Chapter 4
Regulating Pervasive e-Health Services

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Abstract While the development of pervasive e-health services is experiencing growth in many countries worldwide, existing regulatory regimes are ill-equipped for dealing with them. In this chapter, we investigate institutional regulatory factors that can impact pervasive e-health services. These factors are important as they can shape both the nature of these services and their diffusion trajectory. We argue that coregulation, a mixture of direct monitoring and intervention of regulators through legislation and complete industry self-regulation, can be an effective approach for regulating the pervasive e-health services industry. Given the complex and dynamic nature of this industry, coregulation can minimize monitoring costs and enhance compliance.

Keywords e-health · Regulation · Coregulation · Institution-based view

4.1 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; Piotti and Macome 2007; Sohn and Lee 2007). Examples of pervasive e-health services 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 services have the potential to generate enormous efficiencies and services quality as well as to reduce medical errors (Anderson 2007; Hsu et al. 2005).

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Delivering pervasive e-health services 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 services may involve several heterogeneous stakeholders that are often embedded in various technological, economic, and social settings (Holliday and Tam 2004). In order 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 (Camponovo and Pigneur 2003; Kluge 2007; Rao Hill and Troshani 2010; Troshani and Rao Hill 2009). These requirements constitute a regulatory regime, which can operate at either industrial, national, or international levels and can influence, direct, limit, or prohibit any activity undertaken by stakeholders operating in the pervasive e-health services industry (Holliday and Tam 2004; Hsu et al. 2005; 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 (Huang et al. 2010). Credible and transparent regulatory rules can boost much needed investments in the pervasive e-health services industry, promote public confidence and the development of innovative and affordable pervasive e-health solutions and stimulate industry research and development efforts (Kluge 2007; Verikoukis et al. 2006). 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 services by acting as a barrier and thus hampering pervasive e-health innovations (Fisher and Harindranath 2004; Folger 2001; Hsu et al. 2005; Ooijevaar 2010; Tongia 2007).

It is not until particular pervasive e-health services 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 (Hsu et al. 2005; 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 (Fried et al. 2000; 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 services (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 services 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 (e.g., Internet), 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).

In this chapter, we aim to address these concerns by developing an institutional regulatory framework. Our objective is to leverage on extant literature by using the institution-based view as a tool to investigate how regulation can affect pervasive e-health solutions. This chapter is structured as follows. First, we examine the institution-based view as a theoretical base after which we address prominent regulatory issues as they apply to pervasive e-health services. The chapter culminates with an institutional regulatory framework for pervasive e-health services. We conclude by discussing managerial implications and proposing directions for future research.

4.2 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).

There is agreement amongst scholars that institutions are more than background conditions (Ingram and Silverman 2002; Peng et al. 2008, 2009) in that they "directly determine what arrows a firm has in its quiver as it struggles to formulate and implement strategy" (Ingram and Silverman 2002, p. 20). That is, actions that are carried out and outcomes that are sought by organizations and networks of organizations must conform to formal and informal rules of what can and cannot

be done (Lu et al. 2003). Thus, the manner in which organizational stakeholders behave in their environment and their strategic choices are a reflection of the formal and information constraints of the institutional context that practitioners and decision-makers face (Oliver 1997; Peng 2002; Scott 1995).

In the healthcare industry, all stakeholders operate within the boundary 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 2001; Barney et al. 2001; Narayanan and Fahey 2005). Further research is required examining the interactions between institutions and organizations in the healthcare industry, particularly in contexts where pervasive e-health services are growing (Kluge 2007; Narayanan and Fahey 2005; Ooijevaar 2010). However, 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 (Ingram and Silverman 2002). 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. Furthermore, institutional frameworks can also determine the nature of the networks that organizations build (Meyer et al. 2009). Cost and risks of being involved in organizational networks for developing pervasive e-health solutions are likely to decrease (Meyer et al. 2009) as transparency and predictability increase and information asymmetry is reduced (Peng and Heath 1996). Conversely, where institutional frameworks are weaker and information asymmetries exist, their presence maybe "conspicuous," which can increase both the costs and risks of becoming involved in the development of e-health solutions (Meyer et al. 2009).

