Deliverable D3.1.1

State of the Art Technologies and Architectures for EMPOWER

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Abbreviations

ADL	Archetype Definition Language
BP	Blood Pressure
BPM	Business Process Management
CCR	Continuity of Care Record
CCD	Continuity of Care Document
CDA	Clinical Document Architecture
CMS	Content Management System
DCM	Detailed Clinical Model
DICOM	Digital Imaging and Communications in Medicine
DBMS	Database Management System
ECG	Electrocardiogram
EHR	Electronic Health Record
EMR	Electronic Medical Record
ESB	Enterprise Service Bus
GLIF	Guideline Interchange Format
GUI	Graphical User Interface
HIS	Hospital Information System
HIT	Health Information Technology
HL7	Health Level Seven
IHE	Integrating the Healthcare Enterprise
ISO	International Standardisation Organisation
MIME	Multipurpose Internet Mail Extensions
MLM	Medical Logic Module
MUI	Multimodal User Interface
ODL	Observation of Daily Living
PHR	Personal Health Record
PHA	Personal Health Application
RIM	Reference Information Model
SOA	Service Oriented Architecture
TNM	Task Network Model
UI	User Interface
XML	Extensible Markup Language
XPHR	Exchange of Patient Health Records

1 Summary

D3.1.1 “State of the Art Technologies and Architectures for EMPOWER” summarizes an overview about the relevant research topics and technologies for the EMPOWER project. This comprises

- National and European projects of interest for EMPOWER (chapter 2)
- Relevant topics from the medical point of view, in particular diabetes management and diabetes guidelines (chapter 4 and 5) and tools supporting care pathways and guidelines (chapter 6)
- Patient Empowerment approaches and supporting technologies (chapter 7)
- Health information technology standards and interoperability Initiatives such as HL7, IHE, ISO 13606, Archetypes and standards supporting PHR interoperability (chapter 8)
- Security & Privacy Mechanism (chapter 9)
- User environments supporting diabetes patients such as existing applications, sicualization approaches and feedback mechanismen (chapter 10)

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 self-management of diabetes patients based on PHRs and on context-aware, personalised services. EMPOWER focuses the research and development efforts on a patient-centric perspective that also involves healthcare professionals. EMPOWER provides knowledge-based Self-Management Pathways for diabetes patients. This includes

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

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

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

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

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

3 Related RTD Projects

3.1 National Projects

3.1.1 ByMedConnect - Improving communication by linking domains thus fostering integrated healthcare in Bavaria

Only few comprehensive electronic health record (EHR) systems have been implemented worldwide. On top of that, most of the ones in place are limited to regional and in-house use or restricted to health networks. Solutions that go across networks are rare and mostly still in the piloting phase. Reasons for that are manifold. Most doctors' office computers and hospital information systems (HIS) have their own proprietary data structures and interfaces. This prevents seamless electronic communication between healthcare professionals. Successful data exchange has to consider the needs of the recipient regarding form, content and timing of data transfer. However, so far, a unique definition concerning treatment data and a unique patient attribution scheme is missing. Other open questions concern data protection and the liability for the data (who has the right to access/alter the data).
ByMedConnect[3] - sponsored by the Bavarian State Ministry of the Environment and Public Health (StMUG) - develops and demonstrates a communication solution based on the standards Continuity of Care Record (CCR) and ISO EN 13606. CCR describes a central data set, which provides an overall summary of a patient's relevant medical information regardless of time and medical domain. Health professionals in the USA were heavily involved in its development and testing. According to ASTM International CCR is being used in routine in over 100 doctors' office computers and HISs. ISO EN 13606 enables an interoperable exchange of health data. It is based on an archetype model and maps medical concepts. Archetypes consider the variety of clinical requests as well as regional limiting factors. Thus it can be ensured that data from differing sources is correctly analysed and interpreted. By receiving relevant information from co-treating colleagues at short notice, the doctor is better informed on the patient's health status. The information that is being provided is independent from time and place and supports cross-sectoral care of the patient. Data that is being recorded in a standardised way (or was transformed to it) can be reused in different applications. This facilitates the integration of value-added services like a means to selectively explore the information needed that assist with the challenging task to deal with a growing amount of data. Therefore a method that allows for user-friendly and adaptive presentation of information contained in standardised medical records was developed.

Relevance for EMPOWER:
The semantic integration services of ByMedConnect facilitate the collection of data from heterogeneous sources (e.g. EHR, PHA, Measuring devices).
The integrated visualisation services for health professionals can be leveraged for patients.

3.1.2 EHR-Arche - Archetype based Electronic Health Record

Today's health care professionals can access an ever increasing amount of patient-related information and clinical knowledge, one of the most-promising applications being the Electronic Health Record (EHR). While several clinical and economic benefits are expected by the EHR, it may also lead to information overload, as the relevant information item that an EHR user searches for may be hidden in vast amounts of information within the lifelong EHR. Therefore, we see an urgent need for supporting EHR users in selectively retrieving information that is relevant in their respective search context. Besides document meta-data,

[3] www.bymedconnect.de

archetype-based dual-model EHR architectures propose a corresponding support, but it is unclear whether they fulfil this promise. Overall, it is unclear what the information needs of health care professionals are, and how to support them adequately by dual-model EHR architectures.
The objectives of the EHR-Arche project[4] are therefore

1. to identify the information needs of health care professionals when accessing the EHR, considering the respective search context,
2. to develop concepts to fulfil these information needs by combining document meta-data and dual-model EHR architectures,
3. to evaluate the developed concepts in a trial implementation.

The project is innovative in the sense that information needs of health professionals were analysed, and it proposes concepts to combine meta-data-based and archetype-based searching to optimize precision and recall of EHR queries. The concepts are based on international standards such as IHE XDS to provide a future-proof, vendor independent solution. The archetype-based search takes into account ISO 13606 and HL7 CDA, both important international EHR standards.
An IHE-XDS based architecture was developed that comprised, in addition to standard IHE-XDS actors such as Document Repository and Document Registry, the following actors: (a) Document Consumer Actor that allows to query and retrieve both unstructured (PDF) and structured archetype based documents using a standard XDS document query, or to search both for individual information items and for combinations of items using a content-based query.
The project developed 128 ISO 13606 archetypes that support German as well as English language. They represent 446 clinical information items which were collected in an analysis of the information needs of physicians when treating diabetes patients[5].

Relevance for EMPOWER:
The result obtained while developing and testing an approach that combines an IHE-XDS based EHR architecture with ISO 13606 Archetypes can deliver valuable input to the EMPOWER project.
The comprehensive set of diabetes specific Archetypes has the potential to form the basis for the development of the Archetype based knowledge models of EMPOWER.

3.2 European Projects

3.2.1 FP7 248240 – iCARDEA - An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices

Over the last decade, there has been an exponential growth in the number of cardiac implantable devices (CIED), in their electronic and software complexity widening their function and application. However, due to their limited processing capabilities restricted by their size, CIEDs need to be supported with software running on the data centers. Currently, the data center processing is standalone with their custom software and proprietary interfaces. iCARDEA will expose CIED data through standard interfaces to develop an intelligent platform to semi-automate the follow-up of CIED patients with context-aware, adaptable computer interpretable clinical guideline models. The computer interpretable guideline models to be developed will be designed from re-usable building blocks to facilitate personalization of the patient care and follow-up workflow. The CIED data will be exposed

[4] http://www.meduniwien.ac.at/msi/arche/content/project-description
[5] http://iig.umit.at/projekte/arche/Final%20Report%20EHRArche%20April%202012.pdf EHR Arche final project report

through standard interfaces based on the HL7, ISO/IEEE 11073 standards and the IHE IDCO Profile. EHR interoperability will be achieved by exposing legacy EHR systems through standard HL7 CDA interfaces so that information about patients' medical history such as the non-cardiac conditions denoting contraindications to the proposed therapies can be obtained from the patient EHR data and used in the clinical follow-up workflow. The clinical guidelines will automate the risk assessment and hence support medical professionals by automatically assessing the situations and generating alarms. iCARDEA will introduce outcome indicators with the related steps of the clinical guidelines to measure the success of the care process so that it can be combined with expert feedback to achieve a closed-loop system. The patients will be empowered with Personal Health Records (PHR) to enable informed and responsible participation in the process and for their education. iCARDEA platform will provide comprehensive security and privacy mechanisms and will be validated in a hospital in Austria with CIEDs from two major vendors.

Relevance for EMPOWER:
The two partners SRFG and SRDC are also partners in the iCARDEA Project. The know-how gathered in the iCARDEA will be transferred to the EMPOWER project. Especially, the PHR System developed by SRFG and Careplan Engine developed by SRDC will be reused in the EMPOWER Project.

3.2.2 FP6 027074 – SAPHIRE - Intelligent Healthcare Monitoring based on Semantic Interoperability Platform

The medical practitioners of all levels are becoming more overloaded as the aging population of Europe increases. The health services of the EU can claim considerable credit for the decline in mortality over the last thirty years. However, this success, particularly the fall in mortality rates among older people, has increased the demand for healthcare. On the other hand Information technology, combined with recent advances in networking, mobile communications and wireless medical sensor technologies offer a great potential to support healthcare professionals and to deliver health care services at a distance hence providing the opportunities to improve healthcare.

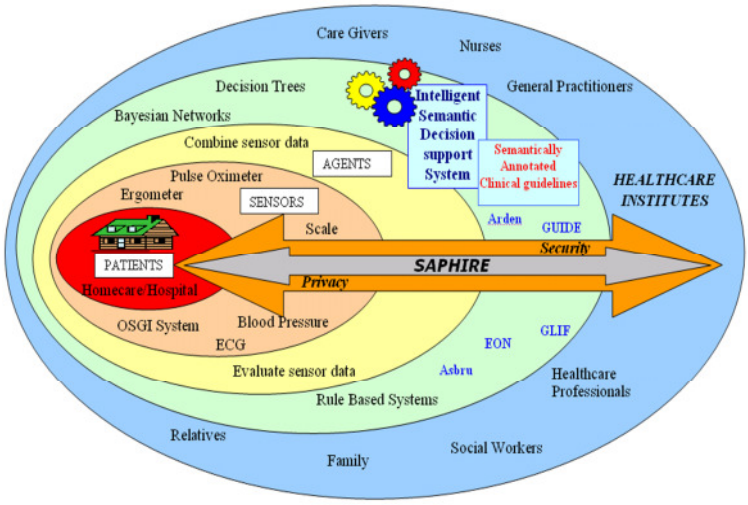

Figure 1 Interaction domains covered by the Saphire project

Indeed, information technology has long promised to improve health care by assigning a scarce resource, a doctor's time, wherever and whenever it is needed, but so far it has struggled to deliver on the promises. The problem is that patients' records, for example, are often stored on different platforms in various formats. Saphire cracks that problem by

converting diverse formats into one that can be combined with other data by using semantically mediated ontology mapping. Figure 1 depicts the different domains that need to be integrated with each other to seamlessly interoperate. It is an intelligent clinical decision support system (ICDSS) offering a range of services that combine scattered information stored in different systems into a new, more powerful application which means better and cheaper medical care. The system also provides an enormous boost to the training of young doctors through the semi-automatic deployment of clinical guidelines to healthcare institutes which eventually minimizes the risk of medical errors.
The SAPHIRE6 project, which started in Jan, 2006 and ended in Jun, 2008, successfully developed an intelligent healthcare monitoring and decision support system which was based on a platform that integrated the wireless medical sensor data with hospital information systems as depicted in Figure 2 to address the problem of an ever-increasing workload in medical fields due to the increasing percentage of elderly people. This system is designed to continuously monitor the patients delivering alarms to the medical personnel.

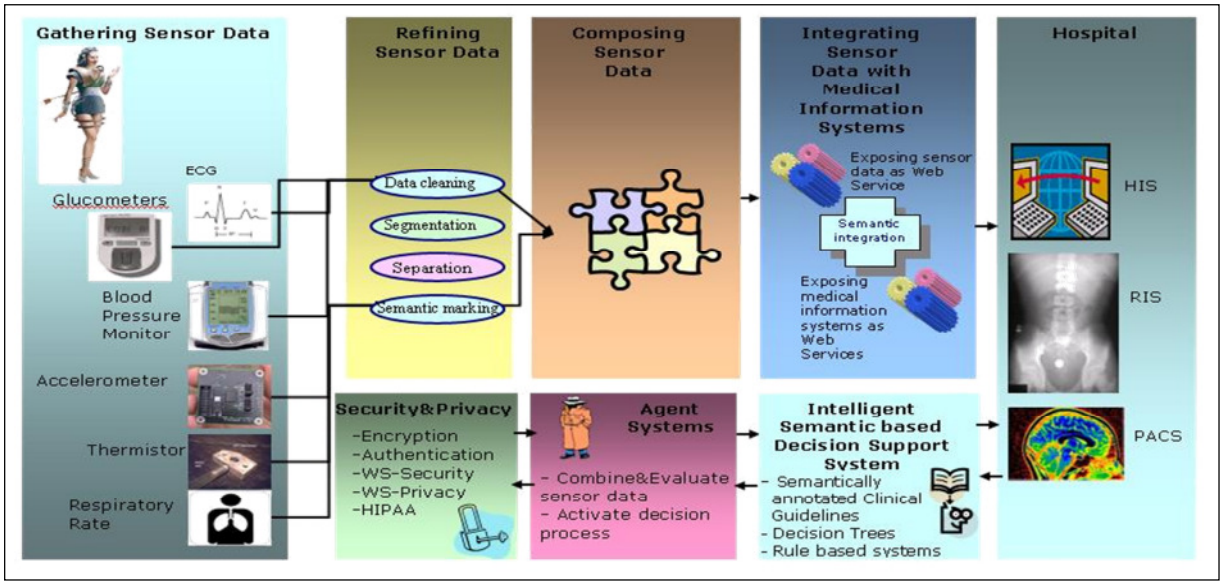

Figure 2 Overview of the Saphire Architecture

Patient monitoring was achieved by using agent technology where the "agent behaviour" is supported by intelligent clinical decision support systems which are based on computerized clinical practice guidelines. Patient vital signs are received through Web services from the sensor devices associated with the Gateway computer, and patient history stored in medical information systems accessed through IHE XDS Registry/Repository to tackle the interoperability problem. In this way, not only the observations received from biosensors but also the patient medical history could be used in the reasoning process in the clinical decision support system. This is an essential component, because in clinical guidelines, the physiological signs received from wireless medical sensors, the patient care plan and medical history (such as previous diagnosis, medication list, allergy/adverse drug reactions) all affect the clinical path to be followed.
The intelligent healthcare monitoring system was deployed through two pilot applications, one for homecare monitoring of cardiovascular patients in Germany, and the other to monitor cardiovascular patients in a hospital in Romania. To subscribe to critical data delivery, clinicians simply used a Web-based program indicating desired alerts, thresholds, delivery methods (SMS / e-mail / Web / Pager) or to build a patient coverage list. Once subscribed, clinicians immediately received clinical notifications and reminders.

[6] http://www.srdc.metu.edu.tr/webpage/projects/saphire/ This work is supported by the European Commission through IST-27074 SAPHIRE project and in part by the Scientific and Technical Research Council of Turkey, Project No: EEEAG 105E133.

Relevance to EMPOWER:
Two most significant contributions of the SAPHIRE Project for EMPOWER are the extended Guideline Interchange Format (GLIF) model for the execution of clinical guidelines and the generic clinical guideline execution engine. These outcomes will be adapted with further extensions and modifications (e.g. to handle PHR data as well) in the EMPOWER Project. SAPHIRE also addressed interoperability of EHRs and medical device information.

3.2.3 DIABCARD - Improved Communication in Diabetes Care Based on Chip Card Technology

DIABCARD[7] -funded by the European Commission in the framework of the research programs on Health Technology and Informatics- aimed at improved care for chronic diseases by using state-of-the-art technology for documentation and communication. Focused on shared care for diabetes patients, the project prepared for routine applications of a chip card-based medical information system (DIABCARD CCMIS[8]) to replace paper records. The DIABCARD CCMIS serves people with diabetes for ambulatory as well as hospital care.
The system consists of an application system, the Core System, a patient chip card ("DIABCARD") and an access card for health professionals. Simplicity, data security and integrity, customisation, internationalisation, inter-operability and confidentiality were major issues. The developed DIABCARD Core System includes a patient record management system and handles administrative and medical data, such as medical anamnesis, and physical examination data. It is based on the DIABCARD data set, which includes common standard datasets (e.g. DiabCare Basic Information Sheet) and consists of over 1500 data items, and is document and visit oriented.
DIABCARD was successfully implemented in Austria, France, Germany, Greece, Italy and Spain. A 3-months pilot showed that the chip card capacities as well as access and security functions are sufficient for a speciality medical record. At that time response time and storage capacity were an issue. It was demonstrated that the introduction of the patient data card does not require any vital modification of existing structures and practices.
The DIABCARD Project offers a solution for standardised computer-based diabetes documentation. DIABCARD considerably contributed to gain knowledge about defining appropriate systems in the field of health care.

Relevance for EMPOWER:
The comprehensive DIABCARD data set can serve as a source for the development of clinical data models for diabetics.

3.2.4 SemanticHealthNet

SemanticHealthNet[9] according to Europe's Information Society Portal[10] is a EU funded 'Network of Excellence' that will develop a scalable and sustainable pan-European organisational and governance process for semantic interoperability of clinical and biomedical knowledge, to help ensure that EHR systems are optimised for patient care,

[7] http://www.ehto.org/ht_projects/html/dynamic/26.html
[8] http://www.helmholtz-muenchen.de/en/medical-information-systems/projects-of-the-workgroup-medis/supportive-systems/diabcard/index.html
[9] www.semantichealthnet.eu
[10] http://ec.europa.eu/information_society

public health and clinical research across healthcare systems and institutions. The kick off meeting gathered, in Bonn early January, all consortium members these comprise more than 40 internationally recognised experts, including from USA and Canada, ensuring a global impact. Through a clinically-driven work plan, exemplified in cardiovascular medicine, SemanticHealthNet will capture the needs for evidence-based, patient-centred integrated care and for public health, encapsulating existing European consensus in the management of chronic heart failure and cardiovascular prevention. Experts in EHR architectures, clinical data structures, terminologies and ontology will combine, tailor and pilot their best-of-breed resources in response to the needs articulated by clinicians and public health physicians. SemanticHealthNet will also refer to the SemanticHEALTH and CALLIOPE roadmaps and will link with epSOS II and the eHealth Governance Initiative. The majority of the deliverables will be made public to ensure a wide dissemination of the project's results.

Relevance for EMPOWER:
SemanticHealthNet aims to develop a scalable and sustainable pan-European organisational and governance process to achieve Semantic interoperability of EHR systems across healthcare systems and institutions. Results of this FP7 project will be considered as soon as they become available.

3.2.5 DIAdvisor - Personal Device for Glucose Prediction and Advice in Diabetes

DIAdvisor is a FP7 project[11] that aims at the development of a Blood Glucose prediction device which uses easily available information to optimise the therapy of patients with diabetes. The key objective of diabetes treatment is to maintain the blood glucose at near to normal level. This is a demanding and difficult task for the individual patient and requires extensive involvement from Health Care Providers. Particularly, the main objectives are:

- Develop a Blood Glucose Prediction and Advisory system to assist • patients
- Implement a device platform including vital sign and blood glucose • sensors
- Improve the DIAdvisor™ system through two consecutive clinical trial iterations
- Provide a medical device technology that minimises the diabetes-related • burden to patients and to healthcare systems by increased patient empowerment.

The DIAdvisor concept includes non-invasive and minimal invasive sensors providing information regarding the patient, a mathematical model for prediction of near-term blood glucose levels and a handheld device platform for computation and interface to the patient. In the hands of the patient DIAdvisor will constitute a mobile near-term blood glucose predictor and treatment advisor useful for optimisation of the therapy.
One main effect of DIAdvisor will be to reduce the negative effects of long-term hyperglycaemia without increased number of hypoglycaemias and therefore provide a reduction of the associated health costs. The expected outcome will represent a sound basis to improve diabetes control and quality of life in large populations of insulin-treated patients in terms of a reduction of debilitating diabetic complications and costly expenses from Health Care Systems.

Relevance for EMPOWER:
Results of the DIAdvisor project, such as models for prediction and advice can be useful for the self-monitoring services in EMPOWER.

[11] www.diadvisor.eu

3.2.6 ICT PSP 297260 PALANTE - Patient Leading and Managing Their Healthcare Through E-Health

The Ministry of Health of Turkey is part of one more international project that is quite similar to EMPOWER. Patient Leading and Managing Their Healthcare Through E-Health (PALANTE), which started on the very same date as EMPOWER, 1 February 2012, is an EC supported e-health project that aims to give patients more awareness of and responsibility for their disease providing online disease management. For the pilot in Turkey, the ankylosis spondylitis disease was selected. Physicians and patients who will participate in the pilot will be provided by the Turkish League Against Rheumatism, the Ministry of Health of Turkey will be giving governmental, legal and administrative support, and SRDC, who is also a beneficiary of the project, will provide web services that will be used by the physicians and the patients. Quite similar to the EMPOWER pilot, the PALANTE pilot will enable ankylosis spondylitis patients to send their health information to their assigned doctors, and doctors will be able to respond to the patients very quickly.

Relevance for EMPOWER:
Because of the resemblance of PALANTE to the EMPOWER project, the activities within the projects will mutually enrich and reinforce each other, even though the two projects are focusing on different diseases.

4 Diabetes Disease Management

4.1 Best Practice and Common Practices

The following information provided in this subchapter is solely written for the purpose of this material, basing on the figures and information contained in several resources such as Turkish Annual Book of Statistics, Common Diabetes Practices, and interviews with doctors and nurses.

HbA1c Diagnosis: The American Diabetes Association recommends HbA1c as well as venous plasma glucose levels to diagnose type 2 diabetes with diagnostic values being ≥6.5%.

Reporting: Internationally there is a move towards a standard based on the chemistry of HbA1c which would result in the reported values being considerably lower (by approximately 2%, e.g. as 6% instead of 8%).

Health care for diabetes Type 2

Quarterly review

- **Discourage smoking**
- **Review symptoms**
- **Check weight, BP**
- **Review self-monitoring**

Once control has been achieved the routine visit should review:

History:

Review SNAP profiles (Smoking, Nutrition, Alcohol, Physical activity), patient's record of home testing and quality control results, foot symptoms.

Examination:

Check weight/waist, height (children and adolescents), blood pressure, feet examination if new symptoms or at risk (e.g. neuropathy, peripheral vascular disease).

Investigation:

Measure glycated haemoglobin (HbA1c) at least six monthly. Watch for intercurrent illnesses such as urinary tract infections, thyrotoxicosis etc. which may alter degree of control. Asymptomatic urinary infections are common in patients with diabetes, especially older women.

Quarterly review

Ask about: Smoking
Nutrition
Alcohol intake
How much exercise and how often
Any problems with medication
Check: Weight/waist
Height (children and adolescents)
Blood pressure
Feet examination without shoes, if new symptoms or at risk
(e.g. neuropathy, peripheral vascular disease)
Review: Goals with patient to identify specific areas of focus for doctor consultation

Annual review

- **Review goals of management**
- **Check for diabetic complications**
- **Update immunisation schedule**
- **Consider specialist referral**

The yearly review is a time for more detailed assessment, updating the problem priority list and re-establishment of goals, and contractual arrangements for management. Eating plan, lifestyle, home monitoring and treatment need to be reviewed. There needs to be a full system review checking for vascular, renal, eye, nerve and podiatric problems. As there is an increasing trend towards involving specialist allied health professionals, the yearly visit is a good opportunity to coordinate follow-up.

Full physical assessment

- Cardiovascular system
- Eyes
- Peripheral nervous system
- Feet

Immunisations:

- Influenza once per year
- Pneumococcal Non-Aboriginal and Torres Strait Islanders:
- <65 – single dose and revaccinate age 65 or after
- 10 years whichever later
- >65 – single dose and revaccinate 5 years later
- Aboriginal and Torres Strait Islanders:
- <50 – single dose and revaccinate age 50 or after
- 10 years whichever later
- >50 – single dose and revaccinate 5 years later
- Tetanus Booster at age 50 (unless booster has been given within 10 years)

Investigations:

(Annually if below target, more frequently if being actively treated)
Lipids – triglyceride; HDL-C, LDL-C and total cholesterol
Renal – microalbuminuria and plasma creatinine (eGFR)

Referral:

Ophthalmologist/optometrist – second yearly with no retinopathy, more frequently if abnormal.
Diabetes educator, dietician, podiatrist – if patient has or has developed a problem requiring review.
Pharmacist – for a Home Medicines Review if the patient is likely to have problems with medication (e.g. taking more than 5 types).
Oral health professional – especially if periodontal disease is present.

