Self-management pathways for diabetic patients: Early findings of the EMPOWER pilot studies

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Abstract: Diabetes is a serious world-wide medical challenge, which affected 382 million people in 2013. This paper describes, how the European Commission supported EMPOWER project fosters the self-management of diabetes patients. The Self-Management Pathways help patients in specifying planned activities based on medical recommendations and personal goals, as well as self-monitoring of Observations of Daily Living (ODLs). The whole process is supported by modern ICT services that motivate patients in changing their lifestyle and adhere to defined medication and activity plans. The system is being validated in Germany and Turkey. Early findings of the first validation phase are described.

1. Introduction

Patient empowerment is a patient-centric concept that is promoted to achieve positive health outcomes. Self-management is one important aspect of patient empowerment. Usually, "change" management is associated with or follows from self-management; whereby changing behaviours or lifestyle helps one achieve positive health outcomes. This paper is, of course, relevant to patients, however, the target audience includes clinicians, and other health related institutions that are interested in adopting patient empowerment approaches for the management of chronic diseases; especially services to promote self-management or change management. In this paper, we will describe the project in context of one chronic disease, *diabetes mellitus*.-The number of people with *diabetes mellitus* has been increasing worldwide in recent years [1]. This disease cannot be controlled without the personal self-management of the disease and requires changes in one's lifestyle. E-Health services and applications providing support for doctors and patients are continuously evolving. However, they are often focused only on a specific task in isolated environments (e.g. clinical, general practitioners) or specialized services (diabetes self-help groups, diabetes trainings). The EMPOWER project [2] aims to overcome such limitations by integration of existing clinical or PHR services and new services to support diabetes patients in understanding and managing their disease.

The approach taken for self-empowerment is described first in the Methodology section. It is important for the patient to adopt the approach with support from the patient's doctor. Next in Technology section, the technology will describe particular services and applications for patients and doctors, including access control based on a patient consent mechanism. Lastly in the Results section, the validation phases will be described and the first validation summarized. Validation of the approach and software occurs in two phases

for two pilot applications (one in Germany and one in Turkey). At the time of this writing, the second validation phase is about to begin. Results from the first phase are briefly presented followed the discussion in the Conclusion section.

2. Methodology

EMPOWER aims to facilitate self-empowerment by providing not only software services but also a methodology for chronic disease self-management based on the Stanford model for chronic diseases [3,4,5]. The EMPOWER "Self-Management Pathway (SMP)", Figure 1, is a cyclical process followed by a patient over time that includes medical consultations followed by the patient's own self-management decisions, goals and activities. Overall, self-management is about change management – from this perspective, goals are first required to achieve a desired future state of health. The first steps involve goal creation:

(1st step: ***Specify recommendations***) In the first step, the patient consults with medical experts (Healthcare Actors). When the patient is first diagnosed with diabetes, it's important that the patient learns how to manage their disease. In particular, the patient must likely change or adopt new behaviours. During the initial or any periodic consultation, a healthcare actor writes self-management goal recommendations for the patient.

(2nd step: ***Define/modify goals***) A critical part of the self-management/empowerment methodology is to gather recommendations from medical professionals and then reflect upon these recommendations in a *mindful way* by formulating personal goals, motivations and rewards. Information material might also be consulted. For example, based on medical recommendations, the patient creates personal goals to lose 4 kilos in 3 months, to be mindful about eating, to "write every bite" in a daily food log, to do particular weekly exercises, and to plan a daily snack at 10:00 and 14:00.

(3rd step: ***Specify Actions***) Subsequently, the patient creates scheduled activities aligned with particular goals. The recommendations, goals, activities and plans comprise the patient's personalized action plan.

