Design of a Remote Treatment Monitoring and Seizure Warning System Framework for Epilepsy Patients

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Abstract: Personal health care technologies in chronic diseases face the challenge to design holistic approaches where health care involves not only the medical specialist for treatment and monitoring, but the patient and the family. Epilepsy is a term used for a group of chronic disorders with diverse etiology characterized by recurrent seizures, caused by an abnormal electrical activity in the brain. Treatment monitoring requires continuous collaboration of the patient and the family to register manually a diary of activities, seizures, seizures triggers and symptoms associated to medication in order to reach optimal therapy. Patients with non-controlled seizures and their families have to deal with a restricted quality of life: the patient is exposed to physical risks when seizures appear under any circumstance and place. In this paper a remote patient treatment monitoring and warning system framework design based on mobile technology is proposed, with multiple input, seizure detection with a smartphone accelerometer, automatic and manual seizure warning and location of the patient through GPS and a social support network. This design approach is patient-and family-centred, as they are the source of individual information in a particular environment, condition and treatment response. It also represents a first proposal of a potential ubiquitous health care system through a wearable device.

1 INTRODUCTION

A challenge in health care technology involves the non-integrated approach of specialists records of patients information, the large volume of data and the difficulties with appropriate information retrieval that have resulted in a lack of use of available electronic health records (EHR) and personalized health records (PHR) while adherence of patients to these systems need to take to account motivation and self-care (Wang & Huang, 2012). In the near future, ubiquitous technology for health care will be a common environment in everyday life with monitoring and prevention purposes (Omary et al., 2011), however, actual technology provides useful and powerful frameworks to design integrative systems where data volume and information actualization should not be an important issue. Patient-centred integrative systems based on individual modules from different sources (ubiquitous or not) with independent updating, still have to be designed. When health has become the following target in personal technology, even more with Apple HealthKit potential, health and well-being smartphone applications represent the 40% of current development (Furht and Agarwal, 2013) with a growing trend.

Several mobile applications are available to aid different chronic diseases like diabetes, obesity, heart diseases, bipolar disorder and epilepsy, for instance. In epilepsy, functionalities like seizure and symptoms diary; medical and emergency information; record of medications; seizure tracking, videotaping and even detection have been widely used for treatment monitoring and diagnosis support (Epilepsy Foundation; National Society for Epilepsy; The National Centre for Young People with Epilepsy, among others). These applications are

not linked to an integrated system, do not solve the main problems of the medical specialist, do not update the patient's record, cannot be used for emergency situations and more important, not all of them involve family intervention, therefore losing important information and feedback.

In many chronic diseases, a holistic approach for treatment is mandatory. The patient cannot be the only source of data for monitoring, for inherent reasons of the disease or insufficient information acquired by this mean. A common way to face this challenge is a combination of interventions as mechanisms to enhance adherence of the patient's behavior on taking medication, modifying habits and attending clinics, according to medical advice and including family participation (McDonald et al., 2002) or using a patient-centered approach. Yet this kind of combined interventions do not make use of an integrative technology support system.

Consequently, treatment monitoring of chronic diseases requires models that consider the participation of all the roles involved in the disease: the patient as the focus, the medical specialist and the family, e.g. in a real patient-and family-centered approach.

The system framework that we propose for epilepsy is intended to accomplish the three main issues in m-health (Furht & Agarwal, 2013) i) access from anywhere and anytime, ii) quality since is designed as an integrated system and iii) value for the target to provide health care in a efficient and effective way. It is divided in three parts.

The first part is a mobile medical device designed for the patient with a small personal health system, with an informative module, medication alerts, social network, automatic seizure detection and manual or automatic seizure warning –that takes advantage of the smartphone accelerometer– and physical location of the patient with GPS data. The second part is mobile medical app for the caregiver use, which contains symptoms observation diary, seizure warning, seizure recording, social network and first aid emergency programmed calls. The third part is the monitoring system by a web system for the medical specialist use; it involves the patient record (personal data, treatment and seizure monitoring, seizure records, EEG data), seizure warnings and emergency services contact. All of these modules linked by a cloud-computing service.

Current mobile apps or systems are designed only for the one final user, as independent medical information systems, without integration of the information from all the input sources; this is the principal innovative scheme of the present work. It

takes into account all the stakeholders that must be involved, is user-centered (UCD) in each module, but patient-and family-centered as an integrative system: the context must be defined on the particular environment and condition of each patient, thus, the profile and use is personalized, the benefit is pretended for the patient, the family and the specialist. Furthermore, an important consequence is the potential use for data generated by the system, for statistical research in epilepsy patients' habits and seizure occurrence. This model also represents a first proposal to be part of a potential ubiquitous health care system.