Annual nursing review

Ask about: Smoking
Nutrition (last contact with dietician or diabetes educator)
Alcohol intake
How much exercise and how often
Any problems with medication
Any changes in medication (by doctor/pharmacist or patient)
Chest pain
Vision (when last checked)
Any foot discomfort
When was last podiatry and dental check

Immunisations (include Flu and Pneumovax)
Family history and update
Check: Weight/waist
Height (children and adolescents)
Blood pressure
Feet examination: without shoes, pulses, monofilament check
Blood glucose at examination
Urinalysis
Visual acuity
Review: Goals with patient to identify specific areas of focus for doctor consultation
Last care plan to identify timely referrals

Records:
The use of a check list and a separate sheet in the patient's notes (preferably attached to the front of the problem list) can be used to record the frequency and results of these assessments.
Medical software incorporates acceptable forms of diabetes records. These accrue to support the annual cycle of care which can be used for the Medicare items.

Relevance for EMPOWER:
Best practices and common practices in diabetes disease management should be taken into consideration when the online disease management system for EMPOWER is being structured.

4.2 Example Germany

Diabetes management in Germany has an informative character. That means the patient is informed about their illness with symptoms, treatment options, medications and medical specialists. The methods of communication are used like brochures, memories (necessary for example doctor visits) by telephone or letter as well advice about the medical therapy in the pharmacy, statistical analyses, training and support of telehealth technique.
The building of a diabetes registry was funded by the Federal Ministry of Education and Research since 2008. Within a project in 2010 starts the diabetes registry "DiaRegis" for ambulant therapy of patient type 2 diabetes. Also there is a diabetes registry (named "DiMelli") of HMGU for Bavaria. The reliability of these numbers depends on the messages of doctors. Before there was a registry just in the east part of Germany, which was not maintained after the german reunification.

Following again the content of EMPOWER D211 (page 27-28) in short form.

Examples for Diabetes Management in Germany

Type 2 diabetes
- agreement on individual outcomes (e.g. HbA1C, blood pressure values) and appropriate therapy planning
- participate in training, including nutritional advice and guidance on blood sugar, high blood pressure and blood pressure self-monitoring
- test for protein in the urine (as needed, for example, once a year)
- annual monitoring of renal function (serum creatinine value)
- at least once a year examination of the retina
- at least once a year, quarterly inspection of the feet, for patients with an increased risk

Type 1 diabetes

- agreement on individual outcomes (e.g. A1C, blood pressure values) and appropriate therapy planning
- participate in training (depending on training level), high blood pressure with instructions for self-control
- to test at least once a year protein in the urine with multiple positive evidence of renal function (serum creatinine value)
- from the 5th year annual examination of the retina
- quarterly inspection of the feet for patients with an increased risk. At least once a year

Relevance for EMPOWER:
Uniform structure and sequences are critical. EMPOWER aims changing the previous treatment of informed patient to active patient, so that the patient perceives self-control and responsibility for his health.

4.3 Example Turkey

Systems for care
Diabetes is a complex disorder and requires a systematic approach to care. There is evidence that this approach in the general practice setting results in better outcomes.

A systematic approach to care is facilitated by the use of:

1. **Disease register:** This is a list of all patients in the practice with diabetes and basic demographic data. The register can also include clinical information. This allows tracking of the patients' clinical status and their need for on-going care.
2. **Recall system:** This facilitates timely recall of patients when certain aspects of their care require review e.g. recall for annual review, ophthalmologist review, etc.
3. **Flow charts:** Included in the patients' notes; these allow following of clinical parameters and flag when interventions or investigations are necessary.
4. **Review charts:** Included in the patients' notes, these are checklists for annual and three monthly reviews to facilitate thorough coverage of all issues at these milestone consultations.

Medical monitoring
Regular follow-up visits offer an opportunity for the general practitioner and patient to explore the patient's understanding, fears and concerns about diabetes. Some practices run diabetes clinics, often delivered by practice nurses. The use of practice protocols, checklists and algorithms that have been developed by the doctors and nurses in a practice ensures that the practice nurse can undertake a large proportion of the routine care (under the clinical oversight of the doctor). The following is a guide for the doctor's oversight of patients. A suggested checklist for nurse activity appears at the end of each section. Results of nurse consultation should be incorporated into the clinical record. As this checklist assumes the knowledge and clinical experience of a registered nurse, practices should use it according to the professional and clinical status of their nursing staff.

- **Relieve acute symptoms.**
- **Optimise control of glycaemia and other risk factors for complications.**
- **Treat existing complications.**
- **Maintain other preventive activities.**

Priorities of management

Patient and carer counselling includes identifying and addressing concerns which maybe causing distress and adversely affecting management. If the patient is symptomatic then treatment of hyperglycaemia needs to be prompt but if the patient is asymptomatic initial treatment can be more relaxed. The long term medical goal is the prevention of complications. Control of blood pressure and dyslipidaemia are important as well as glycaemic control in preventing complications. The overall aim of management is to improve quality of life and prevent premature death:

Short term:

Relief of symptoms and acute complications

Long term:

- Achievement of appropriate glycaemia
- Reduction of concurrent risk factors
- Identification and treatment of chronic complications
- Maintain other preventive activities (e.g. immunisation)
- **All patients should be advised of the risks of smoking and offered assistance with smoking cessation.**
- **Assess cardiovascular risk and consider low dose aspirin for cardiovascular protection in high risk patients.**

Referral

All people with type 2 diabetes need to see an ophthalmologist or optometrist initially and then at least every two years.

Diabetes educator:

Initially and then as patient becomes more familiar with management, as considered necessary by patient, doctor or diabetes educator.

Dietician:

Ideally initially, and as considered necessary by patient, doctor or dietician.

Endocrinologist:

- Children, adolescents and adults with type 1 diabetes if the general practitioner is not confident with management.
- Pregnant women with established diabetes and women with gestational diabetes.
- People with diabetes and uncontrolled hyperglycaemia or with significant complications.

Ophthalmologist or optometrist:

- Fundal examination (dilated pupils).
- The presence of cataracts needs to be checked.
- Assessment:
  - Prepubertal children: referral at puberty
  - Adults: referral at time of initial diagnosis
  - Thereafter at least every two years.

Podiatrist:

Ideally initially, and then regularly if there is/are peripheral vascular disease, neuropathy, skin and/or nail problems and if there is difficulty in cutting toenails. Consider referral to a high risk foot clinic if ulceration or intractable foot pain is present.

The team approach

- Consider referral to a diabetes educator or dietician for consolidation of education.
- A podiatrist's help needs to be sought if neuropathy, peripheral vascular disease, foot abnormality or calluses are present.
- Rebates for attendance at private dentists and exercise professionals are available for patients under the Enhanced Primary Care Program, as part of a Team Care Arrangement.
- Medicare subsidies are available for group education sessions involving diabetes educators, dieticians and exercise physiologists.

In the team management of diabetes the **patient** is the central member. For patients to be actively involved in their care they must understand the condition, its effect on health and the practicalities of management. Good communication between team members is important so that advice is consistent and not confusing for the patient.

Relevance for EMPOWER:
Although it is not foreseen that the Turkish pilot will differ from the German one substantially, it should be remembered that there might be some cultural differences, especially about the lifestyles and daily living patterns of the diabetic individuals.

5 Care Pathways and Guidelines for diabetes

5.1 Best Practice and Common Practices

The German Diabetes Society ("Deutsche Diabetes Gesellschaft" - DDG) created evidence-based guidelines for Germany. They should provide guidance in the care of diabetics. The guidelines support the Implementation of the Health Care Structure Act 2000[12]. Correspond to the benefits, the need and cost effectiveness of a measure under the current state of scientific knowledge. In the diabetes guidelines of the DDG include scientific evidence-based guidelines, appropriate practical recommendations and guidelines, and patient versions of these guidelines will be developed. The goal is ultimately a unified teaching the core content statements for the diagnosis, classification, prevention, treatment, therapy monitoring and long-term care of diabetes and its concomitant and secondary disorders. The guidelines of the DDG program include:

- the creation of evidence-based diabetes guidelines (expert version) on their own initiative or as a partner in the National Program Management Guidelines and
- the creation of practical recommendations based on evidence-based guidelines
- a patient version of the guidelines[13].

Evidence-based guidelines

- Neuropathy in diabetes in adulthood Kidney disease in diabetes in adulthood
- Epidemiology and course of diabetes mellitus in Germany
- Diagnosis, treatment and monitoring of diabetic retinopathy and maculopathy
- Prevention and treatment of retinal complications (type 2)
- Diagnosis and treatment of heart disease in diabetes mellitus Treatment of type 1 diabetes mellitus
- Drug antihyperglycemic therapy for type 2 diabetes mellitus
- Prevention and Treatment of Obesity
- Psychosocial Factors and diabetes mellitus
- Diagnosis, treatment, follow-up and prevention of diabetic foot ulcers
- Prevention and treatment strategies for foot complications
- Diagnosis, treatment and monitoring of diabetes mellitus in childhood and adolescence
- Diagnosis, treatment and monitoring of diabetes mellitus in old age
- Nutrition and diabetes mellitus
- Diabetes and pregnancy gestational diabetes mellitus
- Diabetes and sport

Practice recommendations of the DDG

- Definition, classification and diagnosis of diabetes mellitus
- Diabetic retinopathy and maculopathy
- Diabetes mellitus and heart
- Treatment of type 1 diabetes - Summary Diabetes mellitus type 2
- Obesity and diabetes mellitus
- Psychosocial Factors and Diabetes Mellitus diabetic foot ulcers
- Diabetes mellitus in childhood and adolescence Diabetes mellitus in old age
- Diabetes, sport and exercise
- Gestational diabetes mellitus
- Diabetes and pregnancy

[12] http://www.gesetze-im-internet.de/bundesrecht/gsg/gesamt.pdf
[13] http://www.deutsche-diabetes-gesellschaft.de/leitlinien/evidenzbasierte-leitlinien.html

Patient Guidelines
- Diabetes and pregnancy
- Pregnancy diabetes (gestational diabetes)

Relevance for EMPOWER:
The preparation and publication of a guideline is not sufficient for their use in clinical practice. The challenges are the strategies for implementing guidelines. These must be based on the national and regional conditions and structures of care and support treatment processes. This means ensuring the transfer of recommendations for action in individual actions or behaviour of physicians and other healthcare providers and patients.

5.2 Example Germany

In Germany there are no systematic programs for nationwide implementation of guidelines. Particularly in programs of structured and integrated supply the need for a quality management with a unified documentation and mandatory regulations for diagnosis, treatment pathways, interdisciplinary communication and cooperation processes is obvious. There are limited regional supply and interdisciplinary cross-sectorial programs of care with defined clinical care pathways. The strategies for the implementation must also provide for uniform standards of training, documentation, systems and documentation activities and quality assurance measures and practical tools. The challenge is to implement a comprehensive, integrated and comprehensive diagnosis of evidence-based guidelines focused care.
The diabetes care practice in Germany has been shown that a partnership between dialectologists, podiatrists, angiologists, radiologists, general surgeons, vascular surgeons, orthopaedic surgeons, orthopaedic shoemakers, infection control and patient representatives to be successful. The procedure and instruments of the national programme for supply guidelines provide a suitable platform for evidence-based treatment guidelines agreed amongst the parties. These can meet the demands of a largely standardized diagnosis and treatment of diabetes diseases[14].

Relevance for EMPOWER:
The EMPOWER-platform should be a base to manage the structure und process of diabetes care for all kind of physicians according to the German guidelines. Therefore the platform has to consist components of security (e.g. role based authorizations, single sign-on), data (e.g. indexing, searching, multi language support), integration (e.g. healthcare connectors, web services) and management (e.g. scheduler, data exchange, user preferences).

5.3 Example Turkey

Any guideline should be flexible: management and empowerment should take into consideration the patient's age, educational level, cultural background, the current scientific knowledge, the availability of resources and the range of particular preferences of the patient and professionals involved. The overall goals in degree of control and lifestyle modification must be realistic. The physician can have an important positive effect on the patient's lifestyle. Education of a partner or other responsible carers is an important factor in maintaining positive lifestyle changes in patient. Similarly the physician can ensure that

[14] http://www.aerzteblatt.de/archiv/61200

management and empowerment is individualised to the person's cultural, educational and financial status. The physician is a key member of the therapeutic team. In many instances the physician is the principal medical professional in the vast majority of patients, even though these patients are empowered to observe their daily livings and manager their disease controls. In all situations the paramount consideration is the patient's well being.

Plan of continuing care

Members of the care team:
The following professionals are important in the team approach to diabetes:

- **Diabetes educator:** The person who is capable of educating the patient on diabetes awareness, control and management. May be the doctor himself.
- **Dietician:** Dietary expert who will counsel to the patient about nutrition.
- **Endocrinologist**: The physician who deals with the endocrine glands and their secretions, especially in relation to their processes or functions.
- **Diabetologist:** May be the diabetes educator or endocrinologist.
- **Paediatrician:** A medical practitioner who specializes in the branch of medical science concerned with children and their diseases. May be necessary for the management of diabetes of the young.
- **Exercise Professional:** Physical training, activities and exercises professional. Physical exercises may prevent complications and insulinization (being dependant on insulin treatment) rate in early phases of diabetes.
- **General practitioner:** A medical practitioner whose practice is not limited to any specific branch of medicine or class of diseases.
- **Ophthalmologist/optometrist:** a doctor of medicine specializing in the branch of medical science dealing with the anatomy, functions, and diseases of the eye.
- **Oral health Professional**: Safely managing the patient with diabetes requires effective communication among multiple health care providers. Dentists must be familiar with techniques to diagnose, treat and prevent stomatological (the science dealing with the mouth and its diseases) disorders in patients with diabetes.
- **Pharmacist:** A person licensed to prepare and dispense drugs and medicines; a druggist
- **Podiatrist:** a person qualified to diagnose and treat foot disorders.

Counselling the person with diabetes

The diagnosis of diabetes can be very stressful for both younger and older patients. Initial denial of the condition (i.e. a grief reaction) is normal. But if denial continues, diabetes care can be compromised.

The diagnosis of diabetes may have a profound effect on people engaged in certain occupations, e.g. machinery operators, pilots, heavy vehicle drivers, divers, etc. While not always prohibiting many of these occupations, the diagnosis of diabetes may require careful career counselling.
Lifestyles which have been established for many years are not easy to change and health care professionals cannot expect immediate adherence to the plan of management. Assess the SNAP risk factors (Smoking, Nutrition, Alcohol and Physical activity) and establish a long term lifestyle plan.

It is important for the patient to have all the information available so that a common sense of purpose between the health care professionals and the patient can develop. This takes time and some patients may decide to reject advice. Professionals need to maintain an open approach and emphasise that help is available when required.

Weight reduction is often difficult. A combined program of healthy eating, physical activity and education directed at behavioural changes is often successful. Carer and peer

encouragement helps these behavioural changes. Health care professionals need to be sensitive to patient views concerning diabetes and be ready to counsel. The normal stresses of daily living can affect diabetes control. Seek opportunities to help patients regain.

Education is on-going and needs to continue for the rest of the person's life. Diabetes knowledge, especially self-care skills (blood glucose monitoring, foot care, insulin administration) need to be assessed regularly (e.g. as part of the complication screen at the twelve monthly review).

Physical activity

- Regular physical activity improves metabolic control and reduces other cardiovascular risks.
- Patients on insulin, sulphonylureas or repaglinide may need to take special precautions to prevent hypoglycaemia.
- Appropriate care of feet during physical activity is important.

Increasing physical activity improves metabolic control in people with diabetes. Low level aerobic exercise (e.g. brisk walking for half an hour per day) and physical resistance training have the following benefits:

- Improved glucose tolerance as insulin sensitivity increases
- Increased energy expenditure resulting in weight loss
- Increased feeling of well being
- Increased work capacity
- Improved blood pressure and lipid profiles.

Aerobic training which 'makes you puff ' and brings the heart rate up to 60–70% of maximum (220 – age [years] beats per minute) for a minimum of 30 minutes 3 or 4 times per week, establishes and maintains fitness and aerobic capacity. >150 minutes per week of moderate intensity physical activity (e.g. walking) is recommended. When prescribing a physical activity program a careful history should be taken. Special attention needs to be paid to exertion-induced symptoms such as chest or abdominal discomfort or syncope. People with type 2 diabetes frequently have silent macrovascular disease. Consider second yearly ECG if a patient is over 50 years old and has at least one vascular risk factor. Screening with a stress ECG is not indicated in asymptomatic individuals, but specific symptoms need to be actively investigated. Isometric exercises such as heavy weight lifting (high load, low repetition) may increase blood pressure, increasing the risk of vitreous haemorrhage and sudden cardiac events. However, resistance programs using moderate weights and high repetition can be part of an exercise program for those with diabetes and have been shown to improve glycaemic control.

People requiring insulin may need to increase their carbohydrate intake and/or decrease their insulin before exercise. They need to also carry some refined carbohydrate with them. Similarly people with type 2 diabetes taking sulphonylureas or repaglinide may need to take extra food and/or reduce their medication.

People requiring insulin need to be aware of potential delayed effects of physical activity on glucose levels, in particular delayed hypoglycaemia 6–12 hours after cessation of the activity. People with diabetes need to be advised to cease their activity if they develop cardiovascular symptoms or even if they just feel unwell. However, patients with leg or buttock claudication need to be encouraged to continue physical activity with intermittent rests when leg or buttock pain occurs since this will gradually increase their capacity to exercise. The importance of appropriate foot care and comfortable, well-fitting footwear during physical activity needs to be stressed, especially if there is neuropathy, vascular disease, abnormal foot structure or previous foot ulcer(s).

Self-monitoring

- Self-monitoring is recommended for those on agents that can cause hypoglycaemia.
- Home blood glucose monitoring is the method of choice in most patients.
- The method and frequency of testing need to reflect therapeutic aims.

Blood glucose monitoring is recommended for those on agents that can cause hyperglycaemia (e.g. sulphonylureas and insulin). A balance should be reached considering the patient's age, need for ideal control and ensuring long term cooperation. Despite some recent controversial studies, the current view is that blood glucose monitoring is recommended.

Initially close supervision is recommended. A suggested initial schedule of testing is 3 to 4 blood glucose tests daily (early morning, plus other tests before + after meals). Frequent consultation with health care professionals is important.

Self-monitoring needs to be individualised and assist people with diabetes to understand the impact of medication, food and physical activity on blood glucose control. Frequency of self-monitoring can be determined according to the individual's self management goals.

In elderly patients testing on 1 or 2 days per week, varying the time, may be adequate if diabetes control is good.

Monitoring in Type 2 Diabetes need not be as intensive as with type 1 diabetes except when the normal pattern is broken (e.g. travelling, the festive season, intercurrent illness, changes to medication and diet). The ideal would be blood glucose estimation before + after meals. A reasonable approach in a patient with stable glycaemic control would include blood glucose estimation at different times of the day on 2–3 days each week.

Values before meals give information about baseline glycaemia which is affected by general factors such as weight, diet, activity and long acting medication. Values after meals give information about peak glycaemia which is affected by the baseline level, the food eaten and short acting medication.

People on either insulin or oral hypoglycaemic agents must be able to identify 'hypos' and understand treatment. Blood glucose monitoring can be of help. Targets for self-monitored blood glucose levels are 6–8 mmol/L fasting and pre-prandial, and 6–10 mmol/L 2 hours post prandial.

Many people learn to adjust their treatment schedule according to blood glucose levels and thus improve glycaemic control. People can measure their blood glucose using reagent strips that are read in the meter and/or visually (for some strips). Meters today are quick, reliable and simple to use. Use of the meter should be demonstrated.

People need to be competent in the technique of blood glucose monitoring before treatment decisions based on the readings are made. All meters need regular quality control checks by the user. All self blood glucose measurement systems have quality control materials.

Relevance for EMPOWER:
Since diabetes education is on-going and needs to continue for the rest of the person's life, EMPOWER guidelines should not be static either. When necessary, it should be updated according to the user needs.

6 Tools supporting Care Pathways and Guidelines

6.1 Computer supported Care Pathways

Tools supporting knowledge pathway engine and supporting EMPOWER components

6.1.1 Rule-based Process Platforms

When writing the EMPOWER proposal, a rule-based process engine was identified as a key component in the proposed architecture.

Activiti BPM Platform[15]

License: Apache 2

1. Activiti is a light-weight workflow and Business Process Management (BPM) Platform. The process engine is based on Business Process Modeling Notation (BPMN) Version 2[16] and Java. Web technology, user interfaces, is based on JSF (Java server Faces). Security of the web user interface layer can be configured such as using Spring[17] security. Also there is a means to assimilate individual and group identities. Activiti provides two main paths to integrate the identity solution (User manager and the group manager classes).

With the Activiti integration into Mule ESB, there are two deployment options. The main difference is the Activiti connector configuration in Mule ESB. Deployment otpis Options:

1. Run Mule ESB & Activiti Engine in one Spring container. The communication between Mule ESB and the Activiti Engine use the Activiti Java API.
2. Run Mule ESB standalone. Mule ESB communicates with the Activiti Engine using the REST API.

Of interest to EMPOWER is the

1. Supports BPMN2 process models including rule engine support (JBoss Drools[18])
2. REST API facilitates communication between the Process Engine and EMPOWER components. Also using SAML with REST services could address security issues.
3. Activiti-CDI module supports CDI Contexts and Dependency Injection (CDI), formerly known as JSR 299 is part of Java EE 6 stack, a standard on Dependency Injection, both SpringSource and Google were involved in the specifications
4. A means for integrating EMPOWER Authentication and Identity management[19] For example, providing the means to integrate EMPOWER individual and group identities into Activiti.

An alternative to the Mule ESB integration is the Camunda Fox engine[20] is an **Fehler! Verweisquelle konnte nicht gefunden werden.**example of an integrated JBOSS application server with Activiti, Activii-CDI module and the Drools Rule Engine.

[15] Activiti http://activiti.org/
[16] http://www.bpmn.org/
[17] http://www.springsource.org/
[18] JBoss Drools http://www.jboss.org/drools
[19] http://developer4life.blogspot.co.at/2012/02/activiti-authentication-and-identity.html
[20] Camunda Fox and Activiti http://www.camunda.com/fox/enterprise/open-source-vs-enterprise/ http://www.bpm-guide.de/2011/11/14/activiti-drools-wjax-2011/

Integration in JBoss AS 7 Community Edition bundled with the fox-engine (Activiti and Activiti-CDI)

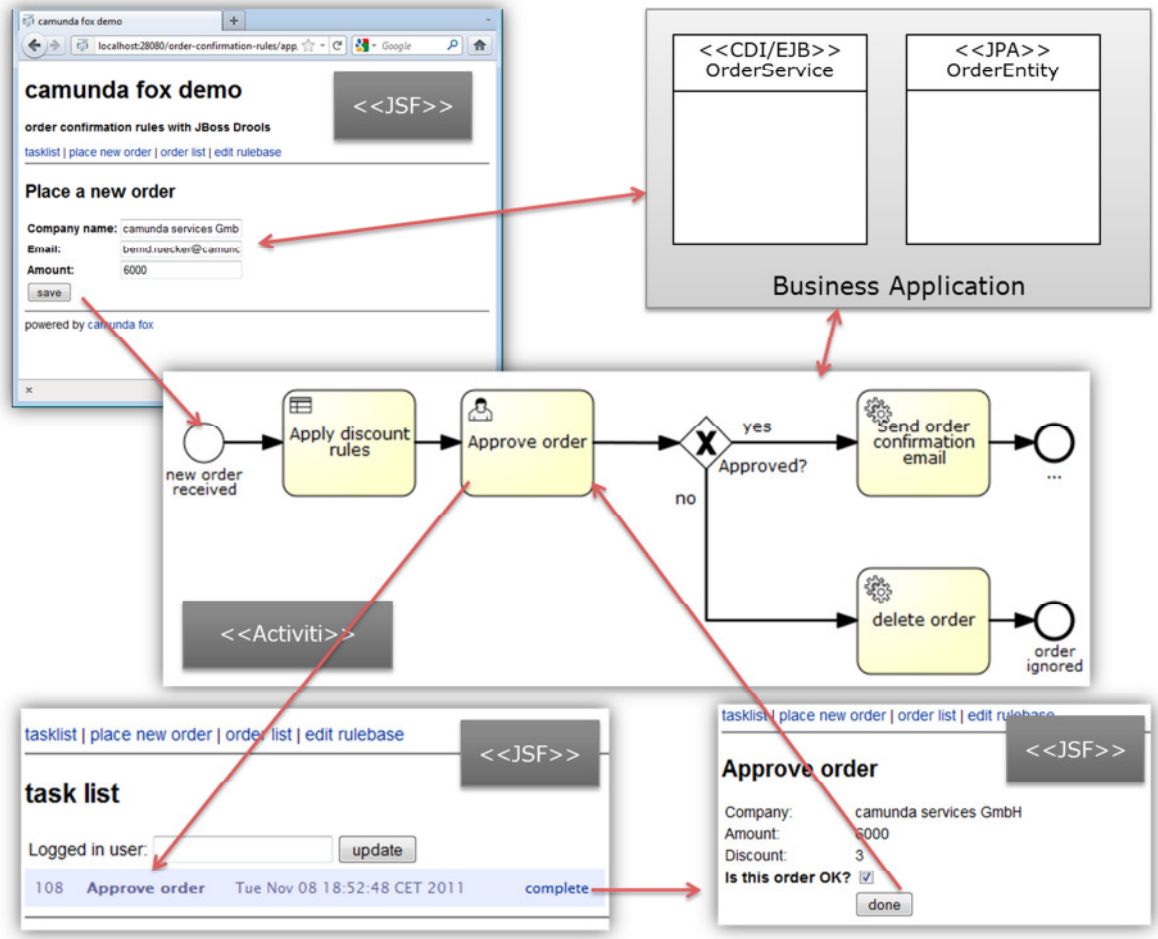

Figure 3 - Example Process engine integration with Activiti BPM Platform[21]

Activiti Process Engine API

From the Activiti ProcessEngine, there are services (Figure 4) for the workflow/BPM methods.

