Deliverable 7.1.1

Quality criteria for Self-Management

Version 1.0

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Contents

Abbreviations

DoW	Description of Work
ED	Emergency Department
EHR	Electronic Health Record
GP	General practitioners
HCP	Health Care Provider
IBCT	Interactive Behaviour Change Technologies
ICT	Information and Communication Technology
ODLs	Observations of Daily Living
PHR	Personal Health Records
SDM	Shared Decision Making

1 Executive Summary

The main aim of this deliverable is to define the self-management criteria for the validation of the EMPOWER pilot application.

The purpose of the validation is to measure the impact of patient empowerment on constructive and destructive self-management activities in diabetic patients.

We propose, overall, that EMPOWER (empowerment) will produce significant changes in patients' constructive self-management activities and compliance and adherence behaviors (as evaluated by e.g. improved blood glucose levels). More specifically, we hypothesize that:

H1: Tailored EMPOWER applications will exert a favorable influence on patient empowerment and related self-management behaviors.

H3: The collection of ODLs will exert a favorable influence on patient empowerment and related self-management behaviors.

H4: High empowerment as fostered by the EMPOWER applications will increase rational (considered) compliance with physicians' recommendations, increase the likelihood that the patient will engage in other constructive health management and increase adherence to treatment protocols.

H2: Personalized action plans will support behavior changes, such as increased engagement in constructive health management and increased adherence to treatment protocols.

Treating physicians:
H1: The usage of the guideline-based recommender engine will facilitate the doctors‘ work with the diabetic patient.

H2: Data collected via ODLs will deliver valuable input to the doctors.

Patients & Treating Physicians
H1: Usage of empower will have a favorable influence on doctor patient communication.

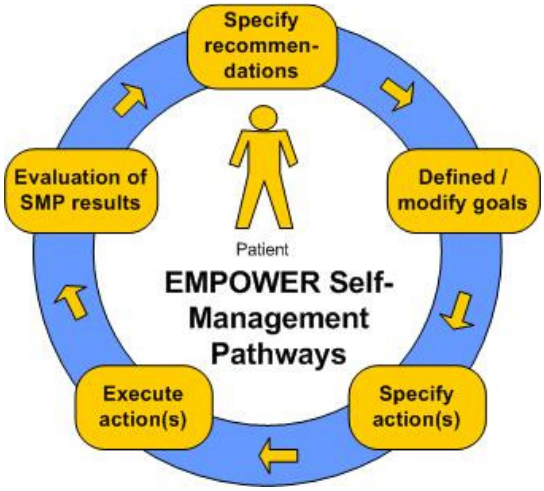
In relation to the hypotheses drawn the main concepts involved and the related measures are described: empowerment, health literacy, doctor-patient communication, health status, diabetes-care. These measures form the questionnaire which will be pre-tested during the first validation phase. The same questionnaire will be administered to the patients involved in the second validation phase with a before-after design.

2 EMPOWER in a Nutshell

Patent empowerment involves patients to a greater extent in their own healthcare process and disease management becomes an integrated part of their daily lives. The capability of self-management opens to them the possibility for patients not only to contribute to their own healthcare but also to be more in control of their disease. EMPOWER develops a modular and standard-based patient empowerment Framework which facilitates the self-management of diabetes patients based on PHRs and on context-aware, personalised services. EMPOWER focuses the research and development efforts on a patient-centric perspective that also involves healthcare professionals. EMPOWER provides knowledge-based Self-Management Pathways for diabetes patients. This includes

(1) Services for the specification and execution of actions to change behaviour according to diabetes-specific health care needs. Patients can develop personalised action plans which include recommendations from the treating physicians and patients' preferences

(2) Services for monitoring of vital, physical, mental parameters as well as physical and lifestyle activities based on health standards.



EMPOWER semantically integrates multiple information sources (EHR/PHR, diabetes guidelines, patterns of daily living) for a shared knowledge model. The Self-Management Pathways facilitate the specification of recommendations that allow specifying individual goals for the patient. Based on these goals, relevant information and their preferences patients can specify their individual diabetes-specific actions. The Self-Management Pathways are an iterative process where executed actions and reported patterns of daily life can be evaluated. Recommendations, goals and actions can be updated iteratively according to current needs and preferences. Finally, the services in EMPOWER will embrace semantic interoperability based on health standards such as HL7[1] and IHE[2] profiles.

EMPOWER addresses long-term goals and short-term activities in order to facilitate the self-management of patients with diabetes and thus the treatment of chronic diseases. The pilot applications in Germany and Turkey will demonstrate that the holistic and patient-centric approach of EMPOWER can improve disease management by personalised self-management services helping diabetes patients to cope better with their condition.

[1] http://www.hl7.org
[2] http://www.ihe.net

3 Introduction to the Deliverable

The aim of the deliverable at hand is to specify quality criteria for Self-Management to be applied at the validation of the pilot applications. Amongst others the catalogue of quality criteria aims to measure self-management indicators and will serve as a benchmark for patient empowerment.
The main purpose of this document is to specify a catalogue of quality criteria for self-management in diabetic patients to be evaluated in a form of a questionnaire. Based on the pre-study and in-depth literature review a questionnaire has been developed that will be pre-tested in the first pilot application to be used in the second pilot application.

3.1 Scope of the deliverable

The following deliverable will describe in details the concepts involved in the development of self-management criteria for validation. The research question and the hypotheses related to the self-management and EMPOWER product will be explained as well as the methodology of the study. The design of the first and the second study is described in details as well as the recruitment process in both countries, Turkey and Germany. A list of measures used with respective references and the final English version of the questionnaire are presented.

The following deliverable will describe in detail:

- the concepts involved with this validation part
- the research question and the hypotheses on EMPOWER and self-management
- the design of the study 1 and 2
- the recruitment process
- the measures used

3.2 Purpose and Context of Quality Criteria Development

The main purpose of this document is to specify a catalogue of quality criteria for self-management in diabetic patients to be evaluated in a form of a questionnaire. Based on the pre-study and in-depth literature review a questionnaire has been developed that will be pre-tested in the first pilot application to be used in the second pilot application.
The catalogue of quality criteria aims to measure the level of empowerment and hence will be a benchmark for patient empowerment. Additionally, this task will analyse constraints for empowerment and related self-management.
Based on a fairly new model of patient empowerment, the level of empowerment for patients will be evaluated based on four concepts: Meaningfulness (relevance), self-efficacy (competence), self-determination (choice) and impact (Schulz & Nakamoto, 2013).
As proposed by the model as an inherent part of empowerment, participants will also be evaluated regarding their (diabetes) health literacy (including declarative and procedural knowledge).
In addition, we will include into the list of quality criteria for self-management outcome variables such as increased proper activities, proper medication usage, and consequently also to better health status and improved quality-of-life. In previous pilot studies (Lorig et al, 2008; Schulz et al, 2010; Spreitzer, 1995; Fox, 2009) these quality criteria have proven to be reliable.
Additionally, we will analyze patients' motivation along the following three aspects: (i) The relevance of the tool for achieving the proper health condition; (ii) The self-efficacy as the belief in one's capabilities to produce desired results by one's actions; (iii) Patients' impact in the sense that the more impact individuals believe they have, the more internal motivation they should feel.

Validation is performed to answer the following question, listed in the deliverable D8.1.1:
Do EMPOWER applications foster self-management with adaptive and secure patient pathways?

This in itself includes the following research questions regarding the quality criteria:

- Do the EMPOWER applications foster empowerment?
- Do EMPOWER applications foster self-management?
- Do EMPOWER applications foster knowledge and related self-management behavior?

Evaluating these quality criteria is an important step towards the final product. Evaluation will allow that the product is being developed along the intended purpose and the requirements of the users. Potential weaknesses can thus be detected and corrected at the earliest possible point of time. A validation of the prototype serves to identify the consumers' responses in order to be able to act on these before the product gets launched. In Empower the validation is structured as follows:

1. A prototype with reduced functionality, called "Prototype I" will be tested concerning technical and with users in Ankara and Ingolstadt from project months 24-30. During this period patient recruitment for study 2 will take place.

2. A prototype final stage will be tested at the pilot site Ankara and Germany in project months 30-36.

3.3 The Validation framework

Study Components
The components developed within EMPOWER will be validated. These are for the patient the personal health application and the self-management client, the Self-Management Pathway, especially the personalized, adaptive Action Plan and the ODLs, and the Personal Health Record, including the monitoring and recommendation facilities. For the health professionals this is the personalized, adaptive Recommender Engine.

Relation to other work packages
The content of this deliverable is mainly interconnected with three work packages. WP2 and particularly task 2.1 Pre-Study – Empowering Patients for Self-management. The hypotheses of this deliverable are amongst other derived from the pre-study. At the same time results gathered through the questionnaire developed in the scope of this deliverable will be an important outcome for dissemination, therefore for task 2.3.
The development of quality criteria for self-management is part of the broader validation framework. In that this content is strongly connected to all the other tasks of WP7, and particularly to task 7.3.
Finally, WP8 is also strongly connected to this deliverable, since the collection of data will occur during the pilot application, and most importantly because study 1 will inform corrections to be implemented before the larger pilot application.