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; Fisher and Harindranath 2004). Thus, a regulatory regime is meant to protect patients, but also to be reactive to market dynamics in order not to over- or underregulate. On the one hand, overregulation can bring several adverse outcomes to the industry including high engagement costs and possible duplicative and confusing rules for all stakeholders including patients (AMTA 2005; Benoliel 2003). On the other hand, underregulation can also lead to adverse outcomes for the healthcare industry including patient exposure to unfair and illicit practices (Benoliel 2003). The manner in which stakeholder interactions are influenced by the regulatory regime has direct implications on the healthcare industry and on the manner in which pervasive e-health solutions are developed and deployed.

4.3 Regulatory Issues

In this section, we discuss prominent regulatory issues as they impact pervasive e-health services including privacy, quality of online health content, and access to development resources.

4.3.1 Privacy

Privacy is the right of individuals to be left alone. It includes information privacy, which represents the individual's desire to have access to and exercise control over their personal information that is collected, held, and used by healthcare providers (Minch 2004; Newman and Bach 2004; Ng-Kruelle et al. 2001). Privacy has been and still is one of the core issues in healthcare generally and pervasive e-health services more specifically (Boulding 2000). Because many pervasive e-health services rely on the Internet and/or wireless networks as data delivery infrastructures, there is unease and concerns of possible patient privacy violations amongst many stakeholders particularly when data are sensitive in nature (e.g., private patient data and health information; Wen and Tan 2002).

Privacy regulation as it pertains to pervasive e-health services 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 or advance consent (e.g., "opt in"; Boulding 2000; Jones et al. 2004). Such obligation of healthcare providers that hold 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 regulations (Lumpkin 2000).

Ineffective and inadequate regulatory conditions can be exploited for illicit purposes by unethical stakeholders that interface with patients (Ubacht 2004). Consequently, the patients' perceived credibility and trust on pervasive e-health solutions and more broadly in the healthcare system can be adversely affected, if undesirable opportunistic behaviors occur (Rao and Troshani 2007; Troshani and Rao Hill 2008). Specific legislation and regulation is, therefore, required for safeguarding patients' rights to privacy (Boulding 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 it is 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 e-mailed). 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 (Galanxhi-Janaqi and Nah 2004;

Lu et al. 2003; 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.

Privacy and the manner in which it is achieved by way of confidentiality and security are critical to create a trusting healthcare environment as well as patient confidence in pervasive e-health services. Trust determines the patients' expectations in their relationships with their healthcare providers, and it increases their perceived certainty concerning the provider's expected behavior. More generally, trust is essential in all economic activities where undesirable opportunistic behavior is likely to occur (Gefen et al. 2003). Trust becomes particularly vital in healthcare settings where pervasive e-health solutions are in use and where situational factors such as uncertainty or risk and information asymmetry are present (Ba and Pavlou 2002). On the one hand, patients may be unable to judge the trustworthiness of healthcare providers, and on the other, the latter can also easily take advantage of the former by engaging in harmful opportunistic behaviors. For example, healthcare providers can engage in illicit behaviors including selling or sharing the personal information of its patients.

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 (Galanxhi-Janaqi and Nah 2004). In healthcare settings where pervasive e-health services are used, a trusting environment can be encapsulated in perceived credibility (Lin and Wang 2005; Lin and Lee 2005; Wang et al. 2003). Evidence shows that there is a significant direct relationship between perceived credibility and the intention to adopt pervasive e-health services (Lin and Wang 2005).

