Modular ICT-Based Patient Empowerment Framework for Self-Management of Diabetes: Design Perspectives and Validation Results

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ABSTRACT

Introduction: It is estimated that more than 382 million people suffer from diabetes across the globe, most of which are between the age of 40 and 59 years. ICT can play a key role in better management of diabetes and in patient empowerment. Patient empowerment involves patients to a greater extent in their own healthcare process and disease management becomes an integrated part of their daily life. Self-management opens the possibility for patients to contribute to their own healthcare as well as to be more in control of their disease.

Objectives: The objective of our study was to explore the impact of an ICT-based patient empowerment framework in diabetes self-management.

Methods: A modular patient empowerment framework that fosters diabetes self-management was designed and implemented. The framework incorporates expert knowledge in the form of clinical guidelines, and it supports patients in the specification of personalized activities that are based on medical recommendations and personal goals, and in the collection of observations of daily living. The usability and usefulness of the proposed framework were assessed in a pilot study with the participation of 60 patients and 12 health professionals.

Results: The study revealed that a patient empowerment approach based on self-management ICT tools is useful and accepted by both the patients and the physicians. For those patients who were already disciplined in their disease management the piloted solution served as a facilitator for data logging. For the rest, it served as an incentive for better adherence to disease management principles. The ICT tools prompted many patients into becoming more physically active and into making dietary habits' adjustments. However, this impact proved to be tightly correlated with the sociocultural background of the subjects. The study also demonstrated that even in patient-centric self-management interventions the physicians still have a key role to play. However, the acceptance of such interventions by the healthcare professionals depends not only on the level of impact in their patients' disease management but also on the level of impact in their workflow.

Conclusions: It is evident that a patient empowerment approach based on self-management ICT tools is useful and accepted by patients and physicians. Further, there are clear indications that ICT frameworks such as the one presented in this paper support patients in behavioral changes and in better disease management. Finally, it was realized that self-management solutions should be built around the objective not only to educate and guide patients in disease self-management, but also to assist them in exploring the decision space and to provide insight and explanations about the impact of their own values on the decision.

Keywords: Diabetes, self-management, disease management, patient portal, mobile app, physical activity, nutrition, patient empowerment framework

1. INTRODUCTION

According to the Diabetes Atlas of the International Diabetes Federation (IDF) some 382 million people worldwide, or 8.3% of adults, are estimated to have diabetes in 2014. If this trend continues, by 2035, some 592 million people, or one adult in 10, will have diabetes. This equates to approximately three new cases every 10 seconds, or almost 10 million per year [1].

Being diagnosed with diabetes often means a major shock to the person concerned. 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 status and one key aspect is self-management. Besides learning about the disease, people have to adapt their lifestyles, particularly those aspects that are related to physical activity and nutrition.

A meta-analysis and review of randomized control trials carried out by Calvin *et al* [2] revealed that the use of consumer health information technologies in supporting diabetes self-management appears to have potential benefits for patients' self-management of diabetes. However, self-management is not something trivial. Type II Diabetic (T2D) patients, who typically are affected at a later stage of their lives, find it particularly difficult to change lifestyle routines that have been formulated over a long period of time. Having a chronic disease means having to cope with "something" that severely impacts one's autonomy. Patients have to learn that their behavior influences their disease status and that continuous adaptations are necessary. However, making the required adaptations may conflict with other priorities and constraints, let alone that perfect control is not possible.

As a self-management facilitator the concept of patient

empowerment has emerged in recent years. Patient empowerment can be seen as a healthcare philosophy that emerges from the perception that optimal outcomes of healthcare interventions are achieved when patients become active participants in the healthcare process [2]. Towards this direction a key point is to make patient empowerment an integral part of daily life and in particular of the healthcare process [2].

In [4] Lucas *et al.* presented a proactive health management and empowerment framework for senior citizens that supported tele-monitoring and tele-nursing functionalities for chronic patients. Its pilot study revealed that a significantly high percentage of participants had some kind of benefit from using the system. For example almost 80% of participants learned more about their health conditions, 71% of participants had an increased awareness of their individual diet and nutrition, and 63% of participants self-reported health improvements.

In the various self-management interventions also the relationship among patients and healthcare professionals is challenged. Bjerkan *et al.* [6] examined the impact of an ICT based collaboration tool in individual care planning and realized that in some cases, a power transition took place in the care process, which led to patient empowerment. On the other hand, the study of Urowitz *et al.* [5] about the impact of a diabetes self-management portal in patients revealed a grey area in the roles that the physicians should play in the facilitation of disease management. The same study indicates that although the patient portal as such can facilitate access to useful information material, usability aspects are very crucial for keeping the users motivated in using the portal. In their study about the role of ICT in diabetes management, Spanakis *et al.* [7] found that although ICT-based disease management may bring profound changes in self-care and empowerment, a careful balance between information and communication is important to avoid information overload and excess. A systematic review of IT based diabetes self-management approaches is presented by El-Gayar *et al* [8].

This paper presents a modular, ICT-based patient empowerment framework that fosters self-management of diabetes. The framework was designed, implemented and piloted in the context of EMPOWER, an FP7 collaborative project supported in part by the European Commission. The framework incorporates and exploits various sources of personal health data and clinical knowledge towards supporting the patients in the management of disease related decisions and actions. Patient empowerment is fostered by personalized ICT services delivered through web and mobile applications that guide the patients in behavioral changes while ensuring adherence with evidence based treatment guidelines. This patient-centric functionality is supplemented by functionality for the physicians who remain present in the disease management cycle by guiding their patients in disease management, whilst staying informed about their progress.