4 Background

The prevalence of diabetes is increasing and the projection for the next decades draws a global epidemic that is constantly expanding. For this reason research from different fields is focusing on fostering diabetes self-management. Traditional approaches are now inadequate because they cannot reach sufficiently people and have demonstrated not to support long-term behaviour change. Although one of the most important factors is the lack of resources needed to establish proper self-management education and follow up support (Glasgow et al. 2012). In addition, since costs for healthcare are constantly increasing the development of interventions based on information and communication technologies (ICT) seem to be the only viable solution. As described by Piette (2007) “Interactive Behavior Change Technology (IBCT) is one potential resource for improving the effectiveness of diabetes management programs given the very real limits on funding and staffing time”. Moreover Verhoeven and colleagues (2010) state that the “use of technology that supports electronic information and communication exchange has a significant positive effect on both clinical and behavioural outcomes” (Verhoeven et al. 2010).
So far many studies have shown to be effective and to produce good outcomes on different levels, including clinical or psychological outcomes. However, some authors point out that without the integration of these systems with personal health records, and without embedding them in the broader healthcare system (Glasgow et al. 2012; Krishna & Boren, 2008; Piette 2007) this effectiveness is drastically reduced. The necessity to integrate new systems into the broader healthcare context is therefore the foundation for new technological interventions to be effective in many respects in the field of diabetes.
In 2005, Jackson reviewed interventions with type I diabetic patients. The interventions observed were: internet-based, telephone-based and computer-assisted integration of clinical information. Those technologies were reviewed with regard to outcomes. Internet based interventions showed a positive impact on patient-centered outcomes. Telephone interventions had a positive impact on primary care visits, whilst computer-assisted integration of clinical management had a positive effect on the health care outcomes (Jackson et al 2006). Internet based interventions were also effective in terms of support, since they were able to affect support both from pre-existing relationships as well as from new relationships formed during the intervention (Barrera et al. 2002).
Verhoeven and colleagues (2010) reviewed technology-based interventions and divided technologies into: asynchronous communication, and synchronous communication. The first typology includes monitoring and delivering feedback via email, internet, cell phone, automated messaging systems, or other tools of this kind. On the other hand synchronous communication involves real-time, face-to-face contact through videoconferencing and connecting two or more persons simultaneously. The latter one appeared to be less suitable to foster self- management, while asynchronous communication was mostly used. Asynchronous interaction reported “more improvements in clinical values and self-care”, synchronous application reported “more improvements in usability of technology and cost reduction”, and combined applications “scored best according to quality of life” (Verhoeven et al., 2010, p. 679). The authors also underscored one common problem related to ICTs, namely that satisfaction with technology depended mostly on education and training (Verhoeven et al., 2010).
In many cases specific kind of technologies, such as the use of telephones, have shown to be also suitable for minorities (Krishna & Boren, 2008). Cell phones have shown to be reliable tools for monitoring and exchanging information between patient and Healthcare providers (HCP), and the new possibilities given by smartphones and applications would enhance this effectiveness. “ICT, especially asynchronous applications such as mobile phones, is being used increasingly for improving diabetes care, resulting in an increased and even more reliable transmission of clinical values and intensified patient-caregiver information exchange.” (Verhoeven et al., 2010)
The scopes of the interventions, their aims and contents are often mixed in the literature, we will try to distinguish here some of the most important. Technological tools in the field of diabetes interventions can serve to:

1. “Assist patients and their clinicians in monitoring changes in health and self-care needs;
2. Support patients’ efforts to make behaviour changes by promoting health and effective self-care;
3. Enhance communication between patients and potential support for their disease management” (Piette, 2007).

In the categorization of Piette (2007) the areas of intervention are: medication adherence; physical activity; patient-to-patient support; informal caregivers, which are four critical parts in diabetes patients’ lives.
In their review Verhoeven and colleagues (2010) concluded amongst others that “Technology-based interventions should not only address clinical or disease aspects but also consider behavioural control and the care delivery process in order to realize sustainable changes in diabetes care. This implies for health care applications that they should combine information with at least one additional ICT functionality for behaviour change, education, decision supports, or social support with peers or families to have optimal results.” (Verhoeven et al., 2010, p. 668).
An extensive part of the literature stresses the importance to design personalized interventions. Most successful technological environments allowed individual access, individual setting of goals, provided motivational support etc. On implication therefore is to design patient-centered technologies, and to involve patients from the very beginning of the design. “The advantage of IBCT (Interactive Behaviour Change Technologies) communication is that diabetes services can enter the real world in which patients live. IBCT services must be based on a holistic patient-centered model that takes patients’ full range of comorbid conditions and their own goals into account” (Piette, 2007).
For a patient to be able to self-manage his/her disease means to have enough knowledge, and also motivation in order to participate in shared decision making and to “work together with their HCPs” (Lorig et al., 2006). Moreover, as assessed by Krishna (Krishna & Boren, 2008), “quality health care requires effective collaboration between clinicians and patients”..

Depending on the focus of the researchers involved, on the theoretical background, and on the areas of intervention of the technology, there are different outcome measures that have been taken into account. A common taxonomy is still lacking, but we could divide them in: behavioural outcomes, biological outcomes, and psychosocial variable following the recent classification of Glasgow (Glasgow et al., 2012). The table below is extracted by a systematic literature review of Boren, and divided the outcomes into classes (Boren et al., 2008).
Different outcome measures are useful in determining the impact of technological intervention systems on diabetes care (Adaji et al., 2008).

Clinical and related outcome measures	**Nonclinical outcome measures**	**Other measures**
HbA1c	Self-efficacy	Usability
Medication	Quality of Life	
Depression	Interaction Effects	
Hospitalization Rates	Knowledge	
Weight Management		

Table 1 Classes of outcomes measures (Boren et al., 2008)

In general web-based interventions or technology-enhanced interventions have shown to be useful in reducing:

- HbA1c levels, by integrating self-monitoring devices, such as glucose meters and blood pressure devices and computerized transmission of these data, as well as by integrating medical health records.
- hospitalization rates.

And are useful in increasing:

- self-efficacy.
- diabetes knowledge, in particular when asynchronous communication is used.
- communication between patients and health care providers.

Only few web-based interventions in the field of chronic diseases have tried to measure empowerment as an outcome measure as such. Samoocha and colleagues (2010) identified in their review on web-based interventions with a focus on patient's empowerment (not diabetes specific) only two studies that measured explicitly empowerment; including one study using the Diabetes Empowerment Scale (DES) (Anderson et al., 2000).
According to Anderson and Funnel (2010) empowerment consists of two components, a process and an outcome component. The former refers to increasing a patient's capacity to think critically and make informed decisions, whereas the second component refers to measurable increases in these abilities. Within this framework health care providers are responsible to ensure that

"(…) patients are equipped to make decisions informed by an adequate understanding of diabetes self-management and an awareness of the aspects of their personal lives that influence their self-management decisions."
(Anderson & Funnell, 2010, p.4).

The most prominent outcome measures are changes in the HbA1c level.
Weight management as an outcome variable of diabetes self-management programs still seems not to reach expectancies. Most studies with the aim of weight management focus on preventing diabetes rather than on self-management strategies for those that already developed diabetes. Nevertheless, it has to be kept in mind that studies that only evaluated e.g. HbA1c can be considered to be an outcome of eventual weight loss.
Reduction or change of medication as an outcome measure has been rarely evaluated.
Reduction of depressions seemed to be rather related to interventions that included psychological components than solely focusing on the enhancement of self-management of diabetes patients.
Quality of life seemed to improve throughout most of the studies, even though slightly less than HbA1c levels. Nevertheless, comparability between studies was distorted due to the fact that most studies use different measures to assess quality of life.
With regard to patient web portals which integrate electronic medical records and patient health records targeting diabetic patients Osborn and colleagues (2010) found that these portals: enhance patient-provider communication, increase overall satisfaction with care, expand access to health information, and improve disease management and patient outcomes in diabetes.

4.1 Purpose of the Validation

The purpose of the validation is to measure the impact of patient empowerment on constructive and destructive self-management activities in diabetic patients.
EMPOWER semantically integrates multiple information sources such as electronic health records and personal health records. In addition the patient is able to register long- and short-term goals and to register patterns of daily living. Based on these goals, relevant information and their preferences patients can specify their individual diabetes-specific actions.

According to the objectives of the overall project, the purpose of the validation phase with regard to self-management behavior can be broken down into the following:
(1.) examine and determine the effect of the adaptive and secure patient pathways of EMPOWER on self-management of patients,
(2.) to examine whether personalized action plans of EMPOWER support behavior changes,
(3.) to examine whether the collection of observations of daily living (ODLs) fosters self-control.

4.2 Hypotheses

Patients
We propose, overall, that EMPOWER (empowerment) will produce significant changes in patients' constructive self-management activities and compliance and adherence behaviors (as evaluated by e.g. improved blood glucose levels). More specifically, we hypothesize that:

H1: Tailored EMPOWER applications will exert a favorable influence on patient empowerment and related self-management behaviors.

> H1a: The use of EMPOWER will favorably influence empowerment, as measured by meaningfulness, self-efficacy, self-determination and impact.
> H1b: The use of EMPOWER will favorably influence patient`s (diabetes) health literacy (including declarative and procedural knowledge).
> H1c: The use of EMPOWER will favorably influence patients knowledge and related self-management behaviors.

H2: Personalized action plans will support behavior changes, such as increased engagement in constructive health management and increased adherence to treatment protocols.

> H2a: The use of action plans will increase physical activity.
> H2b: The use of action plans will increase blood glucose monitoring.
> H2c: The use of action plans will increase adherence to treatment.

H3: The collection of ODLs will exert a favorable influence on patient empowerment and related self-management behaviors.

H4: High empowerment as fostered by the EMPOWER applications will increase rational (considered) compliance with physicians' recommendations, increase the likelihood that the patient will engage in other constructive health management and increase adherence to treatment protocols.

Treating physicians:

H1: The usage of the guideline-based recommender engine will facilitate the doctors‘ work with the diabetic patient.

H2: Data collected via ODLs will deliver valuable input to the doctors.

Patients & Treating Physicians
H1: Usage of EMPOWER will have a favorable influence on doctor patient communication.

> H1a: The usage of EMPOWER will have a favorable influence on information exchange between doctor and patient
> H1b: The usage of EMPOWER will have a favorable influence in creating a good interpersonal relationship
> H1c: The usage of EMPOWER will have a favorable influence in the process of making treatment-related decisions

5. Concepts and related measures

5.1 Empowerment

Shortly after the promulgation of the Ottawa Charter, individual as well as community empowerment became a prominent issue in the health promotion literature (Anderson, 1995; Roberts, 1999). Besides ethical reasons to involve patients more in decision-making regarding his/her own health, also financial reasons have been advanced. Empowerment will allow citizen to participate and take responsibility for their own healthcare, which will eventually control healthcare costs (Neuhauser, 2003). But most importantly, empowerment is health is advocated in terms of its favorable influence on health outcomes (Edwards, Davies, & Edwards, 2008).
Various conceptualizations of empowerment and multiple motivations for its import have been advanced. The central idea of empowerment is that the individual takes increased responsibility for his/ her own health and a more active role in decision-making. For some, the core of empowerment entails a relational (e.g., doctor-patient) dimension—emphasizing the need for more egalitarian structures and more equitable distribution of power between practitioners and patients (Bhopal & White, 1993; Sherwin, 1992). Others take a more individualistic view, focusing more on informed choice—e.g. “Patients are empowered when they have the knowledge, skills, attitudes, and self-awareness necessary to influence their own behavior and that of others … to improve the quality of their lives” (Funnell et al., 1991), or on patient experience of feelings of power, control, or greater self-esteem (Morgen & Bookman, 1988; Rissel, 1994; Wallerstein, 1992). Given these varied emphases, Aujoulat et al. argue that there is, as yet, no proper theory of patient empowerment (Aujoulat, d'Hoore, & Deccache, 2007). Instead, different principles of empowerment are applied to the patient care and education, particularly in the fields of chronic condition.
Empowerment can be defined in general as a *“process by which people gain mastery over their lives”* (Rappaport 1987) and can be therefore applied to different disciplines. However a common basis for every discipline is that in order to improve the quality of their lives in every aspect the individuals should be motivated to change at a personal, social and organizational level. As a result empowerment is a relational construct, as it is for example in doctor-patient communication, which is associated with several other concepts, and implies problem-solving skills (Israel et al. 1994, Schulz et al. 1995).
Starting from the management literature the concept of empowerment inherited two meanings, which are particularly important for the realm of health (Wall et al. 2002). The first one is denoted as “psychological empowerment”, and refers to employees’ subjective feelings of empowerment—in particular feelings of perceived competence to perform tasks well, feeling influential in their work

role, feeling that the work is important, and feeling free to choose how to execute tasks (Conger & Kanungo 1988, Spreitzer 1995, Thomas & Velthouse, 1990). A second meaning of empowerment that is often called “role empowerment” or “situational empowerment” (Logan & Ganster, 2007) refers to objective practices involving the delegation of responsibility to employees in order to give them decision-making authority. Empowerment in this sense encompasses practices such as job enrichment, self-managing teams or autonomous work groups. Research has linked both of these forms of empowerment to improved employee performance and satisfaction.