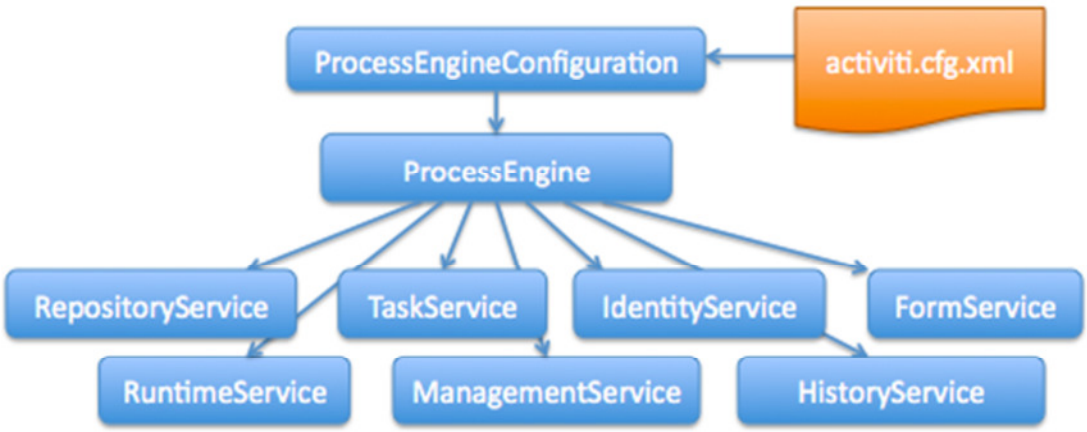

Figure 4 Activiti Process Engine - Engine API

[21] http://www.bpm-guide.de/wp-content/uploads/2011/11/OrderConfirmationProcessWithSurroundings.png

Modelling / Designing of BPM process models

The Activiti Modeller or Activiti Eclipse Designer plugin can be used to test, design, graphically visualize and deploy BPMN2 process models. Furthermore, the Activiti Eclipse Designer plugin provides technical support to add services, listeners, etc.
Useful for non-technical EMPOWER researchers, the Activiti Modeler is a Web UI based modeler for high-level design and requires no technical knowledge; they are simpler to design and communicate with developers.

JBOSS jBPM[22]

License: Apache license

jBPM is an open-source Business Process Management (BPM) software suite based on BPMN 2 and Java. This project relies upon Drools Flow and Drools Rules. Drools is also integrated in JBOSS ESB (Enterprise Service Bus) to support the rule engine.

6.1.1.1 Enterprise Service Bus (ESB) Platforms

As mentioned previously, in the EMPOWER proposal, the process is considered a central key component and it was expected that the latest process engine platform technologies would continue as integration paths into one or more Enterprise Service Bus (ESB) products. It was imagined to utilize an ESB product in the EMPOWER architecture together with the process engine to support EMPOWER services and messaging, and integrate EMPOWER applications and components.
Community projects provide a technology stack and it can be difficult to integrate components from competing projects unless a specific plugin mechanism is used. Plugins provide alternatives to components found in such a particular community technology stack. For example, JBOSS integrates its process engine and tools into its JBOSS ESB product and provides additional application server integration. An alternative approach, from MULE ESB, facilitates integration from non-community components, which might be attractive to prevent coupling all components from one community. To support the alternative approaches, other teams or projects offer system integration of various products.

6.1.2 Overview and issues for the Enterprise Service Bus (ESB)

It is often asked whether an Enterprise Service Bus infrastructure (ESB) is needed or useful[23]. With EMPOWER multiple integrated applications, support the process engine and services, support messaging especially using design patterns (EIP) - Enterprise Integration Patterns[24]. Messaging and services relating to interoperability can be supported such as the handling of HL7 or other standard messaging formats and message routing to dynamically or statically configured endpoints;

Some key ESB benefits include[25]:

- Facilitating a flexible and extensible architecture to grow and change as business needs change
- Easily scalable infrastructure without impact to code
- Separates business logic from protocols and message formats for faster and more nimble development
- Provision of consistent management, monitoring and security across integrations

[22] JBoss BPM http://www.jboss.org/jbpm
[23] Is an ESB needed? http://blogs.mulesoft.org/to-esb-or-not-to-esb/ http://www.mulesoft.org/what-mule-esb
[24] Enterprise Integration Patterns EIP http://www.eaipatterns.com/
[25] ESB features http://www.mulesoft.com/mule-esb-features

Service Mediation	**Message Routing**
• Separate business logic from messaging • Shield services from message formats and protocols • Enable location-independent service calls • Provide protocol bridging	• Route messages based on content and complex rules • Filter, aggregate and re-sequence messages
Data Transformation	**Service creation & hosting**
• Exchange data across applications with varying data formats • Manipulate message payload, including encryption, compression and encoding transformations • Format messages across heterogeneous transport protocols data types	• Expose end-points, EJBs, Spring beans, and POJOs as services • Host services as a lightweight service container
Service Orchestration	**Messaging**
• Create message flows with lightweight orchestration capabilities	• Possible design and integration support for Enterprise Integration Patterns (EIP)[24]
Common Features and Summary	

• Business Process Management and monitoring
• Connectors
• Transaction Manager
• Security
  o Plugins or integration might include Spring Security, CAS Single Sign-on[26]
• Application Container
• Messaging Service
• Metadata Repository
• Naming and Directory Service
• Development and integration tools/plugins
  o IDEs free or commercial
• Possible support for software patterns in IDE or APIs
EIP Enterprise Integration patterns	

[26] CAS - Central Authentication Service http://www.jasig.org/cas

6.1.3 Utilizing EIP Patterns

Utilizing of software patterns is strongly advised, however, (EIP) Enterprise Integration Patterns are neglected perhaps due to lack of publicity or lack of tool support for visually designing them and integrating them into a system. ESB products might include support for both design and integration into the messaging infrastructure. Examples for messaging and services supporting interoperability between systems or applications are shown in Figure 5 and Figure 6.

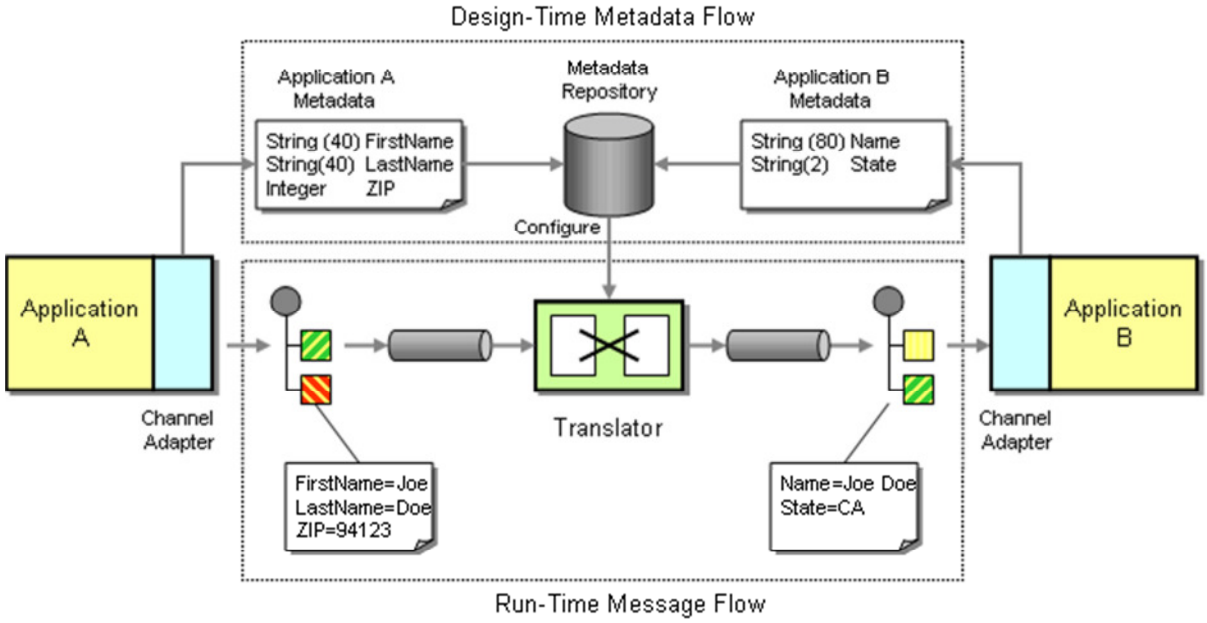

Figure 5 - EIP Patterns -Message Transformation (Interoperability)

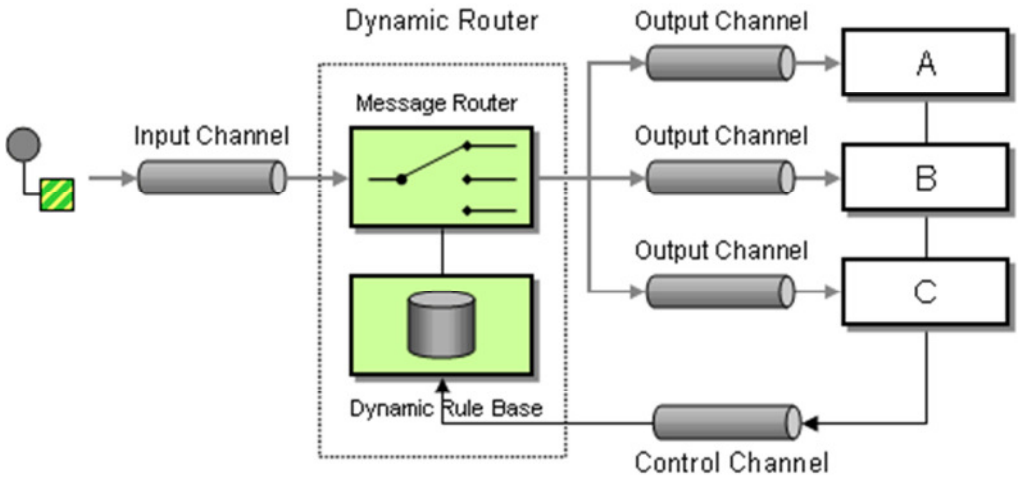

Figure 6 - EIP Patterns - Dynamic Routing of Messages

6.1.4 ESB Products (Open Source)

The following includes a light overview of popular ESB projects. The ESB benefits and features described previously are applicable, however, the EMPOWER developers should analyse these more carefully and consider other issues such as footprint size, vendor lock-in and usability of the platform relevant to the project requirements and architectural considerations. Lastly, the community around the product, the documentation and training are of upmost importance.

Mule ESB[27]
License: Open Source CPAL[28]

Mule is a lightweight ESB and an integration platform that supports services and applications using a variety of messaging and transport technologies. Mule includes cost free developer tools and an IDE[29] (IDE plugins). It also can integrate Fuse Source products based on Apache, or security integration plugins. Example plugins include: Activiti Process Engine, EIP support with or without Apache Camel, and CAS Single sign on. Overall it seems to be the widely adopted by many companies and well documented, providing also tutorials and online courses and commercial support. Overview is also provided at http://www.mulesoft.com/downloads/mule-esb.pdf

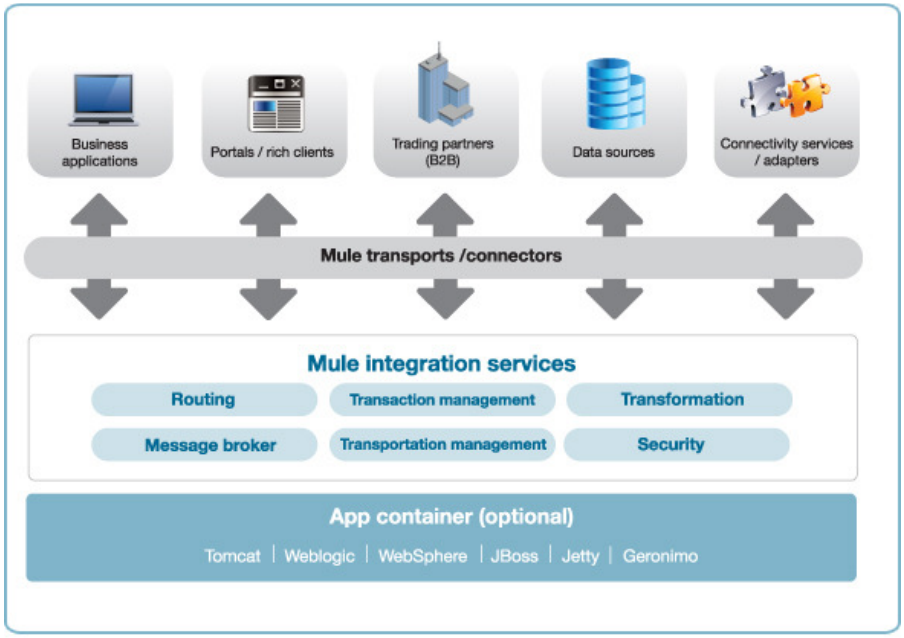

Figure 7 - Mule ESB architecture overview

Fuse Source[30]
License: Apache and commercial

Fuse Source provides commercially supported Apache software, and includes
However, the IDE supporting Apache Camel (EIP based messaging design) is a commercial product.

Fuse ESB[31]
An ESB platform that includes common ESB features and:

- Fuse Mediation Router or Fuse Message Broker (using Apache Camel[32])
- Integration of Drools (Drools - e.g. Drools Rules and Flow)

License: Apache

[27] Mule http://www.mulesoft.com/ http://www.mulesoft.com/downloads/mule-esb.pdf
[28] CPAL License http://en.wikipedia.org/wiki/Common_Public_Attribution_License
[29] Interactive Development Environment
[30] FUSE http://fusesource.com/
[31] Fuse ESB http://fusesource.com/products/enterprise-servicemix/
[32] Apache Camel http://camel.apache.org/

JBOSS ESB[33]
License: Apache 2

An ESB platform that includes common ESB features such as:

- Human Workflow User Interface,

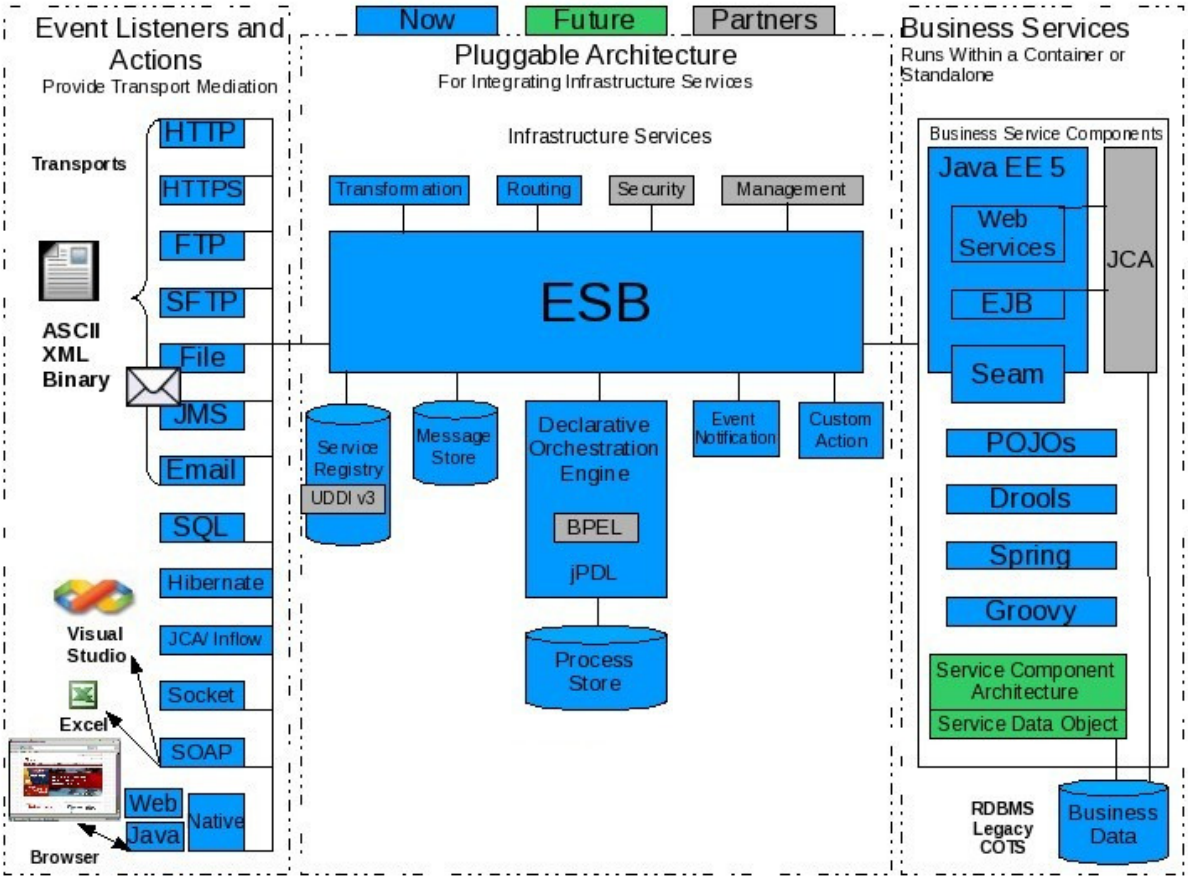

Figure 8 JBOSS ESB

6.1.5 Semantic technologies

Semantic technologies support EMPOWER knowledge models and rules, semantic content and terminologies interlinking for action plans and patient information, and other EMPOWER components. Also of interest are semantic web editors or widgets that support a patient's use (or other roles as well) of the EMPOWER action plan and patient information (also patients, physicians or authors)

The following are tools for semantically enriching content and interlinking materials. Content might be from patient information, patient content from Action Plan related activities, social media, terminologies, etc.

Apache Stanbol[34]
License: Apache 2

[33] JBOSS ESB http://www.jboss.org/jbossesb
[34] Apache Stanbol http://incubator.apache.org/stanbol/

Supports content management systems (CMS) with semantic technologies stack without replacing the content management system. Includes working demos and also demos based on eHealth Use Cases.

Overview

- **Content Enhancement**
  - Services that add semantic information to “non-semantic” pieces of content.
- **Reasoning**
  - Services that are able to retrieve additional semantic information about the content based on the semantic information retrieved via content enhancement.
- **Knowledge Models**
  - Services that are used to define and manipulate the data models (e.g. ontologies) that are used to store the semantic information.
- **Persistence**
  - Services that store (or cache) semantic information, i.e. enhanced content, entities, facts, and make it searchable.
- **Entity Hub and Content Hub**
  - Supports semantic indexing of web resources and local resources. Part of the indexing process can be supported by named entity extraction based.
- **Plugins** for extracting Named entity and indexing
- Vienna IKS Editables and Semantic Editor[35]
  - Enables interactive semantic enhancements e.g. patient education material authoring and interlinking with web contents from DBpedia[36]

Component Overview[37]

- The Enhancer component together with its Enhancement Engines provides you with the ability to post content to Apache Stanbol and get suggestions for possible entity annotation in return. The enhancements are provided via natural language processing, metadata extraction and linking named entities to public or private entity repositories. Furthermore, Apache Stanbol provides a machinery to further process this data and add additional knowledge and links via applying rules and reasoning.
- The 'Sparql endpoint' gives access to the semantic enhancements from the Apache Stanbol Enhancer.
- The 'EnhancerVIE' is a stateful interface to submit content to analyze and store the results on the server. It is then possible to browse the resulting enhanced content items.
- **User Interface tools:** Semantic editor[38] and widgets for end-user (patient action plan, content authors, administrators) http://viejs.org/, http://wiki.iks-project.eu/index.php/Semantic_Editor
- The **Rules component** provides you with the means to re-factor knowledge graphs, e.g. for supporting the schema.org vocabulary for Search Engine Optimization.
- The **Reasoners** can be used to automatically infer additional knowledge. It is used to obtain new facts in the knowledge base, e.g. if your enhanced content tells you about a shop located in "Montparnasse", you can infer via a "located-in" relation that the same shop is located in "Paris", in the "Île-de-France" and in "France".

[35] VIE UI http://viejs.org/,
[36] http://dbpedia.org
[37] Apache Stanbol Components http://incubator.apache.org/stanbol/docs/trunk/components.html
[38] Semantic editor http://viejs.org/, http://wiki.iks-project.eu/index.php/Semantic_Editor

- The **Ontology Manager** is the facility that manages your ontologies. Ontologies are used to define the knowledge models that describe the metadata of content. Additionally, the semantics of your metadata can be defined through an ontology.
- The **CMS Adapter** CMS Adapter component acts as a bridge between JCR/CMIS compliant content management systems and the Apache Stanbol. It can be used to map existing node structures from JCR/CMIS content repositories to RDF models or vice versa. It also provides services for the management of content repository items as Content Items within Contenthub.
- The **Entityhub** is the component, which lets you cache and manage local indexes of repositories such as DBpedia but also custom data (e.g. product descriptions, contact data, specialized topic thesauri).
- The **Contenthub** is the component that provides persistent document store whose back-end is Apache Solr. On top of the store, it enables semantic indexing facilities during text based document submission and semantic search together with faceted search capability on the documents.
- The **FactStore** is a component that let's use store relations between entities identified by their URIs. This relation between two entities is called a fact.

Linked Media Framework (LMF)
License: Apache

Support content management with semantic technologies. Enhance content semantically and especially it is a producer for Linked Open Data[39] that connects data across the web. The architecture overview is shown in Figure 9.

LMF Core
The core component of the Linked Media Framework is a Linked Data Server that allows the exposure of data according to the Linked Data Principles[40]:

- Use URIs as names for things.
- Use HTTP URIs, so that people can look up those names.
- When someone looks up a URI, provide useful information, using the standards (RDF, SPARQL).
- Include links to other URIs, so that they can discover more things.

Beyond Linked media principals, the LMF also supports:

- Linked Data Updates and by integrating management of metadata and content and making both accessible in a uniform way.
- Provides extensions for and configurable Semantic Search service and a SPARQL endpoint.
- Extension modules

[39] Linked Open Data http://linkeddata.org/
[40] http://linkeddatabook.com/editions/1.0/

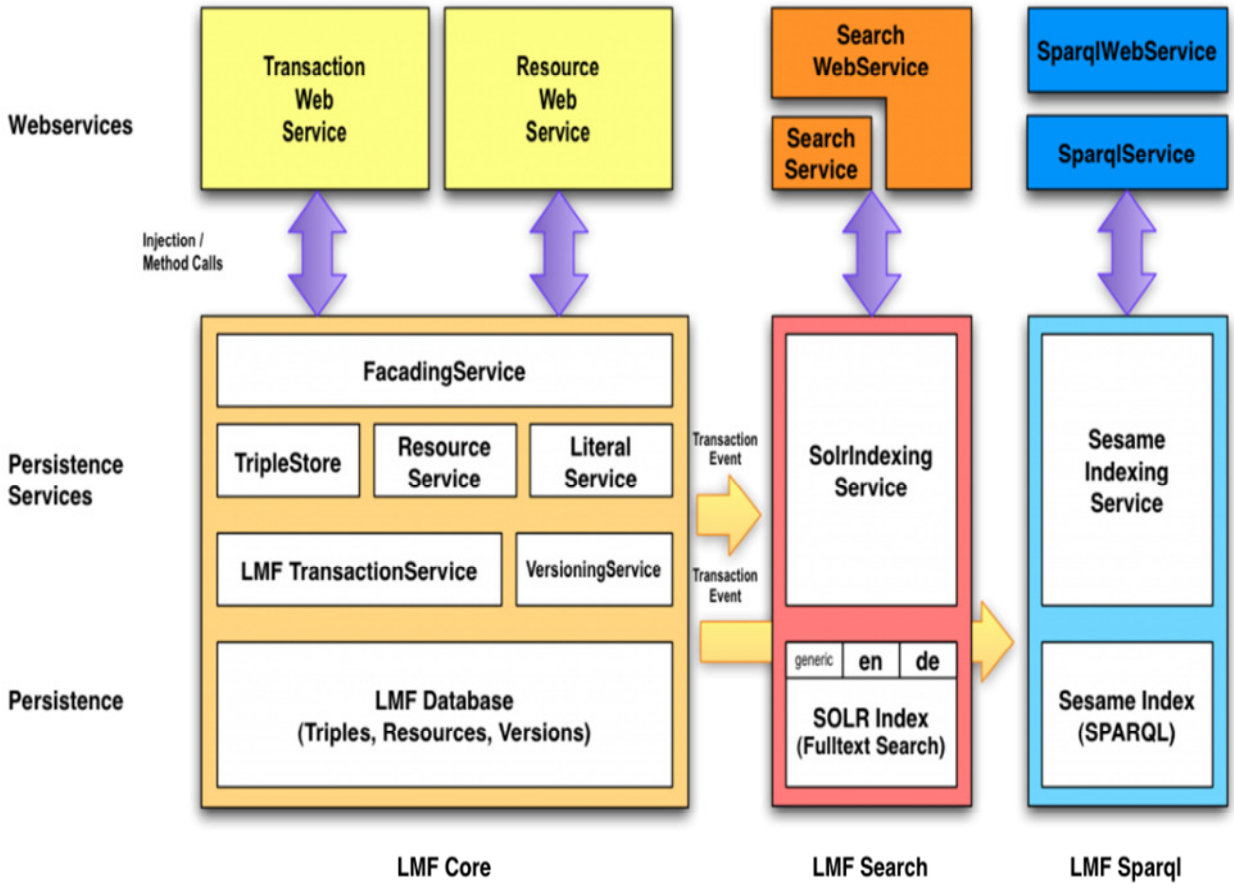

Figure 9: LMF architecture overview

LMF Modules are optional modules that extend the core feature set. The following are of interest:

- LMF Permissions implements and extends the WebID and WebACL specifications for standards-conforming authentication and access control in the Linked Media Framework.
- LMF Enhancer offers semantic enhancement of content by analysing textual and media content; the LMF Enhancer will build upon UIMA, Apache Tika, and the Apache Stanbol framework
- LMF Media Interlinking will implement support for multimedia interlinking based on the work in the W3C Multimedia Fragments WG[41] and the W3C Multimedia WG[42]
- LMF Versioning implements versioning of metadata updates

Relevance for EMPOWER:
These tools can be considered to support the core infrastructure of the knowledge pathways related components.
Software to support rule based process engine platform.
ESB can support EMPOWER SOA and integration of components– communications between components, messaging infrastructure supported by EIP pattern design, process engine integration.
Tools supporting messaging, services, security plugins and integration, rules, application integration.
Tools supporting semantic enhancement of patient information, patient action plans and pathway knowledge models.

