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EMPOWER – Pathways for Supporting the Self-management of Diabetes Patients

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Abstract. Diabetes is a serious world-wide medical challenge and there is a recognised need for improved diabetes care outcomes. This paper describes results of the EMPOWER project, to foster the self-management of diabetes patients by integration of existing and new services offered to patients after having been diagnosed with diabetes. The Self-Management Pathway described in this paper helps patients in the specification of personalized activities based on medical recommendations and personal goals, as well as self-monitoring of the results. The whole process is supported by innovative ICT services that motivate patients to change their lifestyle and adhere to defined medication and activity plans. We describe the approach and present the findings of the validation phase in Germany and Turkey.

Keywords. diabetes, self-management, patient empowerment

1. Introduction

Diabetes affected 56.3 million people in Europe in 2013. According to the International Diabetes Federation (IDF) the number of people with diabetes is increasing in every European country and it is estimated that the number of people with diabetes in Europe will rise from 55.4 million in 2010 to 66.5 million in 2030 [1]. Diabetes is basically a life-long disease and like all chronic diseases it cannot be cured. Nevertheless, there are strategies for improving the patients' health situation and one key aspect is self-management. According to [2] patients with diabetes Type 2 who are sufficiently self-motivated to manage their condition have the potential to reverse diabetes and prevent medical complications through behavioral and pharmacological interventions. 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 with specialized services (e.g. clinical, general practitioners, diabetes self-help groups, diabetes trainings).

In this paper we present the approach of the EMPOWER project[2] to overcome such limitations by integration of services to support diabetes patients in understanding and

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managing their disease. This approach takes both major types of diabetes mellitus into account because for both, Type 1 and Type 2 diabetes the change of lifestyle behavior is an important factor besides medication therapy, in particular in the first phase of the disease where adapting the lifestyle might be a severe challenge to diabetes patients. Especially Type 2 patients may benefit from support by specialized e-Health services to better motivate themselves and to adjust their activities to a pre-defined plan.

The EMPOWER project aimed at developing a modular and standards-based patient empowerment framework, which facilitates self-management of diabetic patients, based on a PHR system and on context-aware, personalized services delivered through Web and mobile applications. This allows patients not only to contribute to their own healthcare but also to be more in control of their disease. The patient-centric approach of EMPOWER also includes healthcare professionals in the EMPOWER cycle as they can guide their patients in managing their disease, whilst staying informed about their progress. In the following sections we provide an overview of the EMPOWER approach, followed by a technical description of the EMPOWER framework and of validation results in two pilot regions in Germany and Turkey. In the final section, we report on challenges encountered and present ideas for future work.

2. Methods

2.1. The EMPOWER approach

EMPOWER aims at facilitating self-management by providing not only software services but also a methodology for chronic disease self-management based on the *Stanford Model* for chronic diseases [3]. The EMPOWER Self-Management Pathway (SMP) is a cyclical process followed by a patient over time (see Fig. 1). It includes medical consultations followed by the patient's own self-management goals and activities and feedback from the system concerning the patient's self-management activities. The EMPOWER cycle comprises the following steps:

Specify recommendations – the first step is a consultation where the diagnosis and the treatment goals will be specified. It is important that the patient learns how to manage his disease. Often the patient must change or adopt, new behaviours. For that reason, the physician specifies recommendations on how the patient can support treatment goals by self-management.

Define/modify goals – in the next step, the patient breaks down the physician's recommendations into individual self-management goals by using the EMPOWER Patient Portal. Following the Stanford model [3] these should be realistic and behavior specific. If the patient wants e.g. to lose weight, he should set a goal based on his current eating behaviour or physical activities. Patients may feel overwhelmed by the all the work that is required from them. In such instances, they should break a goal down into smaller segments. It is also important that patients become aware of their behavior, in particular of unhealthy habits. Really knowing what you are doing when you are doing it (paying attention) is the first step to becoming aware. Only if patients are aware of their habits can they make conscious choices and commitments [4]. While a healthier life is a significant reward in itself, patients should also be encouraged to reward their hard work and discipline and take pride in the positive, new attitudes that they created.

