Accessible Mobile Application to Support Self Testing for Anticoagulated Patients using a Personal Health Record
Appliying Good Practices

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Abstract: Full adoption of Information Technologies in the healthcare domain is a reality. New paradigms as mobile computing can support a big amount of healthcare needs. The aim of this research work is to present the application of good practices in the design of healthcare information technology following a methodological approach for apps in mobile environments involving fictitious users based on knowledge of real users in the app design. Real users' needs have been extracted from empirical researches, guidelines and standards, favoring an outstanding role to users. In order to illustrate the approach and provide a resource to designers, a case study showing how to obtain an accessible design is introduced. The mobile app considered supports a Personal Health Record and self testing for anticoagulated patients who are often elderly. The access characteristics of the elderly and their possible disabilities are essential aspects to keep in mind in the design of a mobile user interface. To address users' needs on the healthcare mobile applications it has been concluded that the requirement elicitation must take into account functional requirements concerning aspects that characterize a disease, and accessibility requirements related to special needs of patients suffering a disease.

1 INTRODUCTION

New laws, global competition, technological advances, and evolving societal values toward disability require the integration of universal and accessible design principles into the general practice of the design community (Erlandson, 2010). Governments support the adoption of Information Technology (IT) on their national health systems and especially Electronic Health Records (EHRs) (Blumenthal, 2009). The purpose of EHRs is to retrieve all the health information of a patient distributed in a national health system and in health providers´ records, giving access to this information to doctors and patients. One way to accomplish the goals of health care IT adoption is to give the patients/health care consumers more control over their health care and wellness by enabling them to own and manage a Personal Health Record (PHR) (Harrison, 2010). PHR is supposed to be used by all citizens, so systems that support PHRs have to be accessible by the population

There are many areas in which medicine and health are being influenced by the impact of apps and mobile technology, from patient education and communications, to biometrics and EHRs (Moore, 2012).

When using a PHR, the ideal situation allows individuals to interact with their health care providers in real-time to review, update and customize their own personal health maintenance and health improvement plans (Harrison, 2010). A set of patients that need periodical interaction with their physicians are anticoagulated people. They receive oral anticoagulants as medical treatment.

Oral anticoagulants are commonly used in the elderly (van Walraven et al., 2007). The rate of venous thromboembolism in the general population is approximately 2.5% (Viale, 2005) and it is estimated that nearly 60% of patients diagnosed with venous thrombosis are aged ≥ 70 years (Bauersachs, 2012).

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The drug dose they have to take has to be regularly adjusted to avoid the appearance of problems. Patients can adjust their daily oral anticoagulant dose using self testing techniques. This issue has motivated the domain of the proposal, which is presented in this work.

In this paper is proposed the design of an accessible app to support a PHR for anticoagulated patients trained for self testing.

Moreover, it is essential to keep in mind the user in the development process of the application, and furthermore to take into account the functional requirements elicitation, to consider accessibility requirements and special needs of the target application, in this case, the elderly. As it is a reasonably well documented fact that software requirements definition has a big impact on final product quality,, app's functional and accessibility requirements have been collected to achieve a proper app design.

In conclusion, we present a case study where is proposed an approach of applying good practices in the analysis and design of an app for the medical domain, which can be extended to others. App's functional requirements have been extracted from medical literature, where is described patients' required care and illness treatment. To obtain app's accessibility requirements, it has been studied standards to first detect target users' accessibility needs.

User target of the app is elderly because they are who usually suffer embolism or thrombosis such as has been indicated, of which prevents oral anticoagulants. Elderly people pay more attention to technology when they consider that it is useful for them (Sayago et al, 2011) Also, to increase the technology acceptance is very important to build and implement an accessible app design because some disabilities are inherent to age like cognitive or visual impairment (Hanson, 2009).

2 RELATED WORK

The PHR adoption for self control of personal health status and the use of IT and mobile devices to develop health applications are two topics that are currently working. The literature review carried out in (Dorr et al., 2007), stands that was found that many of the reviewed systems to support care for chronic illness were successfully implemented.

