literature both formal and informal aspects of the institutional context have been taken for granted and have been assumed away as "background" (Peng et al. 2008, p. 922) conditions (Barney et al. 2001). Further research is required examining the interactions between institutions and organizations in healthcare, particularly in contexts where pervasive e-health solutions are emerging and growing (Kluge 2007; Ooijevaar 2010). Understanding of these interactions and the institutional context is important, particularly in complex knowledge-intensive settings, such as healthcare and e-health, as it can help deepen current understanding concerning ensuing strategic behaviors of stakeholders. Institutional settings can create a conducive (or restrictive) atmosphere that determines an organization's behavior in its market. It follows that the development of pervasive e-health solutions may be better understood with a full examination of the institutional setting where organizations interact in attempts to achieve their objectives. In this chapter, we focus on the formal aspects of the institution-based view in the healthcare industry with particular reference to pervasive e-health. These aspects are encapsulated in a regulatory regime which is "a form of public policy" (Wilks 1996) that includes monitoring and intervention in order to remedy any form of perceived social injustice (Benoliel 2003).

19.3 Regulatory Issues

This section discusses prominent relevant regulatory issues including privacy, quality of online health content, and access to development resources.

19.3.1 Privacy

Privacy regulation as it pertains to pervasive e-health solutions needs to establish that special security measures are undertaken by healthcare providers to ensure that patient information is not inadvertently disclosed or leaked to or even shared with any stakeholder without the patient's explicit agreement (Boulding 2000). Such obligation of healthcare providers that holds personal identifiable health information to protect a person's privacy is commonly referred to as confidentiality (Lumpkin 2000). That is, holders of personal identifiable health information can only share such information on the basis of fair information practices and established regulation (Lumpkin 2000).

Another important concept related to privacy and confidentiality is that of security which concerns the extent to which "information can be stored with access limited to those who are authorized" (Lumpkin 2000). With security, personal identifiable health information needs to be protected while in storage (e.g., in a

hard-disk drive or backup devices) or in transit from one location to another via networked computers or the Internet (i.e., being emailed). Whether in storage or in transit health information needs to be protected against vulnerabilities (e.g., hacker attacks) using technologies such as encryption which have been proven to help achieve confidentiality, authentication, and message integrity (Lumpkin 2000). For example, public key infrastructure and certification authorities which commonly use public key cryptography to encrypt and decrypt mobile transmissions and authenticate both patients and healthcare providers.

Ironically, the same information practices which provide value to both patients and healthcare providers also cause privacy concerns. Some of these concerns include: the type of information that can be collected about patients and the ways in which it will be protected; the stakeholders and entities that can access this information and their accountability; and the ways in which the information will be used. In healthcare settings, where pervasive e-health solutions are used, a trusting environment can be encapsulated in perceived credibility (Lin and Wang 2005). Evidence shows that there is a significant direct relationship between perceived credibility and the intention to adopt pervasive e-health solutions (Lin and Wang 2005).

19.3.2 Quality of Online Health Content

Online health content quality concerns websites that provide medical advice or distribute medical information or healthcare education to patients ubiquitously (Bodkin and Miaoulis 2007; Houston et al. 2003). Patients demand and can have both synchronous and asynchronous access to scientific evidence, online doctors, educational materials, support groups, and online counseling (Cudore and Bobrowski 2003; Paris and Ferranti 2001). Typically online health content sites offer free information concerning disease treatments, wellness, and lifestyle management programs. Quality health content is important because well-informed patients can become productive participants and take responsibility in their healthcare and treatment regimen. There are, however, growing concerns that this information might be incomplete, incorrect, biased, or even misleading since the sites that offer it often rely heavily on sponsorship and advertising revenues from sponsoring organizations such as pharmaceutical companies or even private hospitals (Eysenbach 2000).