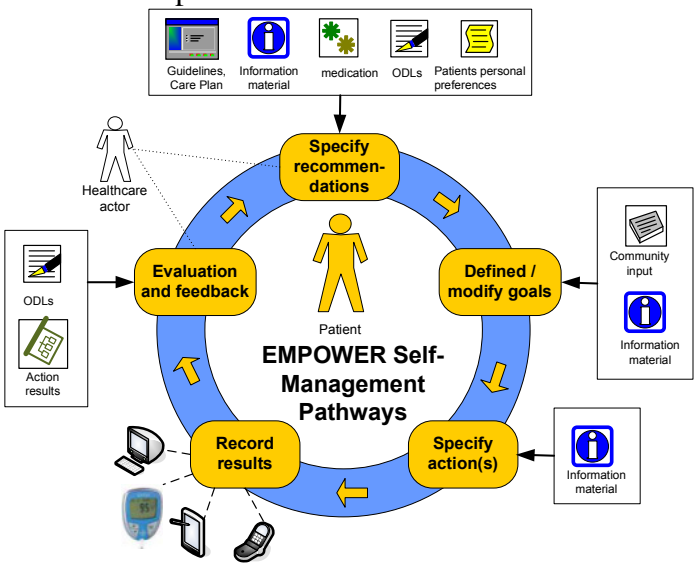

Figure 1. The EMPOWER Self-Management Pathway (SMP).

(4th step: ***Record Actions***) Day after day, the patient records her self-monitoring data based on the types of activities planned using the web or mobile app. The personalized action plan consolidates planned activities and ODLs that are collectively organized into journals for blood glucose, medication changes, physical exercises, sleep and food logs, body weight, blood pressure, mood, stress, opens issues for appointments, problems, etc.

(5th step: ***Evaluation and feedback***) Another critical step in the SMP is the daily and weekly review process. Tools are provided to the patient to review planned versus achieved

results, to update missing data, to provide tips, to review performance feedback – tabular or visualization (charts). Self-monitoring and weekly review can help the patient to be mindful of her health status and behaviour or lifestyle changes needed. At least each week, the patient should review her Action Plan results (weekly review), and perhaps update her Action Plan for the upcoming week. In this step the patient can reflect whether her goals are small and achievable or whether her activities were too unrealistic. Periodically, the patient will consult with medical experts to help her update goals and activities.

3. Technology Description

To realise the self-management pathway, services were implemented to support the integration into clinical or PHRS systems. The EMPOWER core services support EMPOWER specific services and integration, including security services, audit logging services, internationalization services, messaging and configuration services. All steps of the SMP have been implemented to support mobile and web-based application technologies that use common backend services available as Java API or RESTful web-services. The EMPOWER SMP provides services for two groups: medical professionals and patients.

To summarize, the recommender engine guides the medical professional by generating useful recommendations for the patient based on the medical guidelines. The physician approves or writes recommendations for use by the patient in the Action Plan to create smaller personal goals and motivations, and schedules activities to help achieve these goals. The pathway engine supports the patient through the whole self-management process including dashboard and tip feedback or weekly review feedback. ODL services support the collection and visualization (charts) and reporting of both patient source data and EHR data. Additionally, service authorization is supported by the patient consent editor that enables the patient to selectively share their confidential data with their medical care providers.

3.1 Decision Support Service for Medical Professionals

As the core of the disease management service, the Recommender Engine is for use by medical professionals; it is a flexible service module that is interoperable with different PHR systems. The self-management recommendations output of the Recommender Engine serves as input to the patients' self-management services.

The engine is a clinical decision support system that helps medical professionals in their daily practice through consolidating the clinical electronic and personal health record (EHR and PHR) data of the patient, displaying the data or charts to the medical professionals and generating semi-automatic recommendations about the patients. "Semi-automatic" in this context means that the automatically generated recommendations are presented to the medical professionals and are subject to their approval. The expert knowledge is structured in clinical guidelines, which are systematically developed statements designed to assist practitioners to make decisions about appropriate medical problems [5].

3.2 Personal Health Applications for Patients

Using the EMPOWER self-management services, the patient can get actively involved in the self-care process by building a personalized action plan. As described in the SMP pathway, the patient first accesses the self-management recommendations created by the doctor to help define own personal self-management goals and motivations. The patient then creates and schedules activities, corresponding to the ODL models, to support the achievement of their goals in their personalized Action Plan that contains a concrete schedule of activities, including optional reminders to the user during the upcoming weeks.

The framework provides mechanisms to collect ODLs, leveraging different sources for data collection and different user interfaces for data presentation and user interaction within two Personal Health Applications (PHAs): a web portal and a mobile app.