5.1.1 Measuring Empowerment

In the following three measures of empowerment and related constructs are introduced. These measures will be in included in the questionnaire which will be used to evaluate patient`s empowerment in a pre- and post-test design over the course of the second pilot application (8. Annex – Questionnaire English version).

5.1.1.1 Spreitzer`s Empowerment Scale

Drawing from the management literature, Spreitzer (1995) proposed a scale that measures empowerment at the workplace. It consists of four dimensions:

- Meaningfulness: Refers in the workplace to a fit between one`s own ideals and believes and the work goal/purpose.
- Self-efficacy: refers to one`s belief in his or her capability to do a task.
- Self-determination: In contrast to self-efficacy, it refers to one`s belief of having a choice to start and regulate activities. An important part of it is the idea of autonomously initiating and continuing work behaviors and processes
- Impact: refers to what degree someone can influence certain outcomes, such as administrative or operating outcomes. It is different from locus of control, since impact is understood to be influenced by the work context internal locus of control is personality characteristic that exists across different situations.

Reliability of the overall scale in the original study was acceptable namely Cronbach`s alpha.72 (tested in an industrial sample) and .62 (in an insurance sample).

The scale has been adapted for and used in the medical environment with fibromyalgia patients and diabetes patients (Camerini, Schulz, & Nakamoto, 2012; Johnston et al., 2013; Mantwill, Franze, & Schulz, 2013b;). The four dimensions refer in the medical context to the following:

- Meaningfulness (or relevance): In the medical context it refers to the patient`s feelings that what he or she does is relevant for his/her own quality of life. High levels of relevance will eventually lead to more commitment and involvement in the treatment. Again it is about the value of activities in relation to one`s own ideals.
- Self-efficacy (or competence): The concept of self-efficacy has been widely investigated in social psychology. Research in the health domain has shown that self-efficacy has beneficial effects on alcohol abuse, drinking behavior, drug abuse or eating disorders. It refers to one`s beliefs about capabilities to produce desired results by actions.
- Impact: refers to a patient`s belief that what he is doing results in having an impact on the current status.
- Self-determination (or choice); refers to an autonomous decision done by the patient in which he has a true choice without being coerced by others (Schulz & Nakamoto, 2013).

German Version

The scale has been used so far in English, Italian and German language. Where the later version is still investigation but preliminary analysis suggests overall good internal reliability. The first two

version seemed to be reliable measures with mixed results regarding the sub-scales (Camerini t al., 2012; Johnston et al., 2013)

Turkish Version
So far no Turkish version is available.

5.1.1.2 Diabetes Empowerment Scale (DES)

The Diabetes Empowerment Scale (DES) was developed in 2000. It was developed in order to measure psychosocial self-efficacy in people with diabetes.
The long version consists of 28 items (α=0.96) and contains three sub-scales (1. managing the psychosocial aspects of diabetes, 2. assessing dissatisfaction and readiness to change, and 3. setting and achieving goals) (Anderson et al., 2000).
In order to allow for a shorter assessment, the scale was reduced to eight items in a later study, choosing those items that had the highest item to subscale correlation. Reliability for the short version (DES-SF) was high (α= 0.85). In a subsequent study it was administered to another sample confirming the high reliability. Content validity was confirmed by the fact that the DES-SF scores and HbA1c levels changed positively after completion of an educational program (Anderson et al., 2003).

German Version
A German version of DES-SF has been developed in 2012. Overall the scale showed a high reliability (Cronbach`s α=0,89).
Validity of the scale was confirmed by significant correlations with HbA1c values and psychosocial pressure in diabetes patients. In addition patients who beforehand had participated in an educational program had in average higher results than patient who did not participate (Bergis et al., 2012)

Turkish Version
So far only the long version of the DES has been developed in Turkish. The scale was reduced to 21 items and reliability was high (Cronbach`s α=0,75).

5.1.1.3 The Problem Areas in Diabetes (PAID)

The Problem Areas in Diabetes (PAID) scale is a measure for emotional functioning in diabetes, which facilitates the detection of diabetes-related emotional distress (Polonsky et al., 1995; Welch et al., 1997).
The scale was developed in a sample of 451 female patients with type 1 and type 2 diabetes, all of whom were using insulin to treat their diabetes.
The scale consists of 20 items and each item represents a special area of diabetes-related psychosocial distress (Polonsky et al., 1995). Reliability of the scale was very high (Cronbach`s α=0.95) and had good item-to-total correlations. The scale had a positive relationship with other psychosocial measures of distress, such as emotional distress, disordered eating and fear of hypoglycemia. Further, it was associated with short- and long-term complications as well as the Hba1c value and was negatively associated with self-care behaviors. It was found that the PAID was a unique contributor to adherence to self-care behaviors controlling for age, diabetes duration and general emotional distress. In addition, even after adjustment for age, diabetes duration, general emotional distress and adherence to self-care behavior PAID was still associated with Hba1c (Polonsky et al., 1995). A second study conducted in type 1 and 2 patients, including patients who only used medication to treat their diabetes, confirmed the vey high reliability (Cronbach`s α=0.95) (Welch et al., 1997). Patients with type 1 diabetes scored significantly higher than those suffering from type 2. Neither sex nor duration of diabetes were significant predictors of PAID. No difference was found between type 2 diabetes patients who use insulin and patients who use tablets only (Welch et al., 1997).

German Version
A German version of the PAID has been developed and was tested in a sample of 376 diabetic patients, including type 1 and type 2 patients with insulin and non-insulin dependent diabetes. In their study they compared the performance of different depression measures.
The PAID showed satisfactory sensitivity and the authors concluded that using the PAID to screen for depression in diabetic patient seems reasonable. In addition, they suggest that the German PAID is a useful indicator for emotional problems in diabetic patients (Hermanns et al., 2006).

Turkish Version
The Turkish version of the PAID was tested in a sample of 154 type 2 non-insulin dependent patients in two outpatient clinics in Istanbul. Overall reliability was very high (Cronbach`s α=0.95). In contrast to the original English scale a 2-factor structure (1. diabetes distress, 2. support-related issues) was identified (Huis et al., 2011)

5.2 Health Literacy

The Empowerment framework used for this evaluation states that health literacy is an inherent component (Schulz & Nakamoto, 2013). Both concepts are often strongly interwoven with each other but should be considered independently in order to understand where one or the other plays a crucial role (Schulz & Nakamoto, 2013)

"Programs aimed at patient empowerment often assume a high level of knowledge or expertise in patients or incorporate educational components while work on health literacy regularly takes empowerment as a goal but seems to take for granted that high levels of expertise will naturally lead to effective involvement in medical decisions or beneficial self-management. However, this blurring limits the utility of both concepts as illustrated in the four cases below which examine the impact of mismatches between literacy and empowerment." (Schulz & Nakamoto, 2013, p.8)

The literature on health literacy focuses on education as a key to health promotion and disease prevention (Nutbeam, 2000). For example, the idea of the "expert patient" describes a patient who is well informed or has access to crucial information regarding his or her own health conditions (Wilson, 2001). This information allows patients to become responsible for their own health, including activities such as recognizing their own symptoms, managing acute episodes, using medications, interacting with HCPs, seeking information and using (community) resources (Fox, Ward, & O'Rourke, 2005), i.e., both psychologically and situationally empowered.
This view of empowerment highlights that a patient does not only need to have information at its disposition but that he should be also able to use this information to inform judgments and decisions. Traditional analyses of health literacy focus mostly on basic reading and numeracy skills; however, a literate health consumer needs knowledge beyond these basics (Nutbeam, 2000). Nutbeam distinguishes this basic (or functional) literacy from communicative/interactive literacy and critical literacy, which invoke skills that allow the person to derive meaning from available information and to use that information to exercise greater control of and responsibility for his/her health. Schulz and Nakamoto seek to clarify the information and skills needed to attain these further forms of literacy, suggesting the need to recognize declarative knowledge, e.g. information about health and medicine, procedural knowledge, i.e. rules guiding reasoned choice about the proper course of action, and finally judgmental skills (Nutbeam's critical literacy) (Schulz, & Nakamoto, 2005). In order to participate in the manner envisioned for an expert patient, the person would need judgmental skills relating knowledge (both declarative and procedural) to his or her experiences and goals. We therefore incorporate in our model of empowerment literacy components— specifically declarative and procedural knowledge in the relevant health domain and the judgmental skills to make reasoned choices in that domain:

1. Functional Health Literacy describes all basic reading and numeracy skills needed to navigate in the health care system.

2. Declarative Knowledge denotes all factual knowledge that patients could acquire via different information sources such as health professionals, mass media or colleagues, relatives and friends. This type of knowledge is that which can be expressed verbally and is basic to learning how to approach a health condition.