While there are debates in the literature supporting both forms of outright government regulation and industry self-regulation, there is general agreement that the perceived quality of online health content can impact on patient trust which can, in turn, adversely affect patient's confidence in these websites and their intentions to interact with them. This suggests that some form of regulation that attempts to rate content quality is necessary (Huang et al. 2010). Whether implemented by government regulators, industry associations, or third party accreditation agencies, online health content quality should be measured against quality assurance and compliance criteria that are set by credible and authoritative bodies that aim at filtering content for compliance and quality assurance before it is made publicly available (Terry 2002).

19.3.3 Access to Development Resources

Government organizations and industry associations can also facilitate the regulation of pervasive e-health solutions by assisting with knowledge development and deployment, subsidies, and standardization.

Knowledge development. The creation of technical and business knowledge underlying the development of pervasive health content and services is essential for the success of emerging areas such as e-health. Currently, while evidence suggests that many e-health content providers have exhibited a huge interest for distributing e-health content electronically via the Internet or mobile channels, the knowledge concerning the ways that such content can be adequately formatted is limited (King et al. 1994).

Knowledge deployment. Once built, development knowledge and technical know-how needs to be deployed and this is important not only for building awareness amongst stakeholders but also for showing them how e-health business models operate. Government organizations and industry associations could become proactive in undertaking additional knowledge deployment measures including education and training. These measures can help pervasive e-health service developers acquire the necessary knowledge and learn about the ways that they can format and structure e-health content and services for various channels (e.g., mobile), and to distribute to patients.

Subsidies. Often governments, industry associations, and other powerful players in the market may provide subsidies to players in emerging industries such as e-health which can help fund innovative pervasive e-health solutions, and research and development initiatives (King et al. 1994).

Standardization. It involves developing standards or local practices that can be adopted by all stakeholders involved in the provision of pervasive e-health solutions and limiting the use of other options (King et al. 1994; Lyytinen and Damsgaard 2001). Lack of industry standards can make the development of pervasive e-health solutions prohibitively costly.

19.4 DiaMonD: Case Vignette

Chronic diseases are generally incurable diseases, and are said to be the greatest threat to the nation's health and to its health delivery system (Geisler and Wickramasinghe 2009; Bali et al. 2013). There are five major chronic diseases: cardiovascular diseases (hypertension, heart disease, congestive heart disease), strokes, asthma, cancer, and diabetes (some add a sixth chronic disease, arthritis). These chronic diseases account for 83 % of healthcare expenditure in the general population (AIHW 2010).

The focus of this case vignette is on the chronic disease of diabetes. Diabetes is characterized by high levels of blood glucose, resulting from defects in the production of insulin. Regular monitoring of diabetes is a necessary part of controlling the disease and keeping it from becoming life threatening. To effectively and efficiently monitor diabetic patients, there is a role for wireless technologies. They can provide the means to enable affordable superior monitoring anywhere and anytime, thereby allowing the patient to enjoy a quality lifestyle (Rachlis 2006).

19.5 The DiaMonD Solution

INET International Inc., a technology company from Canada, has developed a workable system which connects handheld devices to a stationary center and which allows for the transfer of medical data. This system provides the medical provider with the capability to interface with patients by their use of a cellular telephone. We call this pervasive e-health solution the DiaMonD (diabetes monitoring device) solution

The DiaMonD solution is anchored in the use of a specially equipped cell phone and the installation of a secure wireless application that allows patients to monitor glucose levels and to immediately transfer the data to their care provider (Goldberg 2002a, b, c). The physician or nurse uses a handheld device such as a PDA (Personal Digital Assistant) which is connected to a wireless network to confidentially access, evaluate, and act on the patient's data.

Moreover, the solution calls for the patient to enter readings from the glucose monitor into the special cell phone. This requires the ability to read the data from the monitor and to input the numbers into the cell phone. In the past, INET considered the possibility of the direct reading of the glucose monitor into the special cell phone by utilizing Bluetooth technology. However, the company soon discovered that this significantly limited the pervasiveness of the technology since currently there are very few glucose monitors with embedded Bluetooth technology. The important issue to remember is that the INET approach is based on using cell phone technology that the patient is already using and is familiar with its features; that is, a truly pervasive solution.

