

# Pervasive Health and Regulatory Frameworks

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**Keywords:** Pervasive Computing, Pervasive Health, Mobile Health, Ambient Assisted Living, Regulatory Frameworks.

**Abstract:** Pervasive health deals with the application of pervasive computing for health and wellness management and its developments should be subject of regulatory oversight. The paper presents a general overview of pervasive health concepts and applications, and aims to verify the level of conformity of current developments with existing regulatory frameworks.

## 1 INTRODUCTION

Pervasive health has emerged as a specialization of *eHealth* and deals with the application of pervasive computing (Cook et al., 2009) for health and wellness management, aiming to make health care more seamlessly to our everyday life (Korhonen and Barddram, 2004).

A special attention should be given to *eHealth* appliances and applications that, by nature and if critical aspects are not safeguarded, have the potential to be a source of harm in normal use or if misused. This means pervasive health developments should not merely consider a technological perspective but must combine both the technological and the societal requirements.

One of the most important requirements that should be considered is the level of conformity with regulatory frameworks. Therefore, the paper presents a study based on literature review aiming to systematize concepts related to pervasive health and to verify the level of conformity of current developments with regulatory guidelines and requirements.

In addition to this section (Introduction), the paper comprises three more sections: Literature Review, Discussion and Conclusions.

## 2 LITERATURE REVIEW

During the last two decades, there was a considerable increase in the capacity to develop and manufacture systems that employ smart components highly integrated and miniaturized (Cook and Das, 2012). As a consequence of this remarkable development, pervasive computing is nowadays part of our everyday and social life, and impacts our surrounding environments. Pervasive computing is a multidisciplinary research field aiming the development of appliances and applications to allow convenient access to relevant information and services. It involves technologically oriented research on topics like embedded hardware, software, middleware, wireless communications or cloud computing among others. There are three important enabling technologies related to pervasive computing: ubiquitous computing, ubiquitous communication and ubiquitous user interaction (Korhonen and Barddram, 2004).

According to the vision of Weiser (1993), ubiquitous computing aims to enhance the computer use by bringing computing devices into everyday life (*e.g.* integration of computing power and sensing features into anything, including everyday objects like white goods, toys or furniture), making them available throughout the physical environment in such a way that the users would not notice their presence. In turn, ubiquitous communication comprises multiple technologies to allow the

interaction among multiple devices anytime anywhere. Finally, since ubiquitous computing allows the individuals, within a single session, to interact with multiple devices, user-friendly interfaces are required. These should support natural interaction (*e.g.* speech or gestures) and should consider the preferences of the users.

A pervasive computing infrastructure, hence, is a seamless environment of computing, networking, and natural user interfaces to provide applications supported by a wide range of appliances with unobtrusive, continuous and reliable connectivity. On the other hand, the Ambient Intelligence concept (Augusto, 2008) shares with pervasive computing the vision of technology being embedded and invisible in our natural surroundings, available when needed and providing an effortless interaction. However, Ambient Intelligence also includes the adaptation to the users and the capacity of providing context awareness (Augusto et al., 2012). Therefore, pervasive technologies together with artificial intelligence are used to provide embedded intelligent devices that can sense the environment state, perceive the presence of human beings, track their activities and learn their preferences. For that, artificial intelligence technology is being used not to emulate human intelligence, a goal of its developments in the past, but to combine the synergies of humans and pervasive technologies (Mann, 2001).

The research related to pervasive computing and the associated intelligent components has matured to the point where tangible prototype test beds are becoming a commonplace (Cook and Das, 2012).

## 2.1 Pervasive Health

One of the most important application areas of pervasive computing is health care. Pervasive health can contribute, with different roles, to personalize health and wellness services promoting an evolution from a medical approach to individual-centric operational models, in which the individual becomes an active partner in the care process (Korhonen and Bardram, 2004). The term personalization can be related to different concepts, such as personalized medicine, *i.e.* individual customization of diagnosis and therapy based on information related to the genomic profile of each patient (Genet et al., 2011), monitoring personalization (*e.g.* using wearable sensors), or personalized care (*i.e.* care services delivered independent of time and location according to choice and preferences of the individuals (Blobel, 2012; Rigby, 2012), allowing

them the possibility of being actively involved in their health and care pathway).