3. Procedural Knowledge (or know how) was introduced by the philosopher Gilbert Ryle distinguishing between knowledge in the sense of "knowing that" and "knowing how" (Ryle, 1946). As Ryle pointed out, know-how is akin to a person's ability to conduct a certain activity. A similar distinction is drawn in the psychology literature as "declarative knowledge" versus "procedural knowledge" (Anderson, 2005) and in a related vein "explicit knowledge" versus "implicit" or "tacit knowledge" (Mandler, 1984; Polanyi, 1968), recognizing that procedural knowledge might not be recognized or verbalized. It is procedural knowledge that enables a person to use information in a specific context and that governs the skilled performance of tasks (in this case relative to the management of health conditions)

4. Judgment Skills. Confronted with different or novel aspects that appear in everyday life the patient can manage them due to the acquired skill that allows him to judge on the basis of factual knowledge. Thus s/he becomes autonomous to deal with new situations. It goes without saying that this often requires practice, time, and also initial support from health professionals. For that reason, integral to our model is the patient's progression in managing his disease. And this progression and acquiring performance skill is an integral part of patients' perceived empowerment.

Health literacy is critical to effective patient empowerment, i.e., the patient's ability to participate as an autonomous actor in making healthcare decisions in a particular domain. A psychologically empowered patient lacking adequate knowledge could well make dangerous choices that impede his/her health goals. Highly literate people lacking psychological empowerment may choose to be highly dependent on HCPs, despite their ability to make well-informed decisions for themselves. Thus, the outcomes of autonomous patient participation, thus an effective self-manager, will depend on both literacy and psychological empowerment.

5.2.1 Measuring Health Literacy

Among the most commonly used measures of health literacy is the Short test of Functional health Literacy in Adults (Parker et al., 1999) or the Rapid Estimate of Adult Literacy in Medicine (REALM) (Murphy et al., 1993). Both are measures of functional health literacy. The S-TOFHLA measures one`s ability to read and understand things commonly encountered in health care settings by asking participants to replace missing words in a given text (Parker et al., 1999.
The REALM on the other hand measures one`s ability to read and correctly pronounce words often encountered in the medical environment/health care setting (Murphy et al., 1993).
Both measures have to be administered via face-to-face interviews and are thus less appropriate for online surveys.
In addition those measures have shown to differentiate less in highly educated populations (Connor et al., 2013), such as Switzerland. Since our participants have to actively engage with written online information and negative on the EMPOWER platform, we expect that the majority of our participants will have higher levels of literacy. Therefore we will use measures that are more adequate for those populations.

5.2.1.1 Newest Vital Sign (NVS)

The Newest Vital Sign (NVS) is a measure that tests objective health literacy, which has been originally developed in English and Spanish language. It is a nutrition label that includes 6 questions regarding the label. Administration time is around 3 minutes. Fewer than 4 correct answers indicate limited literacy

Reliability of the test was high (Cronbach`s α>0,76). It further correlated with the longer version of the S-TOFHLA (Weiss et al. 2005).

German Version:

A German version of the NVS was developed within the European Project on Health Literacy and was used in order to validate a newly developed measure of health literacy (Sorenson et al., 2013). So far the test has not been specifically validated in German language.

Turkish Version:

A Turkish version of the NVS was developed (Ozdemir et al., 2010) with high reliability (Cronbach`s α = 0.70) and the mean score was 2.60 % 0.08. The answer that was most often correctly answered was a question that dealt with peanut allergies. 73.7% of participants answered the question correctly. The question receiving the least correct answers (8.8%) dealt with the intake of saturated fats.

5.2.1.2 Chew Items

Other measures that are considered to be less objective but are more useful in self-administration are subjective/self-administered measures of health literacy. One measure that has been widely used in studies on health literacy are three items developed by Chew and colleagues (2004; 2008). Based on a larger set of questions, the authors identified three items for detecting people with inadequate or marginal health literacy. The questions were tested in a large VA population and participants were classified as having inadequate, marginal or adequate health literacy bas on the S-TOFHLA and the REALM.

1796 patients finished the interview. According to the S-TOFHLA 7.4% had marginal health literacy and according to the REALM 17%. Respectively, 6.8% and 4.2% of participants had inadequate health literacy. The Receiver Operating Characteristic Curves (AUROCs) were lower for detecting “inadequate or marginal” health literacy than for detecting inadequate health literacy for each of the 3 questions. The item “How confident are you filling out medical form by yourself?” had the largest area under the AUROC of 74 (95% CI: 0.69–0.79) and 0.84 (95% CI: 0.79–0.89) based on the S-TOFHLA and REALM to detect inadequate health literacy. The other two items included were: “How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials?”, and “How often do you have problems learning about your medical condition because of difficulty understanding written information?”.

It as concluded that each item separately was sufficient to detect differences in health literacy levels (Chew et al., 2004; 2008).

German Version

A German version of the three items was developed in 2012 (Farin et al., 2012) and tested in a sample of chronically ill patients (N01264). Reliability was high (Cronbach`s α=0,77) and one-dimensionality was confirmed. In addition, two of three items have been used in a recent study with diabetic patients in Switzerland. Pre-testing suggested that the items had to be adapted in order to make them more comprehensible to the population, i.e. When you get written information on a medical treatment or your medical condition, how often do you have problems understanding what it is telling you? (Franzen et al., 2013)

Turkish Version:

So far no Turkish version of the Chew items has been identified. It has been part of a study conducted by the Institute of Communication and Health in a population of diabetic patients in Turkey and the results show to highly correlate with the S-TOFHLA. (E. Eyuboglu, personal communication, January 13, 2014).

5.2.2 Measuring Declarative & Procedural Knowledge

Declarative knowledge refers to all factual knowledge a patient has at its deposition and which he may have acquired through different information sources, including HCP, media or social contacts. This knowledge can be expressed verbally and is considered to be basic knowledge on how to approach a certain health condition (Schulz, & Nakamoto, 2013).
Whereas declarative knowledge refers to knowledge in the sense of "know that", procedural knowledge refers to "know how". Procedural knowledge might eventually not be recognized or verbalized. For example a person might be able to swim but it is not able to put precisely into words the activity of swimming. It is about using information in a specific context, which enables the person to perform a certain activity without being completely aware of all information given, i.e. knowledge that automates behavior (Schulz & Nakamoto, 2013).

So far no validated measure exists that would measure both concepts specifically, which might be explained by the fact that both concepts are inherently linked with each other. In the following a general measure of diabetes knowledge is presented that should serve as a proxy for both concepts described.

5.2.3.1 Brief Diabetes Knowledge Test (DKT)

One test that has been widely used to evaluate diabetic patients` knowledge on their disease is the brief Diabetes Knowledge Test (DKT). It was developed by the Michigan Diabetes Research Training Center. It consists of 23 items and it administration time is around 15 minutes. The first 14 items can also be answered by people who do not use insulin to treat their diabetes, whereas the 9 other items are meant specifically for people who use insulin to treat their diabetes.
Reliability was high for the general test and the insulin-use subscale (Cronbach`s alpha $\geq$0.70). Predictive validity was proven by the fact that patients with diabetes type 1 scored in general higher than those with type 2 (not significant). In addition, the measure showed to be stable across different populations. (Fitzgerald et al., 1998).

German Version

So far no validated version has been developed. A short literature review on diabetes knowledge tests in German language revealed that measures are still very dispersed and clear validation criteria are missing. Nevertheless, a German version of the DKT has been recently developed to be used in the German-speaking population in Switzerland. The scale is currently analyzed and preliminary results suggest good reliability (Mantwill, Franzen, & Schulz, 2013a).

Turkish Version

So far no validated Turkish version has been identified. Similar to what has been found for a German-speaking instrument, also here the literature suggests dispersion and lack of clear validation criteria.

5.3 Doctor-Patient Communication

In the past three decades, doctor-patient communication has gained an increasing amount of attention in the field of health communication. Descriptive and experimental research has tried to shed light on mainly three purposes of this sort of communication, that is (a) information exchange between doctors and patients, (b) creating a good interpersonal relationship, and (c) making treatment-related decisions (Mauksch, Dugdale, Dodson, & Epstein, 2008; Ong, de Haes, Hoos, & Lammes, 1995). Beside these different purposes of communication, researchers have focused on the influence of communicative behaviors on patient outcomes (Roter & Hall, 2006). Among the

different patient outcomes that had been identified, there are those as satisfaction, compliance (adherence to treatment), knowledge, understanding, coping, quality of life/health status.

5.3.1 Measuring Doctor-Patient Communication[3]

Measures for doctor-patient communication were derived from a study aimed at understanding the influence of provider styles and patient understanding on self-management. They observed three main measures:
- Physician decision-making style
- Provider communication
- Overall patient understanding

The first measure was originally described by Kaplan and colleague as the property of physician to involve patients in treatment decisions. The second measure is made up of 5 items and it is derived from the American Board of Internal Medicine patient survey. This survey measured the satisfaction with provider communication about their disease and treatment. The last measure aimed at measuring the patient's understanding of diabetes care. All of the questions were originally part of the questionnaire for a large study of Veterans Affairs called Diabetes Quality Improvement Project.

German Version
So far no German version is available.

Turkish Version
So far no Turkish version is available.

5.4 Health Status

Self-management programs have shown to be effective for chronic diseases, and among those for diabetes. Effectiveness of an intervention of such kind is measured in terms of health outcomes: changes in health behaviors, health services utilization, and health status. While the first two outcomes will be mainly observed through objective measures, for the health status we will use a self-reported measure.

5.4.1 Measuring Health Status

In 1990 Aoki & Hammond (Aoki & Hammond, 1992) developed an instrument aimed at measuring health status in adult insulin-dependent (type I) and non-insulin-dependent (type II) diabetic patients. The diabetes impact management scale (DIMS) is made up of 44 items that can be distinguished into five subscales:
- IA, diabetes-specific symptoms subscale;
- IB, nonspecific symptoms subscale;
- II, well-being subscale;
- III, diabetes-related morale subscale;
- IV, social role fulfillment subscale.

In the original study the authors stated that test-retest reliability was satisfactory and the 40 out of 44 items were highly correlated with subscales and the total scale score. The internal consistency

[3] http://onlinelibrary.wiley.com/doi/10.1046/j.1525-1497.2003.21132.x/pdf
http://onlinelibrary.wiley.com/doi/10.1046/j.1525-1497.2002.10905.x/pdf
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1495033/pdf/jgi_10905.pdf

of the scale was satisfactory and even if the correlations of the scale score with clinical data were of low magnitude, they were in the hypothesized direction when significant. The scale was first tested among 130 patients, and administered again to 52 patients.