2 HEALTH CARE REQUIREMENTS IN EPILEPSY

Epilepsy is a term used for a group of disorders with diverse etiology (infections, birth problems, tumors, trauma and in many cases, origin is unknown), characterized by recurrent seizures, caused by an abnormal electrical activity in the brain. In the world, around 50 million people have epilepsy (World Health Organization 2012). Any person, without previous symptoms or circumstances, is susceptible to epilepsy. Diagnosis is achieved in a precise way by seizures description and different medical studies as electromagnetic resonance, tomography and particularly electroencephalograms. The specialists for this diagnosis are a neurologist and an epileptologist. The most known and shocking kind of seizure is a generalized tonic-clonic, where the patient loses consciousness and the entire body convulsions.

Available treatment of a diagnosed patient depends upon the classification of the epilepsy and the seizures; it consists on stopping seizures by medication with anti-epileptic drugs (AEDs), securing appropriate habits, specific diet and in determined cases, surgery is indicated, besides alternative treatments. Treatment monitoring requires continuous collaboration of the patient and his family to register a diary of activities, seizures, seizures triggers and associated symptoms to update the specialist and analyse medication efficacy and tolerability to reach the optimal therapy with the exact combination of AEDs in certain doses.

In some patients, seizures are announced by a certain perception called "aura", a sensory signal like visual, auditory, gustatory, olfactory hallucination or the awareness that something is wrong that indicates an imminent seizure. Then the patient is able to warn someone or to avoid risks by

himself. The patients that do not perceive this aura and are in a vulnerable physical location suffer the risk of accidents, falls and injuries.

Speaking about quality of life, the first of its possible indicators, defined by Cribb (1985) is the quality of lifestyle, associated to the patient's capacities and restrictions in their work, social and home life; the second possible indicator is mental health, where emotional well-being in all levels takes into account. Therefore, patients with non-controlled epileptic seizures and their families have to deal with a restricted quality of life due to the inherent risks of the disease: the patient is exposed to physical risks when seizures appear under any circumstance at any place. Also, per se, epilepsy is involved in underlying discrimination and stigma (Forsgren et al., 2013) and still risks prevention in uncontrolled seizures is limited to the self-exile, affecting family, relatives or caregivers.

Records of seizures observation and medication achieve actual treatment monitoring.

Accordingly, current technology can be extraordinary to support some of the intrinsic mechanisms of the disease with an appropriate holistic design approach, a patient-and-family centred design.

3 PATIENT-AND-FAMILY CENTRED DESIGN

As a starting point for the design approach of this system framework, the patient-centred design basis was proposed —defined by Baecker as the design *with* users or patients in a participatory design— implicating the sense of *person*-centred care, as McCormack et al. (2011) established: an approach that involves care providers, patients, and others significant to them; thenceforth converting our overall design approach in a patient-and-family centred design.

The Institute of Patient-and-Family-Centered Care defines the core concepts in patient-and-family centred care as 1) the dignity and respect of patient and family perspectives and choices, 2) the information sharing, 3) the participation and 4) the collaboration of them in care and decision-making. In ambulatory care specifically, the patient and the family are conveyed to be integral part of the health care team, while self-management of the chronic condition is desirable, getting all them involved in the planning, implementation and evaluation of chronic care strategies (Johnson et al. 2008).

3.1 Design Considerations for Epilepsy

Usability and accessibility are the main features in user-centred design, directly related with a integral approach.

In this remote treatment monitoring and warning system framework for epilepsy, a particular profile of patient must be stated. The specific users of the patient app are persons already diagnosed with epilepsy to achieve treatment monitoring by observing medication effects on seizures recurrence, principally patients with uncontrolled seizures that need to be supervised by a caregiver, commonly someone in the family. Seizure detection functionality is defined for tonic-clonic seizures; thenceforth other kind of seizures may not be detected.

A patient with uncontrolled epilepsy seizures suffers of anxiety due to the unpredictability of the seizures, he or she does not have normal activities and the daily routine needs to contemplate the possibility of falls or injuries.

It is comprehensible that the patient and the family must be considered as the principal role for the design, since the prevalence of use of the system depends on the participation of both users.

The central topics concerning the whole system are:

- *Personal Health Record.* Patient is able to upload personal information related to general data, emergency contact data and health data: medical history, allergies, actual diagnosis and medication. The specialist can upload strategic results of primary neurologic diagnostic technics like magnetic resonance and tomography and principal laboratory tests results like blood test and urine test, if they are able.