2. METHODS

2.1. ICT-Based Patient Empowerment Concept Description

Figure 1: Iterative Self-Management Pathway (SMP)

Patient empowerment interventions aim at involving patients to a greater extent in their own healthcare and disease management cycle. We approach this domain from a technological perspective, by introducing an ICT-based patient empowerment framework that facilitates self-management pathways (SMP). The SMP is a cyclical process that includes medical consultations followed by self-management goal setting, then self-management actions, then feedback collection, and finally evaluation and self-management readjustment. This framework is in line with the generic methodology for chronic disease self-management proposed and applied in practice at Stanford School of Medicine by Lorig *et al.*[9][8]. EMPOWER exploits various sources of personal health data and clinical knowledge in a comprehensive ICT framework that implements all these steps. This is a new concept towards the establishment of a personalized yet evidence-based patient guidance strategy.

We first apply this concept in diabetes self-management. Diabetes is usually diagnosed during a patient encounter at a physician or in a hospital. In such consultation the patient gets informed about the nature of the disease and the various rules of handling it, one of which is self-management. In this context the physician suggests to the patient the use of an ICT-based self-management framework, as a means to support lifestyle and behavioral changes that will facilitate the management of the disease. Following this, an SMP cycle emerges that is composed of the following phases (Figure 1):

Specify recommendations – the entry point to the SMP cycle is a consultation where treatment goals are specified. The physician specifies recommendations on how the patient can achieve the treatment goals by self-management (e.g. "reduce weight by x kg within 3 months", "measure blood sugar before breakfast"). The recommendations are derived from a decision support tool. This blends commonly applied, evidence-based clinical guidelines, the physician's experience

and the actual patient status, as indicated by various data sources. Moreover, the recommendations are issued using an ICT infrastructure in contrast to the traditional oral or written format.

Define/modify goals – in the next step, the patient breaks down the physician's recommendations into short-term self-management goals, stored in her/his individual PHR. These goals should be realistic and behavior specific. For example, if the patient needs to lose weight, she/he should set a goal based on her/his existing eating behavior or physical activities [8]. Otherwise, she may feel overwhelmed at the idea of all the work that is required. It is also important that patients are aware of their behavior, in particular of unhealthy habits. Only patients who are aware of their habits will make conscious choices and commitments [10]. While the goal of 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.

Specify actions – in the third step, the patient breaks down the defined goals into small, achievable portions. This is typically done on a weekly basis, using a calendar. Single activities and personalized schedules for the upcoming week are thereof created. This and also the previous steps are heavily supported by a web application that guides the user in the specification of actions by providing action-specific information material and hints. The recommendations, goals and activities comprise the patient's personalized action plan.

Record ODLs – next, the patient collects and records Observations of Daily Living (ODLs) in alignment with the planned activities using a web or mobile application. 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 to be discussed with the physician, etc.

Evaluation and feedback – in the final step, the patient checks things off as they are completed, usually once per week. This step gives an indication on how realistic the planning was; also, it is useful in making future plans, taking into consideration necessary adaptations and rationalization on the goals and activities so that they are small and achievable. The physicians get aware of the collected ODLs, and -if necessary- updates the recommendations issued in the first step.

2.2. ICT Framework Design

Our approach for patient empowerment is built around a modular, standards-based ICT framework that supports patients in the specification of personalized activities, taking into account medical recommendations and personal goals.

Patient guidance is based on the integration and co-processing of different sources of patient information and clinical knowledge towards the provision of a diverse set of personalized ICT-based patient empowerment services. This set includes: (i) services for the specification and execution of actions to change behavior according to diabetes-specific healthcare needs. Patients can develop personalized action plans, which include recommendations from the treating physicians and patients' preferences; and (ii) services for the collection and monitoring of ODLs, e.g. vital signs, nutrition and sleep schedule, physical parameters such as weight, mental parameters such as self-assessment of quality of life, level of mood and stress, and physical activity related information.

A decision support tool that proposes disease management recommendations to the healthcare professionals supplements the patient-centric functionality. Also, a web application supports them in monitoring and evaluating their patients' ODLs.

From a technical perspective, a service-oriented architecture is adopted, as indicated in Figure 2. The framework is based on a service assembler that supports generic services for standard functionality (e.g. security, audit logging, internationalization, messaging and configuration), and domain-specific services for disease self-management (e.g. action planning, decision support, consent management, ODLs' collection, and charts visualization). A set of web service interfaces enable the import of EHR and/or PHR data into the framework. The service assembler is implemented in a way that supports both web and mobile application technologies. The web application is deployed on a web application server. The system's capacity can be increased because a server cluster with load balancer (Apache Webserver) is used, which favors scalability.
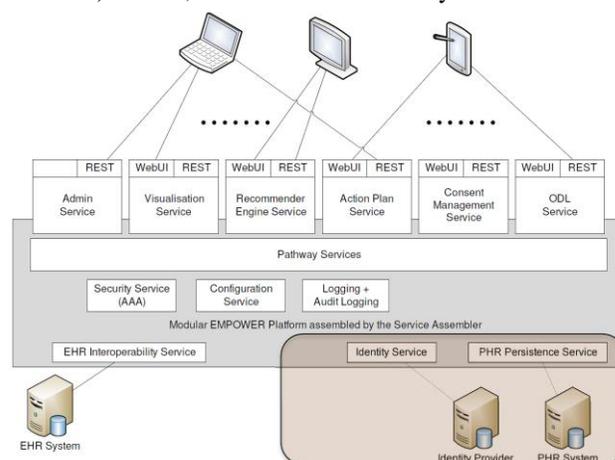

Figure 2: Service-oriented architecture of the ICT-based patient empowerment framework

Several measures safeguard privacy and safety: user authentication, pseudonymization, encrypted connections, encrypted data storage, access control based on patient consent and audit logs.