Apps developed for healthcare domain try to solve different challenges. Some of them are the monitoring of a patient daily life and provide assistance in emergency situations as in (Kozlovszky et al, 2011). The work of (Ogawa et al., 2012) introduces a mobile application in which doctor can look up patient's health information. The data contains information about a patient's medications and medical examinations. The app is not a PHR, it is a Medical Health Record nevertheless, the concept of implementing a medical history can be adopted on PHRs. In (Puustjärvi & Puustjärvi, 2012) authors become aware of new healthcare models in which co-operation between patient's healthcare team is required.

The success of any software system depends on how well it fits the needs of its users and its environment. Requirements Elicitation (RE) is the process by which the requirements are determined. Related work of RE in the domain of mobile app for health have been found in (Widya et al., 2009). Their work is framed in a UCD approach, in which highlight the need for UCD development and argue for an early user involvement (Samaras & Horst, 2005).

Following this approach, in the present work has been taken into account special needs and requirements of the users' accessibility before design. Previous work on addressing accessibility to PHRs has been done. In (Basdekis, Sakkalis, & Stephanidis, 2012), authors present a set of guidelines to implement successfully an ePHR. Their motivation to provide the guidelines is that although web based PHRs systems are plenty of functionalities and are user friendly, they do not fully implement accessibility standards.

3 ANTICOAGULATED PATIENTS

A patient can be considered as anticoagulated when he/she takes medicine to avoid suffering a thrombosis or an embolism. A person should start an anticoagulation treatment when he/she is inside a group composed of people who have known risk factors that potentially can cause a thrombosis or an embolism.

The most popular medicine is oral anticoagulant. Anticoagulated patients have to remember two important facts: oral anticoagulant dose has to be adjusted periodically by a cardiologist and they have to take the dose each day at the same time. A cardiologist has to done the adjustment of the dose measuring the prothrombin time. It is the time that

takes a patient with the coagulation altered to coagulate as compared to the time that it takes to a patient with non altered coagulation. The standard measure unit for prothrombin time is International Normalized Ratio (INR). The test to measure prothrombin time is called PT/INR test. When the dose is not well adjusted, it can cause a haemorrhage or the appearance of clots.

A large group of studies demonstrated that self testing is an effective technique to improve oral anticoagulant treatments and the quality of life of anticoagulated patients (Heneghan et al., 2012). Self testing is when patients measure by themselves their prothrombin time. A customized algorithm for each patient helps to adjust the dose. Anticoagulated patients have to maintain tight control on taking their medication and adjusting the dose.

4 PERSONAL HEALTH RECORDS

A Personal Health Record (PHR) service allows a patient to create, manage, and control his or her personal health data in one place through the web, which has made the storage, retrieval, and sharing of the medical information more efficient (Li et al, 2013). Traditionally, people have not has access to their health information, so a PHR system is focused on collaboration between doctors and patients and they allow patients to manage and monitor their health record.

What it is expected to record on a PHR varies according to user needs and what data can provide doctors and health organisms. The collaborative disease tracking has the potential to lower communication barriers between patients and caregivers (Tang et al, 2006).

PHR's have support of governments and institutions. The IEEE-USA Medical Technology Policy Committee developed in 2012 a position statement to the widespread adoption of PHR's. This statement aims to fit together PHR systems and assistive technologies. Also, instructions about facilitate PHR adoption by implementing the system on mobile devices and tablets are given.

The architecture of a system that implements a PHR has been described in the literature as done in (Tang et al., 2006) and in (Daglish & Archer, 2009). There exist three predominant architectures: tethered PHRs, standalone PHRs and Integrated PHRs. The architecture chosen in this work has been the integrated as it contains the push model: patients are going to be the data providers and it is expected a two side communication with physicians.

5 APP ANALYSIS

This section includes requirements gathering, not only functional type, but also user requirements such as requirements of accessibility and special needs. All knowledge has been obtained through field research and analysis of standards. This information in a case of real application should be complemented by the opinions of stakeholders like patients and medical practitioners.

5.1 Functional Requirements

To support self testing for anticoagulated patients and recording of their personal INR results, user requirements for the app are presented on Table 1. They are closely related to aspects that characterize anticoagulation treatments.

Table 1: App's functional requirements.

