Introduction: Diabetes requires a high level of disease management to be executed by the patient himself in order to succeed in treatment and for improving or at least preserving his health status.

Aim: The main objective of the presented project is to design and implement a web technology based application framework. It shall provide sufficient means for self-management and enable patient empowerment within the treatment process. Its underlying concept will be outlined in this work.

Methods: Common techniques on requirements’ engineering have been applied to derive an initial concept. It is based on a comprehensive state of the art analysis drawn from literature and web search.

Results: A service-oriented architecture could be drafted that enables interoperability with existing eHealth systems on a technical and semantic level. Pilots will be deployed in Germany and Turkey. Pilot specific requirements can be address as well due to its modular architecture.

Conclusion: The given concept gives a high level description of the envisaged approach. An initial prototype has been implemented. A second prototype is well on the way offering all major functionality and will be deployed within the pilot regions.

Keywords
Patient empowerment, self-management, pathways, decision support, medical records, diabetes, semantic integration

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1 Introduction

Within the widespread diseases especially Diabetes requires a high level of disease management to be executed by the patient himself in order to succeed in treatment and for improving or at least preserving his health status.

In the scope of the European EMPOWER project [1] a modular and standard-based patient empowerment framework is being developed which will facilitate self-management [2][3] for diabetes type 1 and 2 patients. Research and development efforts focus on knowledge-based self-management pathways for diabetes patients. These are realized through a combined use of the following services:

- Monitoring of vital, physical, and mental parameters as well as physical and lifestyle activities. Parameters can be recorded within EMPOWER’s Personal Health Record (PHR) [4].

- Generating patient-specific recommendations. Taking into account the monitored health parameters of a specific patient, relevant recommendations are generated based on expert knowledge such as diabetes guidelines. They are then revised and amended by the health professional.

- Definition of goals and corresponding actions to accomplish given recommendations. The patient can define goals and plan specific actions in her/his individual action plan to fulfil the recommendations.
• Support of the patient’s self-dependent execution of actions to facilitate changes of behaviour according to individual diabetes-specific health care needs. By means of intuitive and self-explanatory data visualization, motivating reminders and reward mechanisms, patients will be empowered to achieve their personalized goals.

• Seamless, consistent and standard-based integration of relevant data originating from existing systems like Electronic Medical Records (EMR) [5] of participating health care institutions, Electronic Health Records (EHR) [5], PHRs and Personal Health Applications, (PHA) for example in form of Mobile Apps.

The EMPOWER core services will be implemented in two pilot deployments to ensure the generalizability and applicability of the project’s overall outcome. One pilot system will be implemented in Turkey in cooperation with the Turkish Ministry of Health [6] on a national level. The second pilot will be deployed in the region of Ingolstadt, Germany in cooperation with the Network of Practices GOIN (“Praxisnetz GOIN e.V.”) [7].

Although both pilots share the common goal to empower, support and guide diabetes patients by providing EMPOWER services, they are substantially different regarding the overall technical setup of integrated data sources and the country specific characteristics. This work highlights pilot specific differences and discusses resulting challenges that are addressed in underlying concept.

2 Methods

A comprehensive literature review and Internet research has been conducted in order to assess state of the art technologies and architecture relevant to the EMPOWER project.

Common requirements engineering activities have been carried out. These included requirements analysis, specification and system modeling in order to come up with a detailed requirements specification and design concept.

In the process of doing so regular discussions with experts’ involving the consortium’s partners and domain specialists like doctors and nutritionists have been conducted to clarify the initial setup.

Intermediate work results have been condensed and summarized by means of abstraction in order to provide a convenient overview in form of this concept.

3 Results

3.1 Technical integration of data sources

Data originating from health care institutions is integrated using country specific approaches. Within the German pilot (as shown in Figure 1) so far no regional or national EHR has been established in which aggregated health data could be accessed directly.

As a result the EMRs of the participating health care institutions must be interfaced one by one. As primarily general practitioners and case managers are treating diabetes patients in that region, their referring Practice Information Systems (PIS) must be interconnected with the EMPOWER services. According to previous research those systems offer limited integration capabilities [8] and may even be interconnected only with systems of the same vendors due to proprietary interfaces. To address this short-coming an alternative, archetype-based approach has been defined [9] and is being implemented in cooperation with an exemplary vendor.

In Turkey - in contrast to Germany - a nation-wide EHR is available that serves aggregated data from treating health care institutions and supports common interoperability standards, see Figure 2.

On the technical interoperability level data exchange within both pilots will be based on IHE profiles as defined.

![Figure 1: Integrating data sources of health care institutions in the German pilot.](image-url)
in the IT Infrastructure Technical Framework [10] and the Patient Care Coordination Technical Framework [10] that are commonly used in regional or national EHR projects.