The scale has been reduced to 12 items by Weinrauch and colleagues in 2008 (Weinrauch et al. 2009a; Weinrauch et al. 2009b). They assessed that some studies have demonstrated little relevant clinical value for the full DIMS tool, and that smaller number of questions are more likely to speak directly to outcome results as proven by literature. In their abbreviated DIMS five questions relate to physical and 7 to emotional status during the 1 year of follow-up. Responses were based on a 6-point scale (worst case response being 6 points, best case receiving 1 point).This scale has proven to be very effective in diabetes patients type 1.

German Version
So far no German version is available.

Turkish Version
So far no Turkish version is available.

5.5 Diabetes Self-Care

Diabetes self-care corresponds to self-management. EMPOWER will allow collecting data about the self-management activities of the participants. However there are self-reported measures as well which can help understanding patients' self-management across different components of diabetes regimen, such as the Summary of Diabetes Self Care Activities.

5.5.1 Measuring Diabetes Self-Care

The SDSCA instrument was developed by Glasgow and colleagues and was restructured by Toobert et al. (2000) is a self-reporting 21 items assessing the following aspects of the diabetes regimen:

- general diet
- specific diet
- exercise
- medication taking
- blood sugar testing
- foot care
- smoking
- additional items related self-care recommendations from health care professionals.

On the basis of the results collected in 7 studies, Toobert and colleagues revised the SDSCA. The revised SDSCA consists of a core set of 11 items that have all been used in previous studies along with the expanded list of 14 additional questions that may be of use to researchers or clinicians. The revised version of the SDSCA differs from the versions tested in each of the 7 studies in that the scoring is simplified, and the best items are retained. Criteria used for selecting items for the revised version were: consistency in mean values across studies, sufficient variability and lack of ceiling or floor effects, temporal stability, internal consistency, predictive validity, sensitivity to change, ease of scoring, and ease of interpretation.

German Version
Schmitt and colleagues recently developed a German scale called Diabetes Self-Management Questionnaire (DSMQ), To evaluate its psychometric quality, 261 patients with type 1 or 2 diabetes were assessed with the DSMQ and the Summary of Diabetes Self-Care Activities Measure (SDSCA). (Schmitt et al. 2013)

Turkish Version
Kav and colleagues adapted the SDSCA to Turkish by using translation, content analysis, and psychometric testing. They validated the scale with a sample of 100 patients over 18 years of age in Ankara during one year. Based to their findings, the Turkish version of SDSCA measure is reliable and valid to assess diabetes self-management of patients with diabetes type 2..They also comment that the SDSCA measure is relatively short and easy to administer to Turkish population. (Kav et al. 2010)
A Turkish version has been in use. Preliminary analysis showed high reliability.

5.6 Summary

Other outcome measures included will be physiological parameters collected via the EMPOWER platform in order to investigate the relationship between levels of empowerment and potential changes in e.g. HbA1c levels.
In addition, data from logfiles will be collected so as to evaluate if e.g. increased usage of the platform is related to increased feelings of empowerment or literacy.
Below a list with measures to be used in the questionnaire and their core references is provided (For the full draft of the questionnaire: see 8. Annex – Questionnaire English version)

Construct	Name	Original	German	Turkish
Empowerment	Spreitzer Empowerment	Spreitzer, G. M. (1995). Psychological empowerment in the workplace: Dimensions, measurement, and validation. *Academy of management Journal*, *38*(5), 1442-1465.	A German version has been in use. Preliminary analysis showed high reliability.	A Turkish version will be developed, using 1. Forward translation 2. Expert panel Back-translation 3. Pre-testing and cognitive interviewing 4. Final version
	Diabetes Empowerment Scale (short version) DES-SF	Anderson, R. M., Fitzgerald, J. T., Gruppen, L. D., Funnell, M. M., & Oh, M. S. (2003). The diabetes empowerment scale-short form (DES-SF). *Diabetes Care*, *26*(5), 1641-1642.	Bergis, N., Ehrmann, D., Hermanns, N., Kulzer, B., & Haak, T. Lässt sich Empowerment bei Menschen mit Diabetes messen?. *Diabetologie und Stoffwechsel*, *7*(S 01), P_9.	So far only the long version exists based on that a short version will be developed. Atak, N., Köse, K., & Gürkan, T. (2008). The Impact of Patient Education on Diabetes Empowerment Scale (DES) and Diabetes Attitude Scale (DAS-3) in Patients with Type 2 Diabetes. *Turkish Journal of Medical Sciences*, *38*(1).
	The Problem Areas in Diabetes (PAID)	Polonsky, W. H., Anderson, B. J., Lohrer, P. A., Welch, G., Jacobson, A. M., Aponte, J. E., & Schwartz, C. E. (1995). Assessment of diabetes-related distress. *Diabetes Care*, *18*(6), 754-760. Welch, G. W., Jacobson, A. M., & Polonsky, W. H. (1997). The Problem Areas in Diabetes Scale: an evaluation of its clinical utility. Diabetes care, 20(5), 760-766.	Hermanns, N., Kulzer, B., Krichbaum, M., Kubiak, T., & Haak, T. (2006). How to screen for depression and emotional problems in patients with diabetes: comparison of screening characteristics of depression questionnaires, measurement of diabetes-specific emotional problems and standard clinical assessment. *Diabetologia*, *49*(3), 469-477.	Huis In'T Veld, E. M., Makine, C., Nouwen, A., Karşıdağ, Ç., Kadıoğlu, P., Karşıdağ, K., & Pouwer, F. (2011). Validation of the Turkish Version of the Problem Areas in Diabetes Scale. Cardiovascular psychiatry and neurology, 2011.

Health Literacy	Newest Vital Sign (NVS)	Weiss, B. D., Mays, M. Z., Martz, W., Castro, K. M., DeWalt, D. A., Pignone, M. P., ... & Hale, F. A. (2005). Quick assessment of literacy in primary care: the newest vital sign. *The Annals of Family Medicine*, *3*(6), 514-522.	Developed but not validated yet. Sørensen, K., Van den Broucke, S., Pelikan, J. M., Fullam, J., Doyle, G., Slonska, Z., ... & Brand, H. (2013). Measuring health literacy in populations: illuminating the design and development process of the European Health Literacy Survey Questionnaire (HLS-EU-Q). *BMC public health*, *13*(1), 948.	Ozdemir, H., Alper, Z., Uncu, Y., & Bilgel, N. (2010). Health literacy among adults: a study from Turkey. *Health education research*, *25*(3), 464-477.
	Chew Items	Chew, L. D., Bradley, K. A., & Boyko, E. J. (2004). Brief questions to identify patients with inadequate health literacy. *health*, *11*, 12. Chew, L. D., Grill, J. P., Snyder, A., Bradley, K. A., Nugent, S. M., & Baines, A. D. (2008). Validation of screening questions for limited health literacy in a large VA outpatient population. *Journal of General Internal Medicine*, *23*(5), 561-566.	Farin, E., Nagl, M., & Ullrich, A. (2012). The comprehensibility of health education programs: Questionnaire development and results in patients with chronic musculoskeletal diseases. Patient education and counseling. Franzen, J., Mantwill, S., Rapold, R., & Schulz, P. J. (2013). The relationship between functional health literacy and the use of the health system by diabetics in Switzerland. *The European Journal of Public Health*, ckt202.	Has been part of a study conducted by the Institute of Communication and Health in a population of diabetic patients in Turkey and the results show to highly correlate with the S-TOFHLA. (E. Eyuboglu, personal communication, January 13, 2014).
	Diabetes Knowledge test (DKT)	Fitzgerald, J. T., Funnell, M. M., Hess, G. E., Barr, P. A., Anderson, R. M., Hiss, R. G., & Davis, W. K. (1998). The reliability and validity of a brief diabetes knowledge test. *Diabetes care*, *21*(5), 706-	Diabetes knowledge tests in German language are still very dispersed and clear validation criteria are missing. A	So far no validated Turkish version has been identified. Similar to what has been found for a German-speaking

		710.	German version of the DKT has been recently developed to be used in the German-speaking population in Switzerland. Preliminary results suggest good reliability Mantwill, S., Franzen, J., & Schulz P. (2013a) [Diabetes Knowledge in a Swiss sample of diabetic type II patients]. Unpublished raw data	instrument, also here the literature suggests dispersion and lack of clear validation criteria. A Turkish version will be developed, using: 1. Forward translation 2. Expert panel Back-translation 3. Pre-testing and cognitive interviewing 4. Final version
Doctor-Patient Interaction	PDMstyle PCOM Understanding	Heisler, M., Bouknight, R. R., Hayward, R. A., Smith, D. M., & Kerr, E. A. (2002). The Relative Importance of Physician Communication, Participatory Decision Making, and Patient Understanding in Diabetes Self-management. Journal of General Internal Medicine, 17(4), 243-252.	A German version will be developed, using: 1. Forward translation 2. Expert panel Back-translation 3. Pre-testing and cognitive interviewing Final version	A Turkish version will be developed, using: 1. Forward translation 2. Expert panel Back-translation 3. Pre-testing and cognitive interviewing Final version
Diabetes Self-Care	Summary of Diabetes Self-Care Activities (SDSCA)	Toobert, D. J., Hampson, S. E., Glasgow, R. E., (2000) The Summary of Diabetes Self-Care Activities Measure.Diabetes Care, 23(7)	A German version has been in use. Preliminary analysis showed high reliability.	A Turkish version has been in use. Preliminary analysis showed high reliability.
Health Status (physical and emotional)	Short version of the Diabetes Impact Management Scale (DIMS)	Weinrauch LA, Bayliss G, Gleason RE, Lee AT, D'Elia JA. (2009) Utilization of an abbreviated diabetes impact management scale to assess change in subjective disability during a trial of pulsatile insulin delivery demonstrates benefit. Metabolism. 2009 Apr;58(4):488-91. doi: 10.1016/j.metabol.2008.11.006.	A German version will be developed, using: 4. Forward translation 5. Expert panel Back-translation 6. Pre-testing and cognitive interviewing 7. Final version	A Turkish version will be developed, using: 4. Forward translation 5. Expert panel Back-translation 6. Pre-testing and cognitive interviewing 7. Final version

6 Evaluation and Validation of the EMPOWER prototypes

The validation of the EMPOWER prototype will consist of two phases:

- **Validation Phase 1 (M25-M30)**: aims to test an EMPOWER prototype with reduced functionalities (Prototype 1) in both pilot regions (Gemany and Turkey) with a small sample of patients and doctors. This early prototype aims to get feedback from the users about basic EMPOWER features, usability and possible barriers.

