Mobile Health Systems for Bipolar Disorder

The relevance of Non-Functional Requirements in MONARCA Project

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ABSTRACT

This paper presents a series of challenges for developing mobile health solutions for mental health as a result of MONARCA project three-year activities. The lessons learnt on the design, development and evaluation of a mobile health system for supporting the treatment of bipolar disorder. The findings presented here are the result of over 3 years of activity within the MONARCA EU project. The challenges listed and detailed in this paper may be used in future research as a starting point for identifying important non-functional requirements involved in mobile health provisioning that are fundamental for the successful implementation of mobile health services in real life contexts.

Keywords-component; personal health systems; bipolar disorder; mental health; lessons learnt.

INTRODUCTION

When designing mobile health systems the focal point of research is frequently concentrated on the design of innovative developments for improving the practice of healthcare and increase of wellbeing with a strong focus on functional requirements. On this regard, the aspects related to definition of non-functional requirements of mobile health provisioning are often underestimated or left as a secondary item to take into consideration by researchers. However only through a thorough consideration of potential implications on design of non-functional requirements, the mobile health innovations can find an opportunity to transform into sustainable solutions that can be applied in real life contexts. These kinds of requirements comprise all the practical aspects of healthcare provisioning that are necessary to implement mobile health services ranging from human factors to important medical and technological issues.

In this paper we introduce the experiences learnt in MONARCA project for developing a mobile monitoring system for better handling the treatment of bipolar disorder and the challenges found related to its implementation in a real life context. The main contribution of this paper focus not only on the innovative mobile health solution proposed by MONARCA but also on the technological and clinical aspects that were necessary for conducting multidisciplinary research in the context of such project and on other non-functional requirements that are key in the development of technological solutions for the design, development and evaluation of mobile health systems. Such requirements include aspects related to technology, human factors, medical practice, regulatory aspects and other practical issues that are identified in this paper as key challenges in the development of future mobile personal health systems and services (see figure 1).

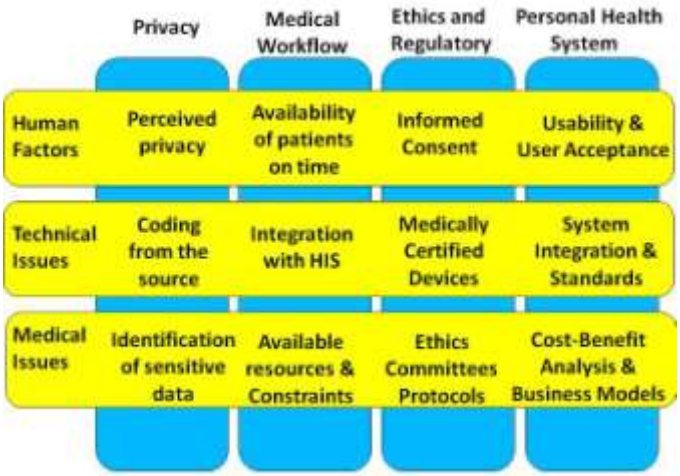

Figure 1: Relevant Aspects in Multidisciplinary IT-based Clinical Research

MOBILE TECHNOLOGY AND BIPOLAR DISORDER TREATMENT

Current medical practice of bipolar disorder treatment is based on identification and analysis of mood instability episodes at different intervals of time without possibility of continuous monitoring in a practical way. On this regard, with the use of currently available technology and innovative processes proposed by recent research approaches [Mayora 2011] it is envisioned in the short term a new generation of services to improve healthcare provisioning in the treatment of mental health diseases [Arnrich et al 2010] [Arnrich et al 2013]. In particular due to the wide acceptability of mobile devices and the growing interest in the development of healthcare-related apps, there is a clear trend on the use of mobile phones as a key enabler of new wellbeing/healthcare services. In fact, some of these new developments are already going in the direction of using mobile phone-based sensing for monitoring conditions related to specific mental diseases such as bipolar disorder [Puiatti et al 2011]. In such kind of applications, the mobile-phone-based sensing architecture integrates the set of novel services and supports key functionalities on sensing and data analysis, patients interfaces (client side) and hospital and health information systems (server side) as in MONARCA system in figure 2 [Mayora 2011].