Functional Requirements	
ID	Description
FR-01	The app shall show the user the dose that he/she has to take.
FR-02	The app shall show the user the time when he/she has to take the next dose.
FR-03	The app shall show the user the current date on the same screen where it shows the dose.
FR-04	The app shall show the user the last INR test results.
FR-05	The app shall show the user if the dose has been validated by his or her cardiologist.
FR-06	The app shall allow the user to update the current INR test results.
FR-07	The app shall allow the user to send to his or her cardiologist the current INR test results.
FR-08	The app should allow the user to edit the current INR test results if them has not been sent to his or her cardiologist.
FR-09	The app shall receive notifications from the user cardiologist that contain the updated dose.
FR-10	The app shall update the dose that shows to the user and mark it as valid when the cardiologist notifies to the app his agreement.
FR-11	The app shall allow the user to save the dose to take and the INR test result of each day.
FR-12	The app shall allow the user to look up previous amount of dose taken together with the corresponding INR test result.
FR-13	The app should allow the user to share by email his or her record of previous amount of dose taken together with the corresponding INR test results.
FR-14	The app should allow the user to set dose reminders.
FR-15	The app should alert the user at the time set for reminders.

5.2 Accessibility and User Needs Requirements following Standards

Accessibility requirements elicitation has been divided in two steps. In the first one, both ISO IEC TR 29138-1 and ISO IEC TR 29138-3 standards have been checked in order to check for accessibility aspects to include on the app. In the second one, accessibility suggestions extracted from first step have been translated to accessibility requirements.

5.2.1 Accessibility User Needs

The ISO/IEC TR 29138 is a set of standards that collects needs for disabled people when using information technologies. It is divided in three parts, but only two of them have been used in this work. The ISO/IEC TR 29138-1 identifies user needs according to both kind of disabilities and the typical interactions with information technologies. The motivation for describing each user need is to get closer to the problems that people with disabilities have when they interact with the technology

These technical reports include disabilities as blindness, visual impairment, deafness, hearing impairment, deaf blindness, physical impairment, cognitive and language and learning impairment. Additionally, when needs match to all the disabilities listed above, “any kind of disability” category is used. As indicated, older people are the target of the app, therefore keeping them in mind their needs are discussed in this section. Older people’s user needs respond mainly to cognitive impairment, as can be read on (Hanson, 2009), and also important ones were found on visual impairment and hearing impairment categories.

The ISO IEC TR 29138-3 groups all the user needs identified on ISO IEC TR 29138-1 by kind of user interactions. This research has consisted on first, understanding motivation for each user need to properly extract those related with app’s target users and second, on mapping extracted users’ needs with accessibility requirements. In this case, thirty four elderly needs have been extracted, taking into account the app context and the app functionality.

5.2.2 Resources for Mobile Accessibility Guidelines

Each mobile platform support different user needs. The major mobile platforms are iOS and Android. With regard to accessibility documentation, the following works have been found: Apple Accessibility Programing Guide for iOS, Apple iPhone User Guide and Android Developer Accessibility API Guide. It can be learnt that iOS operating system supports accessibility since its prior versions by including on itself a group of accessibility features, while accessibility features on Android operating system are mainly provided by third party. So, the chosen platform has been iOS as it provides high maturity level accessibility features on version 6.0, useful for the development of the app. Table 2 shows the accessibility requirements obtained, which have been elicited from the extracted elderly needs.

Accessibility features included on iOS can be directly adjusted by users accessing the settings menu. Features that implement some of the accessibility requirements obtained are: zoom and large text, accomplishes AR-02, mono audio, accomplishes AR-05, and LED Flash for Alerts, accomplishes AR-08.

There are other facilities that are implemented on iOS environment. One of them is the device control volume. Users can adjust sound volume with device volume buttons or inside settings menu. Another is the app design that can be made taking into account the Apple iOS Human Interface Guidelines (Apple, 2013). In this guideline, it is explained how to use iOS technology and UI iOS app elements to improve user experience. By taking in consideration this guidance, AR-15 accessibility requirement could be successfully implemented. For requirements not supported by iOS platform, it is suggested to include a preferences view on the app where the users can adjust required values. Finally, the app shall provide mechanisms to preserve information privacy stored on the PHR.

