Standardization and Innovation for Smart e-Health Monitoring Devices

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Abstract: The challenges faced by standardization in relation to the potential of wireless communication technologies to deliver lower cost, higher efficiency, enhanced quality of experience and diversified smart e-Health services, are multi-fold and determined by the complexity of the myriad of emerging user and usage scenarios. In addition, there is the challenge of protection of privacy and the maintenance of trust. This paper aims to show the evidence of the correlation between standardization and innovation in the area of e-health technology. It describes a capability framework proposed for the delivery of e-Health services in support of independent living. The proposed framework incorporates innovative research and standardized solutions. The paper addresses the correlation between standardization and innovation, in particular for the area of e-Health. It analyzes the potential of research to advance and harmonize the standardization efforts towards sustainable e-Health solutions, and outlines some critical points for the future standardization work in the related area.

1 INTRODUCTION

e-Health environments are extremely complex and challenging to manage, as they are required to cope with an assortment of patient conditions under various circumstances with a number of resource constraints. There is a large number of initiatives (e.g., the EU European Innovation Partnership pilot action on Active and Healthy Ageing –EIP AHA and the EU Joint Programming on Ambient Assisted Living), products and services that aim to provide a robust strategy to face the challenge of designing sustainable e-Health system solutions. The Telecommunication Standardization Sector of the International Telecommunication Union (ITU-T) (ITU-T, n.d.) has recently recommended Y.2065 “Service and capability requirements for e-health monitoring services” – a standards recommendation document that classifies e-health monitoring services (EHM) as EHM Healthcare, EHM Rehabilitation and EHM Treatment services, and describes service requirements according to the different roles involved in the provisioning of these services (i.e. EHM customer, EHM device provider, network provider, platform provider and EHM application provider) (Y.2065, (03/2014)). The EHM capability requirements are defined with respect to the different layers of the ITU-T GSI Internet of Things (IoT) reference model specified in the ITU-T Y.2060 “Overview of the Internet of Things” (Y.2060, (06/2012)). According to ITU-T Y.2060, the IoT is a global infrastructure for the information society, enabling advanced services by interconnecting (physical and virtual) things based on existing and evolving interoperable information and communication technologies. Within the ITU-T concepts, a device in the context of IoT is a piece of equipment with the mandatory capabilities of communication and some optional capabilities of sensing, actuation, data capture, data storage and data processing. The devices collect various kinds of information and provide it to the information and communication networks for further processing. This is also the most straightforward observation of the correlation between standards and research innovation.

While both devices and technologies carry equal weight in the provision of IoT services in general, and e-Health services, in particular, the devices used in research projects are usually already standardized, available on the market solutions. However, the interconnection of devices into intelligently communicating networks, which can be then an inherent part of the infrastructure, requires novel research. This in turn has the potential of enhancing existing standards with new recommendations and
architecture models (R. Prasad, 2013).

The European-funded under Framework Program Seven (FP7) within Information Communication Technology (ICT) project eWALL (eWall, 2013) proposed an affordable, easy-to-implement smart, “caring home” cognitive environment, that “senses” intuitively the wishes and “learns” the needs of the person that lives in this house, providing unobtrusive daily support, notifying informal an formal caregivers when necessary and serving as a bridge to supportive services offered by the outside world. It is a dynamic home environment that unobtrusively monitors and interacts with its inhabitants while they perform their activities of daily living (ADL), able to recognize abnormal events as well as slowly emerging shifts in behavior, and able to inform associated users (caregivers, healthcare professionals, family) appropriately to provide a feeling of safety and comfort for all involved parties. The key aspects of the project eWALL are innovative research, evaluation and implementation towards a short- and long-term exploitation impact. This paper is further organized as follows. Section II describes the eWALL user groups and scenarios and derives the key requirements from a research viewpoint to design a highly usable, efficient and implementable e-Health service framework. The main eWALL services to be provided are defined in Section III. Section IV defines the required IoT framework for the provision of the eWALL services. Section V compares the derived services, devices and capabilities to the ones defined within the ITU-T recommendations and identifies commonalities and gaps. Section VI concludes the paper.