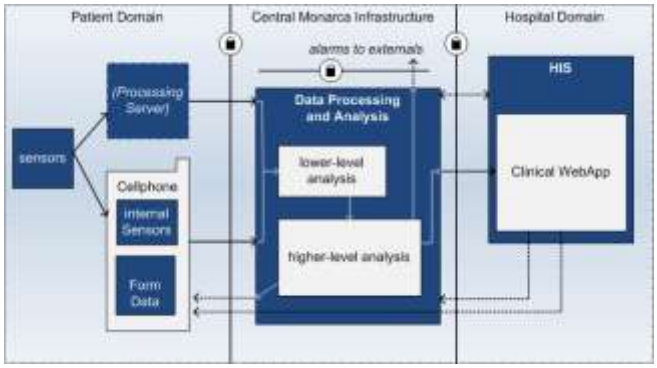

Figure 2: MONARCA system basic components

Regarding the specific treatment of bipolar disorder, during the past years, as well as in other healthcare domains, there has been a major organizational switch in paradigm from inpatient treatment to outpatient treatment. On this regard, there is currently a scientific switch going on in the paradigm of treatment in bipolar disorder from focus on the mood episodes to focus on the inter-episodic mood instability [Bonsall 2012] (see Figure 3).

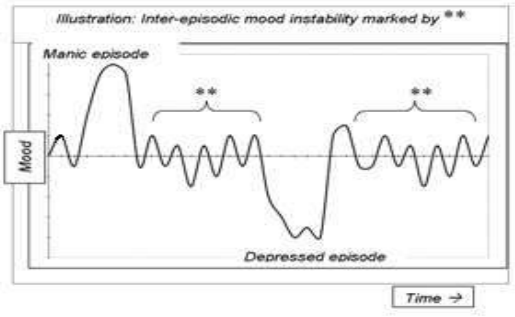

Figure 3: Inter-episodic mood instability from (from Bonsall et al. 2012).

The role of mobile phones in continuous monitoring of personal health condition for bipolar disorder patients implies a novel way to include objective data regarding patients activity and behavioral conduct while allowing also for more subjective input based on self-assessment (as in traditional bipolar disorder therapy). In this way, the information received by clinicians is complemented for a better decision support while defining the patients' therapy. In fact the ability of subjective measures such as self-assessment to detect prodromal symptoms of depression and mania may be not be sufficient compared to objective measures such as speech, social and physical activity that is indeed achievable with the use of mobile eHealth technology [Sobin et al 1997] [Benazzi 2009] [Weinstock et al 2008] [Kuhs et al 1992]. However, all these behavior-related features that are actually obtainable as objective measurements with current technology, pose a series of challenges and open research questions on translating them into meaningful information for physicians and patients.

It is important to consider that the utilization of technical monitoring systems in the field of mental health inevitably causes several challenges on the patients' sphere. On this regard, mobile sensing systems have to be suitable for the daily use and need to incorporate adaptive user-friendly strategies regardless of whether the patient is depressive or manic. The design needs to consider that the use of the system should impact on the patients' mental state because any technical issue that may be cause of additional stress. In addition, future personal health systems should enable agreement (concordance) between patient, relatives and clinicians, which is highly important for treatment outcome. It is very often a crucial problem that patients, relatives and clinicians comprehend the patient condition in different ways and consequently they will each aim for different (treatment) methods and goals.

The following sections provide a series of requirements that have to be taken into consideration when designing mobile health applications in the field of mental health. The proposed requirements are the result of the experiences and reflections on MONARCA three-year project and constitute a series of recommendations to take into consideration in future mental health developments.

HUMAN FACTORS IN MEDICAL HEALTH RESEARCH

Conducting research in healthcare domain that involves humans either if they are clinicians, patients or caregivers is notably different from other domains and presents special challenges to researchers. There is a very high focus on ethics and patient safety, and there are challenges in maintaining confidentiality high while operating in very private spheres. In these contexts, if not treated carefully, there is a high risk that the researcher may be considered an intruder. In addition, there are difficulties in establishing a common language between medical practitioners and technologists, and a high risk of the potential impact in patient treatment that the developed systems may produce. Through our work with patients and clinicians in the MONARCA project, many interesting questions arose, many thoughtful moments occurred, many considerations were done, and many lessons were learnt, and thus, we have tried to summarize some of the key human factors we have encountered during our work:

Exposure to Patients

Emotions among patients with mood disorders are intense and can be twisted. Experiencing patients crying, shouting, wanting to die, strapped to their beds, etc., can be a disturbing experiences for non-clinical researchers. It is hard to prepare for this, but at least you should be aware of it.