The following subsections provide further details about the most important services supported by the ICT-based patient empowerment framework.

Services for the physicians

The entry point to the SMP cycle is the specification of the physician's recommendations. The Recommender Engine, that is available at the web portal, implements this step. This engine is basically a decision support tool that helps physicians in their daily practice by consolidating generic

clinical guidelines along with patient-specific EHR and PHR data, generating semi-automatic recommendations about the patients. Semi-automatic means that the automatically generated recommendations are presented to the physician and are subject to approval. The final output of the Recommender Engine (approved self-management recommendations) serves as an input to the SMP service.

The Recommender Engine incorporates clinical guidelines described in Guideline Interchange Format (GLIF). GLIF is a computer-interpretable language for modeling and executing clinical practice guidelines and supports the sharing of clinical guidelines across different medical institutions and ICT platforms.

The Recommender Engine design follows a Model View Controller (MVC) pattern, as shown in Figure 3. The guidelines are created by the *Guideline Editor* and stored into the *Model* module. This module is a local database, which holds the guideline models, the guideline instances and temporary patient data retrieved from the PHR. The *Service* module executes the selected guideline instances for a specific patient according to the commands retrieved from the *Front End* module. This is a web-based module implemented as Rich Internet Application (HTML5, Javascript, JSON) and comprises the GUI of the Recommender Engine. The communication between the Service and the Front End modules is established through the *REST* module, which is a HTTP REST protocol encapsulation of the Service module.
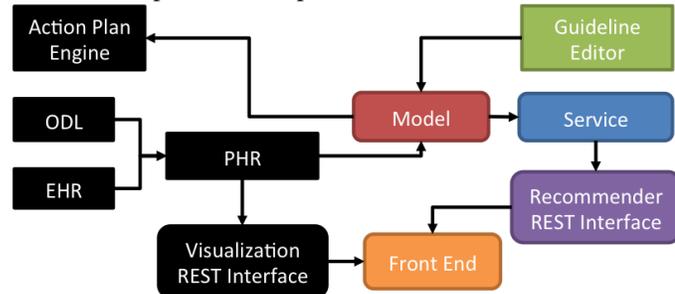
Figure 3: Model View Controller diagram of the Recommender Engine

In addition a dashboard is available that provides the physicians with an overview of the ODLs collected by their patients (Figure 4). Therefore, it combines data on actual problems, glucose measurements and insulin administration; it performs statistical calculations (e.g. weekly blood glucose averages); and, presents diagrams that indicate the ODLs trends.

Services for the patients

At the end of the consultation the recommendations approved by the physician are presented in the patient's web portal. The patient gets involved in the self-care process by reviewing the recommendations and defining self-management goals adapted to the individual needs. At a subsequent phase the patient is guided in the creation of an Action Plan. The Action Plan is a concrete schedule of activities that can 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 for the forthcoming week, on the basis of the patient's personal settings.
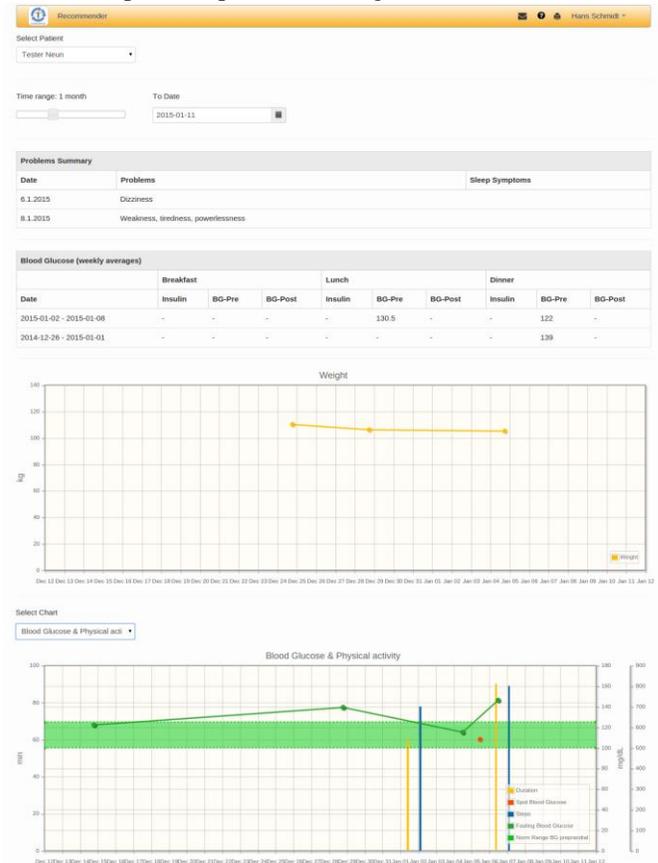

Figure 4: Dashboard for Physicians

Services for collection of ODLs are also available; they are related to vital signs, nutrition, sleep schedule, body weight and body mass index, mental parameters such as self-assessment of quality of life, level of mood and stress, and physical activity. Depending on the preferences of the patient, the ODLs can be collected using a mobile app or online web-forms.