2 EWALL USER GROUPS AND SCENARIOS

2.1 Page Setup Main Requirements for a Sustainable e-Health System

A successful e-Health system should be able to maximize the potential societal impact of its use, and thus, should be able to support a broad range of target users. The general user groups will involve a myriad of primary end users that can be categorized according to their human health state, and a number of secondary end users and third parties (e.g., technology providers). Smart home systems enable constant monitoring and interpretation of health-related parameters (e.g. ADL’s, medicine intake, physiological parameters) in the primary user’s everyday life, which give the informal caregivers (i.e., a group of secondary users) the information necessary to feel comfortable about the person they care for, and need to rely less on professional expertise, leading to reduction in visits to doctors. For various chronic conditions, in which the use of professional healthcare services is mandatory, everyday monitoring and interpretation of the patient’s relevant data can provide professional caregivers (another secondary user group) with the information vital to enable the focus of their efforts on those patients who need it most. The key requirements for enabling a sustainable e-Health system, are the personalization and adaptation to specific needs and preferences, the efficient data and context sharing between the different required services and artefacts, including the handling of multiuser identification, auto configuration and calibration systems. These requirements demand high personalized usability and unobtrusive sensing. eWALL incorporates a myriad of wireless and wired communication and data processing technologies and networked devices that interoperate in the frames of the eWALL platform to provide e-Health services.

Information is collected by means of sensing devices and forwarded further by residential gateways. To improve the interoperability between sensors and residential gateways device type specific standards developed by the Continua Health Alliance can be used. Current solutions lack interoperability and therefore impede the establishment of a remote patient monitoring solution market. The ISO/IEEE Standards 11073 standardizes the transfer of medical information and can be used to achieve the above described aim (M. Benner, June 2011). This is also a standard used in eWALL, which can then be enhanced further by the research performed. Usage of Continua Certified™ products allows for enabling data interoperability, which processing can be challenged by the wide range of sensors from different vendors and standards.

The Smart Open Services for European Patients (epSOS) (epSOS, 2008-2014) is very useful to enable cross-border interoperability and secure access between electronic health record systems. Secure transfer of personal medical data is key to avoiding critical medical errors, and therefore, is a key requirement for enabling a sustainable e-health solution. The role of standards should also extend to cover the critical aspects of privacy and trust. The integration of the eWALL functionalities with epSOS is achieved in such a way that the developed
modules can enhance the existing epSOS platform in return. The proposed integration is vital to strengthen the exploitation impact on a large scale of the eWALL solution.

The patient must give her/his consent before any of her/his data is made available. The health professional’s permission to access the patient’s medical data must be verified according to the national security policy of the specific country the patient originates from, and, if available, through a patient privacy policy. This puts a strong emphasis on the need to involve besides standardization experts, also regulatory ones that would be able to define suitable policies for a more unified framework approach that, however, maintains the specific to a country regulations.

2.2 First Section eWALL User Groups

In eWALL, for facilitating research and evaluation, the human health is seen in one of two possible states: (1) healthy (i.e., elderly users with age related impairments-ARI), and (2) sub-healthy (i.e., users diagnosed with Chronic Obstructive Pulmonary Disease-COPD or suffering from mild cognitive impairments, such as short term memory, language, execution of complex or parallel tasks). Both groups are considered as primary users. Both primary user groups would need to interact to a certain extent with two different types of secondary user groups, namely:

1) **Professional Caregivers**: including nurses, home care support professionals, medical doctors (general practitioners, lung physicians);

2) **Informal Caregivers**: this user category contains the primary user’s family, neighbors, friends and anyone else not from the professional healthcare field that provides any type of support, including social support, housekeeping, or more disease specific support.

In order to define a set of functional requirements that align with the targeted end-user groups, typical human-centered design approaches for e-Health technology, such as ISO 9241-210 (British Standardization Organization, 2010) or user-centered design (Usability Professionals Association, 2013) were applied to enable that the prospective primary end user is the focal point during the design of the capability framework. The four following products are developed in order to inform the design: user profiles, personas, scenarios, and use cases. It should be mentioned, that eWALL is suitable for application to primary users in four possible human health states as defined by (Y.2065, (03/2014)) but for this purpose the set of eWALL services must be redefined accordingly.

2.3 Usage Scenarios

The eWALL usage scenarios are defined from the point of view of the primary and the secondary users with the purpose to create a common view on the services needed. The eWall system is described as a series of functionalities, for each persona. Each one of these functionalities could correspond to a module of the eWall system. Modules should be loosely coupled and as less codependent as possible. Communication between modules is done via middleware and data and knowledge repositories. A module output will be transformed into knowledge that will form the user profile. The user profile describes in depth the profile of the person for which the eWall home installation is being used, from a therapeutic perspective. Based on the scenarios a number of application categories were defined as shown in Table I.