[41] http://www.w3.org/2008/WebVideo/Fragments/
[42] http://www.w3.org/2008/01/media-annotations-wg.html

6.2 Computer Interpretable Guidelines and Models

The clinical practice guidelines are means of encapsulating best practice in evidence-based medical treatment. Clinical guidelines are increasingly being used to support clinicians' decision-making. Such guidelines which have been developed by local, national, and international organizations are intended to improve the quality of patient care, reduce variations in quality of care, and reduce costs. As an example, The National Guideline Clearinghouse™[43] provides a comprehensive database of evidence-based clinical practice guidelines and related documents. It has been demonstrated that clinician behaviour is most effectively influenced through patient-specific advice, particularly if delivered during patient encounters.
However, conventional narrative guidelines present population-based recommendations, and the information contained within such guidelines may be difficult to access and apply to a specific patient during the consultation. Guideline-based point-of-care decision support systems have the potential to address this problem. A prerequisite for the development of such systems is the creation of computer interpretable representations of the clinical knowledge contained in clinical guidelines. A number of groups are actively developing computer interpretable guideline representation languages for this purpose. Groups have adopted different approaches reflecting their interests and expertise. Nevertheless, many of the approaches have in common a hierarchical de-composition of guidelines into networks of component tasks that unfold over time.
Many methods to support the computerization of guidelines have been or are being developed by the Health Informatics community[44]. The following provides a brief overview of major computer interpretable clinical guideline representation formalisms and the guideline execution architectures built based on these formalisms.

6.2.1 Arden Syntax

Arden Syntax [Starren 1994] is cited as one of the best-known language for representing clinical knowledge needed to create patient-specific decision-support systems. It is a rule-based formalism that encodes medical knowledge in a knowledge base form as Medical Logic Modules (MLMs). An MLM is a hybrid representation formalism between a production rule (i.e. an "if-then" rule) and a procedural formalism. Each MLM is invoked as if it is a single-step "if-then" rule, but then it executes serially as a sequence of instructions, including queries, calculations, logic statements and write statements.
Arden was developed for embedding MLMs into proprietary clinical information systems. It was designed to support clinical decision making, each MLM contains sufficient logic to make a single medical decision. Sequencing tasks can be modelled by chaining a sequence of MLMs which are used to generate clinical alerts and reminders, interpretations, diagnoses, screening for clinical research studies, quality assurance functions, and administrative support. With an appropriate computer program (known as an event monitor), MLMs run automatically, generating advice where and when it is needed, e.g. to warn when a patient develops new or worsening kidney failure.
One of the deficiencies of the Arden Syntax is that it does not provide full support for conceptualizing a multi-step guideline that unfolds over time [Peleg 2001]. It has been presented that the Task Network Model (TNM) approach has arisen in response to this problem. TNM languages typically provide modelling primitives specifically designed for the representation of complex, multi-step clinical guidelines, and for describing temporal and other relationships between component tasks. Unlike the rule based systems, alternative pathways or sequences of tasks (i.e., control flow) can be explicitly modelled, and tools for the visual representation of plans and the organization of tasks within them are provided.
In Arden syntax the references to clinical data is represented in curly braces in MLMs. This is because these data references must be adapted to the local institution in order to use the local clinical repository. When a clinical guideline model is to be deployed to a local

[43] http://www.guideline.gov
[44] http://www.openclinical.org/gmmintro.html

institution, these references in curly braces are mapped to the data model of the local clinical repository. After Arden, this localization problem of deploying guideline models is usually cited as “Curly Braces Problem” in the literature.

6.2.2 Asbru Model

Asbru is a collaborative effort of Ben Gurion University and the Vienna University of Technology within the scope of Asgaard project [Shahar 2002]. In Asbru formalism, clinical guidelines are viewed as generic skeletal-plan schemata that represent clinical procedural knowledge and that are instantiated and refined dynamically by care providers over significant time periods. As a reflection of this idea, Asbru designed a task-specific and intention-based plan representation language to embody clinical guidelines and protocols as time-oriented skeletal plans. Skeletal plans provide a powerful way to reuse existing domain-specific procedural knowledge, while leaving room for execution-time flexibility to achieve particular goals [Seyfang 2002]. The skeletal plans have been enriched by adding plan attributes such as intentions, conditions and effects; adding formalisms to support rich set of ordering plans; and defining temporal dimension of states and plans[45]:

- Arguments are values passed from the invoking or calling plan (called parent) to the invoked or called plan (called child).
- Preferences describe the costs, resource constraints, and responsible actor.
- Intentions are high-level goals of the plan - an annotation specified by the designer independently of the plan body. Intentions are represented by temporal patterns of actions and states that should be maintained, achieved or avoided.
- Conditions mediate the changes between plan states. Each plan is initially considered. After the filter precondition is fulfilled, it becomes activated. When it is activated and the complete condition is fulfilled, the plan is completed. When in the same situation the abort condition is fulfilled first, the plan becomes aborted.
- Effects describe the relationship between plan arguments and measurable parameters by means of mathematical functions or in a qualitative way. A probability of occurrence can be denoted.

The plan body contains set of plans to be executed in a particular way. Four different types of plans are available: in sequence, in parallel, in any-order, and unordered. The difference between any-order and unordered is that for any-order only one child plan may be active at a time while for unordered there is not any restriction.

6.2.3 GUIDE

GUIDE [Ciccarese 1999] is part of a guideline modelling and execution framework being developed at the University of Pavia. One of the important properties of GUIDE and its re-engineered execution environment NewGuide, is that it is a component-based multi-level architecture designed to integrate a formalized model of the medical knowledge contained in clinical guidelines and protocols with both workflow management systems and Electronic Patient Record technologies. It proposes an architecture that aims to integrate:

- Guideline Management System (GlMS) (providing clinical decision support)
- Electronic Patient Record (EPR)
- Careflow Management System (CfMS) (providing organisational support).

[45] “The ASGAARD Project: Plan Representation, The Asbru Language”, http://www.asgaard.tuwien.ac.at/plan_representation/asbru_doc.html

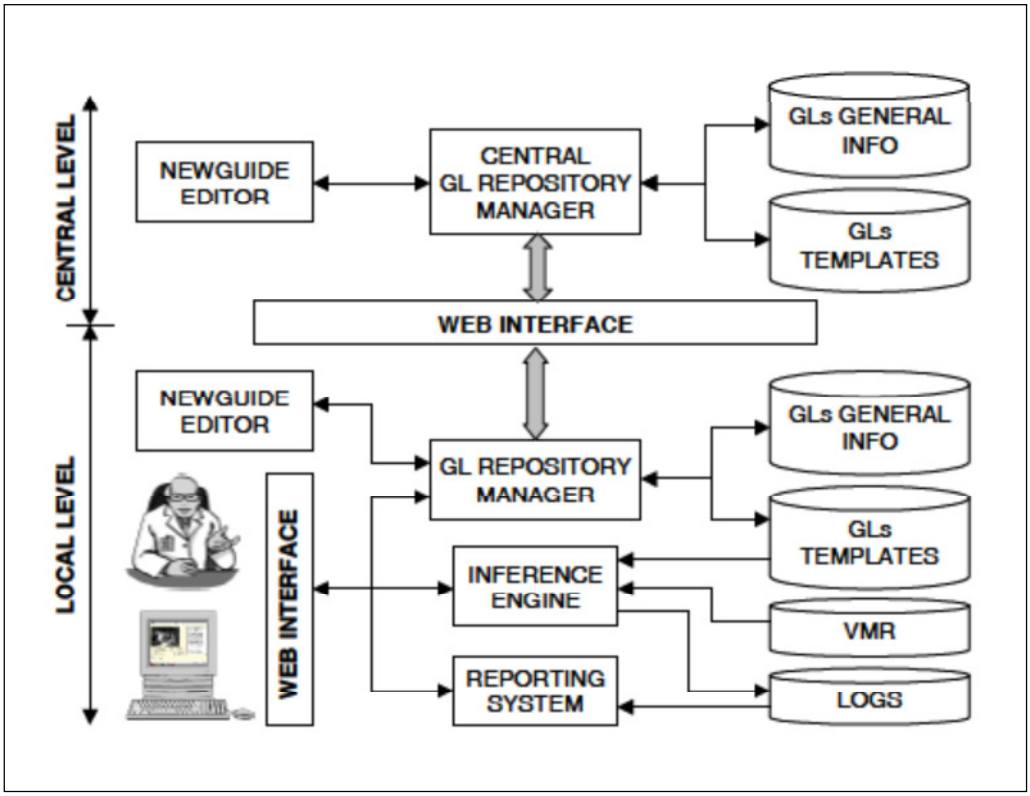

Figure 10: The architecture proposed in GUIDE

The architecture proposed by NewGuide is presented in Figure 10. After the guideline (GL) is formalized through an editor, it is stored to a guideline repository to be shared with other organizations. Then a healthcare organization that aims to run a guideline in its environment selects a guideline from the repository. The final user invokes the inference engine and creates an instance of the GL for the management of an individual patient. This requires data from a Virtual Medical Record (VMR). VMR is the NewGuide middle layer that stores every kind of patient information either acquired through a legacy system (HIS) or entered by the Guideline user. Each inference engine step implies both producing recommendations, such as a drug prescriptions or laboratory tests, and updating a logs database. The latter contains care process information such as progress status of each GL task with relative time stamps. In other words, the VMR and Logs database is the interface of the Guideline Management System with Careflow Management System. In the architecture, the communication between NewGuide and the external world is managed by the message manager, which delegates requests and responses to the web user interface or to a SOAP interface on the basis of the system configuration as presented in Figure .

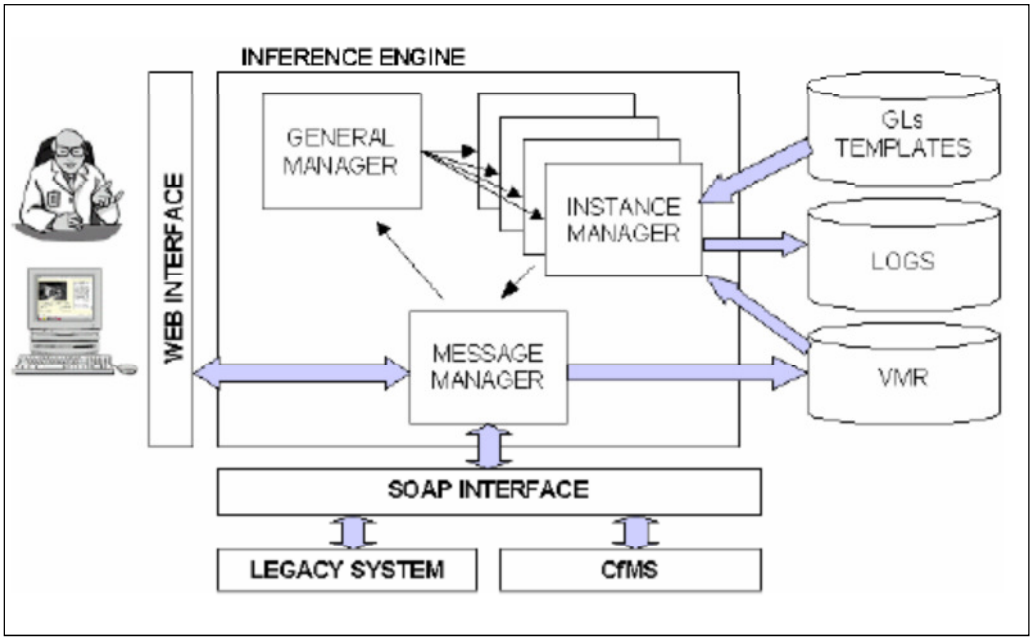

Figure 11: Architecture of the Inference Engine proposed in GUIDE

6.2.4 PROforma

PROforma [Fox 1998] model was developed at Cancer Research UK for the general purpose of building decision support and intelligent agents. The technology includes the PROforma language, which is a formal knowledge representation language capable of capturing the structure and content of a clinical guideline in a form that can be interpreted by a computer [Sutton 2003]. The language forms the basis of a method and a technology for developing and publishing executable clinical guidelines. In PROforma, a guideline application is modelled as a set of tasks and data items. The notion of a task is central - the PROforma task model divides from the keystone (generic task) into four types: plans, decisions, actions and enquiries:

- Plans are the basic building blocks of a guideline and may contain any number of tasks of any type, including other plans.
- Decisions are taken at points where options are presented, e.g. whether to treat a patient or carry out further investigations.
- Actions are typically clinical procedures (such as the administration of an injection) which need to be carried out.
- Enquiries are typically requests for further information or data, required before the guideline can proceed.

PROforma software consists of a graphical editor to support the authoring process, and an engine to execute the guideline specification. The engine can also be used as a tester during the application development phase. Tallis is one of such software which is a Java implementation of PROforma-based authoring and execution tools developed by Cancer Research UK. Tallis is based on a later version of the PROforma language model. It consists of a Composer (to support creation, editing, and graphical visualisation of guidelines), Tester and Engine (to enact guidelines and allow them to be manipulated by other applications).

6.2.5 GLIF

The GuideLine Interchange Format (GLIF) [Peleg 2000] tries to build on the most useful features of other guideline models, and to incorporate standards that are used in health care. It is proposed as a standard computer interpretable representation model for sharing clinical guidelines among different healthcare institutes. It is presented by a research consortium including the Columbia University, the Harvard University and the Stanford University.

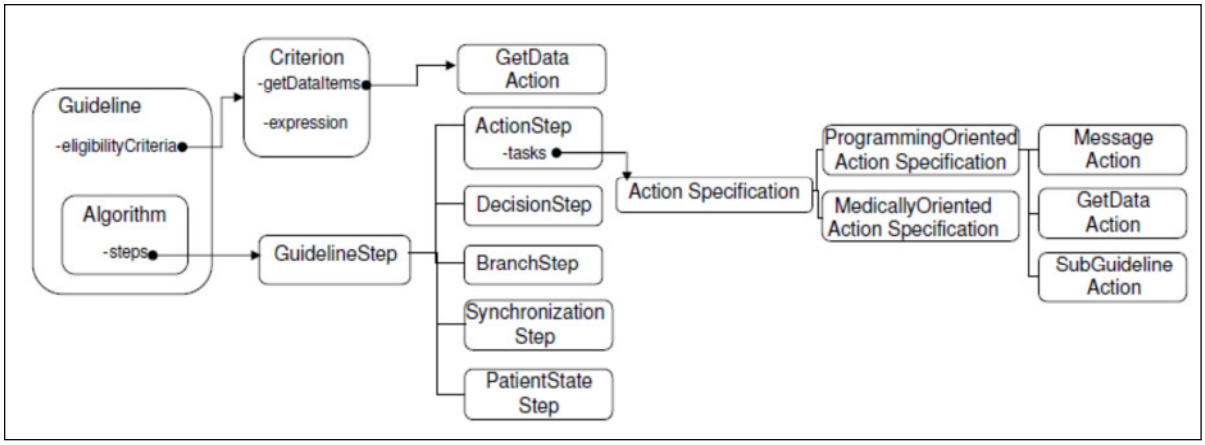

Figure 12: A Part of the GLIF Model

In the GLIF Model, clinical guidelines are represented as instances of a formal model called guideline. This formal model is represented as an ontology and editable by Protege[46]. GLIF uses a "task-based" paradigm for representing the guidelines, i.e., it decomposes the guideline definition hierarchically into networks of component tasks that unfold over time. A brief overview of the GLIF Model is given in 12.

The Eligibility Criteria defines the features of the medical problem for which this guideline can be applied for. It is represented through a number of Criterion classes. The criteria are represented through the "expression" attribute of the Criterion. To be able to assess the eligibility, it may be necessary to check the current situation of the patient and his/her past medical history, hence these data gathering steps are added as "get data item" attributes to the Criterion class.

The clinical process is represented through an algorithm, which is a flowchart of guideline steps, including:

- An Action step is used for modelling actions to be performed which may include two types of tasks: Medically Oriented Actions and Programming Oriented Actions. Through Medically Oriented Actions medical procedures usually run by medical staff such as recommendation for a particular course of treatment can be represented. The Programming Oriented Actions are divided into three: through the Get Data Action the actions that feed data to guideline such as retrieving data from an electronic patient record are represented; through Message Action the messages that should be passed between medical systems, such as reminders, alerts are represented; finally through SubGuideline Actions the guideline definitions can be nested.
- A Decision step represents decision points in the guideline defined in terms of formal expressions. The GLIF specification exploits an expression language that is derived from the logical expression grammar of Arden Syntax [Peleg 2001]. Decision Steps include a number of Decision Options where decision expressions and destination steps that should be followed if this expression evaluates to true are presented.
- The Branch step is used to model concurrent guideline steps. Branch steps direct flow to multiple guideline steps. All of these guideline steps must occur in parallel. A branch step may link a guideline step to any other guideline step.
- The Synchronization steps are used in conjunction with branch steps. When multiple guideline steps follow a branch step, the flow of control can eventually converge in a single step. Each branch may lead to a series of steps, resulting in a set of branching paths. The step at which the paths converge is the synchronization step. When the flow of control reaches the synchronization step, a continuation attribute specifies whether all, some, or one of the preceding steps must have been completed before control can move to the next step.

[46] Protégé Ontology Editor and Knowledge Acquisition System, http://protege.stanford.edu/

- A Patient state step is usually used as a label that describes a patient state that is achieved by previous steps. This way, a guideline may be viewed as a state transition graph, where states are scenarios, or patient states, and transitions between these states are the networks of guideline steps (excluding patient state steps) that occur between two patient state steps. A patient state step has a criterion that describes the state of the patient who is at that patient state.

An example of such guideline algorithm defined in GLIF is presented in Figure 1313.

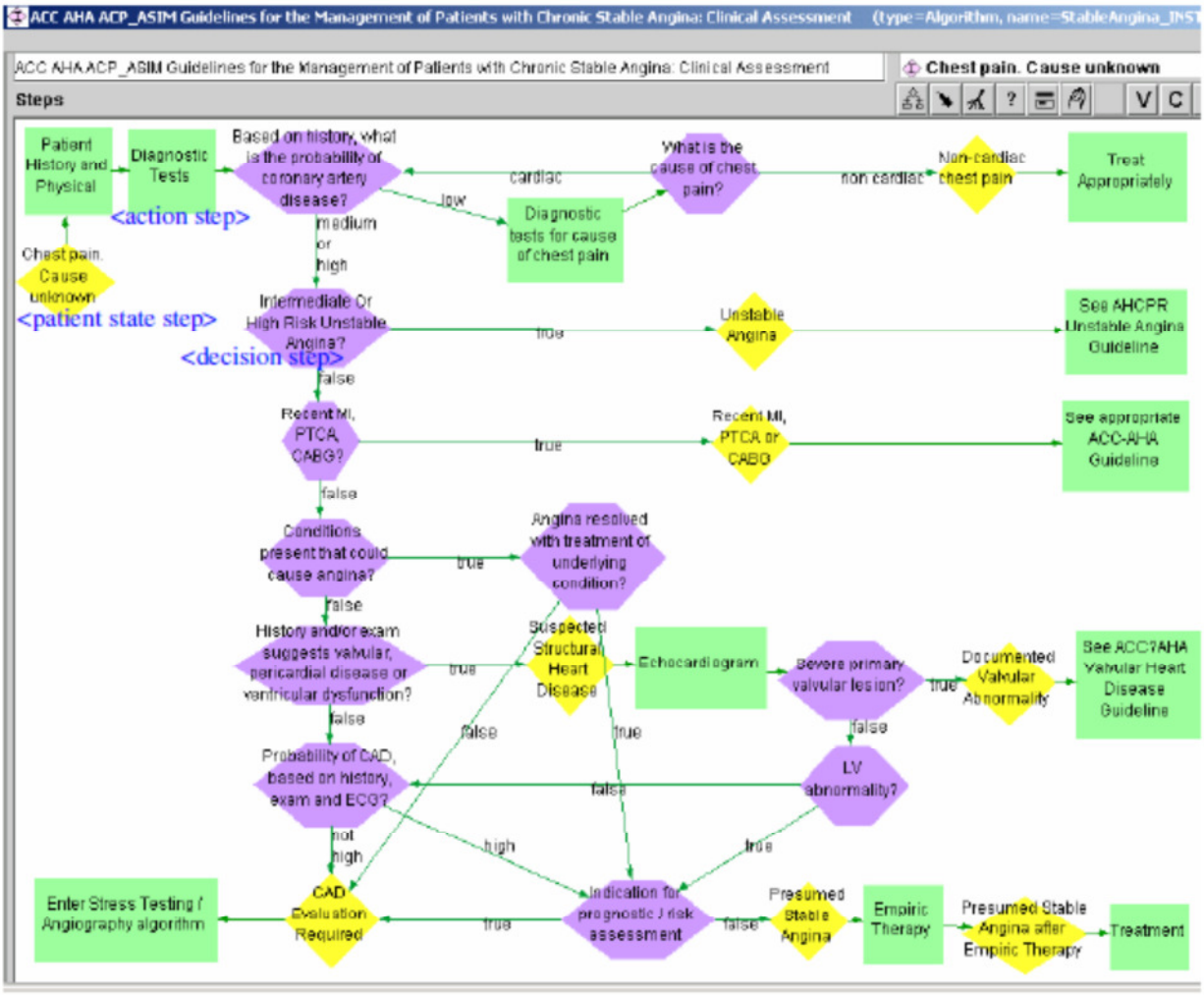

Figure 13: An algorithm for the stable angina guideline in GLIF

The GLIF Model proposes to represent the guidelines in three layers. The Core GLIF Model described above constitutes the “Level A”. It enables the guideline author to concentrate on conceptualizing a guideline as a flowchart: the guideline is defined as a workflow of hierarchical steps defined in GLIF Formal Model. At this level of abstraction, the guideline author is not concerned with formally specifying details, such as decision criteria, relevant patient data, and iteration information that must be provided to make the specification computable. GLIF proposes that in the second level of abstraction, that is, in “Level B”, this workflow is detailed by formally expressing the patient data item definitions, the clinical concepts, and the logical criteria:

- “Level B” the Clinical data is represented as data items. For representing medical data items, GLIF supports the use of a Reference Information Model (RIM) derived from HL7 RIM (USAM)[47] presented in Figure 14. This RIM defines a class hierarchy

[47] HL7 Reference Information Model, http://www.hl7.org/v3ballot8/html/foundationdocuments/welcome/index.htm

that organizes medical concepts into classes. For each class, it provides a data model that defines the attributes of the different classes. This enables the formal definition of high level Patient data items such as Medication, Observation, and Procedure.

- Knowledge items are used to define the clinical concepts which can be used to annotate the data items to relate them with well-known medical terms. Clinical concepts are defined through the tuple <conceptName, conceptID, conceptSource>. For example, the "chronic cough" concept can be represented through the following tuple <chronic cough, C0010201, UMLS> in reference to Unified Medical Language System (UMLS)[48] semantic network.
- A formal expression language is used for representing decision criteria, triggering events, exceptional conditions, duration expression, and states in the guideline definition. For example a decision criteria can be defined as "selectAttribute(pq_value,selectAttribute(value, Current_LDL_Cholesterol)) >= 160" in this expression language.