The mobile app for Android Smartphones operates both in standalone mode and in integrated mode where data is synchronized with the backend infrastructure [19]. On top of the portal's functionality, the mobile app supports integration with consumer medical devices, automatic physical activity tracking, including step counting, and automatic sleep quality tracking. It also supports multimodal interaction, combining visual, haptic, and voice modalities [20]. Some indicative screenshots are presented in Figure 5.
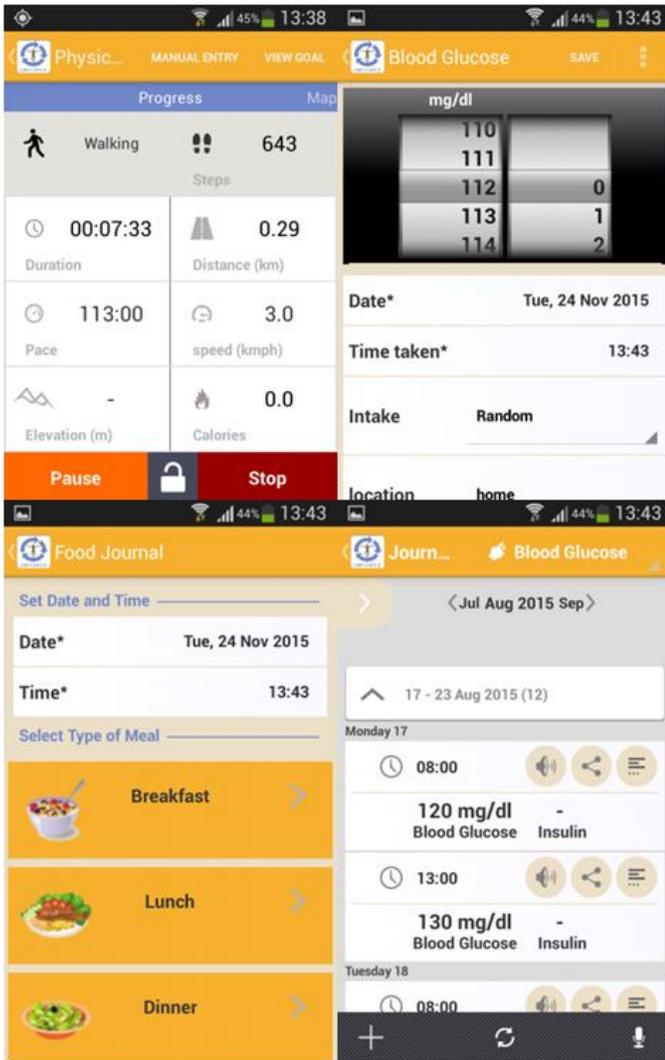
Figure 5: Mobile app screenshots

At the backend, the collected ODLs are associated with Action Plan items, generating feedback on how successful a patient has been in meeting previously defined goals and activities. A tabular and graphical representation of the conformance between the Action Plan items and the gathered ODLs, along with motivational comments for improving performance comprise a comprehensive feedback mechanism for the patient, as indicated in Figure 6.
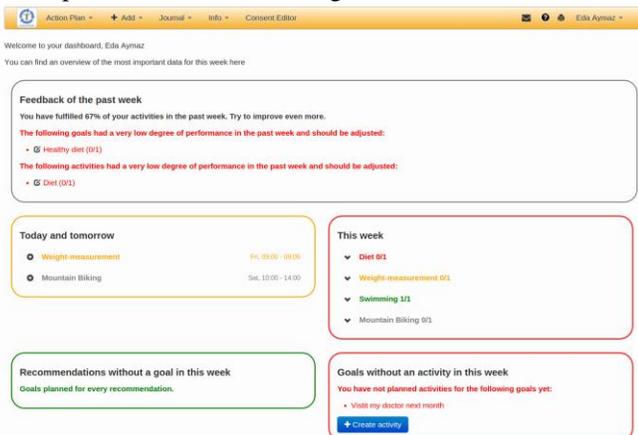
Figure 6: Dashboard for Patients

A visualization software component provides both the mobile and the web apps (Figure 7) with charts. It enables the patient to regularly check data trends, intuitively recognizing the correlation between specific parameters and constantly keeping track of the outcome of the attempts for behavioral changes.

Figure 7: Charts for checking trends in collected ODLs

Common services

Security and consent management

Access to all the framework services is both authenticated and authorized. The patient must be able to control and manage access to the data (for example when the physician wishes to visualize blood glucose charts using not only EHR data but also PHR data. Therefore, the patient defines consent policies (i.e. access rights) using a Consent Editor. This allows him to control the visibility of the recordings and to define who (role-based or individually) may access which kind of data. Consent policies are stored in a standardized policy language, the eXtensible Access Control Markup Language (XACML).

Data integration

Multiple information sources are integrated into a shared knowledge model: EHR data, PHR data, clinical guidelines and mobile app data. On the technical interoperability level data exchange is based on the *Integrating the Healthcare Enterprise* (IHE) [13] profile XPHR, supported by an IHE XDS-based sharing framework. On the semantic interoperability level, the ISO 13606 [11] information model is utilized; thus ensuring that EHR and PHR data are processed safely and consistently.

The ODL information models are specified using openEHR archetypes [12]. Archetype based-data modeling (including data schemas and corresponding rules) is an open and flexible approach. This avoids application lock-in as the knowledge models are reusable and publicly available [14]. In our case, the archetypes of *blood glucose*, *body weight*, *blood pressure*, *medication*, *problem*, and *open issue* were adopted. Moreover, *physical activity*, *meal*, *sleep*, *stress*, and *mood* archetypes were formally specified, expressed in the openEHR Archetype Definition Language (ADL).