### 2.1.1 Monitoring Applications

The advances on sensing technology make it possible the development of mobile and wearable sensors able to continuously monitor physiological parameters, activities and behaviours in out-hospital conditions. Additionally, the existing ubiquitous communications make possible anywhere, anytime transfer and access of health-related information such as measurement data or medical knowledge.

Therefore, a typical pervasive health application consists in monitoring health conditions or the progress of some illness, namely chronic diseases.

For monitoring applications, sensors are required to collect relevant physiological data. A wide range of sensors, including pressure and thermal sensors, might be used to measure blood pressure, temperature of the body, blood glucose, heart sound, heart rate, respiration, blood oxygen saturation or perspiration. Some sensors are non-invasive, but various biological signals require invasive sensors such as electrodes. Non-invasive wearable and textile devices present a considerable potential and, for instance, they allow to measure physiological parameters through the use of techniques such as infrared or optical sensing (Rashidi and Mihailidis, 2013).

However, health conditions are influenced by a wide range of factors distributed across different levels of impact that interact with each other continuously and in subtle ways (Glass and McAtee 2006). These include behavioural (*e.g.* data associated with medication adherence), social (*e.g.* data associated with activities and participation) and environmental factors. For instance, a diet plan is influenced by an individual's health conditions as well as behavioural factors (*e.g.* physical activity) and environmental factors that either hinder or facilitate these behaviour factors (Alvarelhão *et al.* 2012). In this particular, it is important to consider mobile and wearable sensors not only able to monitor physiological parameters, but also to monitor activities and behaviours (*e.g.* recognizing social activity or identifying any changes in activities might be an indicator of decline) (Queirós et al., 2013a).

Monitoring physiological parameters, together with monitoring daily activities (*i.e.* identifying consistency and completeness in these activities), to assess, in a naturalistic and continuous way, health and cognitive status (Rashidi and Mihailidis, 2013;

Suzuki et al., 2007) might help to automate assistance and prevent accidents or disease exacerbations.

Concerning emergency situations, monitoring patients and providing alerts for health care providers might facilitate prompt intervention. In this respect, pervasive health applications might improve access to care, particularly when time is vital (e.g. in stroke or acute trauma).

As falls constitute an important cause of morbidity and mortality in older adults, fall detection is another application area (Rashidi and Mihailidis, 2013). It can be envisaged various types of fall detection systems based on wearable devices (e.g. devices such as accelerometers and gyroscopes to measure posture and motion), ambience sensors (e.g. pressure or floor vibration detection sensors) or real time video and audio analysis (Lai et al., 2011; Rashidi and Mihailidis, 2013).

### 2.1.2 Other Applications

Considering the envisioning goal of personalized care, pervasive health should be much more than monitoring applications. Pervasive health also includes a wide range of applications, namely preventive applications, applications to enhance the communication between care providers and patients and between caregivers or applications to support frail citizens, such as elderly people, to live independently and with wellness.

The preventive measures seek to act in several dimensions (social, family and individual dimensions), to contribute to the adoption of active and healthy lifestyles, to give advice and to promote adherence to long term therapies or to facilitate the early detection of potential problems (Alcaniz et al., 2009; Botella, 2009). Still, in terms of prevention, the information provided by intelligent components makes possible to tailor efficient interventions (e.g. intelligent prediction of the moment and place when intervention can optimally be delivered).

In some instances, pervasive health applications might promote the engagement with primary care, replace time-consuming visits and provide rehabilitation care or assistance (Alcaniz et al., 2009). This might benefit specialties that require frequent follow-up care. For instance, specialized training systems useful to treat stroke patients can be controlled by remote physiotherapists with access to the results, namely in terms of exercise levels (Teixeira et al., 2013).