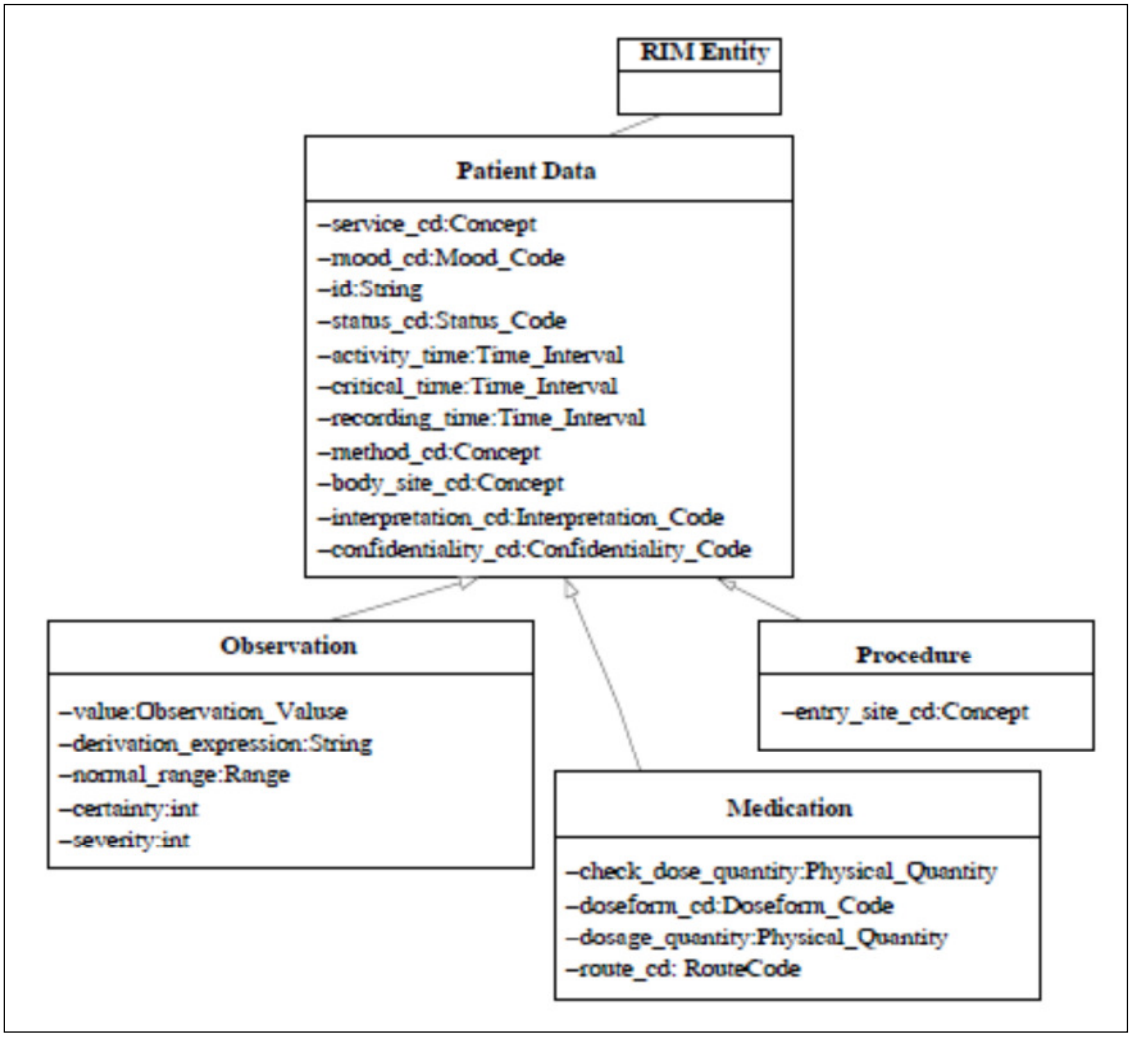

Figure 14: The Reference Information Model used by GLIF

[48] Unified Medical Language System (UMLS), http://www.nlm.nih.gov/research/umls

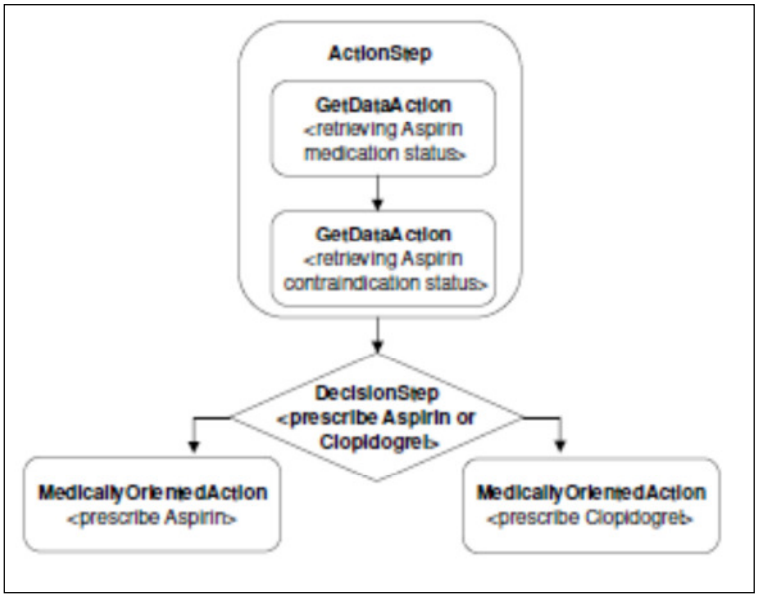

Figure 15: A very simple guideline flow

GLIF uses these two levels of abstractions to represent a guideline definition as follows: Assume an overly simplified guideline that decides whether to prescribe “Aspirin” or “Clopidogrel” as a first line medication to a patient who is suffering from myocardial infarction as presented in Figure 15. The first guideline step in the guideline's “algorithm” can be an “action step” where it is necessary to gather data from patient's Electronic Healthcare Records (EHR). The tasks included in this “action step” are two “get data actions”. The first “get data action” instance as shown in Figure is to discover whether the patient is currently using the medication “Aspirin”. This action states that the information should be retrieved from the “EHR” (also termed as Electronic Medical Record, EMR). The second “get data action” is for accessing the contraindications of the patient to the medication “Aspirin”. After executing these actions, through a “decision step”, it is checked whether it is advisable to prescribe Aspirin to the patient as presented in Figure , in the “OrderAspirin” “medically oriented action”.

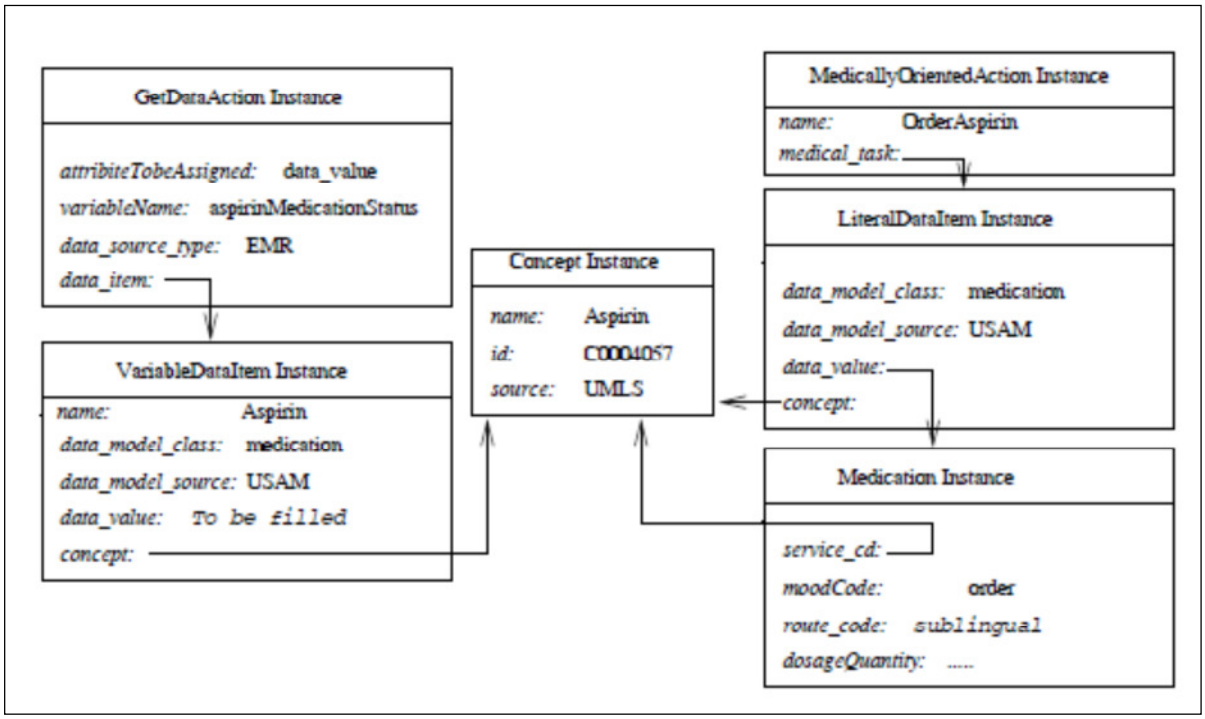

Figure 16: An Example Get Data Action retrieving Aspirin Medication Status and an Example Medically Oriented Action Ordering Aspirin Prescription in GLIF Model

As presented in the example, through GLIF Levels “A” and “B”, a guideline is defined only at the conceptual level. In other words, how this model can be executed at a specific medical institute, how the EHR of the patient can be accessed, how the clinical procedures can be discovered and invoked are not specified. GLIF recognizes this requirement by defining a third level of abstraction, “Level C” or “Medical Knowledge Layer”, which aims to provide an implementable specification. In this layer, the actions specified in the Level “A” and the patient data references presented in Level “B” must be mapped to institutional procedures and the electronic medical record systems of the underlying system of the medical institution where the guideline is to be deployed. For this third level of abstraction, the following needs have been identified:

- Interfaces to clinical repositories to retrieve Electronic Healthcare Records of a patient,
- Interfaces for interacting with applications such as clinical workflows and alert systems.
- In the latest GLIF specification, these requirements have been noted but not addressed.

GLIF Guideline Execution Engine (GLEE) [Wang 2004] is developed as a tool for executing guidelines encoded in the GLIF format. It is built as middleware that is intended to be integrated with the clinical information system at a local institution through defined interfaces to its electronic medical records (EMRs) and clinical applications. GLEE provides interfaces intended to support integration with the host clinical information system at a local institution. These interfaces are used to link GLEE to a local EMR at the back-end and associated clinical applications (e.g., a physician order-entry system) at the front-end. The communication between GLEE and the EMR at the back-end enables GLEE's access to various resources in the local environment, such as retrieval of patient data and monitoring of clinical events in case the local institution needs to trigger a guideline through specific clinical events. The communication between GLEE and associated clinical applications at the front-end is intended to enable smooth integration of the decision support services provided by GLEE, such as alerts and reminders, within a clinician's workflow. In other words, GLEE defines the business logic of a guideline application, the local EMR will provide data, and the associated clinical application will support the interactions between users and a guideline implementation system. The overall system architecture is shown in Figure 17.

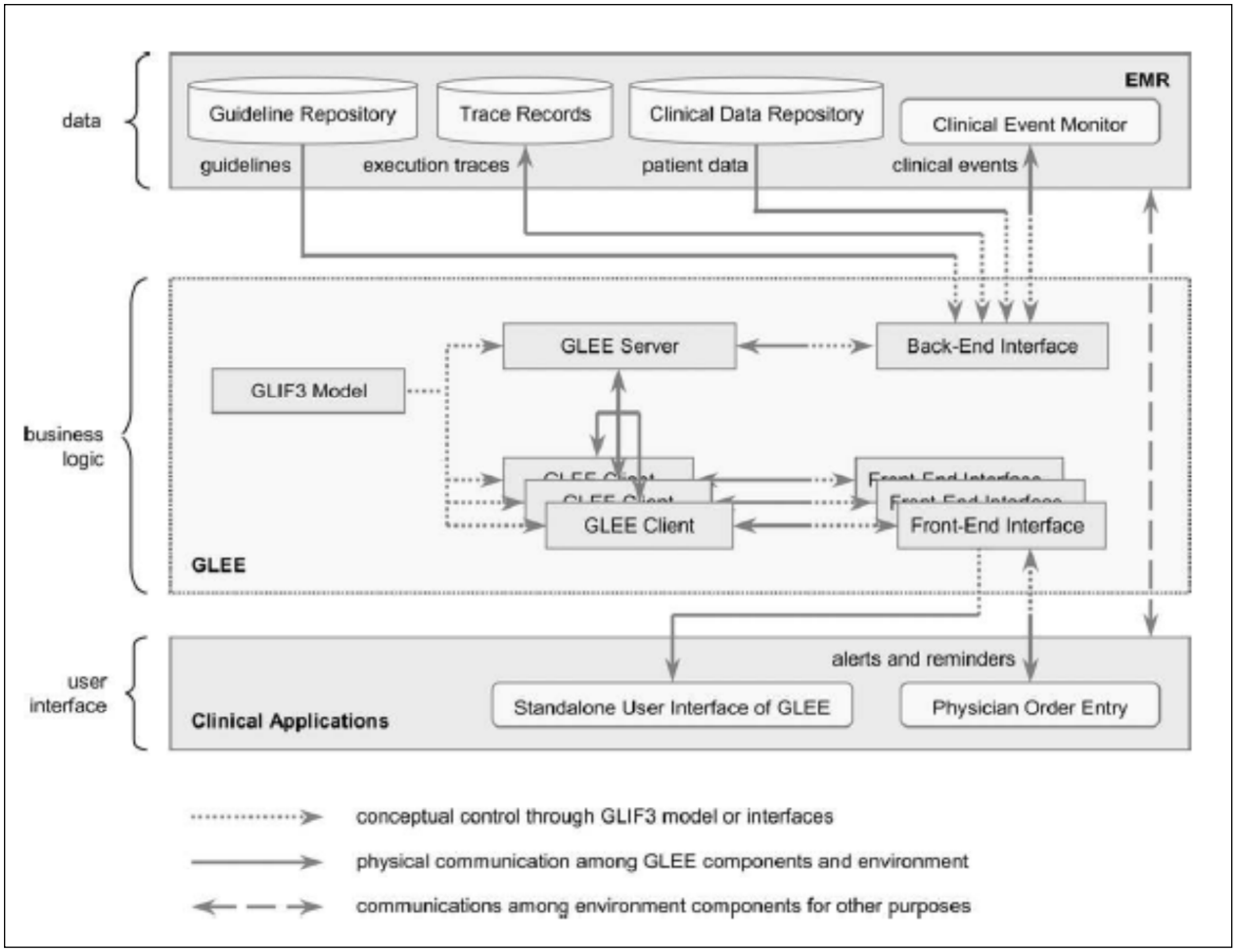

Figure 17: The internal structure of GLEE and its interactions with a local environment

GLEE's components can be classified into three conceptual layers: (1) the GLIF guideline representation model, (2) the core components of GLEE, and (3) the interfaces to a host clinical information system. The GLIF guideline representation model specifies a set of generic functions, such as recommendations for specific clinical actions and assistance in medical decision-making, which should be supported by any tool executing guidelines encoded in the GLIF format. The core components of GLEE, as an execution environment for GLIF, define an execution model to realize the generic functions that are required by the GLIF representation model. The interfaces to a host clinical information system reflect GLEE's assumptions on the interactions between GLEE and its host environment during guideline execution. In the GLEE architecture, the system interface between the GLEE server and a host clinical information system is maintained at the back-end based on these assumptions.

GLEE believes that for guidelines to be shared across different institutions, a standard data encoding system and a generic patient data model are two prerequisites. This standard data encoding system plus a generic patient data model will enable references to patient data in an encoded guideline such as in a specification of decision criteria without the need to know the implementation details. It is believed that once such a standard data model exists, at a local institution, the standard definition of patient data are then mapped to the implementation-specific data schema and access methods of the local EMR. GLEE's implementation is based on this assumption, and it is assumed that using the patient data required by GLEE during guideline execution can then be retrieved from the local clinical data repository where clinical data is stored in this standard data model. GLEE itself accepts that it has not yet solved the curly braces problem which refers to the hindrance of medical knowledge sharing caused by incompatible approaches to patient data representation.

Registration of clinical events and notification of clinical actions are implemented in GLEE using a similar approach, through a standard controlled terminology corresponding to the

events or the clinical actions that will enable the communication between GLEE and the local environment.
Finally it has been stated that wide acceptance of a guideline system in clinical practice depends on the development of a widely-accepted standard patient-data model and the in-depth understanding of local adaptation of guidelines. These issues are not addressed in GLEE but it helps to define the challenges for the future.

6.2.6 GLARE

GLARE [Terenziani 2001] is a domain-independent system for acquiring, representing and executing clinical guidelines. The system is based on a modular architecture, which includes an acquisition tool and an execution tool. The acquisition tool is used when a guideline is introduced in the system, e.g. by a committee of experts, and the execution tool is used when a guideline is applied by physicians to a specific situation.
The GLARE representation language is designed to achieve a balance between expressiveness and complexity. The formalism consists of a limited, but focused and clearly understandable set of primitives. It is made up of different types of actions: plans (i.e. composite actions, hierarchically decomposable in their sub-actions) and atomic actions. Atomic actions can be queries, decisions, work actions and conclusions. All actions are linked by control relations (e.g. sequence, alternative, repetition), defining their order of execution.

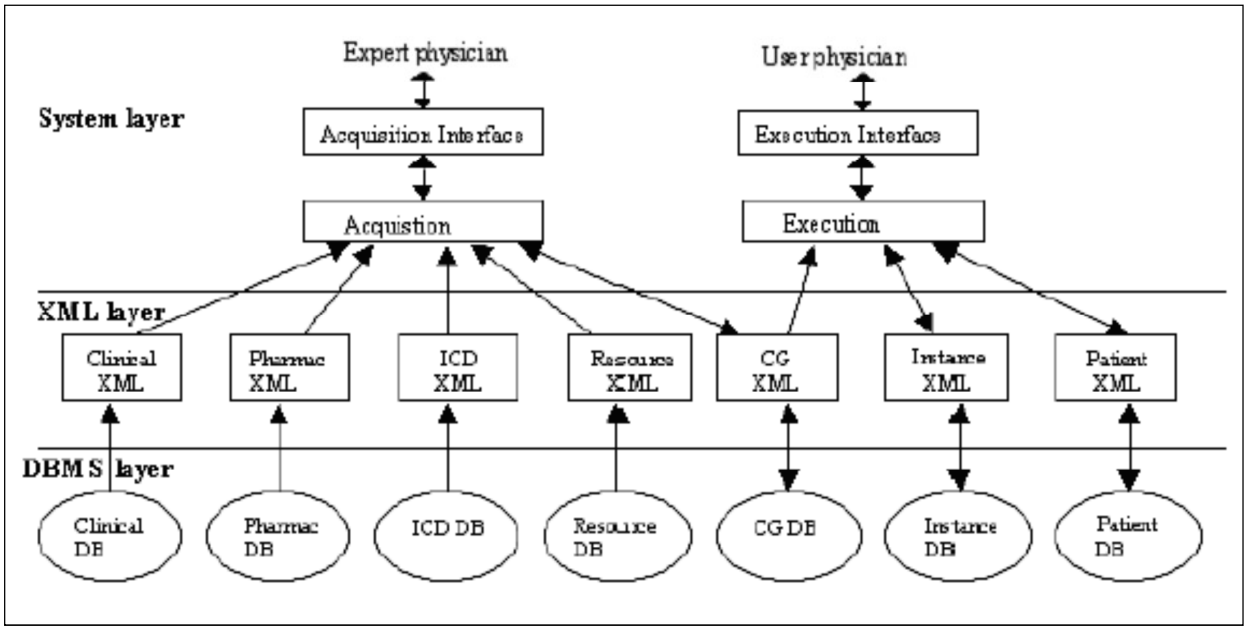

Figure 18: The GLARE's three layered architecture

The GLARE architecture is based on three layers as presented in Figure 18. The System Layer contains the two modules called acquisition and execution. The DBMS Layer contains several databases with all data required to create and execute guidelines. There is stored data about available resources, terminology used in guidelines, information about drugs, information about all open instances of guidelines, a repository of guidelines, and a patient's medical record. Finally, the XML Layer allows to represent/manage/exchange data between DBMS layer and System Layer in a structured way.

6.2.7 SAGE

The SAGE (Standards-Based Sharable Active Guideline Environment) [Tu 2004] project is a collaborative research and development project among research groups at IDX Systems Corporation, the university of Nebraska Medical Center, Mayo Clinic-Rochester, Intermountain Health Care, Apelon, Inc., and Stanford University to develop a standards-based comprehensive technology infrastructure that will enable encoding and dissemination of computable clinical practice guidelines. Key objectives of the SAGE project are: interoperability of encoded guideline content across disparate Clinical Information System (CIS) platforms and active rendering of guideline content via real-time interaction with existing CIS application functions.

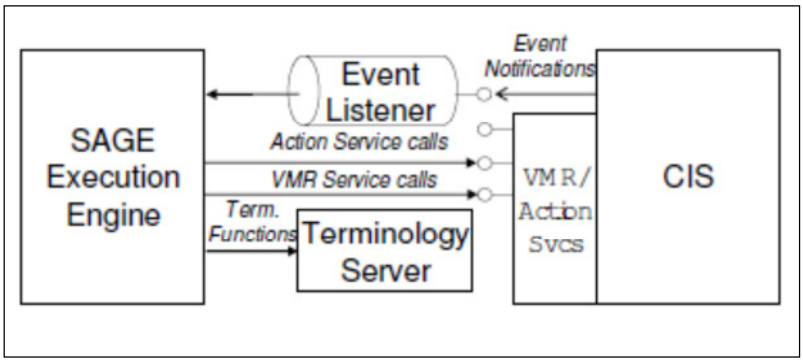

Figure 19: The SAGE deployment architecture

The SAGE guideline model is designed to encode guideline content at the level of detail required for execution within the context of a specific care workflow supported by existing functions of the CIS. To this end, guideline content is represented as detailed clinical "recommendation sets" comprising action specifications, decision logic, and the clinical context in which the recommendations are to be active. The SAGE guideline model uses standard information models, constructs, and data-types to express medical and decision-making concepts. A virtual medical record (VMR) information model [Johnson 2001] has been employed and extended for representation of patient data and guideline-driven actions and all medical concepts are referenced to standard medical terminologies (e.g., SNOMED CT, LOINC).

SAGE aims to develop a deployment driven guideline environment. For this purpose SAGE proposes a methodology for representing clinical content in a standard way through VMR's supported with Clinical Expression Models (CEMs) which place constraints on the attributes of VMR classes. A compositional method is proposed to express new complex concepts.

For technical interoperability with the underlying clinical information systems, SAGE proposes a set of fixed Action Types for abstracting CIS's functions (such as Notify, Inquire, Recommend_OrderSet) inside the guideline model[49]. SAGE engine [Ram 2004] supports communication with clinical workflows through events based on these action types as presented in Figure 19.

In SAGE methodology, before a formalized guideline can be installed and used in a local institution, its medical content must be reviewed and revised (localization process) and its data models, terminologies, and organization assumptions (roles, events, and resources) must be mapped to those of the local institution by the medical staff (the binding process). The semantics represented in the guideline model is presented to the medical staff, which should manually choose and bind the most appropriate clinical workflow interfaces to the "action types" defined in the guideline definition in order to be able to interact the guideline execution environment. SAGE assumes a set of standard VMR Action Service Interfaces will be set by standard bodies and clinical information systems will be using these standard messages, VMR interfaces to interact with guideline execution systems.

[49]SAGE Guideline Model Specification Document, http://sage.wherever.org/references/docs/SAGEGuidelineModelSpec.pdf

Relevance for EMPOWER:

As described in detail, there are many clinical guideline models and execution environments. In EMPOWER, the care plans of the patients will be managed by computerized clinical guideline definitions. The Recommender Engine is responsible for executing these guideline definitions. Among the guideline models presented, it can be concluded that GuideLine Interchange Format (GLIF) is the most promising one as it tries to build on the most useful features of other guideline models. Natively, it is not executable by computers but it offers an extension mechanism, which is fulfilled in the SAPHIRE Project already. iCARDEA has built on top of the extended GLIF model of SAPHIRE Project, and defined Atrial Fibrillation and Ventricular Tachycardia care plans through GLIF Model.
In the EMPOWER Project, corresponding careplans for diabetes management will be defined.