2.3. Deployment and Validation Framework

For the needs of validating the usability and usefulness of the prototype ICT framework a pilot study in two different sites, one in Germany (PS1) and another in Turkey (PS2) were organized at the end of 2014. The user groups included in total 60 patients (21 in Germany, 39 in Turkey) and 13 health professionals (7 in Germany, 6 in Turkey).

Table 1 presents indicative statistics of the patients enrolled in the two pilots. In Germany most of the participants indicated to have obtained a higher education degree (university or equivalent) and participants were relatively equally distributed across the age range from 30 to 70 years. On the other hand, participants in Turkey were slightly younger with 49% being between 20 to 40 years old. Most participants indicated to have finished high school. 62% of the patients were Type II diabetics, while 38% were Type I patients, most of them in Turkey.

For the study needs four clinical guidelines were implemented, one for the pilot in Germany and three for the pilt in Turkey:

1. Anti-hyperglycemic drug therapy of T2D (PS1). The guideline is based on the United Kingdom Prospective Diabetes Study (UKPDS) [16] and on the ADVANCE study [17]; it aims at achieving an HBA1c value less than 6.5%. The HbA1c value should be updated every 3 months.

2. Diagnosis of T2D (PS2). The guideline is issued by the Turkish Endocrinology and Metabolism Society [18].

3. Treatment of T2D (PS2). The guideline is issued by the Turkish Endocrinology and Metabolism Society [18].

4. Monitoring of diabetes patients (PS2). This guideline has been designed by endocrinologists of the Numune Training and Research Hospital in Turkey.

Health literacy of the patients was assessed with three self-reported measures, following the approach of Chew *et al.* [15]: confidence with filling in forms; need for help in reading hospital materials; and, problems in learning about medical conditions because of difficulty understanding written information. In the Turkish population, an overall adequate level of health literacy was found. German participants had slightly higher scores.

The two pilots were exemplary for validating the ICT-based patient empowerment concept and framework and presented the challenges of working with patients and physicians in countries with very different backgrounds in e-Health systems' deployment, with different health care approaches and limitations, and with different rules about privacy, security and health data ownership. Thus, for example patients in Germany will mostly see the same medical team at their encounters, as Turkish patients will not.

TABLE I: STATISTICS ON PATIENTS IN PS1[1] (N=21) AND PS2 (N=39)

Statistic	Value set	PS1 (%)	PS2 (%)
Gender	Male	76.0	54.5
	Female	24.0	45.5
Age	Age < 20	0.0	9.1
	Age 20-29	4.8	15.2
	Age 30-39	14.2	33.3
	Age 40-49	23.8	24.2
	Age 50-59	28.7	18.2
	Age 60-69	19.0	0.0
	Age => 70	9.5	0.0
Education Level		Abitur: 38.1	University: 42.4
		Realschule: 4.8	Secondary: 36.4
		Hauptschule: 19.0	Primary: 21.2
		Not stated: 38.1	
Diabetes Type	Type I	33.4	60.6
	Type II	66.6	39.4

[1] The German nomenclature is used for indicating the education levels in PS1

2.4. Pilots' environment

The deployment infrastructures at the two pilot sites differed, as the local conditions were different. PS1 was performed within a Doctor's Network, the GOIN Doctors' Network in the region of Ingolstadt (Bavaria) and the patients were looked after by general practitioners and diabetologists. Whereas in Turkey the pilot was performed in a university hospital, i.e. Hitit University Endocrinology Clinic, in the city of Corum, and the patients were looked after by a team of mostly endocrinologists. In PS2 the implemented ICT framework was integrated within the National Health Information System (NHIS) of the Turkish Ministry of Health.

The pilot studies in Germany and in Turkey were conducted with the ethical approval of all relevant bodies (Bayerisches Landesamt für Datenschutzaufsicht in Germany, Ministry of Health in Turkey). Moreover, the trial was registered with Deutsches Register Klinischer Studien (German register of clinical trials) under DRKS00007699 on January 30, 2015.

The patients were given the option of using the web portal and the mobile application for 6 weeks within the pilots' runtime of 6 months. The physicians used the web portal, which enabled them to access and evaluate ODL data that patients shared with them, and to execute the Recommender Engine. All the applications were synchronized through a common backend application and database server.

2.5. Validation objectives and methodology

The purpose of the pilot study was to assess whether the implemented ICT framework supports self-management, whether it fosters behavioral changes and whether it facilitates diabetes disease management. On top of that usability, usefulness and acceptance by the user were assessed.

The validation methodology was based on the Model for Assessment of Telemedicine (MAST), a reference model for evaluating the effectiveness of telemedicine applications [21]. The model is intended to summarize and evaluate information about the clinical, social, economic and ethical issues related to the use of e-Health applications in a systematic, unbiased, robust manner. Among the various validation elements of MAST that were considered in our pilot study, in this paper we focus on those related to the *clinical effectiveness,* and the *patient perspectives.*

Data on basic parameters and organizational aspects were collected either manually or extracted from the log files of the ICT platform. In addition, data on behavioral aspects were collected through online questionnaires that explored the

impact of patient empowerment on self-management activities of the diabetic patients. A baseline questionnaire was submitted at the beginning of the pilot phase, before receiving training and a follow-up questionnaire was submitted at the end of the pilot phase. The questions were based on standardized tools. Some valuable questions that had been defined by the EMPOWER project consortium had been validated beforehand. Round-table-discussions and workshops gave additional information on the outcome.