Each of the application categories in Table I contains several possible applications, which have to be prioritized and defined in further detail. Many applications may interact with other applications in various ways.

<table>
<thead>
<tr>
<th>#</th>
<th>Application Category</th>
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<tbody>
<tr>
<td>1</td>
<td>physical exercise</td>
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<tr>
<td>2</td>
<td>daily activity monitoring</td>
</tr>
<tr>
<td>3</td>
<td>daily functioning monitoring</td>
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<tr>
<td>4</td>
<td>nutritional coach</td>
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<tr>
<td>5</td>
<td>safety</td>
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<td>6</td>
<td>medication support</td>
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<td>7</td>
<td>social integration</td>
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<td>8</td>
<td>healthcare support</td>
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<td>9</td>
<td>calendar</td>
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<tr>
<td>10</td>
<td>cognitive stimulation</td>
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<tr>
<td>11</td>
<td>domotics</td>
</tr>
<tr>
<td>12</td>
<td>outdoor guidance</td>
</tr>
<tr>
<td>13</td>
<td>health monitoring</td>
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</table>

3 eWALL SERVICES

eWALL has the purpose to support ADL for the described primary end user groups for an improved quality of life and overall cost-efficiency. ADL can be divided into basic ADLs and instrumental ADLs.
1) **Basic ADLs.**

The basic activities of daily living consist of various self-care tasks: bathing, dressing and undressing, eating, transferring from bed to chair, and back; voluntarily control of toilet use; walking (not bedridden).

2) **Instrumental ADLs.**

Instrumental activities of daily living are not necessary for fundamental functioning, but enable the individual to live independently within a community, e.g., light housework, preparing meals; taking medications; shopping for groceries or clothes; using the telephone; managing money.

The eWALL services are grouped into the following categories: a) risk management and home safety; b) eHealth and c) lifestyle management.

The eWALL services are delivered by the eWALL cloud, and are classified as horizontal and vertical services, given in Fig 1. The horizontal services consist of service bricks that enable the definition of a process, the personalization and adaptation of a vertical service. The vertical services are those developed for the eWALL system, either by the medical service providers, or by the developers.

The eWALL system is composed of two main subsystems: the eWALL Sensing Environment and the eWALL Cloud. The interaction between the two is shown in Fig 2.

The eWALL Sensing Environment is envisioned as a logical environment, deployed over a physical space, which is mainly responsible for the explicit and implicit interaction with the primary user. “Implicit interaction” refers to the collection of various data about the user and the user environment from medical and environmental sensors and the control of the environment through actuators. “Explicit interaction” refers to the direct interaction of the user when using audio/video devices and user interaction sensors.

Two types of the eWALL Sensing Environment are envisioned, namely:

1) **Stationary or a Home Sensing Environment (HSE)**

It is related to the physical surrounding of the user when at home. Home sensing devices monitor the status of vital environmental parameters in the home, such as humidity, temperature, luminosity, motion etc.
The Audio/Visual (A/V) Sensing provides full-body 3D motion capture, face and voice recognition capabilities built over C/C++ processing algorithms. The A/V based emotion recognition system is a considerably challenging field to generate an intelligent system that is able to identify and understand human emotions for various vital purposes, e.g., security, society, entertainment, health care, human-computer interaction, industrial, and personal robotics, surveillance, and transportation. The visual sensing is enabled by the infrared (IR) depth-sensing technology and monochrome complementary metal oxide semiconductor (CMOS) camera of the Microsoft XBOX Kinect sensor. The sensor outputs video at a frame rate of 30 Hz, while the RGB video stream uses 8 bit VGA (Video Graphics Array) resolution (640 x 480 pixels) and 8-bit for each channel, whereas the depth stream is 640 x 480 resolution with 11-bit depth.

The speaker diarisation component is designed to monitor and log the number of people verbally interacting in the living room of the caring home. The component uses one or several audio streams to estimate the number of different speakers in the room.

2) Mobile Sensing Environment (MSE)
It is centralized around the user mobile devices when the user is outside of the home environment. User vitals tracking concerns the person physical activity as a function of time. The integral of the modulus of body acceleration (IMA) values are a reliable indication of activity, but can also be used to classify different events or activities, like falls, walking, running, housework, etc. Other wearable sensors measure body information as they are carried by the user and transfer their signals to the gateway wirelessly. Such devices could be smartphones, smartphones, pulse and SPO2 sensors, the smart stethoscope, body temperature and so on.