- *Treatment monitoring.* Appropriate medication adherence is required in a patient that suffers epilepsy; monitoring effects and tolerability is overriding (Campos and Kanner, 2004), especially with a new anti-epileptic drug, a new combination of them or a different dose. Side effects of medication are important to watch. This monitoring is proposed for the specialist use.

- *Habits, mood and daily activities.* Missing medication, emotional stress, sleep deprivation, fatigue, missing meals, fever and smoking are the most common —but not all— triggering factors of seizures. Identification and recognition of individual seizure triggers and may be beneficial for the treatment; registering

daily habits, mood and specific activities will help to identify the most common for each patient (Balamurugana et al. 2013). Selection of symptoms, moods and daily activities will be available.

- *Seizure records.* A daily registration of seizures in a detailed form is useful to determine the medication efficacy. Time, duration and detailed description are information needed for a correct monitoring. A video recording of the seizure is very valuable, since a patient does not always exhibit seizures during a medical examination.

- *Seizure detection, seizure warnings and patient location.* Paroxysm will be detected by the accelerometer of the smartphone running the patient's app, when seizure is detected, a message will appear to confirm a false detection. If this is discarded, an automatic warning will be sent to the caregiver with the physic location of the patient. If the patient has an "aura", he or she will be able to send a manual warning of an imminent seizure. In both cases, an urgency ID screen will be displayed in the smartphone.

- *Support social network.* A collaborative network is a valuable element in this framework. Epilepsy patients and families live in a constant worry, anxiety and fear. This network could be a platform to share experiences and give emotional support.

3.1.1 Usability and Accessibility

In user-centred design (UCD), a specific iterative cycle is outlined in ISO 9241-210 (Goldberg et al., 2011), where the context of the system use is the starting point –in this framework, for each module, the patient, the caregiver or relative and the specialist–, the requirements specification is the following consideration, to produce, afterwards, the design solutions and evaluate them to update the design until usability is achieved. For the three user profiles of this system, the cycle of UCD needs to be completed.

Usability is considered from the design to the final use of the system; each module must be designed to be effective, efficient and satisfactory in the specified context of use for each user profile (ISO/IEC, 1998). Usability also has to take into account training for the patient, the caregiver or relative and the specialist of the whole system framework in order to understand the main objective and the particular goals for each profile.

Epilepsy is a chronic disease that may or not disable the patient; in either way accessibility will delimit the use of the mobile device by the patient. If the patient is not able to operate the mobile device or use the mobile app, he or she may not use all the potential of the system, but the treatment monitoring with the module of the caregiver can be a supporting data source.

Like any other healthcare system, in epilepsy, confidentiality of the information is a significant subject, correspondingly to the trust of the patient on the security of the data. Confidentiality must be guaranteed as a primary expectation of the users, principally, of the patient. Signed consent must be considered for each patient and the caregiver (family), focusing on confidentiality and use of the data.

4 SYSTEM FRAMEWORK

M-Health or mobile health is the evolution of e-health, with the use of mobile devices and wireless network technologies for healthcare services (Istepanian et al., 2006). The most common mobile health systems are mobile health monitoring systems, designed to store monitor patient status and have been proposed for different purposes,

In the international standardization ISO/TC 215, the proposed module for the caregiver is classified in the category of Mobile Medical App, with the intended use to support the treatment and monitoring of the disease. The particular utilization of the accelerometer as a sensor to detect seizures, gives this patients module a function as a mobile medical *device* (Kim & Song, 2013) with a Personal Health Record (PHR).
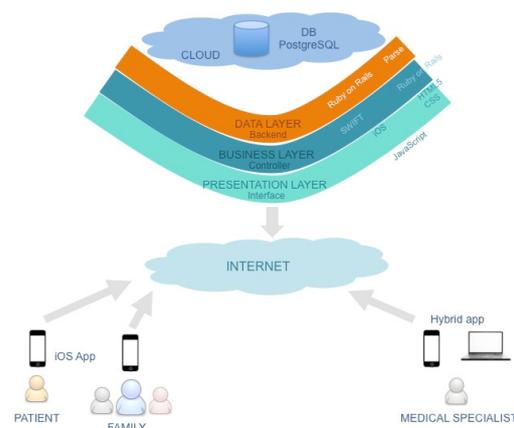

Figure 1: System framework architecture.

The patient and the family modules of the system can be also considered *home* use devices, since their use is proposed for an environment outside a professional healthcare facility (FDA, 2014).

Figure 1 shows the system framework architecture, defined by three layers and two levels, the first level is the backend and the second level, the controller and interface.

4.1 Architecture

The first layer is data layer or backend, the second is business layer or controller and the third is presentation layer or interface. The level one is the backend and the second level is formed by the other two layers, business layer and interface.