Data originating from the patients will be integrated using the same approach in both pilots, see Figure 3. Patients may own a PHR of an external provider and/or decide to use EMPOWER’s PHR. Furthermore, they may start to use or may already be using a PHA to record and monitor personal health data. Additionally we aim at importing biometrical measurements directly from connected medical devices like blood glucose meters or via PHAs that are already paired with the device. Technical interoperability will be based on the IHE profile XPHR [10] supported by an IHE XDS-based sharing framework [10], although especially the connectivity to medical devices may require a different interfacing due to proprietary vendor-specific protocols.

3.2 Semantic integration of data sources

Data collected by the patient (e.g., observations of daily living like weight and mood) and by health professionals (e.g., diagnoses and medication) must be consolidated for mutual information sharing to enable a seamless, cross-sectoral electronic exchange of patient data.

The prevalent lack of agreed and implemented standards impede the transfer of detailed healthcare information in a way that supports full integration of that data within the receiving systems [11]. In order to process EHR data safely, semantic interoperability is required, meaning that computational services are enabled to reliably interpret clinical data that has been integrated from various sources [12].

EMPOWER utilizes appropriate standards from HL7 and IHE (like XPHR and XDS-MS [10]), as well as ISO 13606/openEHR information models [13, 14] to enable semantic interoperable data exchange.

Observations of daily living [15] are being specified using openEHR information models (a.k.a. archetypes) for the usage within PHR systems and PHAs in a patient-centric approach rather than strictly for use by healthcare actors during their observation collection. Archetype based data modeling (including data schemas and corresponding rules) is an open and flexible approach that
avoids application lock-in, as the knowledge models are made publicly available. OpenEHR supports this with the Clinical Knowledge Manager [16] that provides a platform for a collaborative development of clinical archetypes.

Standard Terminologies will be used for semantic binding (mapping to terminology codes) and value binding (specific value sets). A central transformation service will be provided that converts these data to a common format thus facilitating the import of data from legacy systems and medical devices that use proprietary data schemas.

3.3 Service Oriented Architecture

In order to offer a maximum of flexibility and extensibility a modular, service-oriented architecture was drafted, see Figure 4. Beside services providing the primary EMPOWER functionalities as described in the introduction, also additional services are required to ensure consistent data privacy and security, continuous auditing and logging mechanisms, seamless integration of heterogeneous data sources and end-user delivery of EMPOWER services to multiple platforms like smartphone, tablets and desktop computers.

Four layers were defined to offer convenient interaction and integration capabilities at the different levels of abstraction.

3.4 Support of pilot/country specific requirements

A unique feature of the EMPOWER system is that multiple localization environments will be supported. The health care system, diabetes treatment process, underlying medical guidelines, involved actors and further constraints are significantly different in both EMPOWER pilot applications. In order to address these country specific requirements whilst relying on single, commonly developed core services and components, multiple levels of abstraction need to be implemented.

In the area of data and knowledge handling convertible and adaptable models are being designed based on established standards for data communication and information representation as described before. Data will be processed based on standardized terminologies, ontologies and coding systems like LOINC [18] and UMLS [19].

Medical guidelines issued by professional societies or administrations are being computerized by the utilization of clinical guideline definition languages and can thus be easily adjusted to national guidelines and scenarios. Diverse treatment processes at health care institutions must also be equally supported by the EMPOWER systems. To do so the underlying business logic is being modeled by utilizing the Business Process Model and Notation (BPMN) [20] that is being transformed into computer-interpretable instructions.

Finally, comprehensive requirements arise in the fields of identity and data management in respect to identification schema, data privacy and security. For example,

![Figure 4: Overview of EMPOWER’s core architecture of services and abstraction layers.](image-url)
in Turkey a country-wide unique patient identifier was established whereas in Germany it has been introduced only recently in form of the “Gesundheitskarte”\textsuperscript{[21]} that is currently being issued to the wider public. Country-specific legal regulations and the different pilot setups require comprehensive, convenient and adjustable security and privacy services for the management of patients’ consent, access control and overall system auditing capabilities.

4 Discussion

Implementation works such as early prototyping and component integration have recently started and aim to verify adequacy and practicability of the proposed concept. The drafted modular and service oriented architecture offers a maximum of flexibility and extensibility not only for the development and integration efforts within the actual project term. The resulting patient empowerment and self-management framework could even be reused and advanced to support other non-communicable diseases beyond the scope of the EMPOWER project.

On the long-term data exchange between both pilots could also be examined. Although it is not a defined use case within EMPOWER, our outcome in combination with the results of epSOS\textsuperscript{[22]} should enable a straightforward implementation of the inter-pilot connectivity, at least on a technical level.

To sum up – by the innovative and interdisciplinary combination of the latest methodical and technological advancements, EMPOWER breaks new ground in the field of patient-centered, data- and knowledge-based medical decision support systems.

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