The interoperability of all sensing devices is of major importance for the integration and acceptance of the proposed system. Most devices are from different manufacturers and the goal of standardization is to enable large-scale deployment of telecare and telehealth services at reduced costs. In order to fulfil the requirements for standardization, the telehealth devices should meet criteria for data exchange, data representation, terminology for communication between them and the device gateway (e.g., cell phones, personal computers, health appliances).

In the process of device prototyping, eWall uses Arduino and Libelium based sensing environment testbeds, The Arduino uses Atmel ATmega 328P microcontroller that works at 16 MHz clock and the maximum size of the uploaded program - 32 kB. Arduino Wireless Shield allows your Arduino board to communicate wirelessly using ZigBee where in eWall the XBee XB24-Z7WIT-004 module from Digi (Digi, n.d.). Series 2 allows for a set up of complex mesh networks based on the XBee ZB ZigBee mesh firmware. The Libelium sensor nodes and sensor gateway are equipped with XBee 868 PRO S5 radio modules (Digi, n.d.) which use one single communication channel at a frequency of 869.4 – 869.65 MHz (0.25 MHz bandwidth).

The data coming from the sensors is received by the device gateway, processed with C/C++ algorithms and stored in CouchDB database hosted on the “HomePC”. This format is in resource description framework (RDF) triplets and the description of the metadata is in JavaScript Object Notation (JSON) format.

3) eWALL Cloud
The eWALL Cloud is the central processing and data storage subsystem. The eWALL applications are based on “service bricks” that are available in a “pool of services” in the eWALL cloud.

The eWALL cloud is connected to the home of each primary user. The “service bricks” in the eWALL cloud are in fact the various services exposed by the devices. The “service bricks” are in between the applications and the metadata stored in the cloud Data Management Block, and act as providers of specific aggregated data, after making some reasoning on the metadata. The applications get such aggregated data from the “service bricks” via JSON/REST over HTTP communication protocol.

The semantically-rich metadata obtained from the sensing and monitoring devices and the data from the cloud middleware services are fused to extract higher-level context of the eWALL services. The perceived in-house situation is fused with the cloud metadata, allowing for the understanding of the user’s reaction to recommendations and their adaptation to the personal taste of the user. Such an approach results in semantically rich and high level context information that serves as input for the eWALL intelligent decision support (IDSS) system. Fig. 3 shows example of high level models in the IDSS. eWALL implements the IEEE Suggested Upper Merged Ontology (SUMO) concepts and defines a set of specific sub-ontologies based on the it.
Sensors/devices from the home environment exchange information with the cloud storage via the eWall service. In the cloud, there is a peer application that has its own processing logic, adding value to the communication beyond simple data access. As an example, these could be applications that need to take decisions based on data mining and command sensors based on user behavioral patterns.

Another highly innovative aspect is the integration of radio frequency wireless technologies with visible light communications (VLC) (e.g., related to IEEE 802.15.7 standardization) for the provision of very dense low and high data rate smart service connectivity (A. Kumar, 2014). VLC will be investigated in the scope of the eWALL scenarios and services. These are aspects that require an integrated research and standardization effort in order to impact the overall e-Health services and products commercialization.

5 ANALYSIS OF e-HEALTH RESEARCH WITH RESPECT TO USE OF STANDARDS RECOMMENDATIONS

In order to deliver a novel system for personalized and context-aware services that can support the active ageing, there is a clear need for a balanced co-existence of innovative research and development from a medical and technological perspective, on one hand as well as compliance with existing standards, to address advanced networking paradigms, such as cloud connectivity, innovative, simple- and efficient-communication protocols, patient mode surveillance and the development of advanced application and services. Table II shows the main requirements by which a sustainable e-Health system solution should be evaluated and, by which, also standardized solutions should be aligned.

eWALL contributes greatly to the further refinement of standards recommendations by incorporating along with the research activities, strong evaluation strategies, involving real-user trials. Information obtained from such trials, will be mapped to standards requirements for further improvement on usability and user friendliness, which can strengthen the position of standardization as a transfer channel for further innovations.

eWALL involves all relevant end-user groups in the research and development process by the evaluation with real-field trials and thus is able to provide a rich set of intelligent services, deployed in realistic conditions that should be compliant with the minimum set of privacy and ethical requirements. Privacy-by-design is a key aspect to be incorporated into standardization activities, and has the potential to further impact already established e-Health service recommendations such as defined in (Y.2065, (03/2014)). Examples of such services are the personal health monitoring, home safety, mobile services, care and rehabilitation management services.
Table 2: Critical Characteristics for the Evaluation of e-Health Solutions and Standards.