7 Patient Empowerment Approaches

7.1 Health Literacy

The term Health literacy first appeared in a 1974, and since then researchers have been focusing on that concept in order to examine it, to measure it and to understand the problems related with low literacy. Health literacy has received a great deal of attention in the health communication literature because of its proposed impact on individual health and healthcare costs. Lot of interventions have been developed in order to improve health literacy or at least to limit the problems of those with low levels of health literacy. In most of the cases education was considered the key to health promotion and disease prevention. But even if health literacy originally comes from the concept of literacy, its definition have to be expanded, as it is shown by the following list, therefore education just in term of information is not enough:

- ‘‘the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health.” [World Health Organization, n.d.]
- “The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions,” [U.S. Department of Health and Human Services 2010]
- “health literacy incorporates a range of abilities: to read, comprehend, and analyse information; decode instructions, symbols, charts, and diagrams; weigh risks and benefits; and, ultimately, make decisions and take action. However, the concept of health literacy extends to the materials, environments, and challenges specifically associated with disease prevention and health promotion” [National Institute of Health, 2007, n.d.]

Schulz and Nakamoto (Rubinelli 2009; Schulz 2005) felt the need to clarify what are actually the skills and the type of knowledge that are needed to be health literate. At the basis, and shared by everybody, stand functional literacy skills of reading and numeracy. Moreover there are other basic levels of knowledge, which include declarative knowledge such as “Physicians have specialized training in health care” or “My insurance will pay for the treatment I receive in hospital” as well as procedural knowledge such as “Take medication as instructed by the physician”. Declarative knowledge is the knowledge that refers to factual information, in the specific case of health the knowledge about health and medicine that a person has at his or her command. Procedural knowledge refers instead to the rules guiding reasoned choice about the proper course of action; the notion is based on Gilbert Ryle’s concept of “knowing how” in contrast with “knowing that” (Anderson 2005; Mandler 1984). Without procedural knowledge a person wouldn’t know how to use his/her information in a specific context.

Starting from this set of knowledge a person can comprehend health information and make informed choices on its basis, and these skills correspond to Nutbeam’s (Nutbeam 2000) communicative/interactive health literacy. But these skills must account also for personal goals thus to help taking decisions which are critical to some extent. Judgment skills are this part which is allowing this criticism, a criticism similar to what Nutbeam calls critical literacy. These skills allow the person to make an abstraction and a generalization on the basis of his/her knowledge. First presupposition for judgment skills is then the development of a certain knowledge about the experiences and their causal structure, thus to be able to direct actions in the future. Judgment skills are particularly important because they enable patients to manage new health conditions that appear in their lives and prevent them to do their usual activities. By using judgment skills they will be able to become more autonomous and to deal with new difficult situations generated by either acute or chronic condition. Nowadays a challenge of this part of research is to find new validated measures for health literacy other than functional health literacy.

Measurement aside, programs such as the Arthritis Self-Help Course developed by Lorig and colleagues at Stanford University provide excellent examples of how this broader group of literacy skills are playing a role. This course is built around six two-hour workshops covering: 1) techniques to deal with problems such as pain, fatigue, frustration and isolation, 2) appropriate exercise for maintaining and improving strength, flexibility, and endurance, 3) appropriate use of medications, 4) communicating effectively with family, friends, and health professionals, 5) healthy eating, 6) making informed treatment decisions, 7) disease related problem solving, and 8) getting a good night's sleep[50].
The content of the course involve a range of skills consistent with the broader visions of literacy but the goal of the program is improved self-management, i.e., empowerment.

Relevance for EMPOWER:
To evaluate and measure skills and motivations necessary to become an empowered patient and to effectively self-manage his/her disease

7.2 Information, Education & Decision Support

In order to meet patients` needs and to support their self-management in a web-based intervention two major topics were apparent throughout the literature (1.) the necessity to involve patients in the design of the interventions, and (2.) the importance of embedding the technological intervention into the primary care system.

7.2.1 Personalized Interventions

An extensive part of the literature reviewed stressed the importance to design personalized interventions. Most successful technological environments allowed individual access, individual setting of goals, provided motivational support, etc.
The personalized approach has already shown to be successful in Lorig's works. All the programs for chronic conditions she developed with her team were "built on needs assessments that identified patient-perceived disease-related problems" [Lorig 2006, p. 965]. Those interventions included "individualized exercise programs; use of cognitive symptom management such as relaxation, visualization, distraction, and self-talk; methods for managing negative emotions such as anger, fear, depression and frustration; an overview of medications; aspects of physician-patient communication; healthy eating; fatigue management; action planning; feedback; and methods for solving problems that result from living with a chronic disease. The course is taught in an interactive manner designed to enhance self-efficacy."
The necessity to focus on patients and involve them in the intervention's design is also crucial for Verhoeven [Verhoeven 2010] who assessed that there is a need of "better tailored" applications' to patients' needs. Targeting their needs does not only mean to make them part of the process, but also to account for differences in the population. For example in Boren`s study [Boren 2009] persons with low level of health literacy have shown to be interested in telephone support but worse in communication with health care professional and less willingness to engage in medical decision making were reported.

7.2.2 Doctor-Patient Relationship (embedding the system)

Primary care is often lacking the resources to give patients the education they need in the first place, and then to continue the relation with them with follow-up support. Therefore diabetes self-management interventions by means of technology, which aim at facilitating

[50] http://patienteducation.stanford.edu/programs/asmp.html Arthritis Self-Management (Self-Help) Program

patients everyday life should account for an integration of these technologies into the primary care activities. Patients would need to have follow-up and constant monitoring in order to become properly empowered [Glasgow 2012]. Internet-based support interventions for example “affect support from pre-existing relationships as well as the new relationships that are formed as part of the intervention. Internet-based interventions might facilitate support seeking from new and pre-existing sources of support” [Barrera 2002].
Interactive technologies are a potential resource to improve the effectiveness of diabetes management programs. These tools can primarily: “1. Assist patients and their clinicians in monitoring changes in health and self-care needs; 2. Support patients’ efforts to make behaviour changes by promoting health and effective self-care; 3. Enhance communication between patients and potential supports for their disease management.” [Piette 2007].

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

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

And useful in increasing:

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

Reduction or change of medication as a an outcome measure has been rarely evaluated. Reduction of depressions seemed to be rather related to interventions that included psychological components than solely focusing on the enhancement of self-management of diabetes patients.
Weight management as an outcome variable of diabetes self-management programs still seems to not to reach expectancies. Most studies with the aim of weight management focus on preventing diabetes rather than on self-management strategies for those that already developed diabetes. Nevertheless, it has to be kept in mind that studies that only evaluated e.g. HbA1c can be considered to be an outcome of eventual weight loss.
Quality of life seemed to improve throughout most of the studies, even though slightly less than HbA1c levels. Nevertheless, comparability between studies was distorted due to the fact that most studies use different measures to assess quality of life.

With regard to patient web portals which integrate electronic medical records and patient health records targeting diabetes patients Osborn and colleagues [Osborn 2010] found that these portals: “…enhance patient-provider communication, increase overall satisfaction with care, expand access to health information, and improve disease management and patient outcomes in diabetes” (Discussion, para 2).

From the review of the literature some practical implications and suggestions for the development of future technologies for diabetes self-management emerged. In the following they are summarized into six main categories, which are linked to each other:

1. First of all it is important to start from an accurate observation of the studies in the literature, which means identifying the barriers and the enablers of self-management in order to design proper interventions and to identify “potential solutions” [Piette, 2007].
2. A second important implication is to tailor technologies to different populations. This implies to use technologies in a way that they can target the different types of patients distinguished by age, media literacy, technology availability, level of health literacy, needs etc. [Boren 2009; Piette, 2007].

3. A third implication is to avoid the use of technology for the sake of technology but to use it on the basis of a solid behavioural theory. This has two main consequences: the first one that appropriate technology should be used depending on the aims, the target etc; a second one is that every intervention should be theory driven [Glasgow 2012; Verhoeven 2010; Piette, 2007].
4. A fourth recommendation is that ICTs should support human contact and exchange, more specifically monitoring and follow up. This dimension highlights the importance of fostering doctor-patient communication, and in general that ICTs should be able to facilitate contact between patient and health care provider. The stress on communication and exchange is fundamental for the motivation of the patients, who should not just use technology to be informed and to insert data but also to use it to enhance communication between themselves and their health care providers. [Glasgow et al., 2012; Boren, 2009; Piette, 2007].
5. The fifth aspect is the necessity to translate the needs of persons involved in diabetes care into a new technology. Everybody should be involved in designing the intervention, thus allowing the development of personalized medicine. Key stakeholders should participate in the requirement analysis of a new technology in order to have a better definition of the context, the channels and the content [Glasgow et al. 2012; Boren 2009; Verhoeven et al., 2010; Piette, 2007]. Many authors stress the importance of integrating the technologies with primary care activities. This is the logical step for the usefulness of a diabetes intervention.
6. As a last implication it is important to pay attention to content, and not just try to develop self-management strategies but to have an holistic approach. A technology for diabetes patients should account for other needs such as education, information, support or communication [Boren, 2009; Piette, 2007].

Relevance for EMPOWER:

- Tailor technologies to different populations (social demographics, literacy levels, needs, etc.).
- Avoid the use of technology for the sake of technology.
- ICTs should support human contact and exchange.
- Integrate patients into the development of technologies.

7.3 Personal Health Records and PHR Systems

7.3.1 PHR

A key issue for patient empowerment is to facilitate the process of accessing and managing the patient‘s own health data**.** An approach that allows individual persons to manage their health information is an electronic Personal Health Record (PHR). The common goal of a PHR is to provide patient access to personal health data to support personal health management and enable better decision making. Although the implementation of electronic PHRs is still in its early stages in most European countries, the PHR is seen with high prospects for future development and is observed as a basic component for implementing self-care and chronic care platforms.

The PHR is an electronic, lifelong record of health information that is maintained by individuals. These individuals own and manage the information in the PHR, which comes from both their healthcare providers and the individuals themselves[51]. A PHR allows

[51] http://www.hoise.com/vmw/07/articles/vmw/LV-VM-08-07-26.html

individuals to become a more active partner in their own healthcare, and gives a person up-to-date information when and where he needs it. A PHR provides a single, detailed and comprehensive profile of a person's health status and healthcare activities. It facilitates informed decisions about the care of the individual. Additionally, a PHR can help people to prepare for appointments, facilitates care in emergency situations, and helps track health changes[52]. Basically, PHR refers to both paper-based and electronic PHRs. However, current usage usually implies an electronic resource and the following descriptions refer to electronic PHRs.
Hence, a PHR is a tool for collecting, tracking and sharing important, up-to-date information about an individual's health. The position statement of AHIMA (American Health Information Management Association) and AMIA (American Medical Informatics Association)[53] points out basic principles that should be followed when using PHR resp. guiding PHR adoption, such as:

- Every person is ultimately responsible for making decisions about his or her health.
- Every person should have access to his or her complete health information. Ideally it should be consolidated in a comprehensive record.
- Information in the PHR should be understandable to the individual.
- Information in the PHR should be accurate, reliable, and complete.
- Integration of PHRs with EHRs of providers allows data and secure communication to be shared between a consumer and his or her health care team.
- People should have control over how their PHR information is accessed, used and disclosed. All secondary uses of PHR data must be disclosed to the consumer, with an option to opt-out, except as required by law.
- PHR products should be certified (e.g. by CCHIT54) to comply with data standards, include a minimum data set, identify each data's source, and meet security criteria consistent
- The operator of a PHR must be accountable to the individual for unauthorized use or disclosure of personal health information.
- A PHR may be separate from and does not normally replace the legal medical record of any provider.
- Privacy protection of PHR data should follow the data. PHR data must not be used in any discriminatory practices.

A PHR should contain any information relevant to an individual's health. For example, a PHR should contain the following information[55]:

- Personal identification, including name and birth date
- People to contact in case of emergency
- Names, addresses, and phone numbers of your physicians, dentists, and specialists
- Health insurance information
- Living wills, advance directives, or medical power of attorney
- Organ donor authorization
- A list and dates of significant illnesses and surgical procedures
- Current medications and dosages
- Immunizations and their dates
- Allergies or sensitivities to drugs or materials, such as latex

[52] https://www.amia.org/files/ahima-amiaphrstatement_1.pdf
[53] https://www.amia.org/files/ahima-amiaphrstatement_1.pdf
[54] The Certification Commission for Health Information Technology (CCHIT, http://www.cchit.org/) is a private not-for-profit organization that serves as a recognized US certification authority for EHR and their networks
[55] https://www.amia.org/files/ahima-amiaphrstatement_1.pdf

- Important events, dates, and hereditary conditions in your family history
- Results from a recent physical examination
- Opinions of specialists
- Important tests results; eye and dental records
- Correspondence between an individual and his or her provider(s)
- Current educational materials (or appropriate web links) relating to one's health
- Diet and exercise logs
- A list of over-the-counter medications

There are multiple reasons why PHRs are useful for persons. Beyond storing critical information for emergency situation, PHRs can avoid duplicate tests and confusion resp. errors between multiple doctors by having the complete health and medical records available. Maybe the most essential benefit for persons is the aspect of having control of their own medical information.[56] Generally, PHRs improve the understanding of health issues and support healthcare decisions and responsibility for care.

7.3.2 HL7 PHR System Functional Model

A PHR system must be able to help the consumer to collect and manage their health information within a framework of an ever-changing healthcare environment. The HL7 PHR System Functional Model (PHR-S FM)[57] focuses on the consumer knowledge and interaction in managing his/her healthcare along with the healthcare providers and systems. The PHR-S FM does not attempt to define a PHR, but rather identify the features and functions in a system necessary to create and effectively manage PHRs. The level of compliance with PHR-S FM could be accessed by the adherence to the model considering its ranking of functions. Overall, the model does divide PHR system functionalities between to core features and optional features – from the perspective of EMPOWER, the optional features might be the most relevant to patient empowerment.

- Core PHR system functionalities
- Optional PHR system functionalities

Several chapters are distributed in separate electronic documents; the following overview (Figure 20) is useful to navigate through the material. Like the IHE profiles, the functional model includes sample profiles:

- Health Authority profile e.g. National health service provides PHR system for citizens
- Payer profile (industry) e.g. an Insurance or health care organisation providing PHRs to customers

[56] http://www.medmemory.com/youtube-video.html
[57] http://www.hl7.org/dstucomments/

The documents in the PHR-S FM DSTU package include the following:

PHR-S Functional Model Documents & File Names	Content
Reader's Guide PHR-FM_ReadersGuide_R1_DSTU_DEC2008.pdf	• Appendix A: How to Fill Out and Submit A Ballot
Chapter One: Overview PHR-FM_Overview_R1_DSTU_DEC2008.pdf	• Background • Purpose & Scope • Overview and Definition of the Functional Model
Chapter Two: Conformance Clause PHR-FM_ConformanceClause_DSTU_DEC2008.pdf	• The conformance clause for PHR-S Functional Model
Chapter Three: Personal Health Functions PHR-FM_PH_R1_DSTU_DEC2008.pdf	• Function name, statement and conformance criteria for Personal Health Care functions
Chapter Four: Supportive Functions PHR-FM_SP_R1_DSTU_DEC2008.pdf	• Function name, statement and conformance criteria for Supportive functions
Chapter Five: Information Infrastructure Functions PHR-FM_IN_R1_DSTU_DEC2008.pdf	• Function name, statement and conformance criteria for Information Infrastructure functions
PHR-S FM Glossary PHR-FM_Glossary_R1_DSTU_DEC2008.pdf	• Glossary • Manage Hierarchy chart
PHR-S Functional Profile_Health Authority-Based DRAFT	• Reference document • Work-in-process example of a profile
PHR-S Functional Profile_Payer-Linked DRAFT	• Reference document • Work-in-process example of a profile

Figure 20: PHR-S-FM Document Overview

The Hl7 PHR-S FM defines a standardized model of the functions that might be present in PHR systems compliant with PHR-S FM. The model is divided into three sections and each section comprises subsections and a number of individual functions:

- **Personal Health Functions** – managing information and features related to self-care and provider based care over time.
- **Supportive PHR Functions** – these are functions that assist with the administrative and financial requirements associated with the delivery of health care. Supportive PHR functions also provide input to systems that perform medical research, promote public health and seek to improve the quality of health care delivered.
- **Information Structure Functions** – these are common functions that support Personal Health and Supportive functions. Information Infrastructure functions ensure that the PHR system provides information privacy and security, promote interoperability between PHR systems and potentially EHR systems.

With relevance to EMPOWER it is worth to have in particular a closer look to the first category because Personal Health functions enable an individual to manage information about his or her healthcare. These functions provide direction as to the individual's ability to interact with a Personal Health Record in such a way so as to individualize the record and maintain a current and accurate record of his or her healthcare activities. Many functions provide the capacity for functionality (e.g., provide for standards-based interoperability), but do not give implementation details. A function, when implemented, must be implemented within the context of the entire PHR-S FM. The following gives an overview about the six subsections of Personal Health (PH) functions including some examples of functions that might be of interest for EMPOWER:

PH.1 PHR Account Holder Profile – manage PHR Account Holder demographics, preferences, Advance Directives, consent directives and authorizations, e.g.

- Identify and Maintain a Patient Record – unambiguously identify the PHR Account Holder;
- Manage PHR Account Holder Demographics – enable the PHR Account Holder to manage information about demographics.
- Manage PHR Account Holder and Family Preferences – enable the PHR Account Holder to add certain preferences that he or she want health care providers to know.
- Manage Consents and Authorizations – enable the PHR Account Holder to manage consent directives and authorizations.

PH.2 Manage Historical Clinical Data and Current State Data – historical health information as well as current health status should be captured and maintained in the health record, e.g.

- Manage Patient Originated Data – manage information sourced or input directly by the PHR Account Holder.
- Manage Data and Documentation from External Clinical Sources – enable the PHR Account Holder to capture and manage historical clinical information.
- Produce and Present Ad Hoc Views of the Personal Health Record – provide for standard and customizable views of the Personal Health Record.
- Manage Current State Data Set – capture and maintain the summary lists depicting the PHR Account Holder's current medical state and history and including problems (including diagnoses), medications, test results, allergies, medical history, surgical history, immunizations, family history, genetic information and social history

PH.3 Wellness, Preventive Medicine and Self Care – assist the Account Holder with maintaining his or her wellness and management of their health conditions, e.g.

- Manage Personal Observations and Care – provide the ability for the PHR Account Holder to enter personally sourced data and to make it available electronically to authorized health care provider
- Communication with Medical Devices – provide the ability for the Account Holder to capture and view monitoring device data and to make it available electronically to authorized health care provider(s) or other authorized users or applications.
- Manage PHR Account Holder Implemented Care Plans – assist the Account Holder to develop, manage, and follow his or her own care plans.
- Manage Provider Implemented Care Plans – enable the PHR Account Holder to capture, record, and display Account Holder specific care plans received from authorized health care providers.
- Manage Medications – assist the PHR Account Holder to manage his or her individual medications.
- Manage Tools and Functions to Assist Self Care – provide various functions to allow the Account Holder to manage their health care events. These tools might include: a health calendar, a task list, a contact list, reminders, alerts or recommendations.

PH.4 Manage Health Education – provide reliable patient education and information customized to the patient based on the information in the PHR to help the PHR Account Holder explore treatment options.

PH.5 Account Holder Decision Support – provide clinical decision support appropriate to the use of the PHR-S in self-care, home health, and remote settings, e.g.

- Manage Guidelines and Protocols – guidelines for general direction in managing a specific problem or condition can be acquired from a variety of sources for improved decision making.
- Drug Interaction Checking – display warnings and severity levels of potential adverse interactions based on the data in the PHR Account

- Integration with Third Party Clinical Decision Support Services – provide the ability to query external clinical decision support services designed for the lay consumer.
- PHR Account Holder Configured Alerts. Alert and reminder messages can be configured by the PHR Account Holder based on a variety of triggers or conditions.

PH.6 Manage Encounters with Providers – manage information for scheduling, preparation, and assimilation of knowledge gained by encounters with providers**,** eg

- Manage Self-Assessments i.e., Symptoms – manage information related to self-assessments.
- Communication between Provider and Patient and/or the Patient Representative – the system should enable the PHR Account Holder to capture information in preparation for the encounter. The system should enable the PHR Account Holder to request appointments with health care providers and capture information in preparation for the encounter.
- Data and Documentation from External Clinical Sources – the system should capture, index, and store documentation related to the encounter.
- Patient Specific Care, Instructions, Treatment Plans, Guidelines and Protocols - the system should facilitate the development of provider-generated care plans and their capture and integration by the PHR-S.

Relevance for EMPOWER:
The HL7 PHR-S FM can serve as a model for structuring functional Use Cases functions for the EMPOWER PHR portal.

7.3.3 PHR Systems

Typically, PHR systems offer a wide variety of features, including the ability to view personal health data, exchange secure messages with providers, schedule appointments, renew prescriptions, and enter personal health data, decision support (such as medication interaction alerts or reminders about needed preventive services), the ability to transfer data to or from an electronic health record and the ability to track and manage health plan benefits and services.[58] Furthermore PHR systems should provide a range of other services that meet the needs of patients such as[59] :

- Provide wireless access to public and private health and medical knowledge bases
- Allow authorized access to own PHR anywhere, especially in an emergency
- Monitor and record nutrition intake, exercise, and other health related activities
- Order or obtain selected services from the preferred physician or healthcare system
- Have their own PHR updated real-time from wearable or implanted biometric sensors
- Access an array of other services tailored to the medical condition of the patient

7.3.3.1 PatientsLikeMe

- **Site:** http://www.patientslikeme.com/
- **Characteristics**: online health support and social networking platform, free account, services available
- **License**: free online service
- **Patient data model**:

[58] http://www.ncvhs.hhs.gov/0602nhiirpt.pdf
[59] http://www.hoise.com/vmw/07/articles/vmw/LV-VM-08-07-26.html

- **Services**: social networking services, discussion forums, search
- **Interoperability**:
- **Description** PatientsLikeMe is a community platform for patients and provides social networking services (search, forums, health profiles, group/individual communication). From the patient empowerment perspective, the focus is to provide patients with emotional support, especially for those patients experiencing isolation or depression, patients seeking community support to make decisions, patients seeking others in similar situations (health problem, age, gender, treatments, symptoms, time since diagnosis, etc.) for their support or their knowledge and ultimately learn from others. On the main web page, users are provided with tools such as Find patients like you and Learn from others

Relevance for EMPOWER:
Relevant to EMPOWER patient information and accessing online support groups. EMPOWER should provide options to connect to existing social networking services for such features as discussion groups, self-help groups, etc..
The use of Federated users and single sign-on enables users to recuse their social software login credentials (OpenID, Facebook account) The main benefit is providing the user with federated access so that a patient can access EMPOWER applications and external applications using the same login credentials – fewer problems to remember multiple user IDs and passwords by using Federated access.