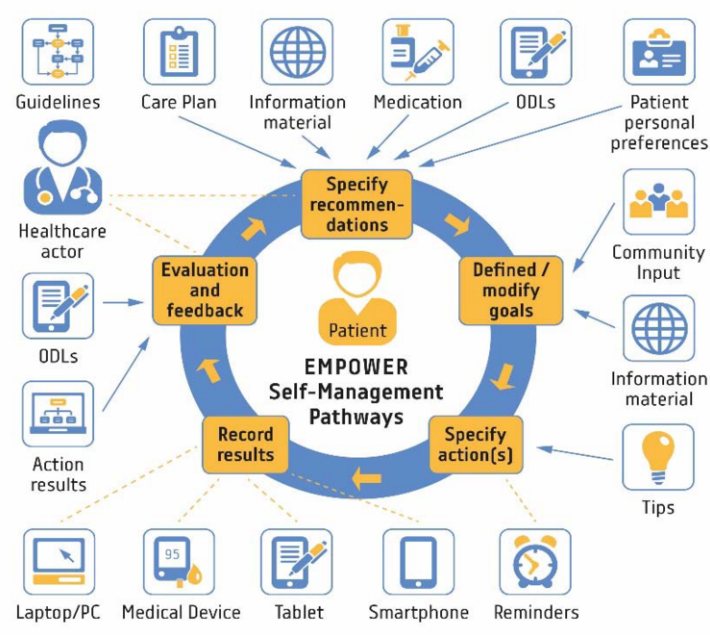

Figure 1. EMPOWER Self-Management Pathway

Specify actions – in step 3, the patient creates scheduled activities aligned with his self-management goals. This is typically done on a weekly basis by using a calendar. Habits for a new lifestyle supporting a healthier life need attention and discipline until the patient is set in these new habits. The recommendations, goals and activities comprise the patient's personalized action plan supporting these changes of behavioral patterns as long they are not yet habituated.

Record actions - Next, the patient records his self-monitoring data based on the types of activities planned using the web or mobile app. Depending on the patient's requirements and needs a variety of data can be collected, such as blood glucose, medication changes, physical exercises, food habits, sleep problems, body weight, blood pressure, mood, stress, open issues for appointments, problems, etc.

Evaluation and feedback – in the final step, the patient should check actions off as they are completed, typically each week. That will give him guidance on how realistic the planning was and will also be useful for future plans, e.g. if it is necessary to modify his goals and activities so that they are small and achievable, and hence realistic. EMPOWER provides tools to the patient to review planned versus achieved results, to update missing data, to review performance feedback (tabular or visualization as charts) and to provide guidance for improving the performance. In this way, the patient updates his Action Plan for the upcoming week and starts a new EMPOWER cycle.

2.2. The technological perspective

The EMPOWER Framework aims at supporting self-management of diabetes patients, in particular aligning behavioural patterns and self-control compliance with diabetes guidelines and suggested treatment. From a technical perspective, the EMPOWER

framework semantically integrates multiple information sources (EHR/PHR systems, clinical guidelines for diabetes, applications for collecting patient data) into a shared knowledge model. On the semantic interoperability level, ISO 13606 [5] and openEHR [6] information models are utilized in order to process EHR and PHR data safely and consistently. The EMPOWER Framework supports specific services, including security services, audit logging services, internationalization services, messaging and configuration services. These services have been implemented to support mobile and web-based application technologies that use common backend services available as Java API or RESTful web-services. EMPOWER provides services for two user groups: medical professionals and patients.

2.2.1. Diabetes disease management support for physicians

The Recommender Engine for medical professionals is based on diabetes guidelines adapted to national requirements in Germany and Turkey and it is interoperable with the EMPOWER patient portal. The guidelines are described in terms of Guideline Interchange Format (GLIF, [7]) a computer-interpretable language for modeling and executing clinical practice guidelines. The output of the Recommender Engine (recommendations regarding eg. medication, further examinations, lifestyle) serves as input for the self-management services of the Patient Portal. This engine is basically 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 to the medical professionals and generating semi-automatic recommendations about the patients. Semi-automatic here means that the automatically generated recommendations are presented to the medical professionals and they can approve, modify or delete them or add new recommendations.

2.2.2. Consent management

The Consent Editor allows the patient to control the visibility of his or her recordings to medical care providers. The patient can control who (role based or individually) may access which kind of data. EHR and PHR data are under access control. Access to all of the services must be both authenticated and authorized, and the patients must be able to control and manage the access to their data – if, for example, at the beginning of the consultation the physician wishes to visualize blood glucose charts using not only clinical data but also including data captured by the patient.