Functional vs. non-functional

Often HCI researchers are very focused on the functionality of the systems, but there are a lot of non-functional aspects that have to be in place for the technology to work. For instance, we encountered examples of ensuring patients having a data plan for their 3G connection, enabling them to transmit their data from the phone to the hospitals server. The need for teaching the clinicians how to operate the system, to be able to access the data, and prepare user guides as well as a hotline for technical assistance for when they encounter issues they cannot solve. For a project to be successful, it is important to pay attention to non-functional aspects, as they can become showstoppers if not taken into consideration. This is a highly difficult and exhausting task, especially with elaborate and multi-user systems, but it must not be neglected.

Trust and Transparency

Trust or the lack there of, is a foundational part of any relationship. In particular it is critical to relationships in the realm of healthcare. The patient trusts that their team of healthcare professionals is going to manage their wellness appropriately. When introducing a new technology, like the MONARCA system, it is important to build a trustworthy relationship with the patients, ensuring their commitment and willingness to provide intimate health care data, which is maintained by a transparency in both systems and actions. If it fails, the patients will stop to use the system and the value of the system supporting the treatment is lost.

Usability and Acceptance Issues in Real-life Conditions

Conducting a real-life study including people suffering from a mental illness who are not necessarily trained in using technology can arise issues of human nature.

- MONARCA Mobile Phone-based Approach – Using familiar devices in these kind of studies such as mobile phones, and base the monitor platform on them could eliminate the main obstacles posed for example in requiring the use of external sensors (i.e. wearable devices) which people may not be so familiar with and that may stigmatize users. On this regard, MONARCA approach was that of proposing a mobile phone sensing approach under the hypothesis that people have a large acceptance of such devices and normally are not afraid to get in touch with them. Nevertheless a certain

attraction of test-subjects and patients to modern technology turned out to be a necessary precondition for a successful deployment of this study. In fact, in some cases we came across this issue especially with the first patients, who even though were very eager to participate in the study, eventually were overwhelmed by the various unfamiliar functionalities the smart-phone provided and therefore dropped out.

- Users Perception of System Usefulness – To our surprise, most patients were not much concerned about privacy as long as it was guaranteed to them a sensitive and anonymized treatment of their data. Bipolar patients, when they start to realize and accept their disorder, are aware that they need help, because they do not want to experience extreme episodes. Therefore, a lot of them were willing to try new ways, especially if those ways might help them to reduce the amount of anti-depressant or mood stabilizing medicine, as these medications normally cause unwanted side effects. Therefore, when they were asked to participate in a study, which might help them in the future to deal with their disease, a sufficient number of patients were willing to participate. So with the help of the psychiatrists who established the contact to the patients, the recruitment of patients was easier than expected.

TECHNOLOGICAL CHALLENGES IN MENTAL HEALTH RESEARCH

When deploying a real-life study in health care and especially in a psychiatric environment a number of challenges have to be faced [Gruenerbl 2012]. Very often these challenges are a mix of regulatory and human requirements that have a strong implication in the technical solution to be implemented. In particular, these requirements pose a series of restrictions that have to be addressed from a technical viewpoint including privacy constraints, security aspects, battery limitations and in general a series of non-functional needs that if not addressed properly during the solution design, can jeopardize the successful adoption of the proposed system.. On this regard, a series of technical challenges faced during the development of MONARCA project were identified as follows:

Need to Technically-Obscuring Sensitive Data

Being a project relying on identifying high-level behavioral information from patients' activity, MONARCA used a number of different sensors acquiring sensitive data. On this regard, a very important requirement was that all the sensor readings had to be anonymized before analyzing them to guarantee the privacy of the participants. This meant that different precautions should have been taken right after the data acquisition to avoid reconstructing signals that could be related to specific patients as follows:

- Location parameters such as GPS coordinates, extracted from the mobile phone had to transferred into a neutral coordination system before processing them. In addition Wi-Fi and Bluetooth signals were used for establishing presence in certain areas and proximity to other users without necessarily establishing a clear correspondence to whom and where in particular.