7.3.3.2 WebMD

- **Site** http://www.webmd.com/health-manager
- **Characteristics**: online PHR, free account, services available
- **License**: free online service
- **Services**: Services for health assessment to support decision making
- **Interoperability**: exchanging data, e.g. via connection services (patient record exchange services, device connection services)
- **Description** WebMD Health Manager complements the WebMD website's health materials. The main user facing components of the system include:
    - **HealthQuotient**-- an health assessment tool that scores a user's health status and provides recommendations to help a person their health, including behavioural, life style changes, etc
    - **Health Record** -- an online health record to manage health data for a user and their family members. A family member can maintain family member health records.
    - **Health Trackers undefined** -- graphical tools to track important health data over time.
    - **Child Health Manager** --parents can track and monitor the health of young children

An example of education materials about particular topics, such as the topic of calorie restriction is shown in Figure 21 and Figure 22

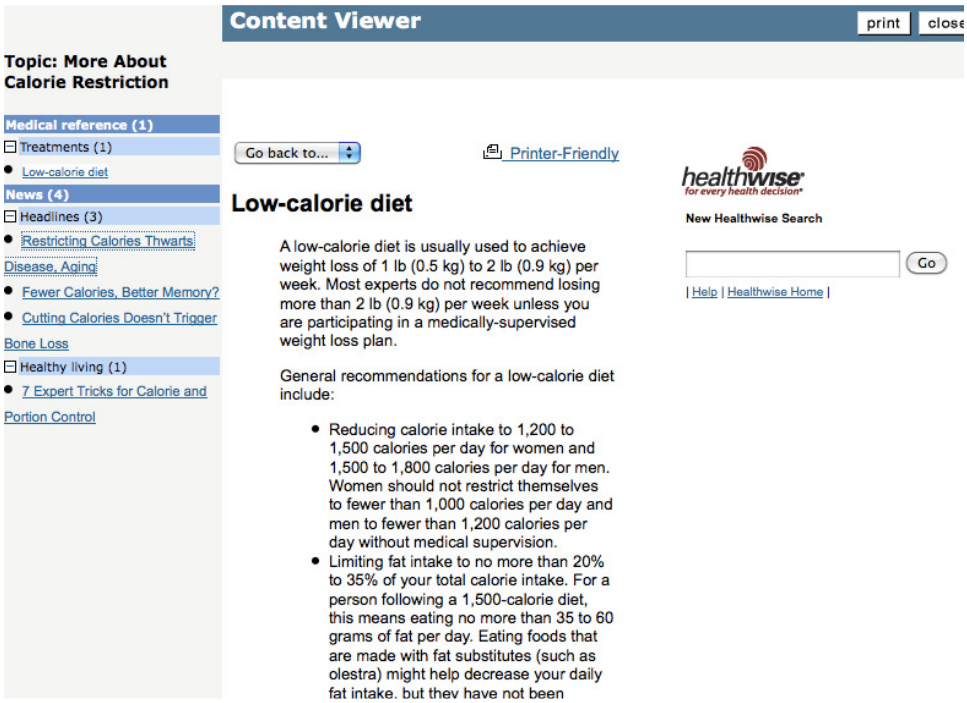

Figure 21: Educational materials

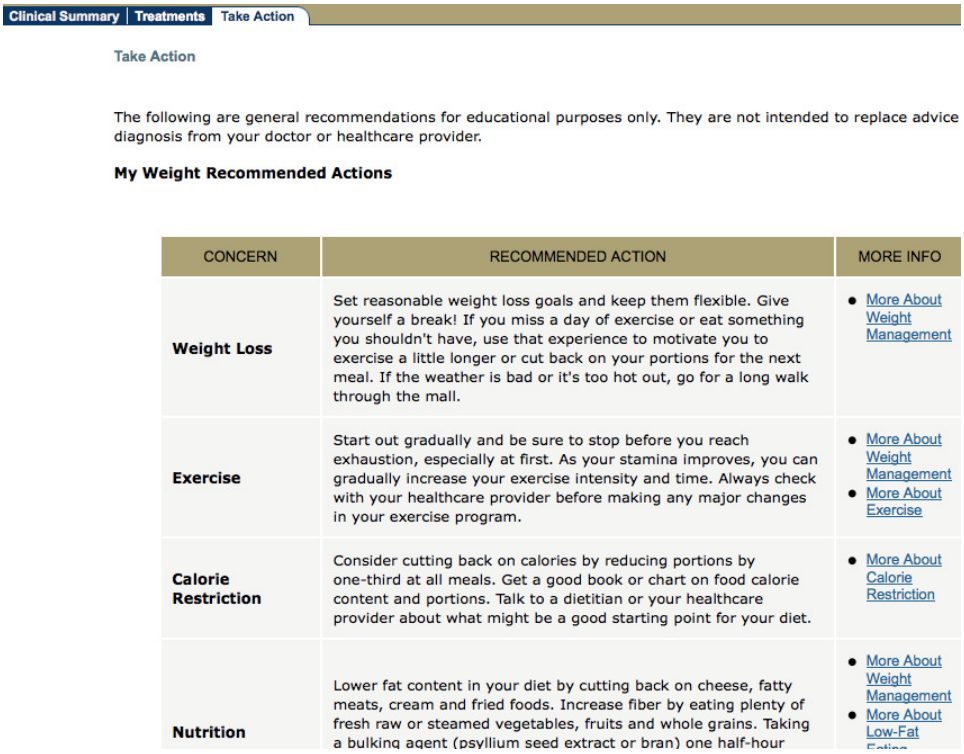

Figure 22: Decision Aids

Relevance for EMPOWER:
Services for patient to assess their health and to support their decision-making with education materials.
Educational material and decision aids provide useful examples for EMPOWER.
WebMD site contains English education materials interlinking by EMPOWER

7.3.3.3 Microsoft HealthVault

- **Site:** http://www.healthvault.com/ and a useful overview[60]
- **Characteristics:** online PHR, standalone PHR via business developer program, free account, services available
- **License:** free online service, mostly closed source, Microsoft business developer program for commercial applications that exploit Microsoft HealthVault.
- **Patient data model:** "Thing Types[61]" are XSD Schema based and define the domain models
- **Services:** core services, 3rd party consumer health services and device connection services
- **Interoperability**: Data exchange via CCR or CCD (see documentation[62])
- **Description:** Microsoft HealthVault describes itself as a health application platform that includes a set of platform services, the means for consumers to include and manage additional services, the ability to share health information electronically. HealthVault also enables consumers to import data from devices. The HealthVault DDK is used to build device drivers for HealthVault compatible devices.

HealthVault strongly supports the development of new applications that connect to HealthVault servers. One can become a HealthVault Solution Provider[63] and build applications use the HealthVault SDK and DDK.

Specialized network device[64] can address device interoperability and transmit data from a variety of compliant home devices via Bluetooth

Relevant to EMPOWER:
Connectivity to user devices might be an important study and compare with EMPOWER approaches.

7.3.3.4 Indivo X

- **Site:** http://indivohealth.org/
- **Characteristics:** standalone PHR
- **License:** open source, http://indivohealth.org/developer-community. The client libraries and sample applications are under LGPL; server sources are GPLV3. Therefore, one must distribute any changes to server sources and make them freely available.
- **Patient data model:** core domain models seem replaceable; to extend, create a domain model and applications to support the domain model. See also Document model schemas[65]
- **Services:** core PHR services for exchanging medical data with EHRs, connecting lab results to clinical studies, diabetes monitor log. Can replace existing services or extend with new services that include a domain model and supporting application and User Interfaces. Interoperability: can create data connectors to other PHRs; actual

[60] Microsoft HealthVault FAQ http://msdn.microsoft.com/en-us/healthvault/cc196394.aspx?rmproc=true
[61] Microsoft HealthVault List of "Thing Types" http://developer.healthvault.com/types/types.aspx
[62] Storing CCR and CCD in Microsoft HealthVault http://msdn.microsoft.com/en-us/healthvault/bb968871.aspx
[63] Microsoft HealthVault Solution Provider http://www.healthvault.com/industry/program-overview.html?rmproc=true
[64] Device interoperability http://www.healthvault.com/websites/MedApps-MedAppsHealthPAL.html
[65] Indivo X Document model schemas http://wiki.indivohealth.org/index.php/Indivo_Document_Model

connectors provided for PHRs: Google Health, Microsoft HealthVault, Dossia. CCR support is mentioned, but lack of CCD support must be confirmed in the latest code of the Indivo X alpha version.

- **Description:** Indivo X is described as a PCHR (Personally Controlled Health Records), platform engine that provides the means to create a PHR and also link other PHRs together. Importantly, they recognise that new data silos are being created in the emerging PHR market; consumers will not have just one PHR. The healthcare company, Dossier, is now involved. Dossier required a governance model to drive future features development.

Indivohealth, the forerunner of Indivo X, has been under development for 15 years, support included the NIH and CDC. The development Community includes Harvard Medical School, Children's Hospital (Boston) and Children's Hospital Informatics program

Relevant features:

- Extend functionalities through modularity. All user-facing apps are modular. Core modules can be replaced with another kind.
- Secure single sign-on, data encryption
- Can connect and share data with other health PHR systems: Google Health, Microsoft HealthVault, Dossia
- Consumer can annotate their data: lab results, allergies, medications (I took 3 tablets)
- Data exchange: Devices, Pharmacy, EHR medical records
- Consumer can share particular data with others by role. Consumer can share particular data with applications. Lab results feed app to find alternative treatments, join studies messaging what available
- One person can manage another person's PHR, e.g. parent manages a child's PHR.
- Consumer has application dashboard and can replace applications, including core applications such as the diabetes log, one can add to the data processing pipeline of an such as providing a graph application for diabetes related monitoring logs

Core Product features

- Module apps integrated into UI
- Management administration tool for organisations that offer Indivo to employees or patients
- Data integration: Data processing pipeline - data derived from many sources (device monitor, CCR record, vitals -->BP over time report)
- Consumer (patient) health messaging for consumption by humans or applications/services
- Sharing and consent management
- Application dashboard for consumer
- Notification board - each application
- Health records and apps
- Languages – python based but includes APIs for Python, Java

Relevance for EMPOWER:
Possible alternative PHR system example, this project recently made a major release that opens more possibilities of integration. Python based, though services might be possible to integrate EMPOWER functionalities.

Licensing is Open Source, but GPL based. EMPOWER will emphasize open source but could provide a more permissive license rather than GPL based.

7.4 Self-Management

Self-management emphasises that persons with chronic diseases has the central role in managing their health. All people with chronic conditions self-manage to some extent, although the ability and resources vary across their lifespan and at different stages of the condition.

7.4.1 What is Self-Management?

People with diabetes have to manage their condition on a day-to-day basis, with the support of their healthcare professionals, their families, friends or maybe other care persons. Self-management enables people to better manage their daily lives with diabetes. Good diabetes management has been shown to reduce the risk of developing complications, enhance quality of life and reduce hospital admissions. But when diabetes is not well managed, it is associated with serious complications including heart disease, stroke, blindness, kidney disease, nerve damage and amputations leading to disability and premature mortality. Typically, diabetes patients have contact with a healthcare professional for a few hours per year, the rest of the time they manage their diabetes and upcoming problems and questions themselves. Approximately 95 per cent of a person with diabetes' management is self-management (Diabetes UK, 2009). Fostering self-management will in particular support patients with long-term conditions to cope better with their disease.

The Diabetes Initiative of the Robert Wood Johnson Foundation[66] defines self-management in the following way (Diabetes Initiative, 2009):

- **Self-management** is what people do to manage their diabetes or other chronic condition and its effects on their physical health, daily activities, social relationships and emotions.
- **Self-management support** is the systematic use of education and supportive strategies to increase patients' skills and confidence in managing their health condition and the problems that may arise. It also refers to the organizational structure health care settings can implement to facilitate improved patient self-management.
- The **goal of self-management support** is to help people achieve the highest possible functioning and quality of life….no matter where along the path they start.
- **Self-Management is the Use of Skills** to
    - Deal with illness, such as medication, physical activity, doctor visits, changing diet
    - Continue the normal daily activities, such as housework, employment, social life, etc.
    - Manage the changing emotions about by dealing with a chronic condition, such as stress, uncertainty about the future, worry, anxiety, resentment, changed goals and expectations, depression, etc.

Successful self-management requires knowledge about the condition, how it needs to be treated and what needs to be done. This may include taking medicines as prescribed, measuring blood sugar and adjusting medications accordingly, eating a healthy diet, getting regular physical activity, and avoiding or managing stress and negative emotions. All of this need to be incorporated into the complex routines of family, workplace, and daily life. And all

[66] http://www.diabetesinitiative.org/whatIsSelfManage.html

of this might also include behaviour changes and learning problem-solving skills and how to cope when things go wrong or become more difficult. Against this background, information about conditions, education and training are key components for self-management and the key self-management activities for diabetes patients comprise the following issues (Diabetes UK, 2009):

- managing the relationships between food, activity and medications
- self-monitoring of blood glucose, blood pressure and having retinal screening carried out
- targeting goals tailored to individual need, for example around footcare, weight loss, injection technique and self-monitoring activities
- applying sick day rules when ill, or what to do if going into hospital
- understanding diabetes, what care to expect and how to access services
- managing acute complications – hypoglycaemia and hyperglycaemia
- understanding legislative issues such as those related to employment and driving.

There are a number of potential barriers to self-management and identifying such barriers can be an essential step in achieving optimal health outcomes. From the patients point of view a primary barrier to diabetes self-management results from the lack of knowledge, in particular when people are not able to access to relevant information or resources that enables them for a more effective self-management. For some people it is difficult to change their long-established behaviours. They may need additional support which needs to be available, too. Financial barriers may include a lack of government support such as an adequate funding for providing education or a local availability of services and on-going support. Barriers can also be conflicting advices or a lack of collaborative working between healthcare professionals not exchanging patient information. From the healthcare professionals points of view they need different skills to effectively support people living with long-term conditions such as diabetes. They have to better understand what self-management means for diabetes patients. Finally, it may also be that people may not want or be able to self-manage. The level of support to self-manage will vary according to what people want or what they feel they need[67].

In 2009, Diabetes UK[67], the largest organisation in the United Kingdom working for people with diabetes, examined how self-management would enable people to better manage their lives with diabetes. They identified six essential elements that people with diabetes need to be able to access:

- **High quality, tailored information** - high quality information in particular for newly diagnosed people was seen as crucial. They should be available in different formats to suit people's varying needs, such as written (e.g. leaflets), visual and/or electronic formats or verbal (e.g. face-to-face support). The need for information to be put into context was raised as a key part of enabling people to self-manage, such as information about test results and the use of self-monitoring where appropriate, so that people with diabetes are not only informed of what tests are required and what their results are, but what those tests actually measure, what the results mean and what effect they will have on the person's management and the actions they take as a result.
- **Access to structured education** – either in group or individual formats, has specific aims and learning objectives, which are shared with people with diabetes, carers and their families.
- **Personalised care planning** – is a joint process between patients and their healthcare professionals and a perfect opportunity to agree goals and provide support to achieve personal action plans around e.g. diet or physical activity. It is also an opportunity to put test results and clinical measures into context and to discuss the patient's self-management goals.

[67] http://www.diabetes.org.uk/

- **Support from family, friends and carers** – access to structured education should also be open to family members, friends and carers. To know how to manage diabetes that they are better placed to support the person with diabetes and be involved in their lifestyle changes. This may help prevent the diabetes patient feeling isolated and also helps integrate self-management into their home and social life.
- **Emotional and psychological support** – the provision of emotional and psychological support should be an integral part of a diabetes service
- **Access to healthcare professionals and trained specialist advises when required** – is seen as a part of good self-management for many people with diabetes who want to contact a trained person for advice when they need it, e.g. for discussing thoughts or ideas, or to ask for advice in times of doubt or difficulty

7.4.2 Self-Management Programs and Initiatives

This section presents some examples of self-management programs and initiatives relevant for the EMPOWER project.

7.4.2.1 The Stanford Chronic Disease Self-Management Program

Chronic diseases influence strongly the daily life of patients. Often health-related decisions and actions can and will be done by the patients themselves. Many of these decisions involve routine activities of daily living (e.g. nutrition, physical activity) and patients should be more involved in decisions about their care, health conditions, treatments and their lifestyle. Consequently patient empowerment should integrate multiple concepts that allow patients to effectively self-manage their disease. Self-management and to work out self-management skills should also be a part of education effort. Lorig [Lorig 1993] defines self-management education as, “learning and practicing the skills necessary to carry on an active and emotionally satisfying life in the face of a chronic condition”. Lorig [Lorig, 2003] also indicates that self-management programs must be also based in on patients’ perceived problems and recommends five major self-management skills as key concepts:

- **Problem solving** – this this means the teaching of problem-solving skills. This will include problem definition, the generation of possible solutions (maybe together with friends or care professionals) or the evaluation of results.
- **Decision-making** – in order to support persons with chronic diseases in their day-to-day decisions which they have to make in response to changes in disease conditions.
- **Resource utilization** – often patients are told about resources but they are not taught how to use them, e.g. the Internet, a library, a community resource guide.
- **Supporting the patient/healthcare provider partnership** – up to the first half of the 20th century the primary reason for seeking health care was to treat acute illness. The role of care provider was to diagnose an illness. Since then, chronic diseases have been increasing more and more. Patients of today are more informed about their diseases. They must be able to report the state of their diseases and discuss that with the health care provider. Against that background the role of the health care provider becomes more that of a professional supervisor.
- **Taking actions in reasonable steps** – this refers to skills in learning how to change behaviour, in particular making short-term action plans and carrying them out. Typically an action plan covers a period of 1-2 weeks and is behaviour specific. At the same time it has to be realistic meaning that a person should be able to accomplish the behaviour in the defined period. If on a scale from 0 (totally unconfident) to 10 (totally confident) the answer is 7 or higher, based on self-efficacy theory, there is a good chance that the action plan will be accomplished.

The Standord model[68] (sometimes called the Lorig model) was developed at Stanford University, USA in the 1990s and has been translated into many languages and implemented throughout the world. Stanford University initially developed the Arthritis Self-Management Program in the 1980s but recognised that self-management skills are common to a range of chronic conditions and a program appropriate for anyone with a chronic condition was developed. The Stanford model offers a workshop, once a week for six weeks, supporting people with chronic diseases (including diabetes) in their self-management. The peer-led program is based on self-efficacy theory and emphasizes problem solving, decision making, and confidence building [Lorig 2001]. It is designed to enhance regular treatment and disease-specific education. The program aims to foster the people's skills to coordinate all the things needed to manage their health, as well as to help them keep active in their lives. Participants will make weekly action plans, share experiences, and help each other solve problems they encounter in creating and carrying out their self-management program. The program for type 2 diabetes covers the topics such as

- healthy eating and menu planning
- managing blood glucose
- techniques to deal with problems such as fatigue, frustration and isolation
- appropriate exercise for managing blood glucose and for maintaining and improving strength, flexibility, and endurance
- appropriate use of medications
- communicating effectively with family, friends, and health professionals
- goal-setting
- disease related problem solving

The Stanford model has a strong focus on goal-setting and problem solving and facilitates empowerment of participants through peer learning and sharing. Additionally, the workshop is also available as online guided by two trained moderators.

7.4.2.2 Diabetes Initiative of the Robert Wood Johnson Foundation

The Diabetes Initiative[69] was a national program of the Robert Wood Johnson Foundation from 2002 to 2009. It focused on improving self-management supports for adults with diabetes in primary care and community settings. The program identified eight organizational and eight patient support characteristics of self-management support that can be improved in a primary care setting to ensure that self-management is an integral part of usual care. These 16 characteristics were developed into a self-assessment tool to be used to assess current capacity and to guide quality improvement. The tool "The Assessment of Primary Care Resources and Supports for Chronic Disease Self Management" (PCRS) is based on the idea of the Chronic Care Model[70] and aims at identifying optimal performance as well as gaps in resources, services and support. Additionally, the PCRS aims to help teams integrating changes into their systems by identifying areas where self-management support is needed.

Organisational support (the macro level) – addresses characteristics of organizations that support the delivery of self-management services

- continuity of care
- coordination of referrals
- on-going quality improvement
- systems for documentation of self-management support
- patient input integration of self-management support into primary care
- team care and
- professional education and training

[68] http://patienteducation.stanford.edu/programs/cdsmp.html
[69] http://www.diabetesinitiative.org
[70] http://www.improvingchroniccare.org/index.php?p=the_chronic_care_model&s=2

Patient support (the micro level) – addresses characteristics of service delivery that enhances patient self-management:

- individualized assessment of patient self-management educational needs
- self-management education
- collaborative goal setting
- problem solving
- attention to emotional health
- patient involvement in decision making
- patient social support and
- links to community resources

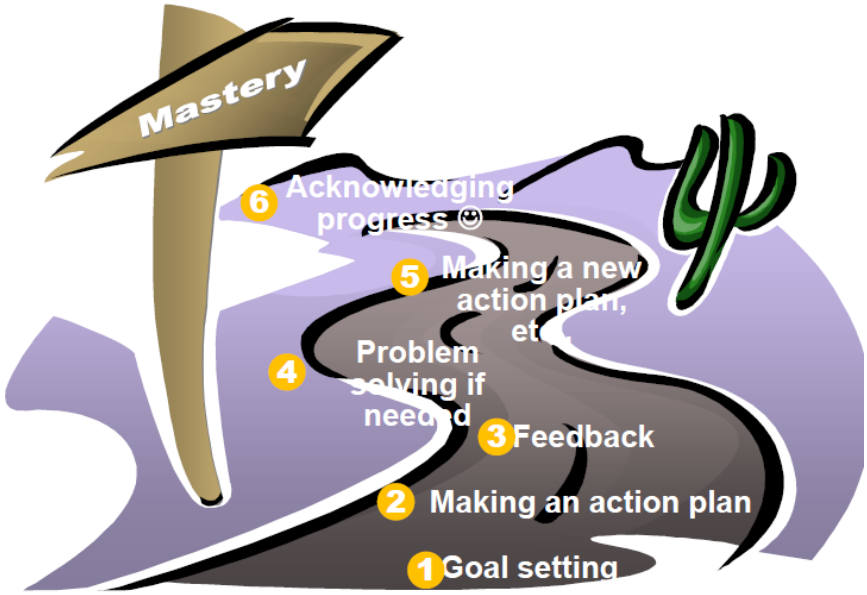

Figure 23: Road to mastering self-management skills (Diabetes Initiative, 2009)

Figure 23 and Figure 24 gives an overview how self-management skills can be fostered and mastered by people. The first step is the specification of personalised goals, ideally together with the treating physician and family members. Goals are major changes that may take a few or many steps to reach. Based on these goals the patient defines the action plan. An action plan is an agreement of the patient with himself to practice positive health behaviours to meet the previously defined goals. The patient should also think about possible barriers or whether s/he would need help from another person for any of the defined actions. The results should be documented and the goals should be systematically reassessed and discusses with the patient. Based on these findings and experiences the action plan can be updated. The progress should be acknowledged.

Additionally, problem-solving strategies can be a helpful component for patients for coping with upcoming diabetes-relevant situations and should be an integral part of the care process (see Figure 24). Basically, problem-solving techniques are applied on the following steps [Fischer 2009]:

1. Specifying the problem
2. Generating alternative ways of dealing with the problem
3. Choosing from the alternatives
4. Implementing the chosen alternative
5. Reviewing results
6. Recycling to previous steps as necessary.

A frequent approach for fostering self-management is to focus on problems identified by participants. This is emphasized, for example, in the Stanford Chronic Disease Self-Management Program (see section 7.4.2.1) in which work on problem solving begins with problems that the participant identifies, whether or not they are directly related to diabetes or other health issues. This issue is of particular concern in diabetes in which there is a direct relationship between disease management and behaviours such as healthy eating and physical activity. In practice, education programs and workshop teach the basic concepts of problem solving [Fischer 2009].

I: PATIENT SUPPORT (circle one NUMBER for each characteristic)				
Characteristic	Quality Levels			
	D	C	B	A (=all of B plus these)
3. Goal Setting	…is not done 1	…occurs but goals are established primarily by member(s) of the health care team rather than developed collaboratively with patients 2 3 4	…is done collaboratively with all patients/ families and their provider(s) or member of healthcare team; goals are specific, documented and available to anyone on the team; goals are reviewed and modified periodically 5 6 7	…is an integral part of care for patients with chronic disease; goals are systematically reassessed and discussed with the patient; progress is documented in the patient's chart 8 9 10
4. Problem-Solving Skills	…are not taught or practiced with patients 1	…are taught and practiced sporadically or used by only a few team members 2 3 4	… are routinely taught and practiced using evidence based approaches and reinforced by members of the health care team 5 6 7	…. is an integral part of care for people with chronic disease; takes into account family, community and environmental factors; results are documented and routinely used for planning with patient 8 9 10
5. Emotional Health	…is not assessed 1	…is not routinely assessed; screening and treatment protocols are not standardized or are nonexistent 2 3 4	…assessment is integrated into practice and pathways established for treatment and referral; patients are actively involved in goal setting and treatment choices; team members reinforce consistent goals 5 6 7	…systems are in place to assess, intervene, follow up and monitor patient progress and coordinate among providers; standardized screening and treatment protocols are used 8 9 10

Figure 24: Patient Self-management Support [Brownson 2007][71]

7.4.2.3 The Flinders Program of Chronic Condition Self-Management

The Flinders Program[72] was developed at the Flinders University in South Australia in the 1990s. It focuses on a comprehensive one-to-one self-management assessment and provides health professionals with tools to assess the self-management capability of patients. Additionally, the Flinders Program supports the development of collaborative care plans with the patients. The program aims providing a consistent, reproducible approach to assessing the key components of self-management that:

- improves the partnership between the client and health professionals
- collaboratively identifies problems and therefore better (i.e. more successfully) targets interventions

[71] Letter A-D: characteristic levels, A=highest level , D= characteristic is not demonstrated; Numbers: within a level, the degree to which a characteristic is being addressed

[72] http://www.flinders.edu.au/medicine/sites/fhbhru/self-management.cfm

- is a motivational process for the client and leads to sustained behaviour change
- allows measurement over time and tracks change
- has a predictive ability, i.e. improvements in self-management behaviour as measured by an assessment tool, related to improved health outcomes

The Flinders care planning process has five functions (e.g. case management) and the self-management support is one of these five functions. The program identified seven characteristics of “good” self- management and summarise a 'good' self-managers as individuals who

1. Have knowledge of their condition
2. Follow a care plan agreed with their health professionals
3. Actively share in decision making with health professionals
4. Monitor and manage signs and symptoms of their condition
5. Manage the impact of the condition on their physical, emotional and social life
6. Adopt lifestyles that promote health
7. Have confidence, access and the ability to use support services.

The essential assessment tool is the Partners in Health Scale (PIH), a questionnaire that is based on the principles of self-management. The client completes the questionnaire by scoring their response to each question on a nine point scale, zero being the worst response and eight being the best. The questions cover the following areas:

- Knowledge of condition
- Knowledge of treatment
- Ability to take medication
- Ability to share in decisions
- Ability to attend appointments
- Ability to monitor and record
- Ability to manage symptoms
- Ability to manage the physical impact
- Ability to manage the social impact
- Ability to manage the emotional impact
- Progress towards a healthy lifestyle
- Ability to know and navigate the health system

The Flinders Program is very individualised but time-intensive and promotes a person-centered focus through emphasis on defining the person’s goals rather than clinical goals.