2.2.3. Diabetes self-management applications

At the end of the consultation the recommendations specified by the physician for the patient's self-management are forwarded to the Patient Portal. Using the EMPOWER self-management services, the patient can get involved in the self-care process, access the self-management recommendations, and define self-management goals adapted to his individual needs. As part of the offered functionality, the patient is supported in the creation of the Action Plan. The Action Plan is a concrete schedule of activities that should help the patient to achieve pre-defined self-management goals. After editing an Action Plan, the information is transmitted to the Action Plan service, which in turn generates reminders to the user based on the configuration during the upcoming week.

Services for Observations of Daily Living (ODLs) are defined to collect the results of the executed actions, such as blood glucose, medication changes, physical exercises,

sleep and food habits, body weight, blood pressure, mood, stress, problems, etc. Depending on the preferences of the patient, the ODLs can be collected using a mobile app or online web-forms. Both the mobile and the web application allow for standards-based observation collection by using openEHR reference information models [6]. This makes feasible the interoperation with third party Personal Health Records and Personal Health Applications. These collected patient data are associated with the corresponding actions, giving feedback to the patient on how successfully he has matched the previously defined goals and activities. A graphical representation of the conformance between the Action Plan and the gathered results serves as additional feedback. A common visualization software component serves both the mobile and the web applications and enables the patient to regularly check data trends, intuitively recognize correlations between specific parameters and constantly keep track of the outcome of the patient's attempts to change her behaviors.

The mobile application can operate both in standalone mode and in integrated mode with the EMPOWER backend. Further to the common functionality with the web app, the mobile app supports integration with consumer medical devices, automatic physical activity tracking including step counting, and automatic sleep quality tracking.

2.3. Validation strategy

The self-management pathway was implemented as research prototype for in-field validation. Usability and acceptance of the EMPOWER tools were evaluated as well as behavioral changes, by assessing, for example, , whether the Action Plan fosters self-management and whether the Recommender Engine facilitate the doctors' work with the diabetic patient. Validation was performed quantitatively by means of extraction from log-files, standardized online questionnaires and qualitatively by means of round table discussions. The validation was built on the methodology of the "Model for Assessment of Telemedicine" (MAST), Domains 1 to 7 [8].

3. Results

The validation of the approach was performed in two pilot applications, in Germany (Ingolstadt) and in Turkey (Corum) from August 2014 – January 2015 (see Table 1).

21 persons participated in Germany and 39 in Turkey. 4 German patients used the mobile compared to 10 users in Turkey. The patients' age ranged from 30 – over 70 years in Ingolstadt, from under 20 – 60 in Corum. The evaluation was performed quantitatively by means of standardized online questionnaires, which were based on

Table 1. Main validation results in Germany and Turkey

	Pilot in Germany	**Pilot in Turkey**
Foot control	No difference	Noticable changes
Eating behaviour	Positive effect	No noticable changes – patients are used to the use of a nutrition plan
Phyiscal activity	Positive effect, slight increase	Very low, but slight increase
Doctor-patient relationship	Improved communication Improved monitoring Improved information exchange	Improved communication
Empowerment	Slight increase on self-efficacy, self-determination, impact	Slight increase on meaningfulness

validated instruments, e.g. the System Usability Scale (SUS) [9], the Technology Acceptance Model (TAM) [10] and the Spreitzer`s Empowerment Scale [11] and qualitatively by round table discussions. All of the developed applications (mobile, web applications and the recommender engine) were assessed.

3.1. German Pilot Application

The German pilot application was performed by the GOIN Doctors' Network in the region of Ingolstadt (Bavaria). 21 patients, 6 physicians and 1 diabetes assistant participated. 16 of the patients were male (and 14 had been diagnosed with Diabetes Type 2.

- On average the German users logged in 43 times and stayed on the system on average for 5.2 minutes. Almost all patients used functions for setting goals (65%) or planning activities (71%). In addition, more than half of the patients reported to have used the charts, the calendar and the journals, while review (29%) and information material (24%) were of little interest. Regarding ODLs, blood glucose and physical activities were used most frequently, values for mood and stress were documented least frequently.
- The usability of the EMPOWER applications can generally be considered as average to good. While the SUS scores indicated modest usability (web application 61/100, mobile app 56/100, recommender engine 50/100), most patients indicated in the round-table discussions that they were well able to use EMPOWER and suggested only minor improvements.
- Inspection of the TAM revealed a mean score of 4.6 on a 7-point scale ranging from "strongly disagree" (1) to "strongly agree" (7) for patients. Physicians scored even slightly higher with 4.7, indicating the usefulness of the EMPOWER approach. In addition, 76% patients reported that they would like to continue using the system beyond the pilot phase, indicating good acceptance of EMPOWER.
- Qualitative feedback on behavioural changes the patients had experienced since having started using EMPOWER indicated improvements with regard to nutrition control and physical activity. Non-behavioural changes included improved handling of diabetes, enhanced self-control and increased knowledge on lifestyle and nutrition.