- In order to perform frequency-analysis on voice during phone calls, the respective algorithms for speech acquisition had to be developed in a way that scrambled the actual signal to avoid its original reconstruction while keeping the required properties for analyzing the voice. The scrambling mechanisms work in a way that the voice was sliced into small chunks and these slices were randomly permuted within each second, resulting in a negligible speech intelligibility. In this way, the speech of the person become not understandable, while at the same time the performance of the acoustic analysis of the speech was not degraded.

- In addition to codifying the speech signal, the recorded scrambled conversations were anonymized before stored on the smart phone.

- Data security was achieved by encrypting all the acquired data directly inside the smartphone memory with the Advanced Encryption Standard (AES) and the communication between the smartphone and the server was done via HTTPS, resulting in an additional security layer in the data transfer process.

Flexible Strategies for Data Transmission

Personal health systems collecting patients' information for further processing need to establish a clear strategy for secure data transmission from the monitoring device to the server. The original set-up in MONARCA project for data transmission was designed to automatically transmit the data. All data would have been transmitted to a secure server belonging to the psychiatric hospital facilities via a secure connection at least once a day. Even though the infrastructure was already set up in this way (and worked properly in Copenhagen trial), in one of the trials in Austria it had to be changed before the study started as it turned out that most of the possible participants neither owned an appropriate wireless Internet connection at home, nor full 3G Network and DSL coverage was guaranteed. To overcome this issue, the set-up was changed to internal storage of all sensor readings using SD Card, which were transferred every 2-3 weeks into the server during the appointment of the patients at the psychiatric hospital facilities. d Even using the external SD Card, it was a challenge to store data in different ASCII format files for more than a couple of weeks. Therefore, we serialized all the data being collected using the Google Protocol Buffers. This resulted in a 70% reduction in size of data stored in the SD Card.

Software stability and OS Versions

Another technical issue consisted in finding an appropriate Android operating system in which implement MONARCA solution. In general, one of the big advantages of the Android system is, that it is not limited to one specific smart phone brand but is available for various different cell phone types from different smart phone producers. Yet this advantage turnout to be a big limitation we had to deal with because the Android OS is partially adapted for different producers. The main issue here was, to find an Android based smart phone with an OS, which allowed accessing the sensors even though having the display turned off. Not all OS variances permitted this by the time the study was conducted. In later updated versions of the operating system this feature came per default and thereby eliminated this issue later. However a relevant aspect to consider in further developments is the extend in which different versions of operating systems may work in different devices and therefore a good strategy has to be defined to overcome this kind of issues.

Devices Performance Limitations

When involving different types of monitoring devices, it is not granted that all devices will have the expected performance in real life as in ideal conditions. In particular in MONARCA, the first tests of the running smart-phone application revealed that the smart-phone tended to get rather hot for some specific set-ups. This was especially true when no Wi-Fi signal was available, because this set-up triggered the Wi-Fi port to increase the scan-frequency by default of the OS. Next to increasing the smart-phone's temperature it decreased the battery-life tremendously. This brings us to another technical issue that is the battery life itself. As in numerous other technical applications, the main critical part in using a smart phone for data recording is the phone's battery life. Constant operating of all sensors in a high-resolution mode reduces the

battery life to few hours making some applications unusable in real-life conditions. To overcome these issues of battery usage, the design of the system was optimized as follows:

- The acceleration sensor was used to trigger most other sensors. This was feasible as for example on unmoved cell-phones (that will not change their position), therefore GPS/Wi-Fi sensing was reduced to a minimum while the cell-phone was identified as not moving.

- Furthermore, as long as a person stays inside of a building GPS is only of little use, while Wi-Fi if available would provide the needed position information. Therefore, the usage of GPS, which itself is highly power consuming, was turned off indoors while Wi-Fi was available.

Physiological Monitoring Constraints

Besides the mobile phone with its incorporated sensors the MONARCA system consists of two further sensing modalities: A wrist-worn activity monitor and a mobile electro-dermal activity (EDA) sensor. The two major technical challenges faced concerning the requirements of these continuous measurements were the mobility and the unobtrusiveness. To ensure the mobility of the system, the sensors have to be lightweight, small and offer an acceptable battery lifetime. Incorporating the wrist-worn activity sensor in an unsuspicious watch and hiding the EDA electrodes under the socks reached the unobtrusiveness aimed for. Since in state-of-the-art EDA systems, the signals are recorded at the fingers and under lab conditions, studies had to be performed to prove the value of EDA signals obtained at the feet during every-day activities [Setz 2013]. Besides these technical challenges, the system has to be certified for clinical use. The Ethical committee issued this legal requirement. Facing limited resources and time, this basically prevented us from developing own custom-designed sensor modules, and we opted for off-the-shelf certified devices.