- **Validation Phase 2 (M31-M36)** – aims to test the final EMPOWER prototype (Prototype 2) in Germany and Turkey.

6.1 Validation and Evaluation of the Early Prototypes (M25-M30)

Evaluation criteria of the early prototype:

- Usability
- Acceptance
- Barriers

Prototype 1 aims to test an EMPOWER prototype with reduced functionalities. This is an enhanced version of the prototype developed for the first review meeting but will cover functions described in both storyboards.

The following functionalities will be assessed

- by the patients
    - Action Plan
    - Web and mobile ODLs
    - Visualisation (Web and mobile)
    - Patient Consent Management
- by the physicians
    - Recommender Engine

The results will be integrated in the software developments for the final prototype.

We aim at the following users

- For the German Pilot Application
  10 Patients
  3 Physicians
  Dr. Zimmer
  Dr. Schnittert
  Dr. Jedamzik

- For the Turkish Pilot Application
    - 6 patients
    - 2 physicians

6.2 Validation and Evaluation of the Final Prototypes (M31-M36)

The final prototype aims to test an EMPOWER prototype which is now enhanced after the results collected during the first phase.

The following functionalities will be assessed

- by the patients:
  - Action Plan
  - Web and mobile ODLs
  - Visualisation (Web and mobile)
  - Patient Consent Management
  - Dashboard

- by the physicians:
  - Recommender Engine

6.2.1 Pilot Application Ingolstadt

The pilot and evaluation will be performed in the GOIN Doctors' Network in the region of Ingolstadt (Bavaria). A description of the Network can be found in D8.1.1. The practice network GOIN will support the Pilot Application I.

We aim at the following users

- 40-70 diabetes patients of Type 1 and Type 2 diabetes, consisting of
  - 30% Type 1 diabetes patients
  - 60% Type 2 diabetes patients
  - 10% Young adults with pre-diabetes
  - speaking the National language
  - voluntary participation
- 10 physicians

Exclusion criteria for patients are

- unable to handle EMPOWER
- unable to give informed consent
- physical conditions that might be at risk by using EMPOWER
- no internet access an no competence how to use it

Study team and responsibilities

GOIN patient administrator (e.g. study nurse or other administrator): first level support to the patients

Medical Team
2 Diabetologists: Dr. Peter Zimmer (dr.p.zimmer@t-online.de), Ingolstadt
Dr. Michael Schnittert (michael@schnittert.de), Ingolstadt
1 General Practitioners:
Dr. Siegfried Jedamzik (jedamzik.siegfried@gmail.com), Ingolstadt

Technical Team

- pilot site technical staff (GOIN) giving general technical support to the users

- pilot site technical staff support (HGMU and EMPOWER technical partners): install and maintain the deployed software and resources
- IT department of the Ingolstadt hospital (Dr. Kleemann): Implementation of the virtual machine and installation of OS; hosting and running the EMPOWER server; running regular backups

The support in Validation Phase will be on 3 levels

- 1st level: GOIN
- 2nd level: HMGU
- 3rd Level: responsible technical partners

6.2.2 Pilot Application I Ankara

The piloting will take place in Ankara.
The patient group will consist of 40-70 diabetes patients, made up of

- Type-2 diabetes and
- Type-1 diabetes and
- pre-diabetes (if necessary)

Study team and responsibilities

- Patient administrator (MoH) taking care of the patients and giving support to the patients

- 5 physicians.
- five physicians from the hospitals
  Hurişah Aksakal, Endocrinology Nurse, Ankara Ulus Public Hospital, aksakal_huri52@hotmail.com
  - Hakan Çörekoğlu, Dietician, Ankara Ulus Public Hospital, diyetisyenimhakan@hotmail.com

- Technical administrators who will be in charge of the installation and maintenance of the system.

- Pilot site technical staff (with support from SRDC and EMPOWER technical partners):
  - supporting the deployment site
  - install and manage the deployed software and resources

The support in Validation Phase will be on 3 levels

- 1st level: MOH
- 2nd level: SRDC
- 3rd Level: responsible technical partners

6.3 Timetable and Milestones

Validation Phase 1 (EMPOWER Prototype 1)

Period	Task	Partner
January 31, 2014	The recruitment of patients and doctors for the Validation Phase 1 for both Pilot Applications (Germany and Turkey) is done. The patients participating in the German Validation Phase 1 have signed the Informed Consent. Registration data for all patients and doctors are available. The doctors for both pilot applications have signed a contract. Training material for doctors and patients (e.g. slides, handout) maybe based on small scenarios will be ready	GOIN (DE) MOH (TR) GOIN (DE) MOH (TR) TECH
February ~12, 2014	The Validation Phase 1 starts with (1) An EMPOWER training for doctors (2) An EMPOWER training for patients, maybe doctors should participate The questionnaire and the training will be in the mother tongue of the users (German resp.Turkish)	HMGU/GOIN (DE) SRDC/MOH (TR)
March– April 2014	Patients and doctors are using the EMPOWER system. This step should starts with a consultation. At the end of the consultation the doctor should specify together with the patient treatment goals and recommendations for self-management goals. On this basis the patient should use the EMPOWER system. Germany: GOIN will contact patients and doctors on a weekly basis. At the end of this step there will be a 2nd consultation with the goal to discuss the results. Additionally, the doctor will have a look at the recorded patient data.	HMGU/GOIN (DE) SRDC/MOH (TR) GOIN
Beginning of May, 2014	Collecting feedback from patients and doctors for Validation Phase 1 (questionnaires, workshops, thinking aloud,…)	HMGU (DE) SRDC (TR)
June 30, 2014	Finalizing Prototype 2 Summarizing the results of Validation Phase 1 in Deliverable D7.3.1 “Validation Report for EMPOWER Pilot Application”	TECH HMGU (DE) SRDC (TR)
July 2014	Integrated test of EMPOWER components for Prototype 2	TECH

Validation Phase 2 (EMPOWER Prototype 2)

Period	Task	Partner
June 30, 2014	The recruitment of patients and doctors for the Validation Phase 2 for both Pilot Applications (Germany and Turkey) is done. The patients participating in Validation Phase 2 have signed the Informed Consent. Registration data for all patients and doctors are available. Training material for doctors and patients (e.g. slides, handout) maybe based on small scenarios will be ready	GOIN (DE) MOH (TR) TECH
July 2014	Interviews and/or focus groups to survey self-management skills at the beginning of the validation phase => before the EMPOWER training for patients	USI
August 2014	The Validation Phase 2 starts with (1) An EMPOWER training for doctors (2) An EMPOWER training for patients, maybe doctors should participate The questionnaire and the training will be in the mother tongue of the users (German resp.Turkish) As the 2nd Validation Phase comprises 50-70 patients per Pilot Application several training workshops with patients will be meaningful.	HMGU/GOIN (DE) SRDC/MOH (TR)
September – November 2014	Patients and doctors are using the EMPOWER system. This step should starts with a consultation. At the end of the consultation the doctor should specify together with the patient treatment goals and recommendations for self-management goals. On this basis the patient should use the EMPOWER system. Germany: GOIN will contact patients and doctors on a weekly basis. At the end of this step there will be a 2nd consultation with the goal to discuss the results. Additionally, the doctor will have a look at the recorded patient data.	HMGU/GOIN (DE) SRDC/MOH (TR)
December 2014	Collecting feedback from patients and doctors for Validation Phase 2 (questionnaires, workshops, thinking aloud,…)	HMGU (DE) SRDC (TR) USI
January 2015	Summarizing the results of Validation Phase 2 in Deliverable D7.3.1 “Validation Report for EMPOWER Pilot Application”	HMGU (DE) SRDC (TR) USI

Additionally, in Germany, GOIN will organize face-to-face meetings (e.g. on a monthly base) for the participating patients during both validation phases in order to exchange experiences with the EMPOWER system, to discuss problems and to encourage motivation for self-management.

In Turkey, MOH will plan a meeting before the pilot starts with the participating patients and the medical staff. Although monthly meetings may be hard to manage, a final meeting may be held to evaluate the pilot period, and throughout the pilot the same information may be gathered from the patients and doctors via online surveys and questionnaires.

7 Methodology and Design of the Validation of Self-Management Criteria

The following part will describe the research design, including population and sampling methods, as well as the analysis of the collected data on self-management.

7.1 Research Design

7.1.1 Study 1 – Pre-test of the Self-Management Criteria

In study 1 the forward and back-translation of the measures will take place. Once done so, the questionnaires will be pre-tested in the respective languages using cognitive interviews/think aloud technique. It is suggested to pre-test the questionnaire until saturation is reached, meaning that a number of 8-10 patients in each language should be interviewed. During the pre-test, it will be investigated whether the questions are comprehensible and clear, and if the format and length is appropriate.

7.1.2 Study 2

A total of 80-140 participants will be recruited, 40-70 for Turkey and 40-70 for Germany. Eligible for this study will be patients suffering from diabetes, who agree to be part of a study and who agree to 1-2 hours per week of log-on time on EMPOWER over a total period of 3-4 months (if they are part of the experimental group). Each subject will be interviewed 2 times over a four month period, one baseline interview, and one follow-up after six months.
Since the system will be novel to the participants, each participant in an experimental condition will be provided with an informational brochure. In addition, before they are using the EMPOWER system all patients and doctors will participate in a training in order to become familiar with the EMPOWER features.
We will apply the standard method used for web-based studies, presenting the informed consent documents before beginning the study and indicating by proceeding to the survey questions itself the subject is consenting to participate (Couper, 2008). In addition, guaranties of confidentiality of all data will be provided in the informed consent. Subjects have to click on a button indicating their willingness before any study materials will be presented. So the data will be anonymous.
In general, we will obtain information via self-administered questionnaires. At the baseline as well as at the follow-up, we will obtain measures of the concepts described earlier. The questionnaire will be administered to the experimental group as embedded in EMPOWER. The first time they will enter they will have to fill in the first questionnaire, and after six months use they will have to fill in the follow up.
Qualitative interviews with doctors will help exploring the hypotheses regarding the facilitation of their work thanks to EMPOWER.

7.2 Population and sampling

Germany
The patients who will be included in the pilot will be chosen from the diabetic population the GOIN network.
Type 2 diabetic patients as well as type 1 diabetic patients will be chosen to use the application.
An equal amount of male and female participants is preferred, however gender will not be a major determiner either. Patients should have regularly access to internet (preferably at home) and be able to use internet and latest desktop and mobile applications.