6 APP DESIGN

Guided by guidelines and results obtained from empirical researches, the next step is to design a prototype based on requirements previously collected. Stakeholders must evaluate the prototype iteratively. To design the app appropriately, it is necessary to consider look and feel empirical guidelines taken from (Rello et al., 2012).

Next, app’s user interface mockups for the prototype are included. A mockup is a middle to high fidelity, design representation.

Figure 1 shows the state of the app when a patient uses it the first time in the day. When opened, the app loads “Today” tab, which mainly

Table 2: App's accessibility requirements.

Accessibility Requirements		
ID	Description	User Need Traceability*
AR-01	The app shall allow the user to change the information's color attending to his or her preferences. By default, text's color in foreground shall contrast with the background color.	1-5, 1-11
AR-02	The text contained in the app shall be readable. If available, it is suggested to use platform's accessibility facilities as zoom or augmented text.	1-6, 5-5
AR-03	The app shall allow the user to suit the sound volume attending to his or her preferences. By default, sound volume is the one configured on user's device.	2-3
AR-04	The app shall implement different vibrations patterns for each alternatively vibration.	2-5
AR-05	Sound provided for notifications and alerts shall be monaural except if platform's accessibility facilities allow combining stereo channels.	2-6
AR-06	Logos and other decorative elements shall not adopt the controls' aspect.	3-2
AR-07	Controls and information areas shall visually contrast between them adopting if necessary the platform's design guidelines.	3-4, 4-6
AR-08	The app shall allow the user to activate visual indicators when a notification or alert occurs. If available, it is suggested to use platform's standard LED flash alerts.	4-5
AR-09	Sound provided for notifications and alerts shall have enough audio quality and shall be free of pith shifts.	4-7, 5-8, 5-9
AR-10	The return of an action shall be predictable according to the instructions contained on the control used to activate the action and shall happen at the same location where the control is.	5-10, 5-12, 12-12
AR-11	The app shall not require using simultaneous gestures to activate controls.	6-6
AR-12	The controls that activate similar or same actions across the app shall be activated in a similar way and located in a similar place	6-2
AR-13	The app shall alert the user when an error occurs and provide him or her clear guidance about what to do to solve it.	9-1, 9-2
AR-14	The app shall provide mechanisms to protect user information and maintain its security.	10-2, 10-3
AR-15	The app navigation and the use of controls shall be designed using platform patterns and human interfaces guidelines.	12-12, 13-6, 13-8
AR-16	To perform and action, the app shall not request for more than three steps.	13-8, 13-9, 13-11
AR-17	The text contained in the app shall be easy to understand and all the icons inside controls must represent correctly their purpose.	13-2, 13-8, 14-1
AR-18	The app shall provide a help screen where the user can learn how to use the app.	13-10, 16-5
AR-19	The accessibility preferences implemented in the app shall be change when the user needs them.	16-2
AR-20	The accessibility features shall not be blocked unless the user deactivates them.	16-10
AR-21	The updates of the app shall respect the accessibility features implemented on previous versions unless are not useful for the users.	16-1

* Elderly user needs extracted from ISO IEC TR 29138-1 and ISO IEC TR 29138-3 standards

supports patient's self testing. As in the current day patient does not have made self testing and thus his or her cardiologist is unable to validate the dose, the app mark the dose as not validated. The app shows information about
next take time. It is required to anticoagulated patients taking only the necessary amount of dose and always to take it at the same time of day. When patient taps on "Insert today INR result", apps navigate to "Today INR result" view showed on Figure 2. In that view, the app asks for today INR result. When inserted, patient has the option of only save the INR result on his/her PHR and send it later to his or her cardiologist, or both save and send the INR result. When result has not been sent to the cardiologist, patient can edit the introduced result. Alerts can indicate the successful or the failure of patient's action.

