

Deliverable 3.4.1

Knowledge Models Specification for SMP and Components

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Abbreviations

Electronic Health Record
Hospital Information System
Observations of Daily Living
Personal Health Record
Practice Information System
Self-Management Pathway

1 Summary

The specific knowledge models specified in EMPOWER aim to support self-management and action planning for diabetes patients. The shared knowledge model of EMPOWER semantically integrates multiple information sources (EHR/PHR, diabetes guidelines, patterns of daily living, etc.), therefore it makes use of existing standards and specifications.

This document defines knowledge models for the single system components as described in Deliverable 3.3.1 Conceptual Design of EMPOWER Architecture. EMPOWER will publish these models to foster the open source implementation of self-management pathways and supporting services e.g. for collecting patterns of daily living. Thus facilitating the health applications communities or partners to exploit the EMPOWER Patient Empowerment Framework.

2 EMPOWER in a Nutshell

Patient 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 selfmanagement 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 knowledgebased Self-Management Pathways for diabetes patients. This includes

- specification (1) Services for the and execution of actions to change behaviour according to diabetes-specific health care needs. Patients can develop personalised action plans which include recommendations from treating the 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 HL7¹ and IHE² profiles.

EMPOWER addresses long-term goals and short-term activities in order to facilitate the selfmanagement 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 selfmanagement services helping diabetes patients to cope better with their condition.

¹ http://www.hl7.org

² http://www.ihe.net

3 Introduction

Task 3.4 of the EMPOWER project is focusing on the specification of knowledge models for diabetes self-management pathways and components. These are based on a variety of input such as diabetes guidelines, guidelines for other related conditions, patient-specific conditions and preferences and observations of daily living. The knowledge model consists of static (terminologies, other data) and dynamic (processes and rules) knowledge and includes entry points and descriptions for the different functional components of the EMPOWER Architecture.

The knowledge models in this deliverable are described as reference models for component and service implementations. Rule sets and relevant terminology codes, for example, will be further specified during component implementations especially in context to each pilot application (GOIN,MOH).



3.1 Overview

Figure 1: Parts of the EMPOWER knowledge model

The comprehensive knowledge model of EMPOWER consists of the models for the central components, the self-management pathways (SMP) engine, the action plan engine, the recommender engine. Together with the related models for collection of Patterns of Daily Living (ODL), the model for consent management and the general administrative models they build the common knowledge for the EMPOWER solution.

Depending on the characteristic of the single components business process models, a diabetes guideline model, metadata for classification and rating of information materials, information model definitions for diabetes ODL monitoring and models for managing patient consents have been developed. The administrative knowledge model is specifying a general model for handling identity, listing established country specific diabetes datasets and defining common metadata. Moreover it details the standard based specification for EHR interoperability and gives an overview on terminologies and data exchange standards used in EMPOWER

Where appropriate business processes and rules are described and diagrammed using meta-modeling for readability. The actual models code, produced by the different modeling tools, will be stored in online repositories, references to these are provided where applicable. This supports reuse and exploitation of the EMPOWER Patient Empowerment Framework.

4 Workflow- and SMP- knowledge model

Based on the pilot application requirements, first the narrative self-management pathways and services supported with flowcharts to be used in the project will be determined and rules supporting these basic Self-Management Pathways will be specified.

4.1 Purpose

The Self-management Pathway (SMP) is an iterative cycle and guides the diabetes patient through the diabetes self-management activities The SMP represents a process covering all essential EMPOWER self-management activities such as specifying and running the Action Plan, executing ODLs and visualizing their results and exchanging patient data with physicians. Additionally, the SMP supports users with different maturity levels based on rules. For instance, a user on a novice level not familiar with EMPOWER and/or diabetes self-management will need more support from EMPOWER than a user who is already experienced.

4.2 Scope

The SMP knowledge model covers the basic self-management processes in EMPOWER and describes a high level view how EMPOWER components are integrated in this process model. Additionally, the model includes rules for supporting categories of maturity levels (described in detail in deliverable D5.1.1 "Learning Paths for Self-Management Services"). For specifying the SMP knowledge model Business Process Model and Notation (BPMN)³, version 2, a standard for specifying business processes, is used.

4.3 Content

Basically, EMPOWER comprises two main components addressing two target groups

- (1) EMPOWER Self-Management addressing diabetes patients
- (2) EMPOWER Disease Management addressing physicians

Both applications form together the EMPOWER SMP. Figure 2 depicts the high level workflow for the iterative self-management cycle. Typically, a consultation with a physicians will be at the beginning, defining the current diabetes treatment (e.g. medication) and treatment goals (so-called recommendations in EMPOWER). The Subtask "Consultation" is described in detail in section 6 "Recommendation knowledge mode". At the end of the consultation the patient data and recommendations (treatment goals) will be exported to the EMPOWER Self-Management component.

³ www.bpmn.org



Figure 2: SMP high level processes

In the next step, the patients import the patient data from the consultation (see section 4.3.2). Based on the doctor's recommendations the patient specifies his self-management goals and based on that his weekly activities. Results of executed activities (ODL results) are collected by EMPOWER and at the end of the week the status of successfully and not successfully completed activities and ODL results are presented to the patient as part of the Weekly Review, e.g. as reports or graphs. These processes of the Action Plan are described in detail in section 5 "Action Plan knowledge model".

The Weekly Review also invites the patient to reflect his goals whether he is really able to fulfill them or whether he should better adapt them. The final step of the Weekly Review will be to specify the actions of the upcoming week establishing a continuous loop of self-management activities and reflection.

Additionally, in advance of a consultation the patient can grant the doctor access to patient data collected by EMPOWER.

4.3.1 Supporting maturity levels

Maturity levels describe different approaches for user profiles based on the patient's personal and individual skills and preferences. Basically, the maturity levels are represented by a matrix (see Table 1) and are described in detail in deliverable D5.1.1 "Learning Paths for Self-Management Services".

EMPOWER maturity levels				
		Novice level	Advanced level	Expert level
	Media type	Mobile / Tablet	Mobile / PC / Tablet	Handy/ PC / Tablet / Smartphone
	Social media participation	No member of social community	Observer of social communities	Active community member
Access	Information search	Basically offline training and paper- based material	Internet search	Social media for exchanging information and experiences
S	Digital competences	Low-level	Medium-level	High level
Competence	Diabetes self- management competences	Guided learner	Supported learner	Independent learner
	Self-care coping strategy	Non-conformist	Passive follower	Active follower
	Feedback and hints from EMPOWER	High need	Depending on the situation	Occasionally or depending on the situation
Motivation	Mindfulness regarding habits	Occasionally / low awareness	Partly aware	Continuously aware
Source: Salzburg Research Team (vhp, mp)				

Table 1: EMPOWER Maturity levels

(Source: EMPOWER Deliverable D5.1.1 "Learning Paths for Self-Management Services")

Maturity levels can be seen as a theoretical concept and EMPOWER Deliverable D5.1.1 also describes several approaches how EMPOWER can support this concept by the EMPOWER prototype:

- (1) By configuring parameters for user settings indicating whether a user e.g. would like to have more hints und feedback or more support for diabetes self-management
- (2) By adapting the Process Models for novice and expert users based on rules and by offering different process peculiarities, e.g. wizards for novice users or compact views and workflow for expert users

- (3) By offering services covering different categories and stages of maturity levels e.g. diaries diary allowing a diabetes patient to become (more) aware about "unhealthy habits" and supporting in this way an user on a novice level for becoming mindful regarding habits or the opportunity for expert users to configure their own individual reports.
- (4) By using appropriate interaction design patterns

Within this document we will have a closer look to (1) and (2). Table 2 gives an overview about user settings supporting the concept of maturity levels.

User Settings	Values	Description & Rules
Wizard	ON / OFF	"Wizards" includes all EMPOWER wizards. The default setting for novice users will be ON and for the basic self- management processes (such as specifying goals or actions or the Weekly Review) the process engine invokes a wizard guiding the user step-by-step. Option – when the Pathway Engine realises that the patient uses a wizard continuously for quite some time EMPOWER will ask the user whether he is now familiar enough with this process step and whether he wants to replace the wizard by using a more efficient and quicker approach.
EMPOWER tips	ON / OFF	The default setting for novice users will be ON. Based on context tips and help snippets will be displayed. Regardless of that "EMPOWER tips" are an included part of wizards.
Reminder ODL results	OFF Once a day	This parameter indicates whether a user wants to be reminded by the Pathway Engine in the case of missing ODL results. By all means, the user will be reminded as part of the Weekly Review.
Charts	Predefined / customised	This parameter allows the user to specify whether he prefers predefined charts and trends or whether he wants to customise them by himself.

Table 2: User settings

Additional user settings might be added during the implementation phase, e.g. different tools on the one hand for novice for a simpler approach and on the other hand for expert user with more functions.

4.3.2 Exchanging patient data between EMPOWER components

As previously described patients and doctors are using different main components in EMPOWER (see Figure 3). The EMPOWER Self-Management component supports diabetes patients in their self-management activities and monitoring and the EMPOWER Disease Management component includes a guideline-based recommender system for supporting physicians in their treatment workflow during consultations. Finally, current patient data from the physician's information system (e.g. a PIS or a HIS) may be needed as additional input data for the Recommender Engine.



Figure 3 - EMPOWER main components⁴

At the beginning of a consultation the Disease Management component has to be provided with patient data from the other two components described in Figure 3. One group of data is relevant patient data collected by the patient in the EMPOWER Self-Management component, enabling the physician to evaluate the monitoring data collected by the patient on a daily basis. These data is listed in the following table:

German Pilot	Turkish Pilot	Comment			
Application	Application				
Diabetes Passport – including relevant diabetes parameters on a quarterly or yearly base (e.g. HbA1c, blood glucose)	 Daily Living Schedule including the basic weekly schedule of the diabetes patients. The forms include: The name of the insulin (or Oral Anti Diabetic) The unit/quantity to be administered The time (meal-based) of the administration The nutrition information The time of glucose measurements in a week 	From the last consultation, e.g. 3 months ago			
Recommendations, e.g. about physical exercises, nutrition and medicines.	Recommendations, e.g. about physical exercises, nutrition and medicines.				

⁴ There is an additional step for the Turkish Pilot Application: The EHR data from the PIS/HIS are not imported into the Disease Management component by a physician. In fact, the patient imports these data into his PHRS to be provided to the Disease Management component.

ODL results	ODL results	Depending what the patient has recorded, e.g. blood glucose values, blood pressure values, weight, physical activities or sleep problems. Based on the ODLs the doctor can
		check the compliance (e.g. to a diet) of
		the treatment goals

Table 3: PHR data provided at the beginning of a consultation

Prerequisite will be that the patient grants access to the doctor to these PHR data by using the Consent Editor. Additionally, the doctor can also use graphical illustrations of these data, e.g. a chart showing all blood glucose values since the last consultation.

Additionally to the PHR data the Recommender Engine also requires current EHR data stored in the doctor's Practice Information System (PIS) or in the case of a hospital in the Hospital Information System (HIS). In the German Pilot Application, the EHR data are directly imported from the PIS or HIS by the physician. In the Turkish Pilot Application, the patient imports these EHR data into his PHRS in order to provide them to the Recommender Engine. The following table depicts an overview of these EHR data:

German Pilot	Turkish Pilot Application	Comment
Application		
Lab results: eg Blood Glucose HBA1c Blood glucose Creatinine LDL / HDL Triglycerides etc.	Lab results Blood glucose Creatinine Urinalysis HBA1c LDL/HDL Triglycerides Vitamin B12 ECG Thyroid-Stimulating Hormone Anti-TPO (Thyroid Peroxidase Antibodies) Anti-GAD (Glutamic Acid Decarboxylase) ICA (Islet Cell Cytoplasmic Autoantibodies) Antiendomysium Tissue Glutaminase 	Depending on the complexity of the current diabetes examinations, e.g. yearly checkups require more data than quarterly checkups
Diagnoses & problems	Diagnoses & problems	Refers to diagnoses and problems influencing the diabetes treatment and to additional diseases
Medication list	Medication list (prescriptions)	
 Vital signs and measurements Height Weight 	Vital signs and measurements: Height Weight	Typically, these data are measured by a doctor

Waist lineBlood pressure	 Waist line Blood pressure (Systolic BP, Diastolic BP) 	
Examinations, e.g. foot	Examinations, e.g. thyroid	
inspection	examination	
Additionally, the following EHR data is required for the execution of the diabetes guideline in Germany: • Demographic Information • Patient preferences • Medical history • Conditions (e.g. advanced age, pregnant, adolescent)	Additionally, the following EHR data is required for the execution of the diabetes guideline in Turkey: Demographic Information Allergy Conditions Encounters Family Histories Immunizations Medical Devices Procedures (e.g. surgeries)	
	 Social Histories 	

Table 4: EHR data provided at the beginning of a consultation

Based on the previously described EHR and PHR data and based on the diabetes guidelines the treatment goals and the medication will be updated. At the end of the consultation the Disease Management component provides an updated version of EHR data and recommendations to be imported by the patient in the PHRS as part of his EMPOWER Self-Management component (see the following table).