To record results of the patients' planned activities, an ODL service collects the results of the executed action, such as an ODL for blood pressure, blood glucose, body weight, a physical activity, nutrition compliance acknowledgements for medications appointments, etc. The ODLs can be collected using either the patient web portal or the mobile app including specialized healthcare devices. The collected ODLs are associated with the corresponding activities, to eventually help the patient review her Action Plan and receive feedback from the dashboard, charts, calendar and weekly review wizard. Overall, the feedback will help motivate the patient toward goals or revise personal strategies.

In the basic version, the EMPOWER mobile application serves as a native, standalone app for observations' collection for diabetics. It enables the users to record a set of vital signs meaningful for diabetes management. The patient can insert a new measurement either manually, through a user-friendly submit form, or automatically, if the medical device supports proper communication features. Furthermore, the app allows indoor and outdoor physical activity monitoring. The co-analysis of input from the GPS and the motion sensors embedded on the smartphone, enables the provision of detailed real-time feedback regarding the duration, distance, speed, pace and altitude of the activity. The EMPOWER mobile application also provides a tool that assists diabetic patients to manage their nutrition. The patient is able to evaluate the nutritional characteristics of her meals, using a food search engine embedded in the application and a locally stored nutrition database. Additionally, with this app the patient can keep a log of her sleep schedule. The application makes use of the smartphone's inertial sensors, to assess the subject's sleep pattern, record sleeping and waking up instances and calculate and store the duration of each particular sleep session.

In addition to the aforementioned functionalities, the mobile app also includes features to facilitate its smooth integration with the core patient empowerment system, and render it into a valuable tool of a holistic diabetes management medical service. The mobile app also includes visualization reports that summarize trends on a weekly or monthly basis. A common visualization software component serves both the mobile and the web applications and enables the patient to regularly check data trends, intuitively recognize correlation between specific parameters and constantly keep track of the outcome of the patient's attempts to change her behaviours.

Furthermore, both the mobile and the web application support standards-based observation (ODL) collection based on openEHR reference information models [6]. This makes feasible the interoperation with third party Personal Health Records (PHR) and Personal Health Applications (PHAs).

3.3 Service Access and Consent Management

Patients control access to particular types of patient data by authorizing particular medical experts or medical roles in the patient consent editor. EHR from the Recommender and PHR data are under access control. Access to all of the services must be both authenticated and authorized, and the patient must be able to control and manage the access to their data – for example, the medical expert wishes to visualize blood glucose charts using not only clinical data but also including patient sourced data.

The consent manager of EMPOWER provides a consent mechanism where all access to the PHR data is under the control of the patient. Before a medical professional can access data, the patient must create the proper read and/or write access rights using the consent editor. Consent Policies are stored in a standardized policy language (XACML) [7].

4. Results

The complete self-management pathway is currently implemented as research prototype for in-field validation. The validation of the approach is being performed in two pilot applications, in Germany and Turkey. In parallel, the consortium will investigate best practices in order to render the technological outcome of the project into a valuable tool for sustainable health services provision to the ever-expanding chronic diseases management market.

The two pilots are exemplary for validating the patient empowerment approach and services and provide the challenges of working with patients and medical professionals in two countries with very different backgrounds in the deployment of e-Health systems, in healthcare approaches and limitations, and with respect to patient privacy, health data ownership and security requirements. Results from two pilots might also indicate how patient empowerment and self-management are perceived by patients and doctors in different systems and cultures. Could it depend on the patient-doctor relationship? For example, patients in the Turkish pilot will likely not see the same doctor at every office visit; in contrast, it was known that the German patients would always see the same diabetologist at each office visit. The study results could provide interesting feedback for adapting the SMP pathway regarding the influence of the given patient-doctor relationship.

The validation of the EMPOWER system is performed in two phases corresponding to the first and second prototypes; each validation phase has pilot applications running in two countries with different requirements: the Turkish and German pilots. The first prototype provided limited features and functionalities. As of writing of the paper the first validation phase of the EMPOWER is finished. In this first phase, the medical professionals and patients have used the system and their feedback was collected through questionnaires and regular meetings with patients and doctors. According to the feedback, the system was improved for the second validation phase. In the second phase, the number of patients and medical professionals will increase and it will finish at the end of 2014. In the next sections, the summarized results for the first validation phase are presented.