Following the success of this solution in Canada, the authors attempted to investigate the possibilities of implementing this solution into the Australian healthcare context (Wickramasinghe et al. 2011; Goldberg 2002a, b, c). The Australian healthcare system is not dissimilar to that in Canada; it has both a government-supported system and a private healthcare model. In addition, it also has state and federal jurisdictions. Figure 19.1 captures schematically the key aspects of the Australian healthcare delivery system.

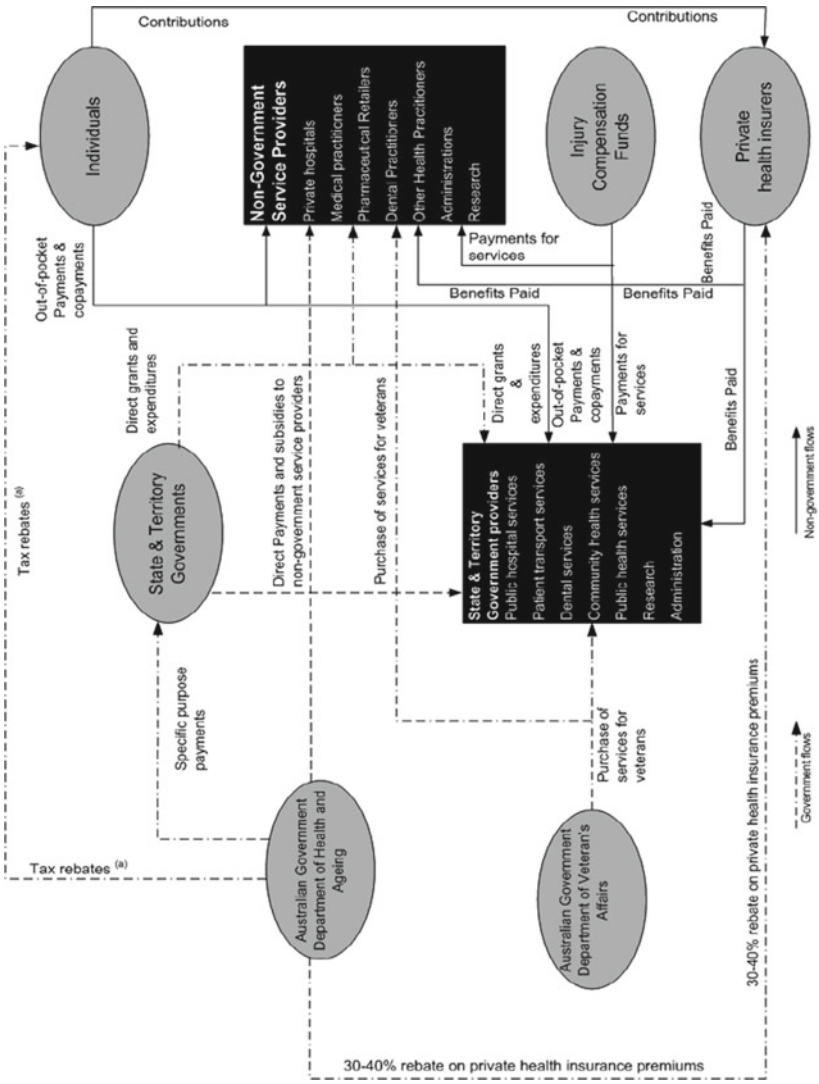

Fig. 19.1 The structure of Australian healthcare system (adopted from AIHW 2010)