Furthermore, it should be understood how pervasive health might facilitate the individuals to be

actively involved in their health and care pathway. In patients with chronic diseases, applications might allow them to receive information to better control their diseases. For instance, educational information about pain (e.g. general information, symptoms or causes) can be provided, as well as information relating to individual health conditions or pain relief (e.g. relaxation techniques or pain reduction techniques, such as acupuncture), through a variety of media, including images, video or animations (Rosser and Eccleston, 2011). Furthermore, applications can be used for cognitive rehabilitation and to support older adults suffering from cognitive decline (Cruz et al., 2014).

Other applications promote self-management, namely lifestyle management, prescriptions reminders, care appointments management, health care record access (e.g. patients having the ability to securely share their health information with clinicians or others, as needed) or help the patients to contribute with observations of their daily living (e.g. Personal Health Records - PHR).

Within the pervasive health paradigm, different groups of technologies, although focused in specific aspects, can contribute to an idealized model of care personalization. Among these groups, mobile health (*mHealth*) (Boulos et al., 2014) and Ambient Assisted Living (AAL) (i.e. the development of the Ambient Intelligence concept to enable elderly with specific demands to live longer in their natural environment) (Queirós et al. 2013a; Rashidi and Mihailidis, 2013) have been object of relevant research. Although, there is a significant overlap between the two concepts, i.e. there are applications that can be classified as *mHealth* or AAL, *mHealth* emphasizes mobility and considers applications to support the care of the patients in their homes as well as applications to be used in clinical environments for professional activities (e.g. training of medical students), while AAL might include static devices and intends to support elderly living at home not only in aspects related to health care but also independent living.

## 2.2 Mobile Health

The World Health Organization has defined *mHealth* as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” (WHO, 2010: 6). Therefore, *mHealth* deals with the use of mobile communication devices, such as smartphones or tablets to support health services (Mosa, Yoo and

Sheets, 2012), both in terms of disease and wellbeing management.

Since health care services involve multiple locations (*e.g.* clinics, outpatient's services or patients' homes) they are highly mobile in nature (Mosa, Yoo and Sheets, 2012). This means *mHealth* might support communication and collaboration among different health professionals in activities related to disease diagnosis, drug reference, medical calculations or literature search, among others.

The pervasive computing landscape includes massive numbers of portable devices (*e.g.* smartphones or tablets) that gather and store information. Current smartphones are fairly robust, truly pervasive and accessible, - they are accessible to over 90% of the global population (Cook and Das, 2012; ITU, 2011) - and they provide ubiquitous user interfaces and have the ability to collect, store and communicate information (Cook and Das, 2012). Therefore, they are considerable relevant to *mHealth*. Furthermore, an interesting feature of smartphone devices is the availability of short-distance wireless data transmission, such as Bluetooth (Mosa et al., 2012). This enables the smartphone applications to work with a wide range of hardware devices (*e.g.* glucose meters, pulse oximeter or thermometers) from different vendors.

Concerning health care professionals, smartphones are being used to perform mobile diagnostic tests, to access Electronic Health Records (EHR) and other patient information, to support decisions related to drugs prescription or to provide new means of medical education and teaching (Boulos et al., 2014), among other activities.

Smartphone patient oriented applications might deliver health care services for patients with chronic conditions (Mosa, Yoo and Sheets, 2012). Examples of chronic disease management applications include self-management (*e.g.* self-management of the chronic obstructive pulmonary disease) (Marshall et al., 2008), expert feedback to patients based on their input (*e.g.* helping diabetic patients by calculating the dose of insulin based on carbohydrate intake, pre-meal blood glucose, and anticipated physical activity reported) (Charpentier et al., 2011), support to rehabilitation programs (*e.g.* real-time remote monitoring of the heart rate during rehabilitation exercises), measurement of physical activity level (Bexelius et al., 2010), integration of data from wearable health sensors (Boulos et al., 2011) or even helping patients to practice meditation (Mosa et al., 2012; Sarasohn-Kahn, 2010).