4.3.2 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 (McKnight et al. 2002). 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). For example, filtering can ensure that: (1) editorially independent health content is not unduly influenced by sponsorship and advertising content, and that website design and layout clearly and unambiguously indicates the differences between these two types of content; (2) websites clearly explain to online patients the limitations and risks of using online health advice exclusively to address their medical problems; and (3) websites provide convenient mechanisms for patients to provide feedback (Boulding 2000; Eysenbach 2000). While additional functionality can be tested for compliance, the general purpose is to protect patients from dubious practices and educate content providers about their responsibilities.

4.3.3 Access to Development Resources

Government organizations and industry associations can also facilitate the regulation of pervasive e-health services by assisting with knowledge development and deployment, subsidies, and standardization. These can assist health content providers and e-health services developers create compliant applications and content repositories.

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. Funding research or coordinating taskforces that build this knowledge are two possible options for e-health industry stakeholders (Choudhrie et al. 2003; Damsgaard and Lyytinen 2001; 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. As part of knowledge deployment, many argue the need for publicizing success stories of exemplar e-health services providers in the local media and industry newsletters. Publicized success stories set examples and could help new entrants in the industry learn about critical success factors and lessons learnt from past experiences.

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 services, and research and development initiatives (Choudhrie et al. 2003; Damsgaard and Lyytinen 2001; King et al. 1994; Muzzi and Kautz 2004).

Standardization Involves developing standards or local practices that can be adopted by all stakeholders involved in the provision of pervasive e-health services and limiting the use of other options (Choudhrie et al. 2003; Damsgaard and Lyytinen 2001; King et al. 1994; Lyytinen and Damsgaard 2001). This is essential for the development and widespread diffusion of these services. The lack of industry standards can make the development of pervasive e-health services prohibitively costly.

4.4 An Institutional Framework for Pervasive e-Health Services

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 services 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. Compliance failure can have serious consequences that can range from fines, to reputation damage or even operation license loss (Fisher and Harindranath 2004). Therefore, the institutional framework can provide regulatory certainty and predictability, which is essential for all healthcare stakeholders (Fisher and Harindranath 2004; Niemeyer 2001). However, for emerging industries such as the pervasive e-health solutions, regulatory authorities have to deal with a multitude of heterogeneous networked stakeholders. Furthermore, as pervasive e-health services 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; Ubacht 2004). Consequently, the institutional regulatory context in the domain of pervasive e-health services can become extremely complex and achieving regulatory certainty may be an elusive undertaking or even unrealistic (Fisher and Harindranath 2004).

We argue that a coregulation approach may be adopted for regulating pervasive e-health services. Accordingly, coregulation 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

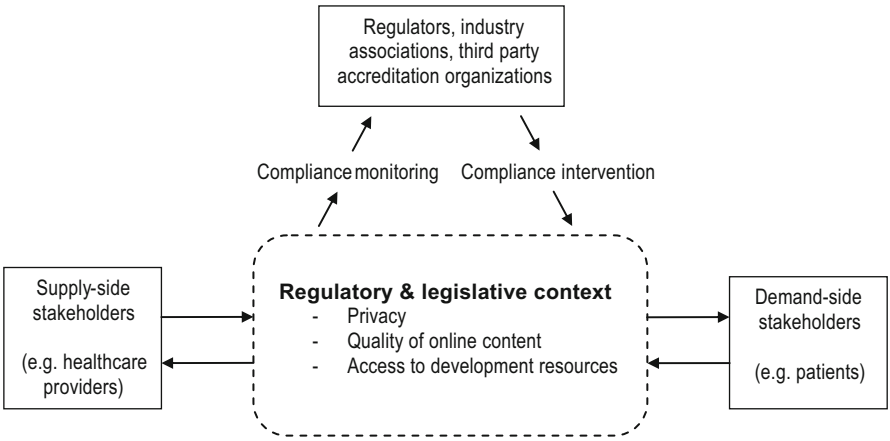

Fig. 4.1 Institutional regulatory framework for pervasive e-health services

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 pervasive e-health services 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. 4.1 integrates the regulatory issues discussed previously with the notion of coregulation to form the proposed institutional regulatory framework for the pervasive e-health services 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 services industry. The issues included in this framework are consistent with the ideas presented in the work of Boulding (2000) and Terry (2002). The institutional context issues covered by the proposed framework are feasible for two reasons. First, they feature heavily in the literature as important prerequisites for the effective regulation of the pervasive e-health services industry. Second, these issues have been implemented in various forms in other industries.

