Human-Centered Design of a Personal Medication Assistant - Putting Polypharmacy Management into Patient's Hand!

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Abstract. Over the past years, the importance of home-care treatments have been emphasized by governments, promoting the adoption of self-care management models, which may have positive effects on patient's empowerment and on the overall healthcare system. In this context, polypharmacy management represents a major concern. A growing number of people are suffering from multiple chronic health conditions, which especially complicate the (self-) management of prescribed therapies, and puts a significant burden on patients' lives. To alleviate that burden, we have developed a mobile health application, Sedato, following a thorough usability engineering process. Usability principles and guidelines have been applied to design a mobile application, which helps patient assume drugs timely and safely. Besides a reliable notification system, a continuous monitoring activity is performed to keep record of patient's compliance to prescribed therapies. That information is shared in the context of a patientcentered digital health ecosystem, and is processed to produce knowledge relevant to the underlying territory.

Keywords: Selfcare management \cdot Human-centered design \cdot Digital knowledge ecosystem \cdot Mobile health applications

1 Introduction

Over the past years, despite a growing number of chronic diseases, all over the world the application of spending review policies have strongly limited the resources available for healthcare. At the same time, the importance and the centrality of home care treatments have been emphasized by governments, promoting the adoption of healthcare models based on Self-Care-Management (SCM) and on Family-Coaching (FC), which could have positive effects on the overall healthcare system. Both SCM and FC support the goal of 'patient empowerment', the former allowing patients to play an active role in treating themselves, the latter relying on persons close to the patient (the so-called 'informal care givers'), who are directly in charge of managing his/her healthcare [8]. In the context of patient empowerment, a relevant issue is polypharmacy management. A growing number of people, especially elderly people, are suffering from multiple chronic health conditions, which especially complicate the (self-) management of prescribed therapies, and puts a significant burden on patients' lives. If a patient does not adhere correctly to the prescribed medication, he/she may encounter safety problems, including risk of toxicity or worse [1].

To alleviate that burden, we have developed a mobile health (m-health) application, which is the result of a thorough usability engineering process. The application, named Sedato, has been conceived as an assistive m-health application, which supports the patient (or his/her care giver) in the management of multiple medical prescriptions, embedded in a more general-purpose infrastructure connected to physicians and healthcare facilities, to gain patient empowerment.

Since the start of this project our challenge has been to create a product which chronic patients would be willing to use all life long. The problem domain analysis, resulting from a literature review and a contextual inquiry, revealed that the main reason why most existing systems failed lies in the poor interaction experience provided and in the low degree of user's engagement achieved [1]. We realized that was the challenge we had to address and that visual interaction could lead to a successful application.

Adequate usability principles and guidelines have been followed to design a mobile application, which helps patient assume drugs timely and safely, preventing missing doses or unwanted overdoses. Besides a reliable notification system, which also alerts patient when the available quantity of a given drug is about to finish, a continuous monitoring activity is also performed to keep record of patient's compliance to prescribed therapies, and to possibly share that information with the physician. That information is shared in the context of a patient-centered digital health ecosystem, and is processed to produce knowledge relevant to the underlying territory.

The paper is organized as follows. Section 2 explains the problem domain analysis and the derived requirements. Section 3 describes the new model of patient-centered digital health ecosystem as the underlying model of Sedato framework. In Sect. 4 the results of the design process are illustrated on the working prototype, which has been implemented for the Android platform. Related work and some final remarks are included in Sect. 5.

2 Problem Domain Analysis

An inquiry carried out with physicians and clinicians working in either public or private medical centers, in the metropolitan area of Salerno, allowed us to depict scenarios of established current practices in self-care management and to understand to what extent technological support is sought and later adopted by patients. We also wanted to identify the possible causes for the little adoption of existing mobile apps. Three categories of stakeholders were considered for our investigation, namely physicians, informal care givers/family members, and patients.

Initially, we interviewed 8 physicians. The first session of the interview aimed at understanding what strategies physicians usually adopt to improve patient's attitude towards complex medication therapies and the requested periodic checks. Physicians reported that, in case of polypharmacy, many patients, especially elderly people, need to be strongly encouraged for the intake of medications exactly at the prescribed times and with the indicated modalities and they are always recommended to undertake medical checks in agreement with their therapy calendar. They insist with patients on the impact of non-adherence on their health as well as on quality of their lives, but full adherence to the therapy is often missed. During the second session, we inquired physician on the use of mobile applications to support patients in therapy management tasks. We asked them to indicate what aspects of the therapy could be improved, if some light technological support was provided to the patient or to his/her care giver. Most physicians agreed that the regular intake of the prescribed medication could be better achieved through an alert system indicating doses and times. They also highlighted the need for a system able to monitor patient's adherence to a given medication plan and share that information with the physician, when needed.