Furthermore, the scientific literature refers a considerable number of fall detection applications

using smartphones together with wearable tri-axial accelerometers (Mosa, Yoo and Sheets, 2012) and applications being used for pain management (Boulos et al., 2014; Mosa et al., 2012; Rosser and Eccleston, 2011).

Smartphone technology has the potential to provide real-time pain reporting, which is relevant, since pain is a diverse and prevalent state that is often hard for patients to describe and, therefore, difficult for caregivers to diagnose and treat (Mosa, Yoo and Sheets, 2012). A systematic review of smartphone applications conducted by Rosser and Eccleston (2011) analyses 111 smartphones-based application targeting various types of pain and different health conditions with pain implications, including applications that provide basic measurement of pain level (either using visual analogue scales or Wong-Baker pain faces scales) or diary tracking applications (Rosser and Eccleston, 2011). The focus of these applications can be divided into general pain (*i.e.* unspecified generic pain), specified pain syndromes (*e.g.* headache and back, neck, chest, dental or menstrual pain) or chronic pain (*e.g.* specific long-term health conditions such as fibromyalgia, arthritis and degenerative disc disease). Predominantly the purpose of the reported applications was pain relief or educational information about pain (*e.g.* general information, symptoms or causes). Additionally, some applications present pain reduction techniques (*e.g.* information on acupuncture, acupressure tutorials and headache prevention), relaxation techniques (*e.g.* meditation or massage tutorials) and skills training exercises for relieving tension, while others employ attributes of the smartphones to reduce pain (*e.g.* use of the vibration capacity of the smartphone as a relaxation mechanism) (Rosser and Eccleston, 2011).

### 2.3 Ambient Assisted Living

AAL is an emerging field that had attracted global interest, both in academia and industry, for the potential of its solutions, namely in terms of health care applications (Augusto et al., 2012). AAL concerns and developments are in line with the World Health Organization active ageing framework (WHO, 2002). Active ageing emphasizes an enabling positive thinking. While a disabling perspective leads to isolation and dependence and increases the needs of older people, an enabling view focuses on maintaining the older adults' functioning and expanding their participation in all aspects of the society. Enabling instruments such as

ALL are essential, considering the fact that as people age their quality of life (*i.e.* perception of the position in life in the context of the surrounding culture and value system) is largely determined by their ability to maintain autonomy (*i.e.* ability to control, cope with and make personal decisions on a day-to-day basis) and independence (*i.e.* the ability to perform functions related to daily living with no or little help from others) (WHO, 2002).

AAL intends to address needs of older adults and respective major diseases (Heath, 2008): cardiovascular disease, hypertension, stroke, diabetes, cancer, chronic obstructive pulmonary disease, musculoskeletal conditions, mental health conditions or blindness and visual impairment. Meeting the specific individual needs, namely providing care services at the home of the individuals together with intelligent applications, is one of the main strategies to guarantee independent living of older people (Kleinberger, 2007). Considering this context, important AAL goals are to promote personal (*e.g.* medication reminder) and distance support (*e.g.* tele rehabilitation programs) or to provide the caregiver with accurate, up to date information so that the right care at the right time can be delivered (*e.g.* continuous monitoring of physiological parameters or behaviours, emotions and activities) (Kapoor, 2010; Mirarmandehi, 2010). These goals can contribute to the overall effort to provide personalized and affordable access to essential services with efficacy and efficiency (Queirós *et al.*, 2013b).

A combination of conventional service provision together with intelligent applications have been designed in a considerable number of AAL projects (Queirós *et al.*, 2013a) to contribute for independent living.