Immediately upon the identification of participating doctors they and their assistants and other medical staff (diabetes nurse, dietician, etc.) will be given an orientation training regarding the project. Although the staff will already have vast knowledge about diabetes and taking care of patients who are living with it, they will require a basic training for using the EMPOWER system.

The doctors and office staff will identify patients who would fit the profile to participate, taking the abovementioned criteria into consideration. The patients will sign consent forms after vis-à-vis interviews, where they will find an opportunity to ask questions and for clarifications. The patients will be given manuals and potentially a training to show them how to use the system, as well as general information notes about the project.
The doctors will also be given a set of manuals to show them how to use their own interface.
The presented questionnaire will be filled out before participants had access to the platform.

After recruitment

The patients will sign consent forms after vis-à-vis interviews, where they will find an opportunity to ask questions and for clarifications. The patients will be given manuals and potentially a training to show them how to use the system, as well as general information notes about the project.
The doctors will also be given a set of manuals to show them how to use their own interface.
The presented questionnaire will be filled out before participants had access to the platform.

GOIN patient administrator will provide identity information for all patients, doctors and organizations using the EMPOWER system (for details see D 8.2.1 Deployment Infrastructure)

Material

- For the patients:
  - General information Flyer on Empower
  - Questionnaire + instructions
  - Informed Patient Consent
  - Manual on how to use the system + short version
  - Set of slides for the training session
  - Scenario

- For the trainers/patient administrators
    - Instruction on how to perform the validation
    - Protocol for the round table discussions

- Physicians
  - General information Flyer on Empower (Phase II)
  - Manual on how to use the system+ short version
  - Set of slides for the training session
  - Questionnaire + instructions
  - For the trainers
    - Instruction on how to perform the validation
    - Protocol for the round table discussions

Turkey
The patients who will be included in the pilot will be chosen from the diabetic population of Ankara. Type 2 diabetic patients as well as type 1 diabetic patients will be chosen to use the application. Although age will not be a primary factor in determining whether a person should be included in the study or not, young adults will be given priority since they tend to use the current technological applications much more easily than the elder population. An equal amount of male and female participants is preferred, however gender will not be a major determiner either. It is very important

that the patients be able to use internet and latest desktop and mobile applications without any problems.

Immediately upon the identification of the clinic and its staff who will be taking care of EMPOWER's validation phase the doctors, their assistants and other medical staff (diabetes nurse, dietician, etc.) will be given an orientation training about the project. Although the staff will already have vast knowledge about diabetes and taking care of patients who are living with it, they will require a basic training for using the EMPOWER system.

Clinical engagement and following traditional clinical rules in the use of telecare and telehealth systems is essential. EMPOWER is no exception. Patient privacy and non-disclosure of the personal information is two of the clinical rules.

The medical staff will identify the patients who will take part in the pilot, taking the abovementioned criteria into consideration. The patients will sign consent forms after vis-à-vis interviews, where they will find an opportunity to ask about all the questions they might have and clarify them. The patients will be given manuals to show them how to use the system, as well as general information notes about the project.

The doctors will also be given a set of manuals to show them how to use their own interface.

In EMPOWER system, the previous health data of the patients will be withdrawn from the National Health Information System of Turkey, namely Sağlık.NET. The ODL data will be obtained from EMPOWER services.

Surveys and questionnaires will be filled after actual consultation visits in the hospitals.

Although the framework of the general layout of the validation phase is planned to work as explained above, the pilot will be defining itself as far as other details and requirements are concerned.

7.3 Data Analysis

As described above data will be gathered through cognitive interviewing, a questionnaire, data on physiological parameters extracted from the EMPOWER platform itself as well from log files.
Data from cognitive interviews will be analysed using a grounded theory approach. Meaning that data will be analysed by two or more coders in order to identify if certain topics emerge more often than others and which of the topics have been discussed most frequently.
Data from the questionnaire will be analysed quantitatively using statistical software. Correlation and regression analysis will allow to identify relationships between the different constructs. In addition collected data from the platform will allow to investigate relationships between the above described concepts and e.g. physiological parameters.
Confirmatory and exploratory factor analysis will be applied in order to investigate the validity of the different scales used. In addition, parameters that are known to correlate highly with the measured constructs (such as age with literacy) will be evaluated in order to test for criterion-related validity.
Depending on the size of the sample structural equation modelling will be used in order to test for a model of empowerment.

7.4 Limitations

One limitation that arises with the research design is the problem of recruiting sufficient participants. To participate in the two pilot applications participants need to have sufficient time at their hand (and willingness) to follow up with the intervention. This does not only influence the retention rate but also the implementation of a control group as such.
In addition, the limited amount of time for the 2nd Pilot Validation, will not allow for long-term follow-ups and therefore conclusions. Further, the fact that two different countries are involved in the pilot project which present two different cultures will make comparisons of data difficult.

RELEVANCE FOR EMPOWER:

- Using a mixed-methods approach, including qualitative and quantitative data will allow a more thorough understanding of the effectiveness (and potential problems) of EMPOWER
- Choosing the appropriate sample (size) will allow to draw (significant) useful information on the effectiveness of EMPOWER
- Identifying relationships between psychological and physiological parameters will allow to identify effective relationships that EMPOWER caters to.

8. Annex – Questionnaire English version

EMPOWER Questionnaire (Self-Management Criteria)

1. Empowerment

1.1 Spreitzer Empowerment

Own introduction (suggestion):
Below is a list of statements regarding diabetes. Please indicate for each statement what applies to you, where 1 is “strongly disagree” and 7 is “strongly agree”.

1. *Dealing with my diabetes* is very important to me.

Strongly disagree	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6	□ 7	Strongly agree

2. I am confident about my ability to *do deal with diabetes*.

Strongly disagree	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6	□ 7	Strongly agree

3. I have significant autonomy in determining how *I deal with my diabetes*.

Strongly disagree	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6	□ 7	Strongly agree

4. My control over *the management of my diabetes* is large.

Strongly disagree	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6	□ 7	Strongly agree

5. The activities I do to *handle my diabetes* are meaningful to me.

Strongly disagree	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6	□ 7	Strongly agree

6. I am self-assured about my capabilities to *deal with diabetes*.

Strongly disagree	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6	□ 7	Strongly agree

7. I can decide on my own how to *handle my diabetes*.

Strongly disagree	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6	□ 7	Strongly agree

8. I have a great deal of control over *the management of my diabetes*.

Strongly disagree	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6	□ 7	Strongly agree

9. *Dealing actively with my diabetes* is meaningful to me.

Strongly disagree	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6	□ 7	Strongly agree

10. I am prepared to do the activities necessary to *handle my diabetes*.

Strongly disagree	□	□	□	□	□	□	□	Strongly agree

11. I have considerable opportunity for independence and freedom in how *I deal with diabetes*.

Strongly disagree	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6	□ 7	Strongly agree

12. I have considerable control over *the management of my diabetes*.

Strongly disagree	□	□	□	□	□	□	□	Strongly agree

1.2 Diabetes Empowerment Scale-Short Form (DES-SF)

The 8 items below constitute the DES-SF. The scale is scored by averaging the scores of all completed items (Strongly Disagree =1, Strongly Agree = 5)

Check the box that gives the best answer for you.

In general, I believe that I:

1. ...know what part(s) of taking care of my diabetes that I am **dissatisfied** with.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
2. …am able to turn my diabetes goals into a workable plan.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
3. ...can try out different ways of overcoming barriers to my diabetes goals.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
4. ...can find ways to feel better about **having** diabetes.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree

5. ...know the **positive** ways I cope with diabetes-related stress.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
6. ...can ask for support for having and caring for my diabetes when I need it.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
7. ...know what helps me stay motivated to care for my diabetes.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree
8. ...know enough about myself as a person to make diabetes care choices that are right for me.	☐1 Strongly Disagree	☐2 Somewhat Disagree	☐3 Neutral	☐4 Somewhat Agree	☐5 Strongly Agree

1.3 Problem Areas in Diabetes Survey (PAID)

INSTRUCTIONS: Which of the following diabetes issues are currently a problem for you?

Tick the number that gives the best answer for you. Please provide an answer for each question.

1. Not having clear and concrete goals for your diabetes care?

☐0 Not a Problem	☐1 Minor Problem	☐2 Moderate problem	☐3 Somewhat serious problem	☐4 Serious Problem

2. Feeling discouraged with your diabetes treatment plan?

☐0 Not a Problem	☐1 Minor Problem	☐2 Moderate problem	☐3 Somewhat serious problem	☐4 Serious problem

3. Feeling scared when you think about living with diabetes?

☐0 Not a Problem	☐1 Minor Problem	☐2 Moderate problem	☐3 Somewhat serious problem	☐4 Serious problem

4. Uncomfortable social situations related to your diabetes care (e.g., people telling you what to eat)?

☐0 Not a Problem	☐1 Minor Problem	☐2 Moderate problem	☐3 Somewhat serious problem	☐4 Serious problem

5. Feelings of deprivation regarding food and meals?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor Problem	Moderate problem	Somewhat serious problem	Serious problem

6. Feeling depressed when you think about living with diabetes?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

7. Not knowing if your mood or feelings are related to your diabetes?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

8. Feeling overwhelmed by your diabetes?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

9. Worrying about low blood sugar reactions?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

10. Feeling angry when you think about living with diabetes?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

11. Feeling constantly concerned about food and eating?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

12. Worrying about the future and the possibility of serious complications?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

13. Feelings of guilt or anxiety when you get off track with your diabetes management?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

14. Not "accepting" your diabetes?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

15. Feeling unsatisfied with your diabetes physician?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

16. Feeling that diabetes is taking up too much of your mental and physical energy every day?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

17. Feeling alone with your diabetes?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

18. Feeling that your friends and family are not supportive of your diabetes management efforts?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