Another relevant issue raised by physicians was the low level of support to interoperability among healthcare actors, in case of complex protocols for integrated cares (e.g., communication with/among different specialists and real-time access to patient's anamnesis for first aid interventions).

The 8 physicians also helped us select a group of 10 family members and 30 patients, who are suffering from multiple chronic health conditions and are subject to complex therapies and polypharmacy management. The group of patients was composed of 20 people aged over 60 and 10 people aged between 23 and 59. Family members represented elderly patients, whom they assist personally or paying some external care giver. We were able to conduct two focus groups with 22 and 18 participants each.

From patients' point of view, we perceived that their expectation from mobile technology as a means to improve quality of life is high. Independence in care management and safety were the major motivations coming out of the focus groups. Some participants, from the group aged under 60, also reported that they experienced the use of existing mobile applications for the management of diabetes care but no attention was given to their co-morbidities and the necessary polypharmacy management.

Since the initial phases of our analysis we kept in mind the claims coming out of the interviews with physicians and of the focus groups. The challenge was to conceive an m-health system which could improve care experience of patients/care givers while enhancing the overall adherence to complex therapies.

In summary, the main requirements were:

- easy setting and updates of medication plans,
- remind alerts for medication intake, with indication of doses,
- remind alerts when some medication stock is about to finish,
- · easy arrangement of periodic/occasional medical checks, and
- easy information sharing with physicians, so as to improve physicians' decision making based on reliable historical data.

Considering the case of professional care givers or family members, who may need to assist more patients, a further requirement for the envisaged mobile application was

• to create and manage multiple patients' profiles.

The design activities that originated from the above requirements was aimed at exploiting the potentials of mobile technology to automate as much as possible in the self-care management activities of chronic patients, and to possibly transform the derived records of activities into useful information for physicians.

3 Promoting Patient-Centered Health Ecosystem

Handling the multidisciplinary complexity of data coming from a spatially enabled territory and supporting a fruitful information exchange which could empower the territory as well as its inhabitants, represent today major challenges for computer scientists [7]. The concept of digital knowledge ecosystem is being brought about as a possible solution, described as an open and shared environment with properties of scalability and sustainability, capable to realize services through the integration of four basic territoryoriented elements, namely content, communities, practices and policy, and technology. As a matter of fact, a digital knowledge ecosystem works as a collector of information derived from multiple sources, which can be processed to produce knowledge relevant to the underlying territory and support the exchange of know-how among local actors of different domains [3, 4, 6, 9]. The healthcare domain represents a field where such a territorial intelligence and information technology can be combined to strengthen the skills of a territory, to understand its phenomena, to interpret local dynamics involving patients, institutions and organizations [10]. The pervasiveness of mobile technology in people's lives has emphasized the role it plays in healthcare management and a new model of patient-centered digital health ecosystem has emerged, where mobile health (m-health) applications and services are used to collect data from patients and build new knowledge (Fig. 1) [5, 11–13].



Fig. 1. A patient-centered health ecosystem vision

In the new model, mutual exchange of information and services among interested actors in a given territory could be strongly beneficial not only to the individual patient but also to the community he belongs to. Ultimately, the whole territory could contribute to the construction of a collective meaning, leverage collective knowledge, produce innovation in the healthcare management, and create cross-fertilization in terms of value added for different domains.

Preliminary results of such an approach have been experimented by developing a mobile-based information system, MyDDiary app, to address self-care management needs for diabetes patients [8].

MyDDiary was conceived as a solution to enable the user to keep track of his/her daily activities and healthcare actions, in a sort of personal diary, which can be shared with other stakeholders in possibly different domains. Figure 2(a) depicts MyDDiary Home interface, which offers the main functionality grouped by scope and context. Figure 2(b) shows the visual synthesis used for the 'Overview' function, which integrates three different parameters, namely the glycemic index, the calorie count and the percentage of fitness activity done in a given temporal range. Besides the hint that the patient himself/herself can obtain from such a view, this function allows different stakeholders to gain an immediate overview of the current health state of a diabetic user. As an example, the image could be automatically shared with the physician who could analyze it and make decisions about the trend of a specific treatment or detect alert situations.