Back to the first view, supposing that the result, together with the dose of the previous day, was successfully sent to the cardiologist, when the patient is back, he/she has to wait for cardiologist dose validation. The user receives the cardiologist dose validation by a push notification. It includes the dose that the patient has to take that day and the INR test result sent for patient confidence in the dose recommended. When the app handles the notification, it validates that data on the first tab.
Tapping on the top left bottom, patients can access to edit the reminders The top right "Gear" button is on both tabs to provide patients always access to set his/her preferences. In the "Preferences" view

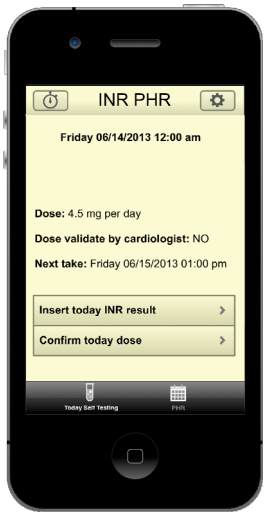

Figure 1: Dose not validated.

Figure 2: Today INR result.

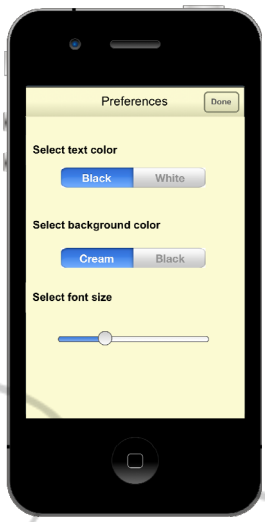

Figure 3: Preferences view.

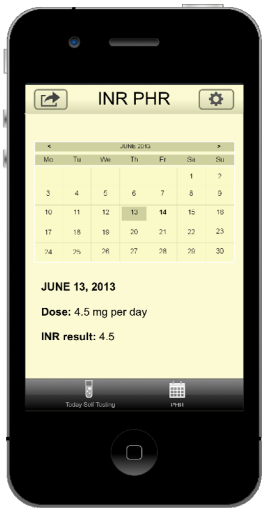

Figure 4: INR PHR.

(Figure 3) they are able to customize text and background colour and font size from defaults. Second tab Figure 4) provides patients access to their previous personal INR test results. Data is the one stored by the patient day by day. In this tab patient can look up by seeking on the calendar his/her personal INR test result and the validated dose for a day, included the current one if the dose has been validated. When the user taps the up left "Share" button, the data can be sent by email default to patient's cardiologist. If the user allows physicians to include his or her PHR on their MHR, the app sends the whole database and attaches a PDF file to allow a fast review.

7 CONCLUSIONS, LIMITATIONS AND FUTURE WORK

Many researches have been focused on supporting conceptual and technologically PHRs. Also new challenges in healthcare domain have been addressing with PHRs.

With an appropriate tracking, anticoagulated patients are able to lead a normal live. To avoid problems arising of a defective dose adjustment, self testing is positioning as a feasible and powerful solution. Mobile technologies can provide an efficient support to self testing. Additionally, with mobile technologies it is possible to implement mobile PHRs that allow both patients and doctors to look up everywhere at every time patients' health data.

All these facts have allowed us to highlight the importance of involving real users. We have to remark that the limitation of the proposal is that in the current state of the research, we do not have feedback from real users. Knowledge about anticoagulated patients and their needs, related to their illness and to accessibility, has been captured from field research, as high impact publications and standards.

In the future works, we are going to situate users as key stakeholders in the development process following User Centered Design methodology, integrating previous approaches such as "Customer Driven Innovation", "Outcome Driven Innovation", "Voice to Consumer", "Open Innovation" or the approximations related with the innovation based on social networks (prosumers).

At the mobile app evaluation phase, the technological effectiveness of the solution will be considered. This is the ability of a solution to be effective, efficient and to solve the real problems of the target population within a real environment. This analysis will be done attending to the following factors: emotional focus, ergonomics (including cognitive, functional and organizational ergonomics, universal design and familiarity), citizen innovation, sustainability (social, economical and environmental), security management, ethics and neuro-usability (evaluation of real perceptions).

All these factors are considered (when appropriate) in the different development phases (from prototype evaluation to market), especially in the design and evaluation stages.

Summarizing, the purpose of the research is to underline the significance of well gathering

requirements in order to they really reflect users' needs. We have work on illustrating with a test case a good practice to define requirements, taking users into account, to get a suitable design. To validate the design is necessary that real users test it.

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