German Pilot Application	Turkish Pilot Application	Comment
Recommendations	Recommendations	As starting point for specifying self- management goals and activities
Medication list	Medication list	Stored in the PHRS
Diabetes Passport – including relevant diabetes parameters on a quarterly or yearly base (e.g. HbA1c, blood glucose)	At the end of the recommendation process, the exercise, nutrition, medication and glucose measurement recommendations will be generated.	The up-to-date version from the current consultation

Table 5: EHR data provided by the Disease Management component at the end of a consultation

4.4 Utilized standards

The business process models are described in a high level notation and implemented using - Business Process Model and Notation OMG specification (BPMN version 2)⁵

4.5 Interdependencies with other models and components

The doctors' access to PHR data will be controlled by the patient. The decisions of the patient regarding access rights will be documented by using the EMPOWER Consent Management Knowledge Model.

The Disease Management Component requires current EHR data, that will be imported from the doctor's Practice Information System (PIS) by using the IHE XPHR Profile as described in chapter 10.3.

The elements listed here for the data exchange between the EMPOWER components are based on existing country specific national diabetes datasets as detailed in chapter 10.4

⁵ BPMN version 2 http://www.omg.org/spec/BPMN/2.0/

5 Action Plan knowledge model

The knowledge model for the personalised, adaptive Action Plan will cover the specification of goals based on previously defined recommendations, the specification of short-term actions, supporting services for the execution of actions (e.g. scheduling, reminders) and the evaluation of executed actions and reported ODLs. The processes will be described and diagrammed using meta-modelling for readability. Processes involving the Pathway Engine will be described. Rules will be summarized for readability and rules requiring data from other models or systems will be noted. The actual models will be stored in the collaborative repository.

5.1 Purpose

Changing behaviour patterns and setting up new habits according to diabetes recommendations need discipline and should become a regular part of a person's daily life. The Action Plan is the central tool in EMPOWER for supporting these changes and should be used at least as long as patients are not yet habituated.

Additionally, the Action Plan is the central tool for the diabetes patient supporting the planning, executing and verifying self-management activities but also for visualising status, results and trends. As concluded from previous deliverables in EMPOWER⁶ it is known that patients want to make sense out of what they are doing but they often don't see the benefit of self-management activities. For that reason it is essential for the Action Plan to support the awareness of individual treatment goals by relating recommendations, self-management goals and activities and hence, to establish a traceable path explaining patients why their activities are important to them.

5.2 Scope

The Action Plan Knowledge Model includes a process model describing the processes for specifying goals and activities, how the Action Plan supports the execution of activities and the Weekly Review allowing the patient reflecting his self-management activities and results on a weekly basis.

5.3 Content

5.3.1 Action Plan Process Modell

For specifying the Action Plan Process Model BMPN⁷, version 2, is used.

5.3.1.1 Specifying and updating self-management goals

The EMPOWER Action Plan starts with the specification of long-term self-management goals. Most of the goals to be set will be based on the physician's recommendations and the previously defined treatment goals. Referring a self-management goal to the physician's recommendations and to treatment-goals facilitates the patient's awareness why a goal is important.

As soon as the patient has imported the EHR data and the doctor's recommendations the next process step will be the specification or the update of the self-management goals.

⁶ Deliverable D2.1.1 "Strategies for Empowering Patients for Web-based Self-management", Deliverable D5.1.1 "Learning Paths for Self-Management Services"

⁷ Business Process Model and Notation (BPMN), www.bpmn.org

Figure 4 describes the appropriate workflow. Based on the user settings EMPOWER decides which view should be presented – the Goal Wizard or the compact view for specifying and updating goals in a quicker and more efficient way.

Patients who are not very used to or familiar with diabetes self-management should think about goals they can easily start with at the beginning. Sometimes it would help to break a goal in smaller sub-goals with a higher likelihood to be achieved. Using the Goal Wizard which also includes additional hints will help novice users or users who seldom specify goals through the goal setting procedure in EMPOWER.



Figure 4: Specifying and updating goals

The patient should describe a goal as concrete as possible. Typically, a goal is related to a recommendation representing a treatment goal. But there might also be goals not based on recommendations. In these cases the patient adds additional self-management goals without relating them to a recommendation. Below an overview of the parameter for specifying goals:

- Goal name
- Goal description
- Goal category e.g. food, medical appointment, medication, monitoring. This is part of the EMPOWER taxonomy
- Related recommendation
- Notes

Inserting or updating goals can be an iterative process depending on the number of goals to be specified. When the Goal Wizard is selected the wizard will refer to the next process step (specifying actions) once all goals are inserted or updated.

5.3.1.2 Specifying and updating activities

Based on the self-management goals the patient should decide what he wants to do in the upcoming week. These activities should be both realistic and behaviour-specific. If it is not

possible for the patient to satisfy a goal he should look for alternatives to meet at least the goal partly.

Figure 5 describes the workflow for specifying and updating actions. Based on the user settings EMPOWER decides which view should be presented – the Activity Wizard or the compact view for specifying and updating actions in a quicker and more efficient way. Planning an activity should be as concrete as possible (what to do, when, how much, how often) and the Activity Wizard facilitates that by a step-by-step execution and by appropriate hints and questions. The compact view is meant for patients experienced in self-management and already knowing how to specify meaningful actions.



Figure 5: Specifying and updating actions

Basically, an action is described by the following parameters:

- Action category e.g. medication, food, sport, monitoring. This is part of the EMPOWER taxonomy
- Activity name
- Activity description
- Action category (optional) e.g. medication, food, sport, monitoring, appointments. The input form is based on the selected category.
- Supported goal(s) associated by the patient to this activity
- Date and time e.g. Standard iCalendar (RFC 5545)⁸
- Reminder parameters
- Related person(s)
- Place
- Notes

Like for goals, specifying actions can be an iterative process depending on the number of actions to be described. Once the patient have specified all activities for the next week,

⁸ iCalendar <u>http://tools.ietf.org/html/rfc5545</u> http://en.wikipedia.org/wiki/ICalendar

EMPOWER will ask him on a scale of 0 (totally unsure) and 10 (totally certain) how certain he is to complete this activity. If the answer is \geq 7 this is probably a realistic plan. If the answer is below 7 EMPOWER advises him to look again to he just specified activities by asking himself why he is not certain. Patients using the Action Wizard are additionally referred to the next process step (performing and recording ODLs).

Activities in the Action Plan are visualised based on a calendar view. Depending on the patients preferences the patient can have a look at his activities of the upcoming week or he could print them out.

5.3.1.3 Running the Action Plan

Basically, the self-management activities themselves such as sport activities, measuring blood sugar or blood pressure or preparing meals are not part of EMPOWER. But EMPOWER can collect observations and results of these activities (the so-called Observations of Daily Living, ODLs) and depending on the ODL services EMPOWER can support the recording of ODL results.

Figure 6 depicts the workflow how EMPOWER supports the execution of ODLs and the recording of ODL results. In the first step, EMPOWER checks whether there are actions with reminders that are newly specified or updated. In that case and based on the reminder parameters EMPOWER sends a reminder to the patient as SMS as an email.



Figure 6: Running Action Plan

Depending on the ODL and on the patient's preferences ODL results can be recorded and collected in different ways:

- ODL results can be recorded instantly, e.g. inserting the blood pressure values with a mobile,
- ODL results can be recorded with delay, e.g. diary entries or
- ODL results can be recorded automatically by special devices (e.g. electronic body weight scale or a glucose monitor device) and forwarded to EMPOWER.

Whatever, if ODL results are missing EMPOWER will remind the patient for inserting them. At any rate, as part of the Weekly Review EMPOWER checks for missing results and in case, requests the patient to complete them.



Figure 7: Updating diaries

A special type of ODLs is a diary. Diaries can help patients to become more aware what they are doing (in particular regarding "bad" habits) and they can be a tool for recording problems, e.g. regarding stress or sleep. The patient can switch off and on different types of diaries (food, mood, stress, sleep, etc.) and they can also configure reminders as depicted in Figure 7.

5.3.1.4 Weekly Review

The final step in the Action Plan Workflow is the Weekly Review. Checking activities whether they are done and completed gives a patient guidance how realistic the planning of the activities was and to which degree they satisfied the goals behind. This is useful for a better understanding what is realistic and possibly and how activities and goals should be adapted.

Figure 8 depicts the workflow for the Weekly Review in EMPOWER. Based on the user settings EMPOWER decides which view should be presented – the Weekly Review Wizard for a novice user or the compact view of the Weekly Review for more experienced users.

A novice user might need some help for the Weekly Review. He would need guidance and hints for this process step and the Weekly Review Wizard will guide him step by step:

- (1) EMPOWER presents the activities of the last week based on a calendar view and checks whether results are missing. In the case of missing results EMPOWER requests the user for inserting them.
- (2) In the next step EMPOWER presents all collected ODL results, gives feedback about the status, the collected ODL results and how successful the patient has achieved his self-management goals. For this purpose preconfigured batches, graphs, trends, etc. are presented..
- (3) Based on the feedback and if applicable the user can update his goals
- (4) In the final step EMPOWER requests the patient to update the Action Plan for the next week by specifying his upcoming activities.



Figure 8: Weekly Review

Patients on an expert level familiar with Action Planning procedure may prefer the compact view of the Weekly Review. It is assumed that they already know to what they should pay attention and hence, they need less or no additional hints. They might also be to configure reports and trends based on their needs and requirements autonomously.

5.4 Utilized standards

5.4.1 Medical Code standards for Goals and Activities

The Bioportal⁹ or UMLS search interface provide many possibilities for deriving the goal and action terminology. Standards should be used, however, if the concept is not found, then a proprietary EMPOWER code will be used as a placeholder until a better solution is found. For non-standard codes, a default coding system for EMPOWER will be used.

	Terminology Standards for coding Goals and Activity categories	
UMLS	UMLS metathesaurus that includes terms and codes from many vocabularies,	
	such as CPT®, ICD-10-CM, LOINC®, MeSH®, RxNorm, and SNOMED CT®	
SNOMED	UMLS coded terms for SNOMED	
Read	UMLS coded terms for Read codes, Clinical Terms Version 3 (CTV3).	
codes	Terms are usually dual authored in SNOMED, however, the Bioportal or UMLS	
(CTV3)	search interface will yield the UMLS code.	
	This terminology might be helpful for specifying goals.	
Activity	Activities are scheduled.	
schedule	Activities to achieve goals can be textual or based on a controlled vocabulary.	
	To support interoperability with calendar systems, the activity model will	
	include the Standard model iCalendar (RFC 5545) ¹⁰ .	
Table 6 Terminology sources for goal and activity categories		

minology sources for goal and activity categories

⁹ Bioportal http://bioportal.bioontology.org/

¹⁰ iCalendar http://tools.ietf.org/html/rfc5545 http://en.wikipedia.org/wiki/ICalendar

The following properties in table Table 7 was derived from patient centric goals taxonomy for dementia patients¹¹ and could be useful for specifying an extended goal model.