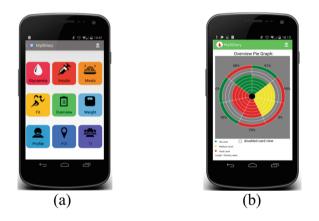


Fig. 2. (a) MyDDiary home interface. (b) The visual synthesis of user's activities.

The framework *Sedato* for medication personal assistance solutions we present in this paper evolved from a MyDDiary long term testing which gave us interesting feedback also concerning possible extensions satisfying requirements arisen from specific needs of a wider users community.

Figure 3 shows how the aforementioned model has been used to design *Sedato*, as resulting from our contextual inquiry described in Sect. 2. The schema is focused on the Web service of Sedato, which is responsible for receiving and sending data useful to the entire ecosystem. As a matter of fact, several actors could interact with it to consume and produce data. One of the main roles is represented by the patient, who provides data regarding s/he state of health, in order to obtain help and any feedback from the entire

ecosystem. As an example, a diabetic patient needs information about the procedure for the treatment plans from a given Department of the Local Health Agency. On the other hand, the Health Department collects data from the approved plans to predict the supply of medicines in the future months to ensure an adequate level of healthcare in the territory. Such an ability to obtain aggregated information related to the territory in nearly real-time opens up the possibility for different companies, organizations and government agencies to enroll in this general-purpose infrastructure and adjust their processes as well as their services dynamically.

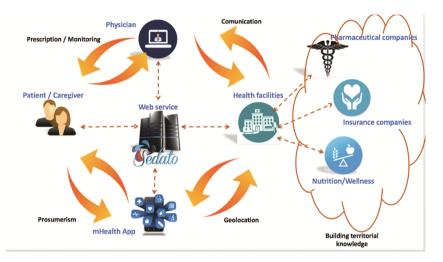


Fig. 3. Roles and actors in Sedato.

An additional important actor is physician, who is responsible to assist patients in the management of care, providing information and suggestions useful to improve their state of health.

The physician is also in charge of communicating with various medical facilities, such as pharmaceutical companies and nutritionists, in order to provide (or receive) data useful for the patient.

As part of this system, both the patient and the physician can be seen as:

- information providers, a useful enrichment of the ecosystem knowledge, and
- consumers, who use the expecially distributed technologies.

Such technologies underlie the so-called mHealth Applications, whose aim is to collect and distribute knowledge within a more general digital ecosystem, conceived also to promote territorial initiatives for a community care.

Finally, various kinds of statistics, ranging from the assumption of certain medications (useful to pharmaceutical companies) to epidemiological analysis on the nutritional needs of a patient, could be produced and shared with the interested stakeholders, new patterns can be discovered and additional facts built also by performing spatio-temporal analyses. The derived collective knowledge could be in turn convenient for the patient himself/herself when it is offered through, e.g., location based services. Figure 4 summarizes basic technologies used in *Sedato*.

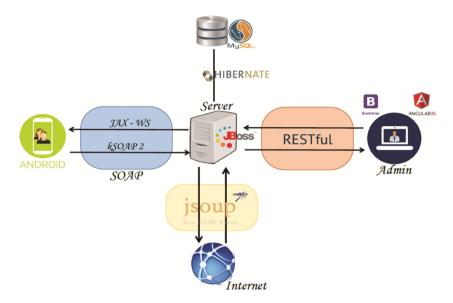


Fig. 4. Technologies in Sedato

Sedato is an Android based application, Java and JBoss have been used for the back end development, while the front-end has been realized by AngularJS and Bootstrap. Moreover, the middleware platform Hibernate guarantees the JBoss-MySQL connection and the RESTful communication is based on the JBoss-Admin connection. JBoss and Client interact via SOAP, in particular, the API JAX-WS for the Android-server communication and the kSOAP2 library for the reverse one. Finally, the parsing of data coming from the external source is based on the JSoup Java library.

4 Design for Usability – Visual Is the Key for Success

A scenario-based design process followed the analysis phase, focusing on activities, information representation and interaction threads. The project team strived to design usable interfaces which would especially support learnability and which would require the least cognitive effort by users, while providing a pleasant user experience and responding to their expectation with respect to self-care management support.

Claims derived from design scenarios included the following:

- For each patient profile, all functionalities should be equally accessible at any moment.
- When adding a new therapy, patient should be able to specify in a seamless way the medication list as well as times and doses for each medication.