19.6 Case Study Findings

Based on our exploratory case study research which subscribes to the recommendations of Yin (2003), several key emergent themes have become apparent with regard to the successful adoption of the DiaMonD solution into the Australian healthcare context. First, given the complex nature and structure of the healthcare delivery system in Australia, at present there exists no clear method to identify how the adoption of a wireless device can assist in providing medical advice that can be coded. Currently, such advice is coded as a consultation in a GP (general practitioner or primary care office). If a service or intervention cannot be coded then it cannot be billed which in turn means that all medical professionals connected to offering/supporting this application do not get reimbursed, while the less efficient and lower quality solutions of the GP visit do bring a set level of reimbursement. Moreover, if such an intervention cannot be coded, regulations and protocols surrounding duty of care and appropriate use cannot be established. Thus what our interim data is showing is that irrespective of how appropriate a pervasive e-health technology solution might be, if the regulatory framework cannot incorporate its existence and use, it is a huge barrier to its adoption. The situation becomes even further complicated when one adds the role of private versus public healthcare insurance. We note that in Canada, INET International Inc. has succeeded in getting the Canadian government to reimburse citizens who use a pervasive e-health solution such as DiaMonD to support their diabetes care. This is further evidence for us that a changed regulatory framework is an essential critical success factor for the adoption and large scale embracement of such pervasive e-health solutions.

19.7 An Institutional Framework for Pervasive e-Health Solutions

An institutional regulatory setting is generally implemented by organizations with legislative powers, such as regulatory bodies. These regulate the context in which pervasive e-health solutions are developed, deployed, and used. It is vital for such a framework to be well understood by all stakeholders that operate in a healthcare system. An institutional framework can provide regulatory certainty and predictability which is essential for all healthcare stakeholders. However, for emerging technology solutions in healthcare such as the pervasive e-health solutions, regulatory authorities typically have to deal with a multitude of heterogeneous networked stakeholders. Furthermore, as pervasive e-health solutions are dynamic and still undergoing rapid changes, regulatory definitions become a moving target which implies that regulators should constantly acquire industry-specific knowledge over time (Tallberg et al. 2007). Consequently, the institutional regulatory context in the domain of pervasive e-health solutions can become extremely complex and

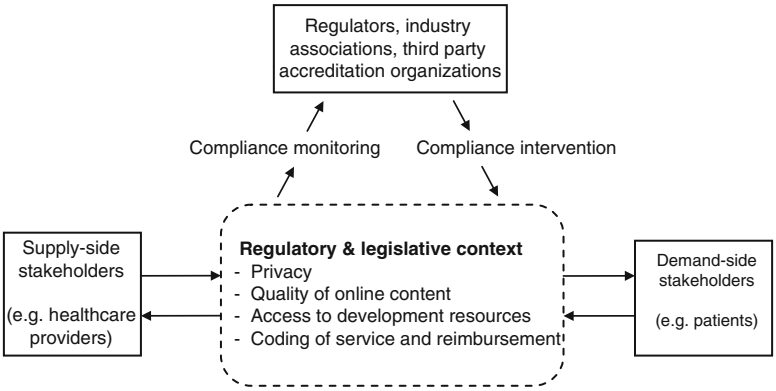

Fig. 19.2 Institutional regulatory framework for pervasive e-health solutions

achieving regulatory certainty may be an elusive or even unrealistic undertaking (Fisher and Harindranath 2004).

We argue that a co-regulation approach should be adopted for regulating pervasive e-health solutions. Accordingly, co-regulation represents close collaboration between regulatory bodies, including government organizations, industry associations, and third party accreditation bodies, and the e-health industry in terms of a mixture of direct monitoring and intervention through legislation, on the one hand, and complete self-regulation, on the other. There is no direct regulation, nor is there pure self-regulation. Regulatory bodies can provide the e-health industry with some parameters concerning the regulatory issues discussed in the previous section in which key problems are to be solved. It is, subsequently, the responsibility of the e-health industry to work out the details that best suit the specific technologies used and business models adopted. The role of the regulator is, thus, to allow the industry to apply its own codes in the first instance and to monitor the effectiveness and enforcement of those codes.