Goal specified by patient	Description
Goal topic	codeValue, coding system
ciour topio	Optional: patient provides their own goal not a taxonomy topic:
	requires and lobel
Deleted Cool	list of topics valation to most (and a) (alua and inc. Quatern) to help
Related Goal	list of topics relating to goal (codevalue, cooling System) to help
lopics	provide into materials or provide motivational resources.
Related tags	Textual tags about the goal
Goal label	Table from patient. What is a short label in the patient's own words
Goal description	What does patient want?
goal	
Goal challenge	How does the patient perceive the level of challenge? Is the goal
level	perceived to be difficult or demanding (special effort) easy to achieve
	unrealistic?
Goal time frame	immediate, short term, or longer term
Goal specificity	Goal specificity refers to the degree of detail with which goals are
	articulated How well can the patient articular their goal. Did they
	choose a goal topic? Ask the patient how specific they are
Goal Assossment	How can we access?
Attributee	Time to achieve goal
Allinbules	Time to achieve goal
a 1	Duration – now long must it last?
Goal user setting	-Reminder and follow-up settings (user settings: Maturity levels)
attributes	-Setup customization
Goal source(s)	To support the patient later or to remind them, the sources of their
	goal are collected, if possible.
	Sources can include Friends, family members, doctor(s), info material
	Which recommendations, info materials, persons? Otherwise, a
	simple list indicates one or more source types: friends, family, doctor.
	info material. etc.
Status	Published for current action plan
Status history	Status over all action plan periods

Table 7 Properties for an extended goal model

5.5 Interdependencies with other models and components

To facilitate the access of patient recommendations and usage of the recommendations, patient encounter and recommendations metadata are needed.

Chapter 10.2 details how the encounter metadata that will be based on IHE XDS are handled in EMPOWER.

The content of the recommendations to a patient from the medical professional will be structured. Below a first specification is given.

¹¹ Taxonomy of patient-centered goals http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1500896/

Recommendations / treatment goals or actions that patient might follow		
Format type of each item in the Recommendation list	List of zero or more recommendation texts per patient encounter	
Item topic	Optional. If doctors could select goal type	
Item content template/format identifier	item format identifier (Recommendation text, manual entry text or other expression Identifier)	
Item Content depending on template/format identifier A list of recommendations might include one or more types of recommendations, such one recommendation per text, a full text of multiple recommendations or an expression.		
Recommender text Recommender based recommendation text that is selected and perhaps modified by the medical professional		
Manual entry text Medical professional provides free text		
Expression Advanced template (data form) to specify goal with property values e.g. lose XX kg by date YYY. Issue: doctor requires more time to use advanced templates		

 Table 8 Structured content for recommendations

The Action plan will use the EMPOWER terminology for capturing goals, activities, patient encounter codes, calendar event categories; supporting the input forms and reports amongst others.

6 Recommendation knowledge model

The knowledge model for the Recommender Engine addresses in particular typical patientphysician situations where the physician has to specify recommendations based in accordance to the patients individual situation. A patient consultation or encounter model is described in chapter 4.3.2 for communicating information with EMPOWER components during the execution of the SMP. The Recommender Engine is a central part of that and derives recommendations that follow a particular workflow and utilize predefined rules (patient conditions, preferences, guidelines, healthcare actor rule).

6.1 Purpose

During the execution of the diabetes guidelines, the Recommender Engine needs to access some data (such as the type of diabetes, latest glucose measurements, weights and medical compliance, etc.) about the patient. Furthermore, the diabetes guidelines, which are currently in textual format, will be described in machine processable format so that the Recommender Engine can process them automatically. All these information (information about the patient and diabetes guideline) are described in terms of standard formats and this constitutes the Recommendation Knowledge Model.

6.2 Scope

The scope of this Recommendation Knowledge Model is to derive (semi) automatic recommendations about the patients by also examining their current status. In this derivation, the Recommender Engine will contact with the PHR tool and get the patient information through Recommendation Knowledge Model and then by applying the rules in the diabetes guideline, the engine will derive the recommendations.

6.3 Content

For the description of long-running diabetes guidelines, the well-known Guideline Interchange Format (GLIF¹²) will be used.

In a previous project of SRDC, in iCARDEA System, a GLIF enactment engine is used. On top of iCARDEA, GLIF definitions will be extended to include diabetes guideline requirements.

The Recommender Engine will be adapted from this iCARDEA GLIF Engine. Especially the Recommender Engine component, which processes the specialized guideline definition and executes the activities specified in this definition, of the iCARDEA system will be used and tailored according to the requirements of the EMPOWER.

The GLIF model is presented in Figure 9.

¹² <u>http://www.openclinical.org/gmm_glif.html</u>



Figure 9: Building blocks in GLIF Model

One of these building blocks is the Eligibility Criteria. The longitudinal records related to a patient have to be eligible in order to perform the guideline execution. Another important building block is the tracing the steps of the guideline algorithm. The algorithm itself is composed of several ActionSteps, BranchSteps, DecisionSteps, PatientStateSteps and SynchronizationSteps in GLIF definition. For each of these steps different handlers are designed to process them as explained in the following sections.

6.3.1 Eligibility Criteria Assessment

As mentioned in the previous section, the conditions have to be appropriate in order to start the execution of guideline algorithm steps. These conditions are combined under the title of Eligibility Criteria. Eligibility Criteria consists of Criterions all of which have to be eligible to start the execution of clinical guideline. A Criterion has a number of GetDataActions, which define the needed data to be acquired from the EHR records or PHR data. The assessment of eligibility criteria is realized via the specification part of the Criterion. The specifications are scripts that evaluate to a result that denotes whether the criterion is eligible or not. In EMPOWER, these specification scripts will be JavaScript expressions. JavaScript Expressions are executed by the Rhino JavaScript Execution Engine¹³. In this execution process, first the parameters of the JavaScript expression are fetched from the global variable pool by their names. Global Variable Pool is a hash table located in Recommender Engine. Keys of the hash table are the names of the variables as java strings. The values of these keys are in PatientData type (Medication, Observation, Procedure, etc.). After each variable is fetched from the global variable pool, they are stored in another hash table named "parameter table", during JavaScript execution, expression variables are accessed through this table.

JavaScript expressions are executed by Rhino and evaluated to true or false. If an expression evaluates to false, it means that the guideline is failed to pass the eligibility test and execution is stopped; otherwise the Eligibility Criteria Handling continues with the next criteria on the guideline specification.

If all of the criteria evaluate to "true", it means that the guideline algorithm needs to be executed. At this point the functionality of Eligibility Criteria handling is complete. The execution continues with Guideline Algorithm handling.

6.3.2 Execution of Guideline Algorithm Steps

After the eligibility test yields to "true", the execution of the guideline algorithm starts. A guideline basically consists of steps. In other words, the Recommender Engine will get every

¹³ Rhino :Javascript for java. <u>http://www.mozilla.org/rhino/</u>

type of steps and calls the appropriate step handlers shown in Figure 10. After specific step handlers complete their tasks, they call the guideline step handler again. As a result, the guideline step trace can be referred as a "mutual recursive" procedure.



Figure 10: Dependencies between step handlers

There will be five basic types of guideline steps in EMPOWER and their processing will be elaborated in the following subsections.

6.3.2.1 Handling of Patient State Steps

Patient State Step is the simplest guideline step that takes place in the GLIF specification.

The functionality of Patient State Step is serving as a milestone in guideline execution. They are used to inform the medical professionals who are monitoring the Recommender Engine about the phases of the guideline execution. In the modelling stage placing Patient State Steps in some certain places of the guideline increases the user friendliness and clarity of the guideline.

Typically in GLIF, the initial and final step of every clinical guideline is a Patient State Step. EMPOWER will not violate this convention, although it is not a technical or medical restriction. Currently the initial and final steps of every guideline used in EMPOWER will be Patient State Steps.

6.3.2.2 Handling of Branch and Synchronization Steps

Branch and Synchronization Steps are required to execute multiple guideline steps at the same time and re-join them when their execution is finished. These steps add parallelism to the guideline execution mechanism of EMPOWER.

In Branch Step, the steps that the guideline execution will branch are placed under the slot Branches. This slot contains a set of guideline steps (branches). Another slot in the Branch Step definition, declares the order constraint of the guideline execution. If the order constraint is parallel, multiple branches are executed parallel. Otherwise order constraint is "any order" and in this case branches are executed one after another. In EMPOWER guidelines all the Branch Steps will declare their order constraints as "parallel". For each branch of the step, a new thread will be created providing the parameters of the parent thread.

In the any order case, threads will also be created for each branch to keep uniformity of the system but in this case, threads will not operate simultaneously.

Synchronization of the branches is performed in Synchronization Steps. To keep the track of the branches, a "synchronization table" will be implemented within the Recommender Engine.

6.3.2.3 Handling of Case Steps

In the Case Steps one of the steps is selected among the options in the option list. The option list of the Case Step is a set of DecisionOptions each of which contains a slot named Condition Value. Condition Value contains a slot named CaseValue which is nothing but a Criterion. Case Value has a GetDataItems list and a specification script to be executed. As in eligibility criteria, first the data items are retrieved from the related sources and put in the global variable pool of the Recommender Engine, parameter list is formed and JavaScript is executed.

If an expression yields to false, the option encapsulating the expression is aborted as false and the next option in the option list is evaluated in the same way. In this way it is analogous to the "if –else" statements in computer programming. The options have priority according to their position in the option list. If the JavaScript of an option returns true, the destination of that option (which is a guideline step) is selected directly and guideline continues its execution from that step. The other steps are directly bypassed.

If all of the options in the option list fail to result "true" then the default next step of the Case Step is compulsorily selected. The guideline execution continues from that default next step.

In case step handling, each executed script and its result are logged and reported to the monitoring component and the selections are displayed to the user.

6.3.2.4 Handling of Action Steps

Action steps are the major group of the guideline steps by means of which the Recommender Engine will interact with the other components of the EMPOWER system. Through the functionality of action steps the Recommender Engine gets data from EHR and PHR sources and conducts medically oriented actions such as recommendation, consulting and waiting.

Action Step consists of a task list the elements of which are performed one after another. It should be noted that there is no defined execution order among these tasks. Each task will be handled by Recommender Engine first and appropriate handlers will be called for each type of tasks. In EMPOWER guidelines the following kinds of action specifications exist and separate handlers will be implemented for them:

Get Data Action

- Message Action
- Medically Oriented Action

In Get Data Actions, the acquired data and its source is sent to the MP-DG System by the Recommender Engine. In Message Oriented Actions, MP-DG System will be notified about the generated alarm. Medically Oriented Actions has a variety of interaction with the MP-DG System. For the recommendation and wait actions Monitoring Messages specific to the characteristic of the action are called (i.e. Wait action notifies the waiting duration, recommendation steps post the name of medical task to be performed). These are all simplex communications that the data flows only in one way. But for the Consult action, the interaction is two ways.

In the following section, the actions that take place in EMPOWER guidelines are explained in detail.

6.3.3 Guideline Actions

As mentioned above, three types of action specifications occur in EMPOWER guidelines: Get Data Action, Message Action, and Medically Oriented Action. In EMPOWER implementation each of these action specification types are dealt by means of separate handlers. The subsections below discuss these specification types.



Figure 11: Dependencies between Action Specification Handlers

6.3.3.1 Get Data Actions

Get Data Action is the action specification where the required patient is retrieved from the related data source. After the data is retrieved from the source, they are stored into the Global Variable Pool with the "variable name" slot and used in JavaScript expression executions when needed. In EMPOWER system, there will be two kinds of patient data source. Each of these sources is accessed through a specialized process. The data source types are namely:

- EHR Data
- PHR Data

The nature of the data in the guideline specification is mentioned in "data source type" slot of the Get Data Action building block of GLIF. According to the "data source type", a patient data could be either EHR Entity or PHR Entity.

6.3.3.2 Message Actions

It is essential to contact the clinicians, patients or patient relatives in some phases of the guideline. The reason might be simply inform the medical professional, or it might be an emergency case that needs urgent intervention of the clinician. Message Actions are used to keep the content, destination and urgency of the messages in the guideline model of the EMPOWER project.

6.3.3.3 Medically Oriented Actions

In EMPOWER a guideline may require to communicate with the underlying PHR, to reflect the results of the guideline execution. These are handled through Medically Oriented Actions. Medically Oriented Actions include instructing a treatment or medical procedure to a patient, waiting for a specific amount of time or consulting a clinician about a decision to be made by the other steps.

6.3.4 Diabetes Guideline Specifications

EMPOWER will provide two different versions of the diabetes guideline. This is due to country specific differences in the health care processes. A brief graphical representation of the Turkish guideline is shown here as an example.



Figure 12: Graphical representation of a diabetes guideline

The complete guideline definitions in XML format will be published at the EMPOWER website¹⁴.