- The management of a personal list of drugs, with the related stock quantities should be allowed.
- The system should notify the user when a drug is about to finish and the geo-locate the closest pharmacy.
- The management of intake of drugs using alarm clocks should be allowed.
- The management of the telephone contacts regarding doctors or medical facilities, with the possibility to associate to each one the appointments and/or the visits at home.
- The management of one or more profiles.

From the above claims we were able to derive a set of core functionalities, which may affect patient's daily life, namely

- therapy management
- creation of a new therapy
- medication association
- stockage automatic checks
- intake notification system
- health indicators management
- periodic updates
- health monitoring
- geolocation
- find a pharmacy
- find a hospital
- find a primary care/consulting physician

During the design process, we depicted a set of activity, information and interaction scenarios, which helped us identify appropriate metaphors for our target users, based on the activities they perform in the real world, the physical objects they manipulate to perform those activities and their behaviors. Table 1 provides an excerpt from the activity design phase.

Metaphors were also identified for the information and the interaction design phases, which would leverage users' familiarity with certain objects such as paper prescriptions, pills, phonebook, calendar, alarm clock, etc. The resulting design is illustrated in the following.

Before using the app, the user needs to register either as a caregiver or as a patient. In the former case, he is able to manage more patients, creating separate profiles which may exploit Sedato functionalities (see Fig. 5b). If the user is the patient himself, he may directly access all the app functionalities (see Fig. 5c).

Activity	Metaphor	Design implications
Planning the therapy is like	scheduling a number of appointments with a friend	User may – set a number of alarms (with repetitions), and associate them with the therapy – make notes and write keywords for the scheduled activity – contact a physician for periodic check
Adding a drug is like	adding an item to the warehouse	User may – add a new medication, and – make stock updates

Table 1. Excerpt from activity design tables.

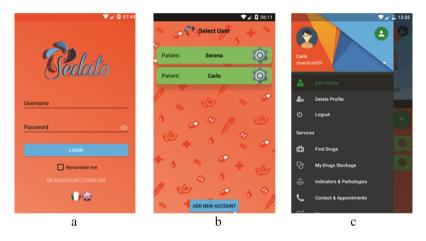


Fig. 5. The personal medication assistant Sedato (a) Login (b) Multi-patient management (only for caregivers) (c) Main navigation drawer with the possibility to modify patients' profiles.

Medication Therapy Management. After the physician has prescribed a new medication therapy, the user may record it creating a personalized therapy, where he specifies the name, the start date, the duration and the associated drugs. For each drug he selects the packaging, sets the daily doses and sets the alarms corresponding to the intake times over the 24 h (Fig. 6).

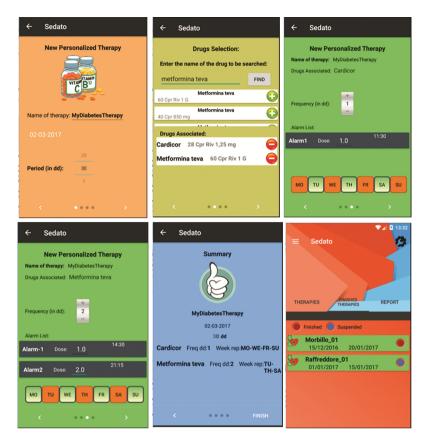


Fig. 6. Adding a new therapy

When the prescribed drugs are added to the therapy, the user may retrieve the details from an Italian public dataset (at http://www.torrinomedica.it/) and choose the right format and packaging. Once the therapy id started, the intake notification system is activated so as to alert the user at the right time and let him confirm or postpone the intake action. Those data are also used to monitor patient's adherence to the given therapy (Fig. 7).

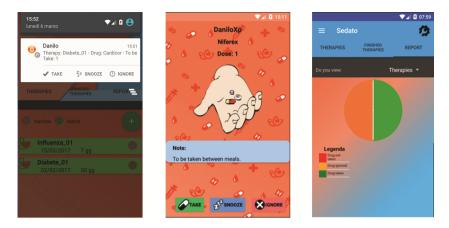


Fig. 7. Intake notification and adherence monitoring.

Health Indicators Management. A set of health indicators, including blood pressure, glycemia, cholesterol, and triglycerides are periodically updated and transmitted to the primary physician to allow monitoring actions (Fig. 8).