The diagram in Fig. 19.2 integrates the regulatory issues discussed previously with the notion of co-regulation to form the proposed institutional regulatory framework for the pervasive e-health solutions industry. This constitutes a contribution to the existing body of knowledge as it provides an integrative view of regulatory issues concerning the emerging pervasive e-health solutions industry. Figure 19.2 also shows that the institutional regulatory framework operates via compliance monitoring and intervention. First, monitoring may be implemented by establishing suitable reporting mechanisms. Second, intervention should only occur in cases of compliance violations or market failure.

With co-regulation, the e-health industry is empowered to take responsibility for participating in the development of its own regulation. Three major benefits emerge with this approach: first, regulation costs are likely to be significantly reduced; second, compliance is likely to occur naturally, and, therefore, regulation in itself is likely to be perceived to be less restrictive and onerous than in traditional regulation

models; third, industry-driven co-regulation also has the advantage to ensure that it is likely to remain appropriate and be responsive to changing market conditions and technology development and capable of delivering timely and transparent outcomes. Taken together, these advantages are likely to promote business activity, market integrity, and patient confidence in emerging pervasive e-health solutions.

19.8 Discussion and Conclusion

This chapter set out to answer the research question "why do current regulatory regimens fail to facilitate e-health solution adoption and what can/should be done to address such barriers?" To answer this question we first drew on existing literature. This not only served to provide the motivation and highlight the critical need but also assisted us in developing the appropriate themes for our exploratory case study research. In addition, we have presented our initial research findings from our research in progress case study, the DiaMonD solution. As noted by Yin (1994) such an approach of focusing on an exemplar case study is most prudent and appropriate for trying to uncover critical issues pertaining to a new phenomenon. While the research still continues, the findings to date clearly underscore the significant barrier posed by regulatory frameworks that have been designed before the development of pervasive e-health solutions and therefore are both archaic and inflexible to accommodate the potential and possibilities afforded to healthcare delivery by such solutions. We have subsequently discussed a proposed framework that provides the foundations for an appropriate regulatory structure. We argue that these encompass the interests of the main stakeholders operating in the e-health industry and given its dynamic and complex nature co-regulation is the most effective approach to minimize costs and enhance compliance.

We believe that this framework is the first of its kind, and, thus, it contributes to the existing body of knowledge which can be employed by both academics and practitioners alike. First, it can be invaluable to stakeholders in the pervasive e-health solutions industry in helping them improve their understanding of the institutional factors that enhance or constrain their positions in their value chain and industry. A deeper understanding of such factors can help stakeholders in many ways in the following: (1) Achieving a valuable competitive advantage. Stakeholders that exhibit compliance with regulatory rules that benefit e-health service users may achieve their trust more effectively than those who do not. (2) Providing stakeholders the opportunity to "achieve knowledge on legal issues, to stay away from legal areas in which processes are unclear, and to avoid related risks" (Kijl et al. 2005, pp. 66–67) which decreases potential transaction costs (Kijl et al. 2005). (3) Helping avoid unbalanced legal rights amongst stakeholders which can severely threaten businesses by causing otherwise innovative business practices to be illicit (Kijl et al. 2005). Second, regulatory and legislative influences can have direct implications on how pervasive e-health solutions and related business practices are

designed and how they operate at organizational, industrial, and institutional levels. Further, these influences can determine the nature of pervasive e-health solutions that can be offered and their diffusion trajectories amongst end-users or patients (MacInnes 2005).

Without a doubt, creating a solid institutional regulatory context in the fast evolving pervasive e-health solutions industry is an extremely difficult task. There are many reasons for this, including the highly complex nature of the networks and stakeholder relationships required to provide pervasive e-health solutions as well as the constantly evolving underlying technologies. However, we close by noting that healthcare will never be able to enjoy the full power and potential of pervasive e-health solutions until this key issue is addressed and we close by calling for both scholars and practitioners alike for further research in this area.

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