<table>
<thead>
<tr>
<th>Critical characteristic</th>
<th>Description</th>
<th>Type of evaluation</th>
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<tbody>
<tr>
<td>Interoperability</td>
<td>Ability of the difference devices and services to cooperate seamlessly and provide a seamless user experience.</td>
<td>System validation and verification. Extensive testing for facilitating the interoperability of the devices and services.</td>
</tr>
<tr>
<td>Easy personalization</td>
<td>Ability of the end user to adjust the system and its building blocks to needs without any special ICT knowledge. Implicit and intelligent adaptation to the user profile and context.</td>
<td>Questionnaires; interviews; process analysis</td>
</tr>
<tr>
<td>Mobility</td>
<td>Ability of the user to be mobile while receiving e-Health services regardless of location.</td>
<td>Observations; interviews; questionnaires</td>
</tr>
<tr>
<td>Low Maintenance</td>
<td>Ability of the system to work for hours without the need of performing maintenance actions. Self-healing mechanisms.</td>
<td>Observations, technical validation and statistical analysis.</td>
</tr>
<tr>
<td>Safety/security</td>
<td>Level of acceptability of the health risk (e.g., due to complications or adverse effect) associated with using a technology. A function of the caregiver’s judgment (in deciding whether to use the supporting technology for a particular case). Preserving confidentiality, data integrity, strong authentication and authorization mechanisms.</td>
<td>Technical validation. Risk assessment. Observations, interviews, questionnaires.</td>
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<td>High reliability</td>
<td>Fault tolerance. Accessibility to the e-Health services from everywhere. Use friendly interfaces, also addressing patients with chronic physical and cognitive impairments. Client: perception of physical improvement, perceived homecare, satisfaction level, self-care at home. Perception for self-care; perception of social inclusion, avoidance of new or re-occurring incidents. Technical aspects, required infrastructure, hardware, software, conformance to standards. Definition of real-world condition for the e-Health system. Involvement of real users.</td>
<td>System validation and verification. Monitoring &amp; Measuring. System validation and verification. Questionnaires; observations; interviews. Tests, reviews, guidelines, evaluation reports. Involvement of relevant end users.</td>
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In addition to the identified state of the art of the art of legal science and data protection policy together with the security and privacy problems in the context of eWALL, the project also will define a “Privacy-by-Design” methodology that would encompass technical, economic and social aspects of critical relevance to e-Health systems. Currently, these activities are closely performed with the European Telecommunication Standardization Institute (ETSI).

The approach should relieve caregivers and other users of any additional bureaucratic legal procedures that the technology deployment may imply.

Standardization can help research by defining target methodologies and requirements that in turn can help scientists and technology producers, both, to develop privacy protecting technical concepts.

6 CONCLUSION

This paper addressed the use of standardized e-Health solutions in innovative research projects. Although, that there is a broad agreement that innovation is a key to economic prosperity, yet for many researchers, companies and organizations, the coupling of standardization and innovation is a rather novel idea.

e-Health as an area of huge economic significance and impact, needs standardization to cope with the complexity of the usage and user scenarios to be supported by the e-Health technological solutions. This paper described and analyzed the use of both standardized and innovative research solutions for the design of highly personalized e-Health services in support of independent living and compensating for prevailing age- or disease-related physical and cognitive impairments. It was shown that sustainable e-Health solutions must adopt standardized solutions in an integrated approach with research and development activities.

Innovative technical concepts for e-Health systems must account for certain privacy and trust goals. Standardization must account for certain basic privacy and trust requirements, and work should be performed jointly with regulatory experts. The challenge is in how to harmonize a variety of e-Health related policies adopted by various countries and regions.

The core e-Health platform functionalities and the embedded intelligence within strongly depend on the actual sensing devices used. Industry accepted definitions generally distinguish between a smart
and an intelligent sensor. Such definitions and their application into innovative solutions are highly dependent on the outcome of the standardization effort.

ACKNOWLEDGEMENTS

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REFERENCES