6.4 Utilized standards

The PHR and EHR information will be retrieved from the PHR tool with the Integrating the Healthcare Enterprise (IHE), *Exchange of Personal Health Record Content Profile*¹⁵ *templates.*

For the description of long-running diabetes guidelines, the well-known Guideline Interchange Format (GLIF¹⁶) will be used. Although the GLIF format is prominently used, it is rather sophisticated. Therefore, in order to ease the development of the Recommender Engine an internal data format will be used. The XSD of this internal data format is presented

¹⁴ http://www.empower-fp7.eu

¹⁵ <u>http://wiki.ihe.net/index.php?title=Exchange_of_Personal_Health_Record_Content_Profile</u>

¹⁶ http://www.openclinical.org/gmm_glif.html

in the Appendix 11.1. An adapter will be implemented to convert the GLIF format to this internal format and vice versa. In addition to this, some recommendations can be derived by using direct recommendation rules. For this rules, Drools¹⁷ rule format and engine will be used.

6.5 Interdependencies with other models and components

The knowledge model of the Recommender Engine is like the business process languages where the activities are processed step-by-step. From the EMPOWER perspective, the information model will benefit from the EHR/PHR Data Exchange Model which models the medical information of the patients. The entire medical professional entered and patient entered data will be modeled in this information model and during the execution of a guideline, the Recommender Engine will retrieve the medical information of the patient by adhering to this EHR/PHR Data Exchange Model.

On the other hand, at the end of a guideline execution, the Recommender Engine creates a number of textual recommendations. These recommendations will be fed into Action Plan Engine. In this respect, the Recommender Engine information model is an input to the Action Plan information model.

The Recommender Engine will access the medical data (PHR/EHR Data) of the patients through standard IHE templates as further detailed in chapter 10.3.

¹⁷ <u>http://www.jboss.org/drools/</u>

7 Information material knowledge model

Patient education mechanisms for fostering self-management and supporting information materials (e.g. including decision aids for patients for diabetes-related decision situations) will be developed. These materials will also facilitate the care process for diabetes patients and hence, reduce the workload of the treating physicians.

This section will describe the metadata data and terminologies that are required for finding information for the patient or medical professional either directly via a query form or indirectly via topics associated with the patient such as action plan goals, activities. Using the metadata description, a content manager can annotate particular materials or collections based on the advice medical experts. The material can be either sourced in a local content management system or available on the Internet. The annotation process might be facilitated semi-automatically using particular semantic harvesting tools e.g. Apache Stanbol enhancement engine**Fehler! Textmarke nicht definiert.** The appropriate tool will have a particular metadata description that will be mapped to or extended by the information material knowledge model.

A rating model will enable the rating of information materials for particular roles (dietician or other specialist, doctor, patient) according to particular topics. For example, a patient might trust a dietician's (role) ranking of a particular information resource for the topics *recipe* and *diabetes*.

7.1 Purpose

The information materials will be created and annotated by content authors and made accessible to the patients. The content enhancements will support the visualization and interactivity of the content.

7.2 Scope

The information material knowledge model describes basic metadata that support the basic classification and rating of information materials. The content model will depend on integrated content management system. In Learning paths Task 5.1, the structure of the materials and organization will be developed, and further definition of metadata and controlled vocabulary (EMPOWER terminology) for the information material knowledge model.

7.3 Content

7.3.1 Information material indexing and cross linking of information material

The content and semantic annotation models will be based on the utilized content management and semantic technology framework. Special software tool from the VIE project - Vienna IKS Editables, will support the development of semantic web functionalities on the user interface level. tools, will enable an author to manually annotate and enhance the information materials. Using Apache Stanbol tools, a semi-automated approach to semantic annotations can be achieved whereby the content author updates semantic annotations linking the materials to EMPOWER content and other health information sources.

7.3.2 Rating of information Material

The rating of the information material will be considered as a review, meaning that a person, a reviewer, might add more information beyond a numeric score. The rating includes a rating for the entire information resource however there can be ratings appropriate for particular topics e.g. the subject matter, the readability and appropriateness for particular patients or maturity levels.

The core properties of the review will be derived from *hReview*¹⁸ and supplemented by the Trust Ontology¹⁹, Schema.org (Medical and Health types, Person, Organization)²⁰, Dublin Core, and Friend of a Friend (FOAF).

The following standards provide the basis for the EMPOWER review and rating model. The relevant properties are listed from hReview, Trust Ontology and FOAF.

7.3.2.1 hReview

The hReview schema properties of the following:

- hReview (hreview)
- summary. Text.
- item type. Optional.
- item info. Required.
- reviewer. Use reviewer role, Note that the reviewer should not be published, especially not the patient.
- dtreviewed. optional. ISO8601 absolute date or date time. Use value-class-pattern if necessary especially for accessibility. (http://www.w3.org/TR/NOTE-datetime)
- rating. optional. fixed point integer [1.0-5.0], with optional alternate worst (default:1.0) and/or best (default:5.0), also fixed point integers, and explicit value.
- description. Text. Optional
- tags. optional. Topics, keywords or phrases that the reviewer associates with the material. using rel-tag, each with optional rating.
- permalink. optional, using rel-bookmark and rel-self.
- license. optional, using rel-license.

7.3.2.2 Trust Ontology

The reviewer provides a rating about a particular subject topic and a rating the entire resource. The TrustTopic includes three properties:

- trust:rustSubject, a topic
- trust:trustValue (rating 1 -10)
- trust Person, the reviewer.

Considering the on the hReview tags specification, a reviewer can optionally provide a rating for each tag in the hReview.

7.3.2.3 FOAF role

Can be used to define how the reviewer participates in the review by role or participation of the reviewer.

What is the role or participation of the reviewer in particular subjects or topics relating to this information material? Is the reviewer a doctor? More importantly what is the particular speciality that is relevant to the information material? From FOAF role vocabulary, *role:participates* can refer to multiple topics: *physician, diabetes, Medical Subject Headings, etc.*

¹⁸ hReview http://microformats.org/wiki/hreview

¹⁹ Trust Ontology http://trust.mindswap.org/trustOnt.shtml

²⁰ Schema.org http://schema.org/docs/schemas.html

• role:participates²¹

7.4 Utilized standards

7.4.1 Proposed Indexing and cross linking of information materials

The automated annotation of information material provides links to heterogeneous sources from the local EMPOWER health information materials, Wikis and other web resources.

The indexing of information materials depends on an Apache Stanbol²² extraction engine and its configured knowledge sources. The constraint for EMPOWER might be the availability of sources in all EMPOWER languages. Possible sources are ontologies, taxonomies, structured Wikis; each providing labels in the language of the pilot application. The sources can include, inclusive but not exclusive, are:

- Medical Subject Headings²³, (MeSH) The content authors could include and hide information if necessary
- DBpedia
- Terminologies used within the EMPOWER system e.g. terminologies supporting Action Plan actions, goals, topics.

The cross indexing of EMPOWER patient information materials content to health content will depending on the pilot application requirements and language.

- EMPOWER patient information materials
- DBpedia
- Health information can be processed by the Apache Stanbol tools.

7.4.2 Rating model for Information material

The following standards are relevant and can be integrated and supplemented by additional standard onlotogies

- hReview rating of a resource
- Trust Ontology evaluates trust of people
- Schema.org/Rating individual rating of a resource
- Schema.org/AgregateRating reporting the aggregate rating of a resource
- Friend of a Friend (FOAF) Role vocabulary²⁴, FOAF document Subject
- Schema.org/MedicalEntity and derivatives
- Dublin Core

7.5 Interdependencies with other models and components

- Patient encounter and recommendations derived from the Recommender; doctor, patient and organization identifiers
- Diabetes Passport (demographic, doctor, patient data)
- White pages for doctor contact information
- SMP pathway processes

²¹ FOAF role vocabulary http://wiki.foaf-project.org/w/RoleVocab

²² Apache Stanbol http://stanbol.apache.org/

²³ Medical Subject Headings http://www.nlm.nih.gov/mesh/

²⁴ FOAF http://wiki.foaf-project.org and http://wiki.foaf-project.org/w/RoleVocab
8 ODL- and medical data knowledge model

The knowledge model for Patterns of Daily Living includes observations about vital, physical and mental parameters and about physical and lifestyle activities. It is based on EHR standards (e.g. openEHR) and medical terminologies (e.g. SNOMED-CT).

8.1 Purpose

In EMPOWER the diabetics will be enabled to collect and report ODLs by using a PHR and PHA system respectively. This way the SMP will be supplied with patient related information like vital signs measurements or food logs. The data acquisition can be done in various ways: data import from medical devices like glucose meter, manually filling of screen forms e.g. for mood reporting or integration of already existing services from other PHAs like apps for walking.

The specification of common information models for these data - originating from various sources - facilitates semantic interoperable data exchange between the heterogeneous systems involved. Moreover EMPOWER intends to avoid fixed application scenarios with regards to ODL collection and utilizes adaptable workflows that allow to continuously fit the software application to the users' actual needs. The archetype based ODL knowledge models offer the flexibility and adaptability needed to support this. They are defined in collaboration with domain experts nevertheless the models presented here are subjected to review and feedback by the medical partners.

8.2 Scope

The ODL and medical data knowledge model is focusing on the definition of archetype based information models for diabetes related ODLs including validation rules (e.g. about the appropriate range for blood glucose values) thus supporting feedback mechanisms (e.g. for alerting the patient or health care actor about a critical value). This way the content of health records that are administered by the patient itself via EMPOWERs' PHR and PHA systems is specified.

8.3 Content

The collection of Observations of Daily Living, i.e. of information related to activities such as sleep, diet, exercise, mood and adherence to medication regimens is an area that is userdirected, both in the kind of information that is collected and in the health-related activities that stem from it. Below we present an indicative set of ODLs and the type of associated data that will be used for data collection by the patient.

ODL	Type of associated data		
Levels /types of	Self report or self-measurement data logs from		
physical activity	physical activity sensors (number of steps)		
	Type (like running, cycling, walking, spinning,)		
	Level (scale for amount of physical activity)		
	Duration (minutes)		
	Distance (km)		
Weight	Self-measurement by Scale (kg)		
Blood glucose	Self-measurement by Glucosemeter (mmol/L or		
	mg/dL)		
Blood pressure	Systolic/Diastolic (mmHg)		
Medication adherence	Self report (free text)		
Diet	Self-report via photo or selection from menu		
	May be split up in components: Energy (kJ/calories),		
	Carbohydrate (g), Protein (g), Fat (g)		
Insulin Dosage	Self-report (unit)		
Sleep	Self-report or Likert scale		
Stress level	Self-report or Likert scale		
Mood	Self-report or emoticons		

Table 9: Indicative set of ODLs with type of associated data

These ODLs were specified in detail by using the openEHR archetype formalism, facilitating the building of sophisticated models for medical concepts that are based on a common reference model. The openEHR Archetype Editor²⁵ was used for that.

Below a short introduction to the openEHR reference model is given that explains how the central building blocks of an EHR are represented by the predefined ENTRY and COMPOSITION class models used within archetypes.

8.3.1 Reference Model Introduction

The archetypes are defined by combining and further constraining elements defined by the openEHR reference model. As the reference model specifies many common attributes (like ACTION.time that documents the time an action took place) these do not have to be redefined. The common attributes are available in every archetype model according to its type.

8.3.1.1 Entry Class

All information that is to be stored in an archetype based health record is expressed as an instance of the ENTRY class described in the openEHR entry package. The ENTRY classes ADMIN_ENTRY, OBSERVATION, EVALUATION, INSTRUCTION and ACTION are essential in the openEHR information model, since they define the semantics of the "core" information in the electronic health record.

An ENTRY instance is logically a single 'clinical statement', and may be a single short narrative phrase, but may also contain a significant amount of structured and coded data, e.g. a microbiology result or a psychiatric examination.

²⁵ http://www.openehr.org/downloads/modellingtools



Figure 13: rm.composition.content.entry Package

As you can see in Figure 13 (from ehr_im.pdf) all Entries have a number of attributes in common. The language and encoding attributes indicate how textual data within the Entry are to be interpreted linguistically and at the character set level.

The other attributes common to all Entry subtypes are as follows:

- subject: this attribute records the subject of the Entry as an instance of a subtype of PARTY_PROXY. When this is the record subject, (i.e. the patient), the value is an instance of PARTY_SELF. Otherwise it is typically a family member or other acquaintance of the record subject.
- provider: the agent who provided the information. This is usually the patient or the clinician, but may be someone else, or a software application or device. If participation details of the provider (e.g. mode of communication) need to be recorded, the details should be recorded once in the EVENT_CONTEXT.participations. The provider attribute is optional, since it is often implicit in the information that was recorded.
- **other_participations**: other participations which existed for this Entry, e.g. a nurse who administered a drug in an INSTRUCTION; only required in cases where participants other than the subject of the information and the provider of the information need to be recorded.