For the assessment of the usability and usefulness of the proposed solution the System Usability Scale (SUS) [22] and a set of questions based on the Technology Acceptance Model (TAM) were adopted [22]. This questionnaire was administered to the patients at the end of the pilot phase.

3. RESULTS

3.1. Usage of the applications and services

We considered the usage of the applications and services of the ICT-based patient empowerment framework separately for the patients and the physicians. Of all the patients included in the pilot study, 46 patients (77%) reported to have been using only the web application (self-management portal), and 14 patients (23%) (4 in Germany, 10 in Turkey) reported to have been using both the portal and the mobile application. All patients in Turkey used the application for collecting ODLs in Journals (Figure 8). Viewing recommendations was used by 77% of the Turkish users, whereas the German users preferred planning activities (71%) and setting goals (65%). More than half of all patients reported to have been using the charts (62%) and the calendar (62%). In these two aspects the patients in Germany and in Turkey behaved very similar. In contrast, the Turkish users found setting goals (51%) and planning activities (46%) less attractive, whereas only one quarter of the German users indicated to have been using the information material (24%). Regarding recording of ODL values, the most frequent action was the recording of blood glucose (58% in PS1, 54% in PS2), followed by the physical activity tracking (25% in PS1, 5% in PS2) and blood pressure measurements (5% in PS1, 24% in PS2). Contrariwise, the sleep tracking and mood diary function was almost neglected (both below 1% in total) by the users.
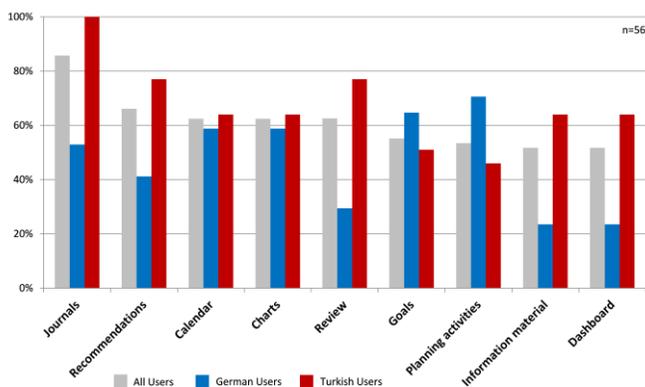

Figure 8: Self-management portal functions used by patients (n=56)

The usage of the applications correlated with the personal temperament of the patients and their digital literacy profile. For some patients, who were already disciplined and had developed certain routines towards their daily living even before the start of the project, the piloted solution served as a nice tool for logging their ODLs. For others, the apps functioned as an incentive for better adhering to disease management principles.

Another finding was that in PS2 the users of the mobile application entered data more frequently than those of the web application. For the former group it was easier and more convenient to make use of the tools without spatiotemporal limitations. For the latter, typically, it was only after coming home at the end of the day that they were interacting with the application

The physicians were interested in reviewing the ODLs of their patients. They appreciated the possibility to interact with their patients in-between consultations.

The charts with the highest popularity in both pilots were those of blood glucose and weight and in PS2 also that of blood pressure. During the pilot study the physicians executed the Recommender Engine at least once per patient (on average 2.4 in PS1 and 1.1 in PS2). The approved recommendations were significantly higher in PS2 (on average 21 per patient) compared to the PS1 (on average 3.7 per patient). This was attributed to the different level of granularity of the self-management actions that are dictated by the clinical guidelines we explored in the two sites.

3.2. Clinical effectiveness

For the assessment of the clinical effectiveness of the implemented solution we considered its impact on *blood sugar monitoring*, on *physical activity* and on *nutritional habits*. At the start of the pilot study, the participating patients indicated their health status to be good to very good, independently from their diabetes.

With regards to blood sugar monitoring, regular blood sugar testing was the most important ODL in both pilot groups. Some of the participants, mostly T1D patients, stated that they would have entered their values, if the application had allowed for more personalization. The general finding for this particular indicator showed that no noticeable changes happened in the transition from the pre- to the post-pilot phase.

With regards to physical activity 25% of recorded ODLs were physical activities in PS1 and only 5% in PS2. While the

TABLE II
SELF-REPORTED BEHAVIORAL CHANGES DUE TO THE USE OF THE ICT-BASED PATIENT EMPOWERMENT FRAMEWORK IN PS1 (N=9)

% of patients	Domain	Indicative answer
44	Nutrition control	"Now I eat less sweets and chocolate"
33	Physical activity	"I now perform physical activities more consistently"
22	None	"No significant change, due to that I am already experienced on self-managing my disease"

low value in PS2 can be explained by a low interest in actively doing sports in Turkey, the German value is partly due to the fact that the values could not be recorded on the track as very few participants used the mobile app. In the round table discussions in Germany the participants stated that the use of EMPOWER had prompted them into being more active. In PS1, nearly half of the participants indicated to have been physically active for at least 30 minutes daily on a week-time period. Nevertheless, 30% indicated that they had not been intentionally physically active within that period. In PS2 physical activity was reported very low: 80% of the participants indicated that they had not been particularly physically active on a week-time period. Unintentional physical activity was reported slightly better, however, nearly 67% of the participants indicated that even this kind of activity happened no more than one day over a week-time period. The general pattern of physical activity did not change significantly from the pre- to the post-pilot phase; only small changes were detectable and particularly for non-intentional physical activity.