4.1 German Pilot Application

The German pilot application was performed by the GOIN Doctors' Network in the region of Ingolstadt (Bavaria). Seven patients (6 men, 1 woman, all of them Diabetes type 2), aged 39 to 53 years, and one diabetologist participated in the 1st validation phase that took place over a 10 week period. The patients and the dietician accessed the EMPOWER system through the German EMPOWER website.

Usability and the perceived usefulness of EMPOWER prototype I were validated by patients and the physician. The evaluation was performed qualitatively by round table discussions and quantitatively by means of standardized questionnaires. Short telephone interviews were conducted about experiences of the patients with EMPOWER each week. Questionnaires comprised several instruments on the use of the mobile and web applications as well as the recommender engine, including the System Usability Scale (SUS) [9] and a scale based on the Technology Acceptance Model (TAM) [10].

The full functionality of the recommendation engine had not been implemented in validation phase 1. Therefore, patients received recommendations from their physician in direct and telephone consultations, respectively. Recommendations will be tested and evaluated during validation phase 2, starting in August this year.

Two patients used both the mobile and the web application in validation phase 1, and 5 patients used only the web application because of restrictions of Android support.

The main results of the German validation phase 1 are summarized as follows:

- Patients logged in to the web application on average 14 times (SD=11.5), the majority of visits at the website (67.3 %) lasted at least 5 minutes.
- "Setting goals" and "planning activities" were most used functions (86 %), while patients consulted the "information material" less often (43%). The "schedule view" was used frequently, more than 100 times by 3 of the 7 patients.
- Regarding ODLs, "blood glucose" and "nutrition" were used most in the web application. Similarly, "blood glucose", "blood pressure" and "weight" were the most frequently used mobile features.
- During the weekly telephone feedback users mostly commented on features with regard to the action plan and ODLs. Suggestions included: accomplished actions should be confirmed directly in the schedule view; include medication (i.e., insulin) change documentation; and make overall layout and language changes.
- The two mobile users tested the stability of the mobile app and reported frequent loss of the wireless internet connection.
- Layout and usability of the EMPOWER applications were rated similarly with a mean of 4.7 and 4.6 on a scale ranging from 1 (very bad) to 10 (very good), respectively. SUS scores altogether indicated poor usability, with the mobile app being rated slightly better (46/100) than the web application (44/100).
- The usability feedback from patients was influenced by missing recommendations (Recommender Engine) that users considered very important.
- Inspection of the TAM revealed a mean score of 3.9 on a 7-point scale ranging from "strongly disagree" (1) to "strongly agree" (7) both for patients and the physician, indicating usefulness of the EMPOWER approach. The majority of patients felt that EMPOWER has a positive impact on their diabetes. Likewise, the physician argued that EMPOWER is beneficial for diabetes treatment. On the other hand, however, patients tended to disagree whether it helps to achieve goals better or is easy to integrate into daily life.
- Four out of six patients (67 %; 1 patient didn't respond) reported that they would continue using the system beyond the term of the project, indicating good acceptance of EMPOWER. Features the patients would like to use in particular included the "recommendations" from the physician, the documentation of "vital signs", and the "setting of goals".
- In the round table discussion, patients suggested several changes to be considered in validation phase 2 in order to enhance the usability and acceptance of EMPOWER. Main topics include:
    - **Compatibility**: The users recommended some technical enhancements, e.g. an iOS version of the mobile app, connectivity with Microsoft Office software, and the use of barcode scanning in the nutrition module.
    - **Personalization**: Patients suggested EMPOWER to be even more customizable to one's own needs, e.g. the filtering of non-used features and the implementation of a dashboard showing individual data of interest.
    - **Simplicity**: Patients would like EMPOWER to be more comfortable and less time-consuming to use, in particular, concerning the scheduling and the confirmation of activities. For the physician, an immediate overview of essential patient records would be efficient.
    - **Presentation**: Users requested an attractive and more colorful design, arguing it would motivating them to use the tools regularly. Rapid feedback on the success/failure of planned activities would be very much appreciated.