8.3.1.2 Observation Class

The Observation class is used to record the observation of any phenomenon or state of interest to do with the patient, including pathology results, blood pressure readings, the family history and social circumstances as told by the patient to the doctor, patient answers to physician questions during a physical examination, and responses to a psychological assessment questionnaire. Observations are distinguished from Actions in that Actions are

interventions whereas Observations record only information relating to the situation of the patient, not what is done to him/her.

The significant information of an Observation is expressed in terms of "data", "state" and "protocol", which can be characterized as follows:

- **data**: the actual datum being recorded; expressed in the form of a History of Events, each of which can be a complex data structure such as a List, Table, Single (value), or Tree, in its own right. Examples include blood pressure, heartrate, ECG traces.
- **state**: any particular information about the state of the subject of the Entry necessary to correctly interpret the data, which is not already known in the health record (i.e. facts such as the patient being female, pregnant, or currently undergoing chemotherapy). For example, exersion level (resting, post-marathon...), position (lying, standing), post- glucose challenge, and so on. The form of the state attribute is the same as that of the data attribute: a History of Events of Item_structures.
- **protocol**: details of how the observation was carried out, which might include a particular clinical protocol (e.g. Bruce protocol for treadmill exercise ECG) and/or information about instruments and other observational methods. This information can always be safely omitted from the user interface, i.e. has no bearing on the interpretation of the data.

Timing in Observations

The openEHR model is modeling historical time inside a History/Event structure defined in the data_structures.history package²⁶.

In short, this package defines the HISTORY class with an origin attribute, and a series of EVENT instances each containing a time attribute. Instantaneous and interval events are distinguished via the EVENT subtypes POINT_EVENT and INTERVAL_EVENT; interval events have the width attribute that is set to the duration of the interval.

8.3.1.3 Composition Class

The Composition is the primary 'data container' in the openEHR EHR and is the root point of clinical content. Instances of the Composition class can be considered as self-standing data aggregations or documents in a document-oriented system. The key information in a COMPOSITION is found in its content, event_context, and composer attributes. Figure 14 illustrates the composition package.

²⁶ Data Structures IM; see

http://svn.openehr.org/specification/TRUNK/publishing/architecture/rm/data_structures_im.pd f.



Figure 14: rm.composition Package

The **category** attribute indicates what broad category this Composition belongs to, e.g. "persistent" – of longitudinal validity, "event", "process" etc.

The **composer** is the person who was primarily responsible for the content of the Composition. It may be the person who entered and committed the data, it may also be a software agent. This attribute is mandatory, since all content must have been created by some person or agent. When it is the patient, the special "self" instance of PARTY PROXY will be used.

The optional **event_context** in the COMPOSITION class is used to document the healthcare event causing new or changed content in the record. Generally this is an

encounter involving the subject of care and physician, but is variable in a hospital environment. In this sense, a visit to a GP is a single care event, but so is an episode in a hospital, which may encompass multiple encounters. The information recorded in Event context includes start and (optional) end time of the event, health care facility, setting (e.g. primary care, aged care, hospital), participating healthcare professionals, and optional further details defined by an archetype.

Situations in which Event context is not used include:

- Any modification to the EHR which corrects or updates existing content, including by administrative staff, and by clinical professionals adding or changing evaluations, summaries etc.
- Patient-entered data where no interaction with health professionals took place; typically readings from devices in the home such as weighing scales, blood glucose measuring devices, wearable monitors etc.

Ultimately, the use of Event context will be controlled by Composition-level archetypes.

8.3.2 ODL Archetypes

The particular openEHR archetype models are presented in form of mindmaps together with the corresponding excerpts of the data definitions in tabular form. The detailed and complete formal specifications (expressed in ADL) can be found in a dedicated Incubator section at the Knowledge Manager online repository²⁷. For now this is a private section that will be released to public access later on.

Below you find the definition of the Physical Activity archetype as an example. The other ODL archetype definitions can be found in the appendix 11.3 and comprise the following further models:

- 11.3.1 Weight
- 11.3.2 Blood glucose
- 11.3.3 Blood Pressure
- 11.3.4 Diet
- 11.3.5 Insulin Dosage
- 11.3.6 Medication
- •
- •
- Sleep
- 11.3.8 Stress Archetype
- 11.3.9 Mood

8.3.2.1 Physical Activity Archetype



Figure 15: Mindmap of the Physical Activity archetype

²⁷ http://okm.oceaninformatics.com/okm/

T Physical Coded Occurrences: (mandatory)	Indicates the physical exercise selected by the patient. Activity Text 11	 Walking [Walking.] Cycling [Cycling.] Dancing [Dancing.] Swimming [Swimming.] Jogging [Jogging.] Bicycling [Bicycling.] Tennis [Tennis.] Weightlifting [Weightlifting.] Skiing [Skiing.] Basketball [Basketball.] Football [Football.] Ironing [Ironing.] Gardening [Gardening.] Painting [Painting.] Mopping [Mopping.] Vacuuming [Vacuuming.]
Q Duration Quantity Occurrences: (optional)	Indicates the duration of the selected physical exercise.	Property: Time Units: • min
Exercise I Ordinal Occurrences: (optional)	Indicates the intensity of the selected exercise. ntensity 01	0: Light [Recreational and household activities. (e.g. bowling, ironing).] 1: Moderate [Feeling of walking at a normal pace.] 2: Hard [Harder than walking but not as strenuous as running.] 3: Very Hard [Feeling of running.]

Figure 16: Dataset of the Physical Activity archetype

8.4 Utilized standards

The detailed ODL knowledge models are specified as OpenEHR archetypes. Thus a standardised formal definition of the data schema, that also encompasses terminology bindings, rules and language translations, will be delivered.

Archetypes are fundamental shareable specifications of clinical information and have been formally accepted as a European standard (CEN 13606 Part II) and also approved as international standard by ISO. Each archetype represents a whole, discrete specification which is as inclusive as possible, always in terms of the ISO13606/openEHR reference model. The reference model guarantees that the context information for information in health records (such as who, when and where) is already taken care of and do not need to be addressed in each archetype²⁸.

Every term in an archetype can be 'bound' to a terminology (e.g. LOINC) to uniquely identify it and assures to understand the authors intent. Further, archetypes allow expression of subsets to determine which terms are appropriate values at a given data field. This way value sets - that may be linked to common terminologies (e.g. SNOMED) - can be defined that are to be offered to the user within the application.

²⁸ http://www.openehr.org/wiki/display/healthmod/Clinical+Content+Models

OpenEHR templates will be applied to further constrain and adapt the archetypes for application in the context of the EMPOWER Use Cases (see OpenEHR WIKI - An archetype or a template?²⁹). This is needed as archetypes are by definition aiming to specify a maximal data set for a given single clinical concept that is able to cover all possible use cases. Therefore they define a data set that should have the minimal constraints on it in order to maximise interoperability. Templates are use case specific and combine archetypes in ways that achieve various purposes. They further constrain the data set definitions down to make them more practical and usable for a certain application. This way elements not needed can be excluded, optional fields can be made mandatory and terminology subsets can be specified for a given clinical setting.

8.5 Interdependencies with other models and components

The ODL definitions make use of the OpenEHR Support Terminology³⁰ for archetype models.

The workflow for the SMP - that is interlinked with the medical data models - is specified in chapter 4.

The data models specifying the exchange with external EHRs are specified in chapter 10.3.

²⁹ http://www.openehr.org/wiki/pages/viewpage.action?pageId=1376257

³⁰ http://www.openehr.org/releases/1.0.2/architecture/terminology.pdf

9 Consent Management Knowledge Model

Due to the extremely sensitive nature of patient related information, both medical records and patient's context information cannot be disclosed indiscriminately and different healthcare providers must have different access rights. The patient should be at the center of this process controlling his/her consent.

Comprehensive identity management, trust and privacy mechanisms are provided through the EMPOWER platform based on the EU directives 95/46/EC and 2002/58/EC³¹ which present the general principles of processing of personal data, and in particular Recommendation R(97)5 of the Council of Europe³² discussing legal protection of medical data collected and processed automatically is taken into account while providing the necessary confidentiality and privacy mechanisms.

To provide these confidentiality and privacy mechanisms, a patient controlled, configurable, patient context dependent privacy mechanism will be developed. Furthermore, a framework for establishing trust mechanisms among the actors involved is provided based on advanced identity management mechanisms. Indeed, a very important part of enforcing patient consent is to be able to identify the functional role of the party trying to access the patient information. Currently there is access control mechanisms used for this purpose within a single organization. However, for its dynamic and distributed environment, new tools empowering the patient to decide what specific types of his/her context and clinical information can be provided to which entities involved in his/her follow-up is provided. OASIS Extensible Access Control Markup Language (XACML) for access control is used to implement the patient privacy mechanisms.

Today the healthcare sector is still using paper based consents usually within a single organisation with very limited patient control. For EHR sharing, the networked health information systems or individual healthcare enterprises mostly use the opt-in/opt-out model which either deny the sharing of all records with outside or allows all accesses. The IHE initiative published a profile in 2006, Basic Patient Privacy Consent (BPPC)³³, which provides more choices to patients regarding the sharing of EHR data in IHE document sharing platform.

In the BPPC profile published by IHE initiative, the patient can choose the policies defined by the legal entity representing the health information network, not able to define its own consent or further restrictions. In addition, the profile does not define the policy structure how the access control is applied.

Related with security and privacy, EMPOWER project will address challenges, including defining fine-grained document sensitivity levels and functional roles for healthcare providers as the basis of patient-controlled attributes in privacy consents; enforcing patient requested obligations for privacy consents; handling patient and healthcare provider context; assessing risks and damages through the novel federated audit mechanisms; establishing trust among the actors and all the involved interoperability problems.

9.1 Purpose

Consent mechanism is one of the most important parts of a PHR system. It is a crucial issue that patients having the control of who can access and update all their health and personal

³¹ EU Directive 95/46/EC (<u>http://europa.eu.int/com-m/internal_market/privacy/law_en.htm</u>), Supplementary Directive 2002/58/EC http://europa.eu.int/information_society/topics/ecomm/useful_information/library/legislation/in

dex en. htm

³² Council Of Europe – Committee of Ministers, Recommendation No. R(97)5 of The Committee Of Ministers to Member States on the Protection Of Medical Data, Council of Europe Publishing, Strasbourg, 12 February 1997

³³http://www.ihe.net/Technical_Framework/upload/IHE_PCC_TF_BPPC_Basic_Patient_Priva cy_Consents_20060810.pdf

information. There are both ethical and legal issues to be concerned while publishing patient related or any other information of any person. Development of a tool that taking care of these issues, and also enabling patients to control who can access their data is an obligatory in this respect. Therefore, the aim of this data model is to address the consent rules defined by the patients.

9.2 Scope

In this Consent Management Knowledge Model, the data format of the consent rules (XACML) and the data model for the access requests (SAML) are defined.

9.3 Content

9.3.1 Consent Document Model

Within the development of EMPOWER Consent Editor, XACML Policy based model is needed along the. Despite the fact that XACML provides a powerful and extensive model, a new model based on XACML is useful to provide completeness and simplicity. This model can easily be translated to XACML or vice versa. Furthermore, decision engine to be developed within Consent Editor tool, can support both types of models while validating requests.

9.3.1.1 Consent Document

There will be a Consent Document at top of the Consent Document Model. Consent document is a container which contains several consent rules. Consent Document will contain a metadata element which holds the characteristic information of consent document and a list of Consent Rules.



Table 10.

Table 10 Consent Document Meta Data Fields

Field	Description	
id	The unique consent id of a consent document. Every consent document has a different id for every user, hence even different users cannot have same consent id.	
patientId	The patient id of a consent document. It specifies that whom the consent document is belong to.	
definition	Definition (description) of the consent document.	
creationDate	The date when the consent document is created.	
modificationDate	The date when the consent document has been updated.	
expirationDate	The date when the consent document expires(loses its validity).	

9.3.1.2 Consent Rule

Consent rule is a control mechanism over the information of patients to specify **who** can access to **what** for what **purpose**.