Finally, with regards to nutritional habits the study revealed significant variances in the two pilot sites. Only 13% of the participants in PS1 indicated the use of a nutrition plan, while in PS2 the corresponding value was almost 93%. In PS2 60% of the participants stated to have followed the plan. The amount of nutrition related ODLs stored in our database was rather low (PS1: 6%/ PS2: 6.7%) and this was attributed to the lack of user-friendliness of the nutrition component. The pre-evaluation and after-evaluation showed a positive effect for the German users. This was confirmed in the round-table discussions where the German users reported that the use of EMPOWER had made them more aware of their eating behavior and that it had made them try harder to comply with their diets. Contrarily, in Turkey no difference could be seen in the pre-and post-questionnaire. This might be due to the use and adherence to the nutrition plan.

3.3. Behavioral changes

Qualitative feedback was collected, in the form of round table discussions in PS1, where the patients were asked to think about behavioral changes they had experienced since they had started using the platform (Table II). The patients considered two important changes in this regard: nutrition control and physical activity. They stated that they had paid more attention to their lunch breaks and to the regular intake of meals since they had started using the self-management tools. Also, some admitted to have made adjustments to their dietary habits. Moreover, patients stated that the platform had helped them in performing physical activities more consistently.

3.4. Usability of the applications

The notion of usability is related to the way the user interacts with the application: it is desired that this interaction is easy, time-efficient and fosters the ultimate objective of the application (i.e. patient empowerment through self-management of the disease, in our case).

In our study, usability of the implemented applications was examined twice. At an early-prototype phase, we collected informal feedback, which allowed for adjustments and modifications to the system. At the end of the pilot study the usability of the final prototype was examined, using a scale ranging from 1 (very bad) to 10 (very good).

The users rated the usability of the system from medium to good. These values are based on too few participants to show a definite assessment. However, the results clearly indicate that there is some need for adjustments and modifications to the ICT solution.

The qualitative feedback of the patients indicated an overall positive feeling about the applications and also revealed a set of possible extensions and enhancements of the prototypes. In particular, we received requests for interfaces to and synchronization with existing tools (e.g. popular web calendar applications) for easier integration into the daily living of the users. The possibility to enter activities "on the go", integration of a broader set of blood glucose measurement devices and interoperability with various measurement log applications were common requests.

From the physicians' point of view, the general feedback was that the supported functionality was adequate. On the other hand some users criticized the fact that the Recommender Engine functionality was not as consistent as expected and that the system should be more self-explanatory.

3.5. Perceived usefulness

Perceived usefulness refers to an individual's perception of the ability to achieve an individual goal by using a particular system [23]. Most users are willing to accept and use a technology if it is considered useful in achieving their goals, even if the system lacks usability [24].

With regards to the EMPOWER solution the perceived usefulness indicates the degree to which the users believe that the system empowers them to improve diabetes self-management. On a scale from 1 (strongly disagree) to 7 (strongly agree) the system was rated with a score of 4.6 by the German patients. When looking at the single questions asked, patients thought that the system did have a positive effect on their diabetes and that it helped them to better handle their disease. The Turkish users stated in interviews that EMPOWER influenced their behavior positively. However, both user groups found that the application was not all that easy to smoothly incorporate into their daily living.

The physicians in both countries reported that the system did influence their patients in a good way and that it had a positive effect on them, particularly in terms of increased compliance with recommendations for disease management.

The physicians were also queried about the impact of the system in their workflow and overall efficiency. In PS1, the Recommender Engine had some problems at the start of pilot and the users found it at times cumbersome to handle. Due to the lack of integration with the legacy IT systems the users had to enter the patient's data twice which proved time-

consuming and lowered the physicians' acceptance. Extra time was also spent on patients' recruitment and for discussing the results with the patients. The physicians stated that these discussions and being able to view the ODLs were very helpful towards the treatment of the patients, but, at the same time, complained that this service could not be claimed to the health services' payers. Regardless of this, they declared that the pilot had helped them to understand the challenges the patients face in their daily routines.

In PS2 the individuals focused on the fact that the Recommender Engine retrieves existing patient data and enables the automatic execution of clinical guidelines. It was reported that due to these features, the system eliminated the step of searching patient related information and lowered the possibility of making mistakes or missing a vital step in the treatment process. These advantages were correlated with the fact that in Turkey the doctors spend on average 6min for each patient, out of which 3min are devoted to data entry. It was estimated that this time period could be reduced to 1.8min. Notwithstanding the fact that a more critical assessment should take into account also the time needed for reviewing the ODLs outside the patient's visit context, the Turkish physicians felt confident that the tested solution would lead to workload reduction in mid to long term, since eventually they could advice their patients without having to see them.

3.6. Acceptance

The acceptance of the proposed solution by the end users was also assessed. The acceptance ratio from the patients' side was reported quite high. One of the reasons was that the ICT solution had been proposed by their physicians. Another reason was that it served as a good opportunity to keep in contact with the physician in the interval between regular visits. Several patients reported that one of the major incentives for using the self-management solution was the fact that their doctors would have access to their ODLs, which softened their sense that they have to deal their disease on their own. Many, especially German patients stated that EMPOWER helped them to adjust to their schedule and motivated them to better comply with the necessities asked for by their diabetes. The majority of the patients stated that they would like to continue using the system after the end of the pilot study. Only those patients who already had established non-ICT based routines for disease self-management expressed reservations.

Particular attention was given on the assessment of the acceptance of the solution with reference to privacy concerns. The majority of the German users indicated that they were satisfied with data protection and security within the EMPOWER project. They rated their level of satisfaction as good (with a mean of 7.1 on a scale from 1 to 10). Yet three patients stated that they preliminary quitted their participation in the pilot due to data protection concerns.