Figure 4.1 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. Regulatory issues included in our framework impact all stakeholders in the pervasive e-health services industry. It follows that during compliance, stakeholder interaction is likely to be frictionless.

However, if conflicts do occur, regulators, industry associations, or third party accreditation organizations can intervene. In any case, the development and operation of the proposed institutional regulatory framework should not interfere with or distort future market or industry developments.

With coregulation, the pervasive e-health services 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; and third, industry-driven coregulation 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 services.

4.5 Conclusion, Implications, and Future Research

Creating a solid institutional regulatory context in the fast evolving pervasive e-health services industry can be 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 services as well as the constantly evolving underlying technologies. There are growing calls from both scholars and practitioners alike for further research in this area. In response to these calls, this chapter draws on existing literature and it proposes an institutional regulatory framework suitable for the pervasive e-health services industry. We have first provided the motivation for further work in this area. We have subsequently discussed the proposed framework, which comprises three major components: first, privacy, including confidentiality and security, second, quality of online health content, and third, access to development resources, including knowledge development and deployment, subsidies, and standardization. We argue that these encompass the interests of the main stakeholders operating in the pervasive e-health services industry and given its dynamic and complex nature, coregulation 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 services 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: (1) achieving a valuable competitive advantage. Stakeholders that exhibit compliance with regulatory rules that benefit e-health services users may achieve their trust more effectively than those who do not (Killström et al. 2006; Meyer et al. 2009);

(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; Woolfson 2005); and (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; Killström et al. 2006; Meyer et al. 2009; Woolfson 2005). Second, regulatory and legislative influences can have direct implications on how pervasive e-health services and related business practices are designed and how they operate at organizational, industry, and institutional levels. Furthermore, these influences can determine the nature of pervasive e-health services that can be offered and their diffusion trajectories amongst end-users or patients (MacInnes 2005; Meyer et al. 2009; Spiller and Zelner 1997).

There are certain practical implications that can be derived from this discussion. First, the framework shows that critical dependencies exist amongst stakeholders in their networks and the institutional context in which they operate. A deep understanding of the institutional context is critical for enabling the development and deployment of pervasive e-health services. Knowledge and appreciation of the importance of the institutional context factors discussed in this chapter may help healthcare providers to both design new services or enhance existing ones in order to both help patients and gain competitive advantage (Feldmann 2002). Second, our analysis also offers insights to proactive and reactive stakeholders about the manner in which they can interact with others without violating the existing institutional context. Third, understanding of institutional context factors in the pervasive e-health services industry can provide insights to marketers in designing high-quality and effective promotional campaigns for their new service offerings and by doing so promote the establishment of a trusting environment (Feldmann 2002; Xu 2007). For instance, marketing campaigns may emphasize privacy protection, etc. as a way of establishing and strengthening trust in the emerging pervasive e-health services industry.

While we have used extant research as a primary basis to make a contribution to current understanding of institutional regulatory factors operating in the pervasive e-health services, we also recognize that this review can be more comprehensive. We appreciate that a limitation of this study is that the institutional factors examined in this chapter were sourced by using secondary data, which suggest that the proposed framework may not be generalizeable or even exhaustive. Therefore, we propose that for using our institutional framework as a starting point further research is needed to both validate these factors and extend them further. In addition, further work should focus on enforcement mechanisms of the components of the framework. Third, different countries represent different regulatory jurisdictions (Verikoukis et al. 2006). As various supply-side stakeholders (e.g., healthcare providers) increasingly offer pervasive e-health services across national borders, further research is required for developing regulatory interfaces for transnational healthcare (Rao Hill and Troshani 2010; Troshani and Rao Hill 2009).

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