- Consent rule contains a consent rule target element and lists of conditions and obligations.
- Consent rule target is a container which contains subjects, resources and actions of consent rule.
- Consent rule also has a field called isAllow which specifies the effect (permit or deny) when the target is matched with request.

Below, description about the fields of Consent Document Rule is given in Table 11.

Table 11 Consent Rule Fields

Field	Description
id	The unique consent id of a consent rule. Every consent rule has a
	different id for every document, hence even different documents cannot
	contain consent rules with same id.
description	Description of the consent document.
isAllow	Specifies the effect of the rule provided that the rule is satisfied.

9.3.1.3 Consent Rule Target

Consent rule target is a container which contains target elements of a consent rule. These target elements can be separated under three titles:

- Subjects
- Resources
- Actions

If we want to clarify all target elements briefly;

- 'Subject's are target person of the rule. They can be individual people or a group of person who are grouped according to their roles.
- 'Resource's are the target object of the rule. It can be anything related with medical information of user such as 'Allergies' or 'Medications'.
- 'Action's are the target purpose of the rule. There are limited default actions; however, new actions can be defined like subjects and resources if needed.



9.3.1.3.1 Subjects

There will be two types of subjects: Group and Individual. Group refers to some roles such as Doctor, Pharmacist, Family Member etc. 'Group' may also include specific members. However, 'Individual' refers to a specific person such as "Dr. Gregory House". 'Individual' may also have a specified role. This is facilitating to prepare rules such as "All doctors but Dr. XYZ can read my test results".

There will be 6 groups defined by default. However, number of groups will be extended by users. Default group ids are listed below:

- DOCTOR
- NURSE

Below, a description of the fields of the subjects is provided in Table 12 and Table 13.

Field	Description
ld	The unique id of the individual.
Name	Real name of the individual.
Surname	Real surname of the individual.
Role	Role of the individual. (Doctor, Nurse, etc)

Table 12 Individual Subject Fields

Table 13 Group Subject Fields

Field	Description
ld	The unique id of the group.
Name	Name of the group.
description	Description of the group.
Members	Specific members of the group (if there is any).

9.3.1.3.2 Resources

Resources will be identified according to their resource ids. There will be 11 different resources as default. However, these may be extended by the user. Below, ids of these resources are provided that correspond to elements of the IHE XPHR (see chapter 10.3):

- Alerts
- Encounters
- Family Histories
- Immunizations
- Medical Devices
- Medications
- Pregnancies
- Problems
- Procedures
- Results
- Social Histories

Below, a description of the fields of the resources is provided in Table 14.

Table 14 Resource Field

Field	Description
id	The unique id of the resource.
name	Name of the resource.
confidentialityCode	Confidentiality Code of the resource. (HIGH, NORMAL, LOW, etc)

9.3.1.3.3 Actions

Actions are only presented with string values which refers the name of the actions themselves. There are three default actions provided, however users may extend the list of actions. Below, names of these actions are provided:

- READ
- CREATE

9.4 Utilized standards

9.4.1 Extensible Access Control Markup Language (XACML)

The economics of scale have driven computing platform vendors to develop products with very generalized functionality, so that they can be used in the widest possible range of situations. "Out of the box", these products have the maximum possible privilege for accessing data and executing software, so that they can be used in as many application environments as possible, including those with the most permissive security policies. In the more common case of a relatively restrictive security policy, the platform's inherent privileges must be constrained, by configuration. The security policy of a large enterprise has many elements and many points of enforcement. Elements of policy may be managed by the Information Systems department, by Human Resources, by the Legal department and by the Finance department. And the policy may be enforced by the extranet, mail, WAN and remote-access systems; platforms which inherently implement a permissive security policy. The current practice is to manage the configuration of each point of enforcement independently in order to implement the security policy as accurately as possible. Consequently, it is an expensive and unreliable proposition to modify the security policy. And, it is virtually impossible to obtain a consolidated view of the safeguards in effect throughout the enterprise to enforce the policy. At the same time, there is increasing pressure on corporate and government executives from consumers, shareholders and regulators to demonstrate "best practice" in the protection of the information assets of the

enterprise and its customers. For these reasons, there is a pressing need for a common language for expressing security policy.

If implemented throughout an enterprise, a common policy language allows the enterprise to manage the enforcement of all the elements of its security policy in all the components of its information systems. Managing security policy may include some or all of the following steps: writing, reviewing, testing, approving, issuing, combining, analyzing, modifying, withdrawing, retrieving and enforcing policy. XML is a natural choice as the basis for the common security-policy language, due to the ease with which its syntax and semantics can be extended to accommodate the unique requirements of this application, and the widespread support that it enjoys from all the main platform and tool vendors.

XACML (eXtensible Access Control Markup Language) is an XML-based language for access control that has been standardized in OASIS. XACML describes both an access control policy language and a request/response language. The policy language is used to express access control policies (**Who** can access **what**, under what **conditions**, and for what **purpose**). The request/response language expresses queries about whether a particular access should be allowed (requests) and describes answers to those queries (responses).

In a typical XACML usage scenario, a subject (e.g. human user, workstation) wants to take some action on a particular resource. The subject submits its query to the entity protecting the resource (e.g. filesystem, web server). This entity is called a Policy Enforcement Point (PEP). The PEP forms a request (using the XACML request language) based on the attributes of the subject, action, resource, and other relevant information. The PEP then sends this request to a Policy Decision Point (PDP), which examines the request, retrieves policies (written in the XACML policy language) that are applicable to this request, and determines whether access should be granted according to the XACML rules for evaluating policies. That answer (expressed in the XACML response language) is returned to the PEP, which can then allow or deny access to the requester.

A sample XACML document is presented in the Appendix 11.2.

9.5 Interdependencies with other models and components

Each access request to PHR data will be checked against the consent rules defined by the patient.

10 Administrative knowledge model

The purpose of this section is to identify information from neighboring systems (PHRS, EHR, contact info or identity management) about patients and medical personnel that are needed by EMPOWER components. The diabetes passport, for example, is a critical assembly of information that components will use. Medical contact information, including personnel identifiers from identity management info, will be linked to physician identifiers in PIS/HIS/PHR data and EMPOWER patient encounter metadata from the Recommender Engine. The contact information is also used by user interfaces, and Action Plan Engine

10.1 Identity Management for patients and medical professionals

Provided that EMPOWER combines multiple information sources, each piece of information must be able to be referenced unambiguously to support interoperability.

Especially administrative data, including identifiers and contact information (name, address, telephone, fax numbers, email address) for patients, doctors (healthcare person) and healthcare institutions must be stored in an interoperable form, because the same patient can have different identifiers in each of the existing systems. This means, that there is a chance for ambiguity among identifiers from different systems like PHRS, EHRS (PIS), Consent Manager, and Recommender Engine. For example, multiple identifiers are combined in recommendations including the following

- Identifiers of persons (patient, medical professional), including system identifier e.g. a PHRS ID should include a namespace or be wrapped in one within EMPOWER.
- Identifiers of systems.
- Identifiers of all EMPOWER born entities (ODLs, action plan, patient encounter metadata, recommendations/treatment goals, etc.).

The approach in the EMPOWER knowledge model must therefore be able to link the existing identities, rather than following a stand-alone user management approach. In addition EMPOWER wants to provide the administrative data in interchangeable formats, such as vCard (hCard)³⁴, FOAF³⁵, Schema.org³⁶, etc.

The EMPOWER administrative data model will be derived from information required for the *diabetes passport*, the *PHRS* and the *Practice Management Systems*, some of them already described in "D8.1.1 – Requirements Specifications and Scenario of the Pilot Application". The linking of IDs between the systems is done by defining a namespace (or code system) along the existing system-specific identifier (as character-string) to combine them to a globally unique identifier. This allows the connection of multiple "namespace-identifier" pairs to identify one and the same person in multiple systems.

Further exploiting the described approach, a patient, doctor or "system" does not need to use only a single EMPOWER-ID, but can also have separate IDs per EMPOWER module, such as the Recommender Engine, the Consent Manager, etc. For each PHRS user, a unique empower identifier (empower namespace) should be generated and linked to the PHRS user and either a patient ID (with namespace) or a healthcare person. In addition to persons also systems will be identified using the same mechanism.

³⁴ vCard (hCard) JSON representations should be used to support data exchange between PHAs and the EMPOWER core services via RESTful services.

³⁵ FOAF provides descriptions of people, organizations, and personal user accounts. For example, the FOAF OnlineAccount (http://xmlns.com/foaf/spec/#term_OnlineAccount), could be subclassed to support EHRS and PHRS account information: *EHRSAccount*, and *PHRSAccount*.

³⁶ <u>http://schema.org</u> is supported by the major web search engine vendors such as Microsoft, and Google, supports a variety of schemas including Medical schemas that also reference personal and organizational ontologies.

In order to distinguish between the different kinds of users (patient, doctor, healthcare institution, etc.) the role of the user needs to be associated in the knowledge model. This is also important to conform to the Consent Engine role terminology for the administration of the access rights. The role must be able to be derived via the identifier (e.g. via the name space).

A flexible approach should provide both contact information and support the registration of identity information for patients and medical personnel. The identity information model will depend on the open source frameworks used, however, EMPOWER should include a standard-based approach for exchanging this information.

Therefore, software adaptors should be created for the particular Identity provider. EMPOWER core will maintain a common data store (and services) to manage identity information derived from pilot applications for patients and medical professionals.

10.2 Meta-models

Metadata are needed to facilitate the access of patient recommendations and usage of the recommendations.

10.2.1 Patient Encounter Metadata

The recommender engine will collect recommendations/treatment goals for the patient from the doctor at each consultation. This patient encounter is characterized by metadata wrapping the patient recommendations/treatment goals. These data are important to link a patient encounter to an appointment in the action plan calendar and to help organize his/her recommendations chronologically, while keeping track of single consultations with doctors.

	Patient Encounter metadata	Standards and notes
Encounter ID	unique identifier of this encounter	
Encounter Date	Encounter date and time	
Encounter Type	Encounter type	If there are different types consultation is default type
Identifier of patient	Patient	(schema.org/MedicalCode) properties: codeValue codingSystem
Identifier of healthcare person	This identifier should have a white pages entry, otherwise provide also the first name, last name, role of healthcare person	(schema.org/MedicalCode) properties: codeValue codingSystem
Source system or organization	Source of recommendations Which system produced recommendations?	(schema.org/MedicalCode) properties: codeValue codingSystem

Ta	able	15:	Tentative	Patient	Encounter	Metadata
			1 0111041110	i adone	Linoodintoi	moladala

For the handling of patient encounter metadata in EMPOWER the IHE XDS.b³⁷ profile for document metadata will be used as shown by the example given in the Appendix 11.4.

10.2.2 Visualisation and Reporting Templates

Visualisation templates define the content and layout of graphs and reports. A set of default templates will be provided for use by the patients and health professionals. Templates for different kinds of graphs like line charts, smiley ratings, gauge scales, trend indicators and table or diagram based summaries will be provided. The single templates are identified by a unique name like "Diet and glucose" or "Weight and physical activity" and they may comprise different time frames like "Glucose Week" and "Glucose Quarter".

The EMPOWER system components can obtain a graph or report by calling the visualisation and reporting modules with the corresponding template name. The list of available templates is stored within the system and can be retrieved from the visualisation module.

Name	Туре	Parameters	Description
Glucose Week	Line chart	Blood glucose, per week	Series of measurements
Weight and	Line chart	Weight, exercising	Series of measurements
physical activity		events (step count), per	with marked exercising
		month	events
Weight gauge	Gauge scale	Weight, Target Weight	Shows the weight
			measurement compared to
			target weight

Table 16: Example for Visualisation Template List

10.3 EHR Interoperability Specification

IHE XPHR will be used to support EHR interoperability in EMPOWER. This profile provides a standards-based specification for managing the interchange of documents between a Personal Health Record (PHR) used by a patient and systems used by other healthcare providers to enable better interoperability between these systems. To be more specific, it describes the content and format of summary information (like Allergies, Problems, Medication and Vital Signs) extracted from a PHR system used by a patient for import into healthcare provider information systems, and vice versa.



Figure 19 XPHR Actors

As the information model the PHR Extract module of XPHR will be used. The PHR Extract module describes the document content that summarizes information contained within a Personal Health Record. While mappings have been provided to various standards, this content module conforms to the HL7/ASTM Continuity of Care Document³⁸ (CCD).