3.2. Turkish Pilot Application

The EMPOWER Turkish Pilot was conducted in Hitit University, Endocrinology Clinic, in Çorum City. Six medical professionals (three endocrinologists, two diabetes nurses and one dietician) and 39 diabetes patients participated. 22 male and 17 female patients whereof 16 patients had Type 2 and 23 patients Type 1 diabetes. The Turkish users logged in 2356 times, on average 60.5 times. On average they stayed on for 7.4 minutes. Often did those users stay on longer that used the system less often. On the other hand, the Recommender Engine was executed once for each patient; 20.97 self-management recommendations per patients were sent to them by their medical professionals. All of the Turkish participants used the journals and the vital sign function. Almost 77% of the patients used the recommendations and the review. Contrary to the German users also the dashboard and the information material were well liked by the Turkish users. Physical activity was one of the least used ODL functions, while blood glucose and weight were monitored often. From the evaluation it was deduced that the patients mostly used the

system because it improved the patient-doctor communication. Instead of the usual one encounter with the doctors in three months, with EMPOWER the users were able to communicate with the doctors anytime. Another lesson learned is that the mobile users entered data more frequently than the web users, because it is more convenient to access the EMPOWER system. According to the questionnaires from doctors, the patients feel better with the system because of the improved communication and effective ODL recording mechanism.

3.3. Empowerment and Self-Management Behavior

Using a pre- post-test design, empowerment was measured using a 12-item scale, assessing four dimensions of empowerment: *1. meaningfulness* (actions are relevant to one`s ideals), *2. self-efficacy* (belief about one`s capability to produce desired results), *3. impact* (actions have an impact on current status), *4. self-determination* (actions being one`s own choice) [11, 12]. Initial testing showed an overall high level of empowerment. Nevertheless, despite the short intervention time, improvements for self-efficacy, impact and self-determination were observable with the German users and meaningfulness with the Turkish users. Diabetes-related distress was measured using a slightly adapted version of the Problem Areas in Diabetes (PAID) scale [13, 14]. Participants were asked 21 items on emotional aspects that are often reported by diabetes patients. In general, scores improved during the intervention phase. Participants became less worried about nutrition, long-term complications and felt less guilty about the potential negligence of their disease management. However, results pointed towards the fact that the involvement with the EMPOWER system may also increase emotional distress with the German users and the feeling of burnout with the Turkish patients. An increase of uncertainty with regard to participant`s own feelings and their diabetes in general was detected. Also feelings of anxiousness when neglecting the accurate management of the disease and people`s anger about living with diabetes increased during the intervention phase. Diabetes self-care was measured using the Summary of Diabetes Self-Care Activities (SDSCA) [15]. Small changes were detectable for *non-intentional* physical activity: *On how many of the last seven days did you participate in at least 30 minutes of physical activity (total minutes of continuous walking, including walking)?* (Pre-Test: M=6.25, SD=1.73; Post-Test: M=6.50, SD=1.51). In the pre-test more than 50% of the participants indicated to have measured their blood sugar level on a daily basis within the last seven days. No noticeable changes were observed over the intervention phase.

4. Discussion

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 a valuable feedback for both and will, therefore, support the treatment process for managing this chronic disease. The validation of the approach was performed in two pilot applications in Germany and Turkey, each of them with a different background in the deployment of e-Health systems. Motivating the patient to participate in the trial was a challenge. It became clear that convincing the doctors of the benefits resulted in highly motivated doctors who did actively motivate patients to participate in the validation phase. Additionally, an incentive-package (vouchers for fitness training and swimming and a step-counter) was offered to the

patients as a means to encourage participation and motivate patients to engage in the study.

However, the validation was restricted to 6 months and included 50 patients. Although the results present promising indications for increased self-management activities of diabetes patients a longer clinical study with a higher number of participants would be necessary for demonstrating reliable results and possibly, proof of sustainable improvements. The validation also reveals cultural differences and preferences. This was not primarily in the focus of the project and further research would be necessary. Despite the fact that further research is needed EMPOWER has shown to be a promising approach for faciltiating self-management for diabetes patients and it may also be developed further, to cater for other chronic diseases which also benefit from self-management by patients. In such a case the EMPOWER tools can be a basis on which to add additional requirements related to those chronic diseases.

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