Dependency is strongly related to the ability to perform Activities of Daily Living (ADL). The impossibility of performing basic ADL (*e.g.* personal hygiene, dressing and undressing, self-feeding or ambulation) and instrumental ADL (*e.g.* housekeeping, managing money, shopping or clothing, use of telephone and other forms of communication or transportation within the community) usually implies that the individual (although, in some circumstances, living alone) is on the border of dependency and needs help and support. It is clear that technology cannot supply these needs completely, but it can mitigate the dependency impacts by means of specialized solutions (*e.g.* a nutritional adviser or an electronic commerce solution for shopping) with the general aim of increasing the performance of older adults in

their activities and participation.

All these AAL applications can maintain, or even increase, the confidence of the individual in their domestic spaces and thus increase their well-being at home in general. However, assistance applications must also address less tangible values such as participation. In particular, they should consider, in a comprehensive way, the possibility of the technologies facilitate social, religious, civic and political participation of older citizens.

### 3 DISCUSSION

Pervasive health has a huge potential in terms of innovative solutions that might mitigate, in political, economic and social terms, the consequences of the contemporary demographic ageing.

A relevant finding of the study is that the developments related to pervasive health are still focused on technology and often potential users, both patients and professionals, are not conveniently involved.

For instance, the systematic review conducted by Rosser and Eccleston (2011) reports a significant percentage of applications (86%) with no health-care professional involvement, either as the application creator or as a source of information or evaluation of the application content. Furthermore, a systematic literature review related to AAL (Queirós *et al.*, 2013a) shows a high percentage of articles on specific components (87%) when compared to the percentage (13%) related to full systems. This review also shows that a considerable number of the articles describing systems focus on how technology can be used in the AAL context instead of looking at the users' needs and proposing ways to address them.

In order to solve this identified problem, it is required that research teams should be composed of professionals with different backgrounds and skills such as health or social professionals and engineers and that all the stakeholders, including potential users, should be actively involved in all the stages of the applications developments and evaluation processes, including the conceptualization phase.

The studies reviewed also show the applications are subject to very little or absolutely no regulatory oversight, with a small percentage of articles reporting evaluations or trials. However, pervasive health solutions deal with sensitive health-related aspects of a person's life and this should put strong demands in the development of these technologies. Therefore, it is necessary to consider the risks

associated with pervasive health appliances and applications, including the possibility of the individuals being misled. This is reinforced by the fact that, often, the potential users are fragile and vulnerable individuals, or their families, desperately seeking solutions to acute problems. Thus, even for appliances or applications that appear to be extremely useful, there should be a concern for their efficacy and efficiency, or for possible adverse effects when being used.

### 3.1 Regulatory Frameworks

The obligation of an appliance or application being classified as a medical device depends on its functions and the corresponding level of patient risks. For instance, a device able to measure heart rate as a fitness tool is not a medical device, but it is definitively a medical device if the resulting information is sent to a health care professional (FDA, 2013).

Worldwide, a wide range of organisms, including the Food and Drug Administration (FDA) of the United States and the European Medicines Agency (EMA) of the European Union, have the mission to safeguard the interests of the citizens by establishing standards for the development, manufacture and marketing of medical devices.

In 2013, the FDA issued a guidance concerning the regulation of mobile medical applications (FDA, 2013). It considers that all the applications that transform a mobile platform into a medical device by using attachments, display screens, sensors, or other such methods, regardless of the mechanism behind the transformation, should be regulated (FDA, 2013). Furthermore, FDA intends to exercise enforcement discretion for mobile applications that (FDA, 2013): help patients self-manage their disease or conditions without providing specific treatment or treatment suggestions; provide patients with simple applications to organize and track their health information; provide easy access to information related to patient's health conditions or treatments; help patients to document, show or communicate potential conditions to health care providers; automate simple tasks for health care providers; or enable patients or health care providers to interact with health care record systems (*e.g.* EHR).