Integration Issues

A multi-component project like MONARCA typically needs to integrate multi-parametric data with origin in different sources such as sensing devices, mobile technologies, medical records, data repositories, etc. This is a challenging task that has to be clear well in advance of the development of single components. The definition of input and output data formats, communication protocols and synchronization parameters is of utmost importance for a proper integration. Moreover, due to the usually high complexity of heterogeneous clinical IT environments, particular focus should be put on robust, flexible, scalable and secure system architecture. MONARCA platform utilized an approach based on a flexible technology (CouchDB) for storing and rendering multi-parametric data accessible from the different modules of the system.

ETHICS, REGULATORY AND INTEGRATION IN MEDICAL WORKFLOWS AND TRIALS

Ethics and regulations

While conducting experimentations involving clinical trials, it is necessary to be compliant with ethical and regulatory constraints. In fact, it is necessary to get the approval of an Ethical Committee before starting any data collection with patients. Moreover, the regulations in each Country (and occasionally in different states of the same Country), very often are different and in general are complicated and time consuming. Because of this, it is crucial to contact very early in the process the respective Ethic Commissions and to get a clear knowledge of the regulatory framework and potential limitations to the expected trials. In fact, during MONARCA we were required to work at several ethic approvals. First of all the approval for the acceptance of conducting clinical trials for a project with the conceptual framework of continuous monitoring like MONARCA and second an approval for each single trial during the project including in detail the scope of

the trial, the policy for users consent and the specific devices to be utilized. This process is a time consuming one and if not done in an opportune way can slow-down and jeopardize the timeline of the project. Moreover, the use of medically certified devices in clinical trials is mandatory and very often this situation constrains researchers to utilize off-the-shelf certified devices to avoid delays. On this regard, special attention has to be put to specific state-of-the-art devices that still don't have a general regulatory framework regarding their potential use as medical devices (i.e. mobile phones and mobile e-health apps).

Integration in clinical/medical workflows

Clinical workflows describe the processes a clinician is working in with patients towards provisioning the required healthcare services. On this regard, in order to implement an accurate working plan towards the development, testing and validating of a PHS, the single steps required to build a continuous healthcare services workflow have to be modeled in a coordinated way between clinicians and technologists. Secondly, the integration of extra working steps for a clinical trial and later for the use of the PHS has to be discussed and modeled into the existing workflow in a way that does not disrupt the healthcare service provisioning plan but instead improve it. Moreover, it remains a significant challenge to fit the workflow into clinical routine since patients or existing resources may not be available as planned for specific trials.

Trials Constraints

The entire study was conducted in a real-life deployment. In order to avoid difficulties in following deployments an important part was to learn every possible lesson: The first big issue we came across was obtaining the approval of the ethics committee. Not every parameter can be influenced here yet the better one is prepared the less surprises will come along. As long as authorities (specifically in health care) do not approve a study the hands are tied and this can turn down or cut in a study or cause severe delays. Therefore it is important to carefully examine and understand local and countrywide laws and regulations in order to design equipment to be as fitting to the regulations as possible. More over in real-life deployments in health care it is inevitable to use certified equipment. If sensors used, are in-house productions they should be certified beforehand. Otherwise the study might run into trouble. Here it can help a lot to have a back-up solution available and ready.

As part of the trials, the appropriate rewards and compensations for motivating patients to take part should be considered. While conducting MONARCA studies it turned out that an appropriate beneficiary/compensation system was useful for motivating participation. This is particularly relevant specifically in the studies where the pool of possible test subjects is limited. In our study the practice of letting the test subject keep the smart phone after the trial proved to be an additional motivation for some of the participants.

CONCLUDING REMARKS

This paper presented a series of challenges for developing mobile health solutions for mental health. The proposed challenges can be codified as a set of non-functional requirements that are relevant in the design, development and evaluation of mobile monitoring systems. In fact the general requirements presented here are a collection of recommendations from the lessons learnt after three years of the MONARCA EU Project on supporting the treatment of bipolar disorder with mobile technologies. The challenges discussed in this paper may be used in future research as a set of relevant guidelines in the development of innovative solutions for mental health treatment and in a broader way for future research on personal health systems.

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