³⁷ http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Supplement_XDS-2.pdf ³⁸ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6

Data Element Name	Template ID
Personal Information	1.3.6.1.4.1.19376.1.5.3.1.1.1
Languages Spoken	1.3.6.1.4.1.19376.1.5.3.1.2.1
Employer and School Contacts	1.3.6.1.4.1.19376.1.5.3.1.2.2
Hazardous Working Conditions	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.1
Patient Contacts	1.3.6.1.4.1.19376.1.5.3.1.2.4
Healthcare Providers	1.3.6.1.4.1.19376.1.5.3.1.2.3
Insurance Providers	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7
<u>Pharamacy</u>	1.3.6.1.4.1.19376.1.5.3.1.2.3
Legal Documents and Medical Directives	1.3.6.1.4.1.19376.1.5.3.1.3.34
Allergies and Drug Sensitivities	1.3.6.1.4.1.19376.1.5.3.1.3.13
<u>Conditions</u>	1.3.6.1.4.1.19376.1.5.3.1.3.8
Conditions (cont)	1.3.6.1.4.1.19376.1.5.3.1.3.6
Surgeries	1.3.6.1.4.1.19376.1.5.3.1.3.12
Medications – Prescription and Non-Prescription	1.3.6.1.4.1.19376.1.5.3.1.3.19
Immunizations	1.3.6.1.4.1.19376.1.5.3.1.3.23
Doctor Visits / Last Physical or Checkup	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3
Hospitalizations	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3
Other Healthcare Visits	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3
Clinical Tests / Blood Type	1.3.6.1.4.1.19376.1.5.3.1.3.28
Pregnancies	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
Medical Devices	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5
Family Member History	1.3.6.1.4.1.19376.1.5.3.1.3.15
Foreign Travel	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.6
Plan of Care	1.3.6.1.4.1.19376.1.5.3.1.3.31
Coded Vital signs	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2
Functional Status	1.3.6.1.4.1.19376.1.5.3.1.3.17

The following IHE templates³⁹ will be used in EMPOWER according to this document model:

10.4 Country Specific Diabetes Datasets

10.4.1 Diabetes Passport, DE

In Germany the Diabetes Passport of the DDG (German Diabetes Society) is providing a tool to document the examinations and treatment of diabetes including medication, problems and recommendations. Furthermore it includes a dedicated section to determine targets for the diabetic and to support a structured education plan. The diabetes passport is derived from patient data from the PHRS. The PHRS could have received data imported from the EHR (PIS) or manually input by the patient. The diabetes passport provides the patient with an overview of patient data relevant for their self-management and to also facilitate communicating between the patient and physician during a consultation.

³⁹ <u>http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.5</u>

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The contained data elements are listed as follows:

Administrative Data:

- Patient Details: Name, Address, Telephone / Fax, Email
- Contact Details: Name, Address, Telephone / Fax, Email
- Healthcare Person: Name, Address, Telephone / Fax
- Diabetologically Specialised Practice: Name, Address, Telephone / Fax
- Primary Care Center: Name, Address, Telephone / Fax

Basic Information:

- Date of Birth
- Sex
- Height
- Year of diabetes diagnosis
- Type of diabetes
- Therapy of diabetes (diet only / oral antidiabetics / Insulin, since, until)
- Medications (Date, Description)
- Problems (Description, Since, Until)
- Education (Programme, date)
- Physician Advices (Date, Recommendation)

Year Targets:

- Year
- Weight
- Blood pressure
- HbA1c
- Blood glucose
- Number of blood glucose measurements (per week)
- Injection sites
- Smoking
- Cholesterol
- Cholesterol HDL / LDL
- Triglycerides fasting
- Albuminuria
- Creatinine / eGFR
- Eye findings

Period Data:

- Date
- Targets
- Weight / Waist line
- Blood pressure
- HbA1c
- Blood glucose fasting/postprandial
- Hypoglycaemia episodes
- Number of blood glucose measurements (per week)
- Injection sites
- Smoking

Period Data (to be entered once a year):

- Cholesterol
- Cholesterol HDL / LDL
- Triglycerides fasting

- Albuminuria
- Creatinine / eGFR
- Eye findings
- Physical examinations
- Foot inspection
- Peripheral/Autonomic Neuropathy
- Technical Examinations (e.g. Sonography, ECG, longtime RR)
- Wellbeing (WHO scale)

10.4.2 National Health Data Dictionary – Diabetes MHDS, TR

In Turkey, after each visit the information about the encounter is submitted to the National Health Information Server. In EMPOWER, this data will be retrieved from this central server. Detailed information about this information model is presented in D8.1.1 Requirement Specifications and Scenario of the Pilot Application, Section 3.2.2.1.1 "National Health Data Dictionary (NHDD)".

The diabetes specific health dataset used in the National Health Information System is as follows:

Diabetes MHDS				
MHDS No:	31	Creation Date:	01.06.2007	
Version No:	1	Version Date:	01.06.2007	
Status:	In Use			
Source Organization:	Presidency of Strategy Development			
Registration Authority:	Department of Chronic Diseases			
Descriptive and Qualitative Features				
Scope:	This data set covers the diagnosis and monitoring processes applied to all diabetes patients.			
Context:	Diabetes is the most common non-communicable chronic disease in our country. Therefore, the analysis of the monitoring and treatment applied to diabetes patients is very crucial for the planning of future services for them.			
Method of Gathering	Diabetes MHDS is sent along with Examination MHDS. In this way, data about the diabetes examination is also registered.			
Graphical and Relational Features				
National Reporting:	This data set is sent either through Saglik-Net portal or from remote clients through HL7 v3 messaging protocols to National Health Information System.			
Data Set Elements:	Name	Cardinality	Optionality	
	Organization	1	Required	

	Diagnosis Date	1	Required
	Height	1	Required
	Weight	1	Required
	Waist	1	Required
	Exercise	1	Required
	Compliance to Diet	1	Required
	Systolic BP	1	Required
	Diastolic BP	1	Required
	Thyroid Examination	1	Required
	Additional Diseases	1+	Required
The data providing organizations:	Family Doctors	Hospitals	Community Health Centers

In addition to this data model, the lab results, medications and encounters of the patients can also be retrieved from the National Health Information System of Turkey. Currently, MoH (in a separate national project) is working on extending this data model.

10.5 Terminologies

The purpose of the EMPOWER terminology is to support user interfaces forms or views, reporting and visualization, and information classification and interoperability. The terminology can be derived from both standard and non-standard sources when standards are not available.

The terminology should support Internationalization for the pilot application language. The system should track and report codes without appropriate labels for the EMPOWER User interfaces, not all medical codes need labels unless viewed by users. Labels derived from standard codes might not be suitable for patients; therefore, user-friendly labels should be supplied.

The following are examples that the terminology supports:

- Action plan patient encounter codes, goals, activities, calendar event categories supporting the input forms and reports
- Reporting and visualization categorization
- Role categorization for healthcare persons, and users. Sources include the consent manager roles. Roles are also configurable by the PHRS
- ODL related terminology codes supporting EMPOWER ODL interoperability and labels supporting internationalization.
- Classification (manually, machine) of content to support access to help information and patient information materials. Classification supports search by users or by association with activity or goal categories.
- Rating system categories and subject categories e.g. a rating level for a particular category.
- Mapping of local EMPOWER codes to future standard codes, where standard codes are resolved or improved later.
- Standard medical codes supporting EMPOWER interoperability with PHRS and EHRS interoperability can be provided where needed. The PHRS is mainly responsible to provide mapping tables for accessing labels and internationalization, otherwise, EMPOWER should determine the level of support possible.

The OpenEHR Support Terminology document⁴⁰ describes the openEHR Support Terminology and code sets, which define the vocabulary and codes needed (e.g. languages, clinical settings, instruction states) for the openEHR Reference, Archetype and Service models.

⁴⁰ http://www.openehr.org/releases/1.0.2/architecture/terminology.pdf

10.5.1 Overview on Terminologies used in EMPOWER

An overview on the terminologies and information exchange standards being used in EMPOWER is given. The presentation is based on the different components that constitute the EMPOWER framework.

		Detail	ed outline		Information	
Knowledge Model	High-level outline	German Pilot	Turkish Pilot	Terminology standards	exchange standards	
Workflow and Self Management Pathway	Imported EHR data	Recommendations Medication Lab results: • HbA1c • Blood glucose • Cholesterol HDL / LDL • Triglycerides fasting • Albuminuria • Creatinine / eGFR Diagnoses Vital signs: • Weight • Waist line • Blood pressure Diabetes related: • Hypoglycaemia episodes • No. blood glucose measurements (per week) • Injection sites • Smoking status	 Demographic Information Exercise Compliance Medication Compliance Nutrition Compliance Patient preferences Medical history Problems Diagnosis Conditions (i.e. the current status of the patient, e.g advanced age, pregnant, adolescent) Lab results Blood Glucose Measurements 	 For the pilot in Germany: UMLS coded terms wherever possible, PZN codes for medication and non-standard (i.e. EMPOWER specific) for the rest For the pilot in Turkey: UMLS coded terms and ATC codes for medication 	IHE templates (XPHR)	
	ODLs	refer to OD	Ls section below	SNOMED CT		
	Goals					
	Actions					
	Recommendations					
	User Maturity Level	see Table 1: EMPOWE	R Maturity levels in D3.4.1	-	-	

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Recommender Engine	Imported EHR data Imported PHR data			 For the pilot in Germany: UMLS coded terms wherever possible, PZN codes for medication and non-standard (i.e. EMPOWER specific) for the rest For the pilot in Turkey: UMLS coded terms and ATC codes for medication 	IHE templates (XPHR)
Action Plan		 Action category (e.g. monitoring. Activity name Activity description Action category (option sport, monitoring, appoin Supported goal(s) associativity Date and time Reminder parameters Related person(s) Place Notes 	nedication, food, sport, nal) – e.g. medication, food, ntments. ociated by the patient to this	UMLS coded terms wherever possible and non-standard (i.e. EMPOWER specific) for the rest. For date and time (Standard iCalendar RFC 5545)	IHE templates (XPHR, XDS)
ODLs	 Levels /types of physical activity Weight Blood glucose Blood pressure Medication adherence Diet Insulin Dosage Sleep Stress level Mood 	see Appendix in D3.4.1 the archetypes corresp	for a detailed description of bonding to each of the ODLs	SNOMED CT OpenEHR Support Terminology for archetype models	

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Information Material				 Depends on the terminology standards applied in the information material sources Trust Ontology will be used for people trust rating hReview will be applied for information material rating 	
Consent Management	Consent Document	Consent Document, includ date fields: • id • patientId • definition • creationDate • modificationDate • expirationDate Consent Rule, including the • id • description • isAllow	ding the following meta he following fields		Based on XACM model
Administration	Disease specific PHR data			 Diabetes Passport for the pilot in Germany National Health Data Dictionary for the pilot in Turkey 	
	Patient Encounter Metadata				IHE XDS.b
	Contact information	administrative data in inte	erchangeable format		vCard (hCard) , FOAF , Schema.org ,

Table 17: Overview on terminologies and information exchange standards being used in EMPOWER