In backend, patients and specialist data will be in stored in a cloud database, allowing to be retrieved from any business layer to be shown by the interface.

For the controller, the patient and caregiver apps were proposed to be developed for iOS and the specialist module for web browser visualization. Required data are obtained by requests to the data layer.

Mobile apps need an intuitive interface, according to the visual design of components from Apple guides. Data obtained by the requests must be correctly showed in this layer.

4.1.1 Specifications

For backend, web services were proposed on Ruby programming language and the database system manager, PosgreSQL. Cloud storage achieved by Parse backend platform for iOS.

For the controller or business layer, the programming language is SWIFT for iOS platform for mobile apps and Ruby on Rails for web access.

As for the interface, for mobile apps, the native of iOS was proposed and for web access interface, JavaScript, CSS and HTML5.

4.1.2 Notifications, Warnings and Seizure Detection

Push notifications are used to send seizures warnings to the app for the relative or caregiver. The patient or the caregiver must program drug administration schedules in the specific app for each profile user.

To detect seizures, the accelerometer of the iOS device (iPhone) is used. Continuous shaking is considered as the paroxysm of a seizure, then a warning message will appear on the screen to discard a false alarm and in a positive case, seizure

detection warning will be send to the caregiver app. GPS data will be attached to indicate the current location of the patient.

Patient's app will show an urgency ID screen with emergency contact data and aid information when a seizure is detected or manually warned (Figure 2).
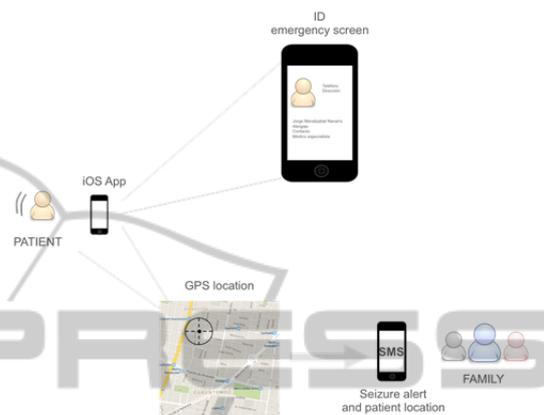
Figure 2: Seizure detection and alert with patient location.

4.2 Accuracy and Specificity

In-situ and *in-depth* trials must be planned and achieved as a main part of the methodology of development to determine reliability of the system.

The defined user's profile of the patient and the or caregiver or family modules is an epilepsy patient with tonic-clonic seizures and a caregiver that is in charge of the health care and support, the patient could be a child, an adolescent or adult, as long as the caregiver is engaged with the treatment monitoring and updating of the data. A typical use of the system depends on the participation of the patient, the caregiver and the specialist.

4.3 Development Methodology

Rational Unified Process is a conventionally used software engineering methodology. Roles, activities and artefacts delineate it and use cases and iterative processes are the main features. In the present work, RUP was proposed implementing UCD through an explicit role of usability designer, as Svanæs & Gulliksen (2008) recommended. There have been some experiences with this methodology for systems development in industry without desirable success (Vukelja et al., 2010) in the case of healthcare information systems, the participation of particular stakeholders in usability design is crucial and final users must share this role in the development team.

5 CONCLUSIONS

The system framework design presented here is a hybrid approach to a remote treatment monitoring with a module of a cloud Personal Health Record for the patient and the family (both functioning as home use medical devices) and a module of an Electronic Health Record for the specialist, based on an integrative holistic approach of patient-and-family centred, that could be linked to other medical systems.

The main use requirement for the patient and the family is active participation; for the patient to carry the mobile device, especially in environments out of home, to fulfil information of habits and perceptions and for the family or caregiver and to fulfil observation data of the patient' habits and seizures.

Information collected in this way gives the patient the possibility to share his or her health history when an emergency occurs.

This framework is intended to be an holistic approach design, considering all roles involved in a remote treatment monitoring, the design methodology could be used to design for other chronic diseases.

Patient's module could serve as a basic approach to a pervasive system as well, reminding the patient to keep an appropriate lifestyle and determining real criteria for detecting personal seizure triggers (lack of sleep, certain food or activities, personal conditions or sensibility and stress), when a large amount data is collected and analysed to determine personal tendencies that even offers an interesting potential use of collected data for research purposes, taking into account confidentiality and security of the information.

After current development, the accelerometer of the smartphone for seizure detection will be substituted by a very sensitive sensor kit in a wearable device to detect other kind of seizures with minimum clinic symptoms like tremors and temperature and cardiac rhythm changes.

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