19. Coping with complications of diabetes?

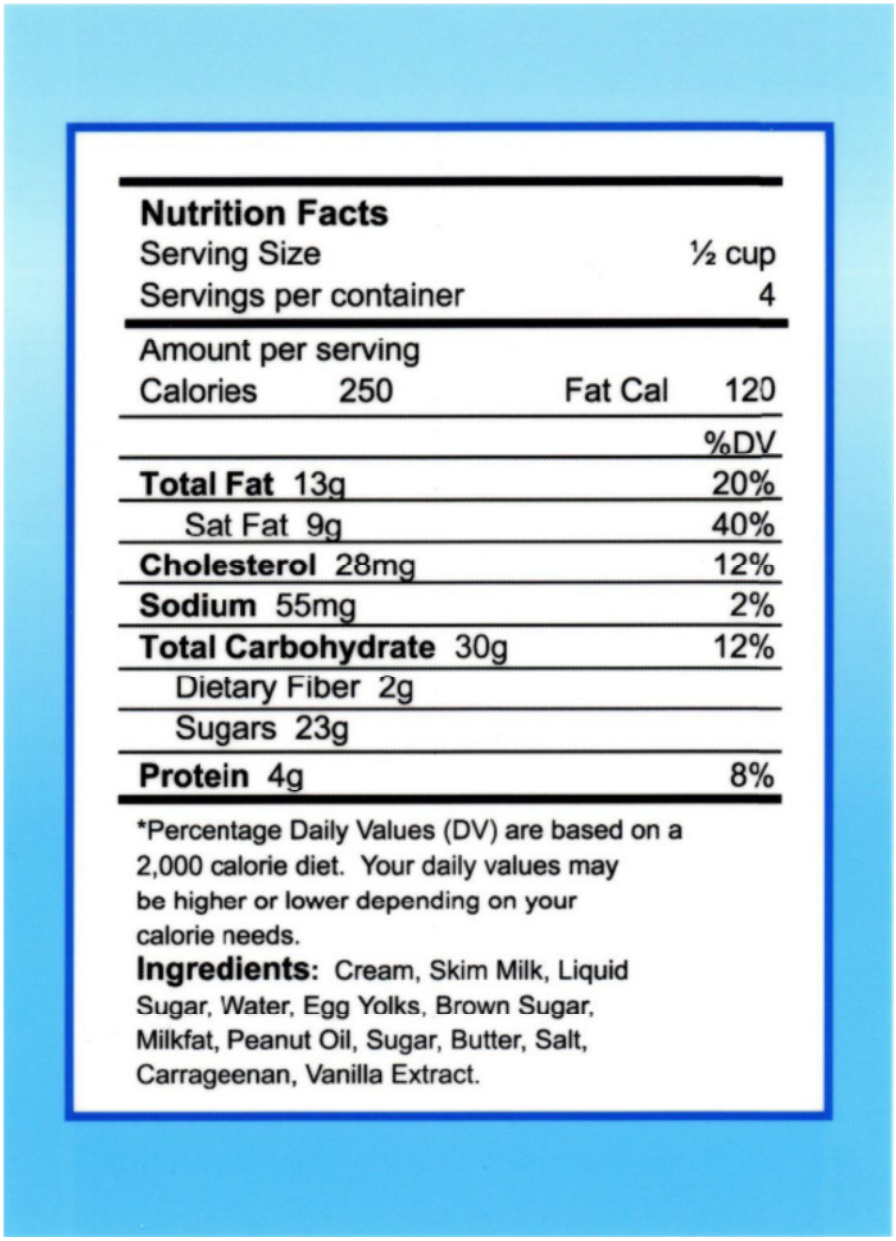
☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

20. Feeling "burned out" by the constant effort needed to manage diabetes?

☐0	☐1	☐2	☐3	☐4
Not a Problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem

2. Health Literacy

2.1 Newest Vital Sign (NVS)



Nutrition Facts

Serving Size	½ cup
Servings per container	4

Amount per serving

Calories 250 Fat Cal 120

	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

Score Sheet for the Newest Vital Sign Questions and Answers

READ TO SUBJECT:
This information is on the back of a container of a point of ice cream.

1. If you eat the entire container, how many calories will you eat?
   Answer: *1,000 is the only correct answer*

2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?
   Answer: *Any of the following is correct: 1 cup (or any amount up to 1 cup), half the container. Note: If patient answers "two servings," ask "How much ice cream would that be if you were to measure it into a bowl?"*

3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?
   Answer: *33 is the only correct answer*

4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?
   Answer: *10% is the only correct answer*

READ TO SUBJECT:
Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.

5. Is it safe for you to eat this ice cream?
   Answer: *No*

6. (Ask only if the patient responds "no" to question 5): Why not?
   Answer: *Because it has peanut oil.*

	ANSWER CORRECT?	
	yes	no
1		
2		
3		
4		
5		
6		
Number of correct answers:		

Interpretation

Score of 0-1 suggests high likelihood (50% or more) of limited literacy.
Score of 2-3 indicates the possibility of limited literacy.
Score of 4-6 almost always indicates adequate literacy.

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2.2 Chew Items

1. How often do you have someone (like a family member, friend, hospital/clinic worker, or caregiver) help you read hospital materials?

☐0	☐1	☐2	☐3	☐4
All of the time	Most of the time	Some of the time	A little of the time	None of the time

2. How often do you have problems learning about your medical condition because of difficulty understanding written information?

☐0	☐1	☐2	☐3	☐4
All of the time	Most of the time	Some of the time	A little of the time	None of the time

3. How confident are you filling out medical forms by yourself?

☐0	☐1	☐2	☐3	☐4
All of the time	Most of the time	Some of the time	A little of the time	None of the time

3. Doctor-Patient Interaction

3.1 Physician decision-making style (Kaplan et al.)

How often the doctors or health care professionals who take care of your diabetes:

1. Offered you choices in your medical care

☐0	☐1	☐2	☐3	☐4
Non-of the time	A little of the time	Some of the time	Most of the time	All of the time

2. Discussed the pros and cons of each choice with you

☐0	☐1	☐2	☐3	☐4
Non-of the time	A little of the time	Some of the time	Most of the time	All of the time

3. Got you to state which choice or option you would prefer

☐0	☐1	☐2	☐3	☐4
Non-of the time	A little of the time	Some of the time	Most of the time	All of the time

4. Took your preferences into account when making treatment decisions

☐0	☐1	☐2	☐3	☐4
Non-of the time	A little of the time	Some of the time	Most of the time	All of the time

Provider communication

How the doctors or health care professionals who take care of your diabetes were at:

1. Telling you everything

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

2. Letting you know test results when promised

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

3. Explaining treatment alternatives

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

4. Explaining side effects of medications

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

5. Telling you what to expect from your disease or treatment

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

Overall patient understanding

How well did you understand:

1. How to care for feet

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

2. How to take medications

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

3. What to do for symptoms of low blood sugar

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

4. How to make food choices

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

5. How and when to test blood sugar

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

5. Diabetes complications

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

6. How to exercise

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

7. What target blood glucose values should be

☐0 ☐1 ☐2 ☐3 ☐4
Poor Excellent

4. Health-Status

4.1 Health-Status

In general, would you say your health is: (check one box)

☐1 ☐2 ☐3 ☐4 ☐5
Excellent Very good Good Fair Poor

During the past month:
1. Did burning, tingling, pain, or numbness bother you in your hands?

☐6 ☐5 ☐4 ☐3 ☐2 ☐1
Never Rarely Sometimes Often Usually Always

2. Have you been bothered by blurring of vision?

☐6 ☐5 ☐4 ☐3 ☐2 ☐1
Never Rarely Sometimes Often Usually Always

3. How often did you have diarrhea?

☐6 ☐5 ☐4 ☐3 ☐2 ☐1
Never Rarely Sometimes Often Usually Always

4. How often were you able to function sexually as well as you wanted to?

☐6 ☐5 ☐4 ☐3 ☐2 ☐1
Never Rarely Sometimes Often Usually Always

5. Have you been bothered by feeling faint/dizzy on sitting up/standing up?

☐6 ☐5 ☐4 ☐3 ☐2 ☐1
Never Rarely Sometimes Often Usually Always

6. How much of the time were you lacking enough energy?

☐6 Never ☐5 Rarely ☐4 Sometimes ☐3 Often ☐2 Usually ☐1 Always

7. Have you felt optimistic about your diabetes?

☐6 Never ☐5 Rarely ☐4 Sometimes ☐3 Often ☐2 Usually ☐1 Always

8. During the past month, how well have you slept?

☐6 Never ☐5 Rarely ☐4 Sometimes ☐3 Often ☐2 Usually ☐1 Always

9. Have you felt depressed during the past month?

☐6 Never ☐5 Rarely ☐4 Sometimes ☐3 Often ☐2 Usually ☐1 Always

10. Have you eaten what you wanted to?

☐6 Never ☐5 Rarely ☐4 Sometimes ☐3 Often ☐2 Usually ☐1 Always

11. Have you participated in and enjoyed family life?

☐6 Never ☐5 Rarely ☐4 Sometimes ☐3 Often ☐2 Usually ☐1 Always

12. How often have you been able to function well in your usual occupation?

☐6 Never ☐5 Rarely ☐4 Sometimes ☐3 Often ☐2 Usually ☐1 Always

5. Diabetes Self-Care

5.1 The Summary of Diabetes Self-Care Activities

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

Diet

How many of the last SEVEN DAYS have you followed a healthful eating plan?

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Exercise

On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Blood Sugar Testing

On how many of the last SEVEN DAYS did you test your blood sugar?

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Foot Care

On how many of the last SEVEN DAYS did you check your feet?

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

On how many of the last SEVEN DAYS did you inspect the inside of your shoes?

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Smoking

Have you smoked a cigarette—even one puff—during the past SEVEN DAYS?

☐0. No

☐1. Yes. If yes, how many cigarettes did you smoke on an average day?

Number of cigarettes:_____

6. Social-Demographics

1. Because the following questions are very important, I need to ask you once more if you suffer from Diabetes mellitus type 1 or type 2, also called adult-onset diabetes (Alterszucker)?

☐ Type 1

☐ Type 2

☐ I do not know.

☐ No response

2. For how long have you been diagnosed with diabetes mellitus type II?

|____| years |____| months

OR [if people only can remember the year they were diagnosed]: I__I__I__I__I

3. Do you use any insulin to treat your diabetes?

☐ Yes

☐ No

☐ No response

3.1 IF YES: For how long?

|____| years |____| months

OR the year they started using insulin: I__I__I__I__I

4. Do you suffer from any other chronic condition ?

☐ Yes

☐ No

☐ No response

4.1 IF YES: Which other chronic condition do you suffer from?

……..

5. Which year were you born?

I__I__I__I__I

☐ No response

6. Which is your highest level of education?

☐ primary school, no degree

☐ secondary school

☐ apprenticeship

☐ high school (A-Levels, university entrance diploma)

☐ professional school (business school, technical school, etc.)

☐ university of applied sciences

☐ university

☐ Other: _____

7. What is your nationality?

☐ German

☐ ….

8. What is the postal code of the town or village you are currently living in?

I__I__I__I__I

8. Are you male or female?

☐ male

☐ female

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