3.7. Impact on patient empowerment

Patient empowerment was measured using a 12-item scale, assessing four distinct dimensions: *meaningfulness* (actions are relevant to one`s ideals); *self-efficacy* (belief about one`s capability to produce desired results); *impact* (actions have an impact on current status); and, *self-determination* (actions being one`s own choice) [25][26]. Diabetes-related distress was measured using a slightly adapted version of the Problem Areas in Diabetes (PAID) scale [27][28]. Participants were asked about 21 different emotional aspects that are often reported by diabetes patients.

The pre-test at the patients who were recruited for the pilot study indicated a rather advanced level of empowerment. Even so, and despite the short intervention time, improvements in self-efficacy, impact and self-determination were observable. Participants became less worried about nutrition and felt less anxious about their disease management due to the existence of a supportive tool.

On the other hand, the study revealed that an ICT-based self-management intervention might potentially increase emotional distress. Particularly a feeling of anxiousness when neglecting to use the system was observed during the intervention phase.

3.8. Technical performance and functional shortcomings

From a technical performance viewpoint, the system was stable and ran without outages at both pilot sites. However, due to problems with the domain name provider, the web application of PS1 was down for 4 days. This resulted in an uptime of 97% versus 99% for the web application of PS2.

From a functional perspective, the piloting of the system revealed interesting insights for potential optimizations, such as that of the plausibility check for the patient-entered values. In the piloted prototype input validation was only partially implemented in the front-end: while numerical fields allow only numerical inputs and all required fields must be filled before the record can be stored, the system cannot detect wrong values entered deliberately by a patient.

4. DISCUSSION AND CONCLUSIONS

Being diagnosed with diabetes is a major issue for the persons concerned and imposes the need for non-trivial changes in their lifestyle. Diabetes' treatment involves a lot of self-management activities, many of which are related to their daily lifestyle, like nutrition and physical activity.

Several studies highlight the positive impact of ICT on disease self-management. The pilot study presented in this paper confirmed this principle and revealed that a patient empowerment approach based on self-management ICT tools is indeed useful and widely accepted by patients and physicians. Further, it showed that disease management interventions which make use of ICT tools can support patients in behavioral changes and in better disease management.

Additionally to the above, our study gave useful insights on the role of two more factors that determine the impact of ICT-based disease self-management solutions: the sociocultural background of the patients and the position of healthcare professionals in the disease management loop.

With regards to the former, it was realized that factors such as the ability to conform to lifestyle disciplines, or the way nutrition is perceived and used in some cultures as a tool for socializing, affect significantly the final outcome of an ICT-based disease self-management intervention. In line with this, it was concluded that self-management solutions should be built around the objective not only to educate and guide patients in disease self-management, but also to assist them in exploring the decision space. On top of that, self-management solutions could provide insight and explanations about the impact of their own sociocultural values on the decision process.

With regards to the later, the study confirmed the necessity of a trustful partnership between patients and physicians and highlighted the key role of the treating physician even in patient-centric disease management solutions. A common finding in both the pilot sites was the fact that the participating patients have great appreciation for their treating physician. This finding gives evidence to the principle that the success of an ICT-based disease self-management solution depends also on the level of its acceptance by the healthcare professionals. In turn, the physician's acceptance depends on the way the ICT solution affects -positively or negatively- the professionals' clinical workflow.

The presented study has some noteworthy limitations: a rather limited number of end users participated and those who participated had better digital skills, compared to the average potential user. Another limiting factor was the short evaluation period that did not allow measuring ongoing changes over a significant period of time. In that sense a larger pilot study over a longer time period is required to confirm the validity of the initial concept. On top of that, a deeper exploration of the patient empowerment aspects is necessary in order to gain better knowledge on the effect of these aspects in chronic disease self management and eventually foster its acceptance by all those involved in healthcare. Another dimension that needs further assessment is related to the impact of the platform into the workload and efficiency of the physicians. Known limitations of the study related to the level of integration of the EMPOWER framework with other IT systems in the physician's office as well as the non systematic assessment of the impact of the proposed solution into the average time spent per patient, impose the need for a large scale pilot where the economic aspects and impact of the implemented system will be assessed in a systematic way.

Following the validation of the first integrated prototype, we see good opportunities to expand it in several ways: first, to render it into a personalized patient-oriented decision support tool that not only supports custom tailored recommendations, but also provides a means to individualize / personalize the decision making role that the patient prefers, while at the background keeping the same model and base of expert knowledge; second we see good opportunities to expand the core concept of ICT-based patient empowerment to other chronic diseases that can also benefit from self-management activities. The design of the EMPOWER framework supports transferability in various ways: the Recommender Engine's standard clinical guidelines' format makes the adaptation to the needs of studies with varying disease management procedures easy; and, the Action Plan design, inspired by well

established chronic disease self-management programs is customizable to other diseases (heart diseases, depression), with minor adjustments to the ODL and feedback services.

AUTHORS' CONTRIBUTIONS

All authors made substantial contributions in the methods' design. H. Demski, S. Mantwill, and C. Hildebrand extracted and analyzed the data. I. Lamprinos drafted the manuscript. All authors interpreted the results and were involved on revising the final draft.

CONFLICT OF INTEREST

None of the authors has any conflict of interest in the manuscript. There were not any financial or other relations with relevant parties that could have affected the results and conclusions of the study.

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