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Weight (kg): 210.0	Total Cholesterol (mg/dl): 250	Emicrania	Legenda Low Boot Pressure
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Glycemia (mg/dl): 150	HDL Cholesterol (mg/dl): 57		differential Hypertension
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Fig. 8. Intake notification and adherence monitoring.

Geolocation. The app also keeps track, for each drug, of the remaining amounts in the stocked packagings and notifies the user when the stockage is about to finish allowing him to locate the closest pharmacy (Fig. 9).

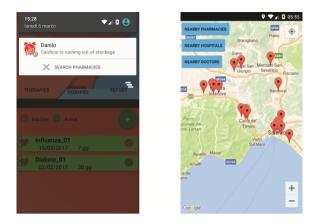


Fig. 9. Drugs shortage notification and pharmacy geolocation.

5 Related Work and Final Remarks

Several studies have demonstrated that poor adherence to drugs therapies can have a negative impact on both the potential clinical benefits of treatment and the cost-effectiveness of medicines. On the average, 50% patients fail to adhere to their prescribed regime and among the common causes are the difficulty to keep in mind drug names, doses and intake times, and the little perception of the beneficial effects of the prescribed treatment. This also generates additional costs for the healthcare system due to avoidable hospitalizations and to waste of resources (e.g., unused drugs), often funded by public healthcare systems. A notable amount of mobile apps have been developed to address the challenge to enhance adherence to medication plans. A recent study [2] reports on 160 apps available from different mobile platforms stores, which were evaluated and ranked against a set of desirable attributes, as described in Table 2.

As a result of the study, the authors report that most of the evaluated apps do not possess every desirable attribute but three commercial ones, MyMedSchedule [14], MyMeds [15], and MedSimple [16] do offer the widest range of features like medication databases, cloud data storage, and tools for health professionals to review data or "push" complex medical regimens to patients' mobile devices. In Table 3 we compare Sedato against the three best apps.

Attribute	Description		
Online data entry	Companion website(s) for data and medication regimen entry		
Complex medication instructions	Capability to schedule medication instructions that are considered complex		
Cloud data storage	Capability to back up and retrieve a medication regimen from a cloud storage system		
Database of medications	A medication database is available allowing user to enter, search, and select medications using features such as autopopulation		
Sync/export/print data	Capability to transmit, print, or export medication regimens and/or medication-taking behaviors for use by the patient or health care providers		
Tracks missed and taken doses	Capability to remind patients to take their medication and to record taken and missed doses that could potentially be used to calculate adherence rates		
Remote data entry by caregiver	Caregivers may remotely input and maintain the patient's medication regimen and "push" the regimen to the patient's device		
Multiple platform app	Available on more than one platform		
Free-only apps	Completely free (i.e., no fees for pro upgrades or charges to unlock additional features)		
Generates reminders with no connectivity	Capability to generate medication reminders without the use of cellular (3G/4G/LTE) or wireless (Wi-Fi) connectivity		
Multiple profile capable	Capability to generate medication reminders for multiple individuals on different medications (i.e., enabled family use)		
Multilingual	Available in English plus any other language		

Table 2. The set of desirable attribute for an app which supports medication plan adherence [2].

The table shows that all the desired attributes characterize our app, except the multiplatform feature (Sedato is an Android app) and the cloud data storage. Although none of the existing apps was conceived as part of a digital knowledge ecosystem, the result of this comparison encouraged us to plan a longitudinal testing of Sedato with a group of people similar to those who took part in the initial inquiry. Apart from the 8 physicians, who will test the prescription and health monitoring functionalities in the ecosystem, the app will be given to patients to be deployed for a period of at least four months. The final goal of the user study will be to verify the extent to which Sedato can improve adherence and therapeutic outcomes in chronic conditions.

	MyMedSchedule	MyMeds	MedSimple	Sedato
Online data entry	\checkmark	\checkmark	\checkmark	\checkmark
Complex medication instructions	\checkmark		\checkmark	
Cloud data storage			\checkmark	
Database of medications	\checkmark	\checkmark	\checkmark	
Sync/export/print data	\checkmark		\checkmark	
Tracking of missed and taken doses				\checkmark
Generates reminders with no connectivity		\checkmark	\checkmark	\checkmark
Multiple profile capable		\checkmark		\checkmark
Multilingual				\checkmark
Remote data entry by caregiver	\checkmark			\checkmark
Multiplatform app				
Cloud data storage			\checkmark	
Free-only app	\checkmark			

Table 3. Comparing Sedato to the three best apps resulting from a recent study.

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