4.2 Turkish Pilot Application

The validation of the Turkish pilot application of the EMPOWER Project took place at the Hitit University, Endocrinology Department [11] in Corum, Turkey. The system was validated by 8 medical professionals (2 endocrinologists, 2 diabetic nurses, 1 dietician and 3 general practitioners). In addition to the medical professionals, there were 8 diabetic patients (3 type 1, 5 type 2 – 5 male, 3 female). The Turkish web site was established for both, medical professionals and patients, through which they can access the system, the user guidelines and information material.

The initial results from the patient questionnaires are as follows:

- The user interface should be more user-friendly and contain more feedback to motivate the users regarding goals.
- More patients used the portal than the mobile application. The reason for this is that most of the type 2 patients are above 40 and are more accustomed to using web browsers than mobile apps. In contrast, about 25 patients with type 1 diabetes use the mobile application.
- As a general evaluation, the users graded the system 2.8/5. They see the system as useful especially for recording their blood glucose measurements and physical activities.

The initial results from the medical professional questionnaires are as follows:

- EMPOWER increases the work quality: 2.5/5
- Makes the work faster: 2.5/5
- Increases the efficiency: 2.5/5
- Better treatment for patients: 3/5
- Better diabetics process: 3.5/5
- Efficiency on diabetics treatment: 3/5
- Helps the treatment: 2.5/5
- Useful in general: 3/5
- Does it cover all treatment mechanisms: Yes

In Turkey, the diabetic patients visit their doctors every 3 months. In the duration between their visits they are on their own and the doctors do not have an application to monitor their patients during that time. Therefore, both doctors and patients see the EMPOWER system as an excellent opportunity to collaboratively manage the disease.

5. Conclusion

The next step of the project involves the second validation phase based on the second prototype. Feedback from patients and doctors has been integrated into the second prototype. An important issue was also addressed regarding patient recruitment. An important limitation in validation or clinical trials is the patient motivation to participate in the trial and also to engage themselves in the group meetings that occur periodically. From experience, a few highly motivated patients usually participate in validation studies. It is clear that convincing the doctors of the benefits resulted in highly motivated doctors who did actively motivate patients to participate in the first validation phase. Considering patient recruitment for the second validation, the clinics decided to also create incentive-packages to offer patients as a means to encourage participation and motivate patients to engage in the study. The incentive package is comprised of vouchers supporting health related activities involving sports, relaxation and nutrition.

An important conclusion of the first validation was that the usability issues could have been avoided by involving only role playing test users in the first phase and to start the patients with the resulting prototype. Instead the patients were given a first prototype in the

first phase. Pre-studies were performed with patients and medical doctors and doctors provided feedback, however, usability issues were apparent because first prototype had a limited feature set. Furthermore, the configurable dashboard component was not available to provide daily feedback on the progress of activities and goals. For example, in the current week a personal goal does not have planned activity or vice versa; or there are no personal goals based on a doctor's recommendation, etc. Another important finding from the user meetings revealed that the patients saw benefits by using the tools both for the doctor as well as to enhance the dialog with the doctor. Clearly, the doctor's role is desired by the patient! Given the quantity of personal health apps, the role of the medical doctor is usually missing and should be considered when clinics offer health apps to patients.

In this paper, we presented the approach of the EMPOWER project to diabetes self-management. The combination of disease management services for doctors and self-management services for patients provide valuable feedback for both and can therefore, support the treatment process for managing not only diabetes but as a basis for other chronic diseases. Additional requirements for each chronic disease can be considered and what will be challenging is the degree of self-management possible for the patient or chronic disease. In this case, we see good opportunities to expand the tools to involve groups such as informal caregivers (family, friends, trainers), and engage them in not only to support a patient's action plan and suggest goals, monitor planning and review progress, but also help informal caregivers engage in their own personalized action plans to address health related goals. Given the patient consent tools, controlling access by group members naturally follows.

In conclusion, Consortium partners will continue to address other chronic diseases using the EMPOWER tools as a basis on which to add additional requirements from other chronic diseases. One concrete step in progress is creating a standalone tablet application version for engaging organizations, such as clinics, patient support organizations, insurance or pharmaceutical companies that are interested in providing patient empowerment services. However, a systems integrator should be involved to address integration within each organization.

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