11 Appendix

11.1 Guideline Internal XSD Format



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```
<xsd:attribute name="value" type="xsd:string"/>
                  <xsd:attribute name="options" type="xsd:string"/>
<xsd:attribute name="unit" type="xsd:string"/>
                   <xsd:attribute name="description" type="xsd:string"/>
                   <xsd:attribute name="umlsCode" type="xsd:string"/>
                   <xsd:attribute name="display" type="xsd:string" default="true"/>
         </xsd:complexType>
         <xsd:complexType name="Recommendation">
                   <xsd:sequence>
                            <xsd:element name="ConditionScript" type="xsd:string" minOccurs="0"/>
                   </xsd:sequence>
                   <xsd:attribute name="ID" type="xsd:ID"/>
                   <xsd:attribute name="description" type="xsd:string"/>
         </xsd:complexType>
         <xsd:simpleType name="VariableType">
                   <xsd:restriction base="xsd:token">
                             <xsd:enumeration value="binary"/>
                             <xsd:enumeration value="string"/>
                             <xsd:enumeration value="date"/>
                            <xsd:enumeration value="time"/>
                             <xsd:enumeration value="datetime"/>
                             <xsd:enumeration value="list"/>
                            <xsd:enumeration value="integer"/>
                            <xsd:enumeration value="float"/>
                             <xsd:enumeration value="radio"/>
                             <xsd:enumeration value="radioText"/>
                             <xsd:enumeration value="combobox"/>
                   </xsd:restriction>
         </xsd:simpleType>
         <xsd:complexType name="Configuration">
                   <xsd:sequence>
                             <xsd:element name="JDBC" type="JDBC"/>
                             <xsd:element name="XSLInformation" type="XSLInformation" minOccurs="0" maxOccurs="unbounded"/>
                             <xsd:element name="DataElement" type="DataElement" minOccurs="0" maxOccurs="unbounded"/>
                   </xsd:sequence>
         </xsd:complexType>
         <xsd:complexType name="JDBC">
                   <xsd:attribute name="hostname" type="xsd:string"/>
                   <xsd:attribute name="port" type="xsd:integer"/>
<xsd:attribute name="username" type="xsd:string"/>
                   <xsd:attribute name="password" type="xsd:string"/>
                   <xsd:attribute name="database" type="xsd:string"/>
         </xsd:complexType>
         <xsd:complexType name="XSLInformation">
                   <xsd:attribute name="actionStepID" type="xsd:IDREF"/>
                   <xsd:attribute name="xslURL" type="xsd:string"/>
         </xsd:complexType>
         <xsd:complexType name="DataElement">
                   <xsd:sequence>
                            <xsd:element name="PreparedStatement" type="PreparedStatement" maxOccurs="unbounded"/>
                   </xsd:sequence>
                   <xsd:attribute name="umlsCode" type="xsd:string"/>
                   <xsd:attribute name="displayName" type="xsd:string"/>
         </xsd:complexType>
         <rsd:complexType name="PreparedStatement">
                   <xsd:sequence>
                            <xsd:element name="RefinementScript" type="xsd:string" minOccurs="0"/>
                   </xsd:sequence>
                   <xsd:attribute name="accessType" type="xsd:string"/>
                   <xsd:attribute name="type" type="VariableType"/>
                   <xsd:attribute name="sequenceInInsert" type="xsd:integer"/>
                   <xsd:attribute name="statement" type="xsd:string"/>
         </xsd:complexType>
         <xsd:complexType name="Patient">
                   <xsd:attribute name="patientID" type="xsd:string"/>
                   <xsd:attribute name="name" type="xsd:string"/>
                   <xsd:attribute name="surname" type="xsd:string"/>
                   <xsd:attribute name="birthDate" type="xsd:string"/>
                   <xsd:attribute name="gender" type="xsd:string"/>
         </xsd:complexType>
</xsd:schema>
```

11.2 Sample XACML Policy File

This sample specifies an exemplary XACML file defining that "Doctors can update my hospital visits and operations"

<PolicySet xsi:schemaLocation="urn:oasis:names:tc:xacml:2.0:policy:schema:os http://docs.oasisopen.org/xacml/access control-xacml-2.0-policy-schema-os.xsd" PolicySetId="A67E444C-5C74-7ABB-5CF6-86387ED40DBC" PolicyCombiningAlgId="urn:oasis:names:tc:xacml:1.0:policy-combining-algorithm:denyoverrides" xmlns="urn:oasis:names:tc:xacml:2.0:policy:schema:os" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"> <Description>Doctor Consent Document</Description> <Target/> PolicyId="12345678hnvdsad" RuleCombiningAlgId="urn:oasis:names:tc:xacml:1.0:rule-combining-<Policy algorithm:permit-overrides"> <Description>Doctors can update my hospital visits and operations</Description> <Target> <Subjects> <Subject> <SubjectMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:string-equal"> <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#string">ROLECODE:DOCTOR</AttributeValue> <SubjectAttributeDesignator AttributeId="urn:oasis:names:tc:xacml:1.0:subject:subject-id" DataType="http://www.w3.org/2001/XMLSchema#string"/> </SubjectMatch> </Subject> </Subjects> <Resources> <Resource> <ResourceMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:string-equal"> <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#string">RESOURCECODE:HOSPITALVISIT</AttributeValue> <ResourceAttributeDesignator AttributeId="urn:oasis:names:tc:xacml:1.0:resource:resource-id" DataType="http://www.w3.org/2001/XMLSchema#string"/> </ResourceMatch> </Resource> <Resource> <ResourceMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:string-equal"> <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#string">RESOURCECODE:OPERATION</AttributeValue> <ResourceAttributeDesignator AttributeId="urn:oasis:names:tc:xacml:1.0:resource:resource-id" DataType="http://www.w3.org/2001/XMLSchema#string"/> </ResourceMatch> </Resource> </Resources> <Actions> <Action> <ActionMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:string-equal"> <AttributeValue DataType="http://www.w3.org/2001/XMLSchema#string">READ</AttributeValue> AttributeId="urn:oasis:names:tc:xacml:1.0:action:action-id" <ActionAttributeDesignator DataType="http://www.w3.org/2001/XMLSchema#string"/> </ActionMatch> </Action> <Action> <ActionMatch MatchId="urn:oasis:names:tc:xacml:1.0:function:string-equal"> AttributeValue> <ActionAttributeDesignator AttributeId="urn:oasis:names:tc:xacml:1.0:action:action-id" DataType="http://www.w3.org/2001/XMLSchema#string"/> </ActionMatch> </Action> </Actions> </Target> <Rule RuleId="12345678hnvdsad:rule1" Effect="Permit"/> </Policy> </PolicySet>

11.3 ODL Archetypes

11.3.1 Weight



Figure 20: Mindmap of Body Weight Archetype from openEHR

Excerpt of tabular description:

Q	The weight of the individual.Propert Units:	iy:	Mass
Weight	•	0.01000.0 k	g
Quantity D	•	0.02000.0	b
Occurrences: 11 (mandatory)			
T	nment about the measurement of we	ight.Free or c	oded text

Comment Text Occurrences: 0..1 (optional)

11.3.2 Blood glucose



Figure 21: Mindmap of Blood Glucose Archetype from openEHR

Excerpt of tabular description:



empower_d3.4.1_v1.0.docx

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An additional device attribute, which declares the type of measuring device e.g. Accu-Chek, could be introduced to clearly distinguish the self-measured value from a lab test.

11.3.3 Blood Pressure



Figure 22: Mindmap of BP Archetype from OpenEHR

Excerpt of tabular description:

Q	Peak systemic arterial blood pressure -Prope measured in systolic or contraction phase ofUnits	erty: :	Pressure
Systolic Quantity Occurrences: (optional) [SNOMED- CT(2003)::163030003]	the heart cycle. • 01	0.0<1000 mm[Hg] Limit places: 0	.0 decimal

Minimum systemic arterial blood pressure -Property:

measured in the diastolic or relaxation phase ofUnits:

Pressure



11.3.5 Insulin Dosage

The Blood Glucose archetype is including insulin challenge in its state section





11.3.6 Medication

Medication Action openEHR-EHR-ACTION.medication.v1 will be used that contains the following Medication description archetype.

Where the Name of medication contains the name as string and optionally the coded value from a code system like ATC⁴¹ (from WHO) or PZN⁴² (German Pharmazentralnummer).



⁴¹ http://www.whocc.no/atc_ddd_index/

⁴² http://www.ifaffm.de/leistungen/pzn.html

Excerpt of tabular description:

The name of the intervention - which may be codedFree or coded text Name of medication Text 💴 Occurrences: 1..1 (mandatory) The generic name of the drug which is an alternativeFree or coded text name to the name of medication name Runtime constraint: (Generic name) Text 💴 =Generic name OR Occurrences: 0..1 Brand name [*] (optional) The dose unit that isany term that 'is a' Dose unit for this form (A set of terms that given for this type ofdescribes the dose units for medication - e.g. tablet, puff, **unit**medication Dose ampule etc - which allow the dose to be expressed as a number.) Coded Text 💴 Occurrences: 0..1 (optional) The form of theFree or coded text medication Form Text 🖾 Occurrences: 0..1 (optional)



Т	A di	.ny istu	comment rbance.	related	to	the	cause	of	sleepFree	or	coded	text
Comment Text									Possik null:	ole	reasons	why
Occurrences: (optional)	01								•	no	o informati	on
		F	igure 24: D	ata set c	of th	e Sle	ep arch	etyp	e			

11.3.8 Stress Archetype



[MTH::C0233475]

empower_d3.4.1_v1.0.docx

(mandatory)

[MTH::C0424113] 2: Indifferent [Lack of emotion or emotional expression; a disorder of motivation that persists over time.] [**MTH**::C0085632] 3: Sad [Feeling sad.] [MTH::C2987511] 4: Depressed [Feelings of grief or unhappiness.] [MTH::C0344315] Indicates the externalFree or coded text Т attribution for the patient's Comment current mood state. Text 💴 0..1

Occurrences: (optional)

Figure 28: Dataset of the Mood archetype

11.4 Sample IHE XDS File containing Document Metadata⁴³

```
-<s:Envelope>
  -<s:Header>
     <a:Action s:mustUnderstand="1">urn:ihe:iti:2007:ProvideAndRegisterDocumentSet-b</a:Action>
      <a:MessageID>urn:uuid:6d296e90-e5dc-43d0-b455-7c1f3eb35d83</a:MessageID>
    -<a:ReplyTo>
        <a:Address>http://www.w3.org/2005/08/addressing/anonymous</a:Address>
      </a:ReplyTo>
    - <a:To s:mustUnderstand="1">
       http://localhost:2647/XdsService/IHEXDSRepository.svc
      </a:To>
   </s:Header>
  -<s:Body>
    - <ProvideAndRegisterDocumentSetRequest xsi:schemaLocation="unnihe:iti:xds-b:2007 ../schema/IHE/XDS.b_DocumentRepository.xsd">
      - <lcm:SubmitObjectsRequest>
         - <rim:RegistryObjectList>
           - <rim:ExtrinsicObject id="Document01" mimeType="text/xml" objectType="um:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1">
             - <rim:Slot name="creationTime">
               -<rim:ValueList>
                  <rim:Value>20051224</rim:Value>
                 </rim:ValueList>
              </rim:Slot>
             - <rim:Slot name="languageCode">
               -<rim:ValueList>
                   <rim:Value>en-us</rim:Value>
                 </rim:ValueList>
              </rim:Slot>
             - <rim:Slot name="serviceStartTime">
               -<rim:ValueList>
                   <rim:Value>200412230800</rim:Value>
                </rim:ValueList>
              </rim:Slot>
             -<rim:Slot name="serviceStopTime">
               - <rim:ValueList>
                   <rim:Value>200412230801</rim:Value>
                </rim:ValueList>
              </rim:Slot>
             - <rim:Slot name="sourcePatientId">
               -<rim:ValueList>
                   <rim:Value>ST-1000^^&1.3.6.1.4.1.21367.2003.3.9&ISO</rim:Value>
                 </rim:ValueList>
              </rim:Slot>
             - <rim:Slot name="sourcePatientInfo">
               -<rim:ValueList>
                  <rim:Value>PID-3|ST-1000<sup>^^</sup>&1.3.6.1.4.1.21367.2003.3.9&ISO</rim:Value>
                   <rim:Value>PID-5Doe^John^^^</rim:Value>
                   <rim:Value>PID-7|19560527</rim:Value>
                   <rim:Value>PID-8|M</rim:Value>
                   <rim:Value>PID-11|100 Main St^Metropolis/II/44130/USA</rim:Value>
                 </rim:ValueList>
              </rim:Slot>
             - <rim:Name>
                 <rim:LocalizedString value="Physical"/>
              </rim:Name>
              <rim:Description/>
             - <rim: Classification id="cl01" classificationScheme="urn:uuid:93606bcf-9494-43ec-9b4e-a7748d1a838d" classifiedObject="Document01">
               - <rim:Slot name="authorPerson">
                 - <rim:ValueList>
                     <rim:Value>Gerald Smitty</rim:Value>
                   </rim:ValueList>
                </rim:Slot>
               - <rim:Slot name="authorInstitution">
                 - <rim:ValueList>
                     <rim:Value>Cleveland Clinic</rim:Value>
                     <rim:Value>Parma Community</rim:Value>
                   </rim:ValueList>
```

⁴³ ftp://ftp.ihe.net/IT_Infrastructure/iheitiyr5-2007-2008/Technical_Cmte/SupportMaterial/examples/XDS.b/