In the European Union, the European Medical Device Directive (MDD 93/42/EEC) defines a medical device as any instrument, apparatus, appliance, software, material or other article that when used alone or in combination with accessories, including specific software, aims to prevent,

diagnose, treat, monitor, or alleviate an illness or injury in humans (EC, 1993). The CE mark assigned to a device guarantees to users and health professionals that the device complies with all guidelines provided by all the applicable regulatory frameworks.

Medical devices are divided into risk classes according to different criteria, namely, the intended purpose, potential risks arising either from its technical conception and in its manufacturing methods, duration of contact with the human body (temporary, short or long period), invasiveness of the human body (invasive, invasive of bodily orifices, surgically invasive, implantable and implantable absorbable) or the anatomy affected by the use of the device.

As part of the technical documentation, the developers also need to perform controlled tests and risk assessment to demonstrate that their products might improve any existing process used for the same purpose. This implies the need to assess the validity (validity refers to the degree of accuracy of measurements or actions taken by an appliance or application, *i.e.* if they actually measure or perform what they intend to measure or to perform) and the reliability (reliability refers to the consistency of the measurements or the actions over time) of the appliances and applications, which might be supported by observational clinical trials involving human subjects that, like all the clinical trials, must comply with the ethical principles established by the Declaration of Helsinki (WMA, 2013) and must follow good clinical practices. These trials can provide evidence to conclude that the measurements and actions performed by the appliances or applications are, respectively, consistent with the measurements and actions associated with existing similar appliances and applications.

Despite all the regulations, it is perhaps surprising that relatively little research has been undertaken so far to investigate the validity and the reliability of pervasive health developments (Mosa et al., 2012; Rosser and Eccleston, 2011).

### 3.2 Clinical Evidence

Besides the assessment of validity and reliability, there is a need to understand the quality of the available solutions and their clinical usefulness. This requires interventional clinical trials to provide clinical evidence of efficacy and efficiency of the pervasive health applications.

Despite a high level of technological innovation and implementation, and promising early results,

most of the developments aimed the design, development and evaluation of prototypes (*i.e.* proof-of-concept). In contrast, evidence-based medicine is supported on statistical and clinical significance and the new developments are required to show they are able to make a difference and are cost-effective (Korhonen and Barddram, 2004). Furthermore, high-quality efficacy and efficiency evidence must also adequately address usability, accessibility, readability (reading with understanding) or health literacy needs of target audiences, since they might have different and unique usability requirements related to ageing and physical or cognitive impairments. This requires adequate development and evaluation methodologies (Martins, 2012).

Collecting this kind of evidence requires interventional clinical trials. These demands considerable resources to integrate new applications with daily care delivery, to be used by thousands of users, both patients and health professionals, and running over long periods of time (Rashidi and Mihailidis, 2013).

Examples of questions that must be answered by interventional clinical trials are: Is the information being provided beneficial in clinical practice to guide diagnosis, decision making or intervention? Is that appliance or application going to have an impact on patients or health care provider's? Is that change beneficial for the patient in any way? Is the use of the appliance or application making the diagnosis, the decision or the intervention processes any better?

Multidisciplinary large-scale collaboration with technology developers, companies, policy makers, patient organizations and health professionals is essential for pervasive health surpass this methodological challenge (Korhonen and Barddram, 2004).

### 3.3 Limitations of the Study

The study was not based on a systematic literature review. Therefore, the degree of generalization of the study findings needs to be evaluated through further research. Presently, the authors are conducting a systematic literature review to support this exploratory study.

## 4 CONCLUSIONS

The pervasive health paradigm has a huge potential in terms of innovative solutions that might mitigate, in political, economic and social terms, the

consequences of the contemporary demographic ageing. However, their development should not be seen merely from the technological point of view because there is a wide range of ethical and organizational issues that need to be considered.

In particular, in this paper the authors focused on the need to complement the pervasive health developments with strong evidence of their validity, reliability and clinical usefulness. For that it is necessary to implement strict evaluation processes according to regulatory frameworks, which requires observational and interventional clinical trials involving patients and care providers.

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