7.4.2.4 Behaviour Change Model (The 5As)

The Behaviour Change Model[73] is used to train health professionals in behaviour change counselling. The model is based on five steps that will enable health professionals to understand the beliefs and knowledge that inform a person’s perception of their wellbeing and condition. This can be a basis for discussions with the patient. The five steps are:

- **Assess** – explore the patient’s knowledge, belief and values, e.g. does s/he has sufficient knowledge about the illness to effectively and confidently self-manage?
- **Advise** – Share with the client information about risks, health enhancing behaviours, the illness and treatment. Find out what your client already knows and build on this information. Give a clear message of encouragement to change.
- **Agree** – jointly set goals based upon readiness to change

[73] http://www.selfmanagement.health.wa.gov.au/self-management/self-management-support/the-5-as-cycle.html

- **Assist** – help the client to identify barriers and problem solve to identify potential solutions. Discuss strategies and resources available to help them
- **Arrange** – arrange a follow up appointment or visit before the client leaves. This provides the client with a time frame for achieving some or all the goals and also indicates support.

Based on the five steps health professionals are enabled to understand the patient's beliefs and knowledge about their disease. The model is a counselling approach used to enhance the likelihood of behaviour change in patients.

Relevance for EMPOWER:
Basically, the self-management approach in EMPOWER is based on the key concepts of Kate Lorig (Lorig, 2003), in particular the concepts about decision making, resource utilisation, supporting the patient-physician relation and taking actions in reasonable steps implemented as the Action Plan in EMPOWER.
Additionally, some of the results of the Diabetes Initiative of the Robert Wood Johnson Foundation can also be adopted for EMPOWER but will need further analysis in the course of the EMPOWER project, in particular, their recommendation and their road map for mastering self-management skills (including goals setting, making an action plan and problem-solving).
Finally, the 5 A's of the Behaviour Change Model baseline for the appointment of the physicians with his diabetes patients and hence, for the workflow supported by the Recommender Engine in EMPOWER.

7.5 Observations of Daily Living

Observations of Daily Living (ODLs) are considered important to managing one's health as well as managing various treatment plans. ODLs are "patterns and realities of daily life" including but not limited to "diet, physical activity, quality and quantity of sleep, pain episodes, mood" and adherence to medication regimens.[74] ODLs support the idea of people tracking aspects of their health. ODLs may support personal health goals (e.g. monitoring blood pressure) but they can also be person-defined observations. Questions such as whether variations in stress, exercise, and diet affect the blood glucose level have much more relevance to someone who suffers from diabetes than to healthy people. Another example is patients with diabetes who may record their blood glucose levels every day at home, generating data to share with their clinician. That kind of patient-generated data can be a crucial input for medical decision making. ODLs may very well complement biomedical indicators and inform medical decision making by providing a more complete and holistic view of the patient as a whole person.

Typically, ODLs are connected to Personal Health Records (PHR). PHRs are designed for individual users to help them engage in their own health management. The information stored in a PHR can be radically different from Electronic Health Records (EHR). Both should contain accurate data on the patient's current medical status such as lab values and medications but they have different target groups – the EHR for medical and care persons, the PHR for patients - and hence, they are designed for different purpose.[75] For that reason, PHR systems should additionally collect observations and patterns of the patient's daily living such as physical activities, mood, pain episodes, medication adherence and sleep patterns

[74] Robert Wood Johnson Foundation, http://www.rwjf.org/pr/product.jsp?id=51248
[75] http://www.scribd.com/doc/14427729/Observations-of-Daily-Living-primer-from-Robert-Wood-Johnson-Foundation

and be able to make personalized recommendations for e.g. minimizing chronic pain or the blood sugar level.

Observations and patterns of daily living are cues that people attend to in the course of their everyday life, that inform them about their health. They are different from signs, symptoms, and clinical indicators and can therefore not be directly mapped to biomedical models of disease and illness. Typically, they are defined by the patient and their families because they are meaningful to them, and help them to self-manage their health and make decisions about it.

The process of collecting ODLs might require a person to express and articulate their health cues – both this input process and the trend reporting can be beneficial. For example Intel Corporation's Mobile Therapy application helps the user to manage stress, improve mental health and reduce the risk of cardiovascular disease[76]. Sports related mobile applications might motivate users toward health goals, especially in a social and "collaborative web" lightly competitive atmosphere, such as GPS-based mobile sports applications that share across social applications and report a runners' routes on a map, their times, and moods. The concept is "improve yourself" and pertains not only running, but many exercise related activities that users can report. The social-competitive actions we make can clearly motivate us to improve health

To support health applications, the Robert Wood Johnson Foundation created Project HealthDesign[77] in 2006 that also provides core services for Observation and Calendaring, and enables registered health applications to potentially even interconnect and share data based on access control settings. The following Personal Health Applications were developed as medical applications[78] [79].

- *iN Touch*- is working with low-income teens who are obese to see whether and how tracking ODLs informs the participants' health management and well-being
- *Breath Easy* – for patients with asthma to provide a clearer picture of their health in everyday life for treatment and self-monitoring
- *Chronology.MD – for* young adults who suffer from Crohn's disease create visual narratives of their condition and treatment to provide concrete feedback to providers about how they feel from day to day.
- *FitBaby* – is a mobile application to collect information from high-risk infants and their caregivers and allows the caregivers to more easily interface with clinicians to improve care and communication

Beyond any the context of medical applications, there is a plethora of health realty applications for mobile devices as seen in the smart phones application marktet places (food logging, weight management, fitness management).

Mobile technologies and ODLs – One important question relevant to EMPOWER is: Can mobile eHealth applications be used to change or improve one's health related behaviors? The conference, *Mobile Health 2010 Using Mobile Technology to Change Health Behavior*[80]*,* brought the mobile health community to address this very question. A patient does not have only one condition; a patient will have other conditions, some associated with the particular disease, some not or not yet medically proven. For example, ODLs relevant to conditions of diabetes, obesity and depression can be collected and assessed depending on what the healthcare provider or patient determines is best for motivating the patient in achieving their health goals.

[76] Metal Health Apps http://www.npr.org/templates/story/story.php?storyId=127081326
[77] http://www.projecthealthdesign.org/
[78] HealthDesign Projects http://www.projecthealthdesign.org/projects/current_projects
[79] HealthDesign blog, projects– Embedded Assessment http://projecthealthdesign.typepad.com/project_health_design/
[80] Mobile Health 2010 Using Mobile Technology to Change Health Behavior http://www.mobilehealth2010.org/

The use of these health applications includes social features especially to encourage people to share and even compete. EMPOWER should consider allowing patients to share results to motivate patients (compliance/motivation related to an EMPOWER action plan, patient information) within a peer group.

Today's mobile applications often can be exploited for achieving one's health goals. Many existing tools are either used as is or specialized for health us to realize our health goals, such as social web, blogging, forums, electronic calendars – people create our spaces for discussing health, recording our planned activities and results – our observations. Logs for diet, exercise, or medication are easily created in electronic calendars or shared in social applications such as Facebook. Texting and messaging have been cited as positive for one's health goals. Texts delivered to mobile devices (phones, watches). Texts can be referenced, collected and used for self-management or for interacting with a health care professional.
People actively engage in creating plans and record both the plans and often the resulting observations. Unfortunately, very little semantics are involved and application providers create more data silos, leaving applications to handle the interoperability problems when attempting to aggregate patient data from these applications. Even applications, such as calendars or blogs could be categorized as health applications when used to support one's health related activities, events, or appointments. The application marketplace supporting smart phones (e.g. iPhone, Android based) includes many social health related applications, such as Runtastic[81], to capture ODLs relating to exercise events, including mood.

Relevance for EMPOWER:
Many ODL applications are found in the mobile market place, however, many are not specifically used in patient context.

7.5.1 Project HealthDesign

- **Site:** http://www.projecthealthdesign.org/artifacts/artifacts-2006-08
- **Characteristics**: standalone PHR component platform, services available
- **License**: open source (LGPL)
- **Patient data model**:
- **Services**: supports Personal health applications that can include core functionalities of a PHR system and other applications relating to patient empowerment.
- **Interoperability**: exchanging data among Personal health applications and PHRs via component available via software interfaces or SOAP services. Interoperability is addressed at the level of shared components for authentication (single sign-on), common security (access control) and common service registry
- **Description:** The applications include core PHR functionalities such as managing PHR data, however, there is no default implementation for connecting to EHR systems or exchanging data using standards (e.g. CCR). Health applications created focus mainly on particular *Patient Empowerment* related themes and includes, a calendaring service, observations of daily living (ODLs) core service, a specialized Medications service that enables the medication application user to manage and annotate medication related data.

Platform enables multiple registered health applications to store and retrieve common data as well as to share users' authentication (login) information and patients' access-control

[81] http://runtastic.com/en

(security) rules. Patient information entered by one Personal health application (PHA) may be shared with other PHAs, and patients can centrally manage the rules for sharing their information.

Core shared components (applications and shared services rely upon)

- Authentication
- Registry Service for registering applications services and manages user, password and demographic data
- Access control service

Available Services include

- Security related (Authentication, single sign-on, access control functionalities)
- Medication list management includes management (record, track, share) annotation of data, provides advice to patient based on medication list
- Observation Service – supports applications for Observations of Daily Living (ODL); observations that are input by or for patients (by services, other users) outside of health care encounters
- Calendaring: Resources to help registered applications to record, track, share, and remind patients of specific scheduled events that are relevant to their healthcare
- Identity Management: services to manage users and respective application or system components that may access specific patient data; handles user and service authentication that request access to patient data; provides means for users to monitor and manage access control to their health data.

Example Projects based on the PHR system

The following Personal Health Applications have been developed by the community [82] [83] Diabetes self-management, Embedded Assessment, *iN Touch*, *Breath Easy* (addresses Asthma, depression and anxiety), *Cronhnology.MD*, *FitBaby*. Depression and anxiety are two issues are relevant to all patients.

Relevance for EMPOWER:
Many ODL applications are found in the mobile market place.
Applications and infrastructure supporting ODLs.
Relevant diabetes related subprojects – Diabetes Self-management.
Security architecture: consent management & authorization, authentication.
Services architecture supporting ODLs including medications.

[82] HealthDesign Projects
http://www.projecthealthdesign.org/projects/current_projects
[83] HealthDesign blog, projects– Embedded Assessment http://projecthealthdesign.typepad.com/project_health_design/

8 Health Information Technology Standards and Interoperability Initiatives

There is a multitude of heterogeneous and fragmented healthcare information systems used, that mostly are designed to mirror the current, manual way of using and exchanging clinical data. The prevalent lack of agreed and implemented standards impede the transfer of detailed healthcare information in a way that supports full integration of that data within the receiving systems [SemanticHealth 2007]. In order to process EHR data safely, semantic interoperability is required, meaning that computational services are enabled to reliably interpret clinical data that has been integrated from diverse sources [Stroetmann 2009]. So far various initiatives have contributed towards establishing a semantic framework for health records as described below.

8.1 HL7

Founded in 1987, Health Level Seven (HL7) International[84] is a not-for-profit, ANSI-accredited standards development organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.
HL7's has more than 2,000 members representing 500 corporate members, which include more than 90 percent of the information systems vendors serving healthcare.
Currently, 90% of hospitals in the US implement HL7 in the lab. HL7 has 35 national affiliates (2009), while recent HHS interim rule specifically mentions the following standards:

- Clinical Document Architecture (CDA) for Patient Record Summary
- Continuity of Care Document (CCD) for - Patient Record Summary
- Messaging Standard Version 2.5.1 for Submission of lab results to public health agencies. Submission to public agencies for surveillance or reporting (excluding adverse events reporting); may be used in place for 2.3.1 for this purpose
- Messaging Standard Version 2.3.1 for Submission to public agencies for surveillance or reporting (excluding adverse events reporting); may be used in place for 2.5.1 for this purpose.

[84] www.HL7.org

8.1.1 Clinical Record Architecture

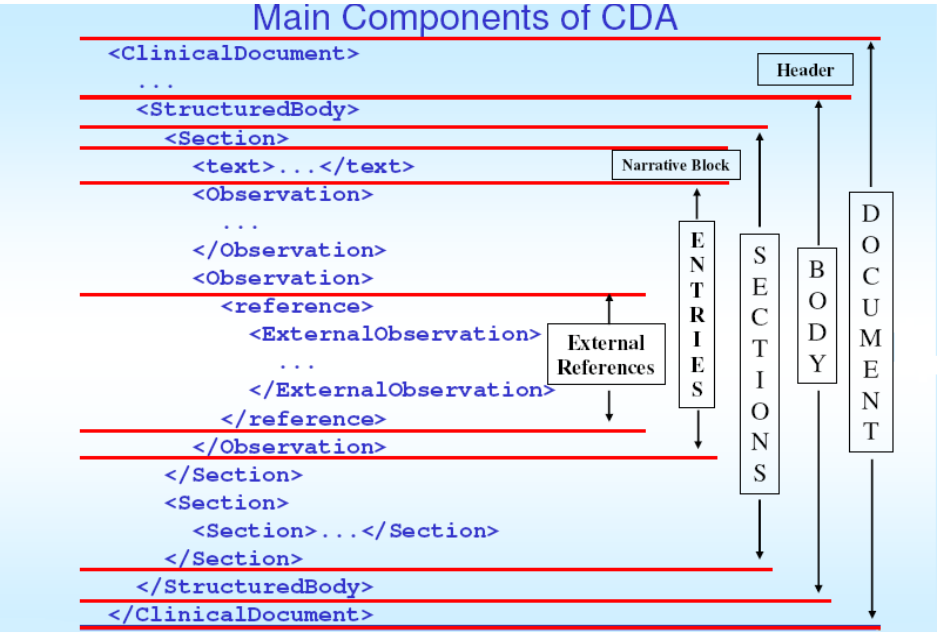

Figure 25: Clinical Document Architecture structure [Source and ©R. Spronk]

HL7 CDA is the Clinical Document Architecture, an ANSI-certified standard from Health Level Seven (HL7.org). Release 1.0 was published in November, 2000 and Release 2.0 was published with the HL7 2005 Normative Edition. Currently,HL7 is working on CDA release 3.0.
HL7 CDA is specifies the syntax and supplies a framework for specifying the full semantics of a clinical document. It defines a clinical document as having the following six characteristics:

- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

A CDA can contain any type of clinical content. Typical CDA documents would be a Discharge Summary, Imaging Report, Admission & Physical, Pathology Report and so on. CDA uses XML, although it allows for a non-XML body (pdf, Word, jpg and so on) for simple implementations.

8.1.1.1 CDA Tools

Many vendors have developed CDA-compliant applications for document generation, management and viewing. Since CDA is implemented in XML (Extensible Markup Language, see w3.org), any XML-capable application can work with CDA. So, for example, any web browser, such as MS Internet Explorer or Firefox can parse a CDA document and using an XSL stylesheet, to convert it to HTML for display. Similarly, any XML-capable repository can manage CDA.
For document generation, implementers have a variety of choices. Several dictation/transcription vendors offer CDA as an output format. Many EHR vendors can produce CDA, typically as a conversion from a native format. In addition, eForms applications have been developed for CDA using readily-available desktop technology. Some implementations use dynamic forms population from distributed sources to pre-populate CDA with existing data.
The only barrier to CDA generation with existing technology is where insufficient information is available at the source for conversion, but to-date, this has not been a problem from either voice-interface or keyboard-entry applications.

CDA introduces the concept of "incremental" semantic interoperability. What this means is that there is a range of complexity allowed within the specification and users must set their own level of compliance. The minimal CDA is a small number of XML-encoded metadata fields (such as provider name, document type, document identifier, and so on) and a body which can be any commonly-used MIME type such as pdf or .doc (Microsoft Word) or even a scanned image file.
While the body of such a document would not be interpretable for applications like decision support, the minimal, standard metadata set and display characteristics mean that such a document could be filed, searched, categorized and retrieved along with more richly-encoded documents. They would all be equally readable at the point of care.
CDA R2 was updated to the most recent RIM and adds significant functionality to the CDA body. The major addition to the CDA body is the clinical statement model which uses RIM structures and controlled vocabulary to permit a much higher level of semantic interoperability. In contrast, R1 was restricted to single coded entries which were not fully expressive. CDA R1[85] allowed Levels 1 & 2 (with coded entries); R2[86] allows Levels 1, 2 and 3 (with clinical statements). While R2 allows greater complexity, it still allows the same low level of encoding as R1 and needs not to be any more complicated to implement.
At the high end, CDA documents can be encoded with the full power of the HL7 Reference Information Model (RIM) and controlled vocabulary such as LOINC, SNOMED, ICD, CPT and so on. There are rich free resources on CDA available on the internet[87].

8.1.1.2 CDA Implementation Guides

CDA implementation guides constrain CDA to specific domains. Particular implementation guides of interest to EMPOWER are:

- HL7 Implementation Guide: Continuity of Care Document (CCD) Release 1
- Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm)
- HL7 Implementation Guide for CDA Release 2: Imaging Integration; Basic Imaging Reports in CDA and DICOM, Release 1.

Relevance for EMPOWER:

CDA is a specially significant format for exposing EHR data to the EMPOWER system. It supplies an essential building block for the system architecture, providing syntactical interoperability with EHR/HIS systems (the semantic level being addressed by the use of HL7 common terminology services). Therefore the use of CDA contributes to solve the issues at the core of Task 6.4 – EHR/PHR interoperability with Health Applications - in the project.

8.2 IHE

Integrating the Health Enteprise (IHE)[88] promotes the coordinated use of standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. The IHE process is defined in ISO28380, and according to that one starts with an existing interoperability problem e.g. scheduled workflow in radiology. Using existing standards it develops a domain specific profile: IHE profiles address critical interoperability issues related

[85] http://www.alschulerassociates.com/library/documents/Dolin_JAMIA.pdf
[86] http://jamia.bmj.com/content/13/1/30.full.pdf+html
[87] http://www.alschulerassociates.com/library/?topic=documents
[88] http://www.ihe.net

to information access for carers & patients, clinical workflow, security, administration, information infrastructure.
The implementation of IHE profiles is based on IHE technical frameworks comprise detailed specifications for: IHE actors, IHE transactions.
IHE Connectathons play a key role in the IHE process: at least 3 independent companies prove interoperability according to a profile in this event that lasts one week. Following a Connectathon, a vendor may publish an Integration statement, a document created by vendors to describe conformance of their products.

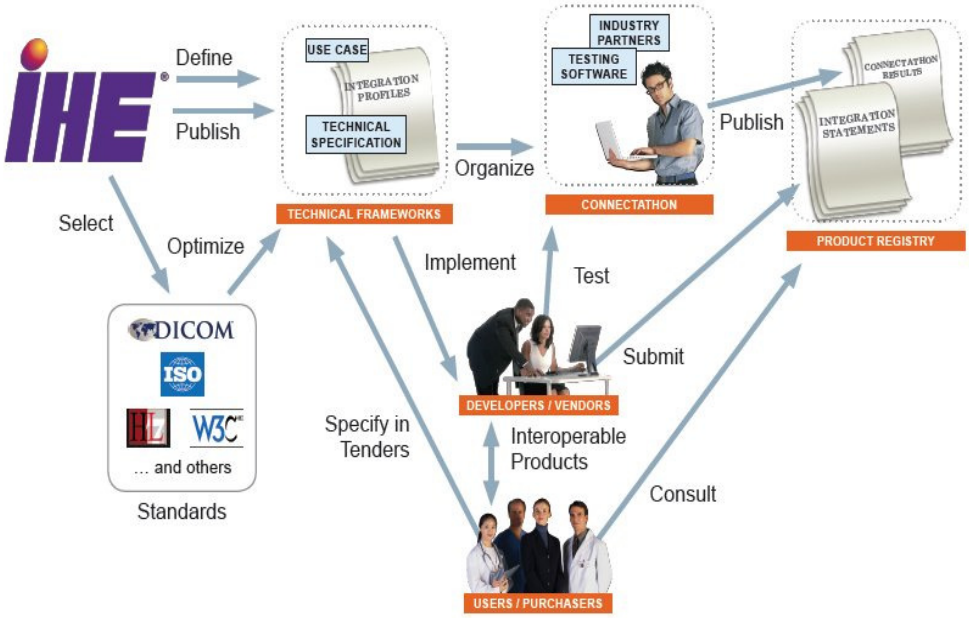

Figure 26: The IHE methodology.

IHE Domains are responsible for the development and maintenance of the IHE Technical Frameworks that document the Integration Profiles. Each Domain manages Integration Profiles in a particular part of healthcare. For convenient reference, each Domain has a short acronym.

8.2.1 IHE Profile XPHR - Exchange of Patient Health Records

Specific for PHR and EHRs data exchange, the IHE describes the XPHR Profile, the profile for the Exchange of Patient Health Records. The IHE profiles address how standards or specifications can be implemented to meet specific clinical requirements - provides a means to help compliance with standards and achieve interoperability. See also the IHE Patient Care Report IHE Patient Care Report
IHE Profiles address interoperability and they are a means to support developers in the use of standards and processes that use these standards.
There are other IHE profiles that we might consider in EMPOWER, but specifically, we are interested presently in the profiles organized under the IHE Patient Care Coordination. The IHE Exchange of Patient Health Record Content Profile (XPHR) specifies HL7 document exchange standards and processes described as: PHR update and PHP Extract, two processes to exchange patient information between an EHR and PHR. The XPHR profile is part of a larger profile called the IHE Patient Care Coordination Profiles We expect the OpenEHR IPF interoperability framework will undertake XPHR profiling in the next year.

8.2.1.1 IHE XPHR references

Patient Care Coordination Framework Technical documents, for the latest documents relevant to the CDA Content Modules (XPHR Extract and XPHR Update)

- XPHR Exchange of Patient Health Record Content Profile
- XPHR Extract - initial extraction of content and further sharing of content (bidirectional)
- XPHR Update - to keep the PHR system updated when something changes in the EHR
- The Figure 27 XPHR Process flow between a provider EHRs and PHR system outlines the data exchange process involving XPHR Extract and XPHR update.

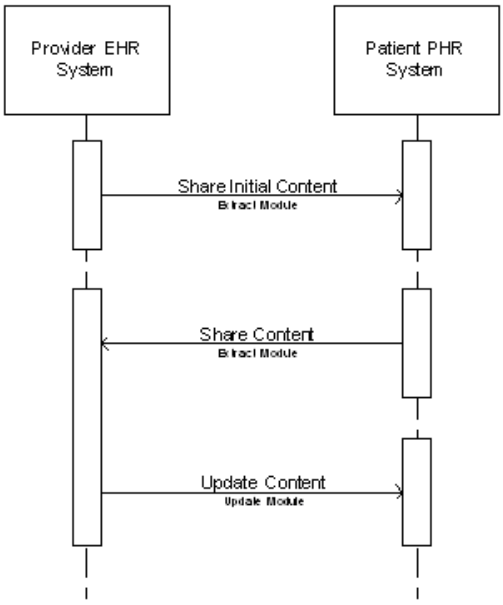

Figure 27: XPHR Process flow

8.2.2 Relationship of Continuity of Care Document to IHE

The HL7 Clinical Document architecture (HL7 CDA) includes the specifications for the CDA Document Content Modules that include specifications for Medical Summaries, XPHR Extract and XPHR Update, etc.(see Figure 28).

CDA Document Content Modules

Medical Documents Specification	(1.3.6.1.4.1.19376.1.5.3.1.1.1)
Medical Summary Specification	(1.3.6.1.4.1.19376.1.5.3.1.1.2)
Referral Summary Specification	(1.3.6.1.4.1.19376.1.5.3.1.1.3)
Discharge Summary Specification	(1.3.6.1.4.1.19376.1.5.3.1.1.4)
History and Physical	(1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4)
PHR Extract Specification	(1.3.6.1.4.1.19376.1.5.3.1.1.5)
PHR Update Specification	(1.3.6.1.4.1.19376.1.5.3.1.1.6)
Emergency Department Referral Specification	(1.3.6.1.4.1.19376.1.5.3.1.1.10)
Antepartum Summary	(1.3.6.1.4.1.19376.1.5.3.1.1.11.2)
Triage Note	(1.3.6.1.4.1.19376.1.5.3.1.1.13.1.1)
Nursing Note	(1.3.6.1.4.1.19376.1.5.3.1.1.13.1.2)
Composite Triage and Nursing Note	(1.3.6.1.4.1.19376.1.5.3.1.1.13.1.3)
ED Physician Note	(1.3.6.1.4.1.19376.1.5.3.1.1.13.1.4)
Antepartum History and Physical	(1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1)
Antepartum Laboratory	(1.3.6.1.4.1.19376.1.5.3.1.1.16.1.2)
Antepartum Education	(1.3.6.1.4.1.19376.1.5.3.1.1.16.1.3)
Immunization Detail	(1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2)
Prehospital Patient Care Report	(1.3.6.1.4.1.19376.1.5.3.1.1.19.1)
Care Plan	(1.3.6.1.4.1.19376.1.5.3.1.1.20.1.1)
Subsequent Evaluation Note	(1.3.6.1.4.1.19376.1.5.3.1.1.20.1.2)
Labor and Delivery Admission History and Physical	(1.3.6.1.4.1.19376.1.5.3.1.1.21.1.1)
Labor and Delivery Summary	(1.3.6.1.4.1.19376.1.5.3.1.1.21.1.2)
Maternal Discharge Summary	(1.3.6.1.4.1.19376.1.5.3.1.1.21.1.3)

Figure 28 - CDA Document Content Modules List[94]

The IHE includes the CCD for Patient Care Coordination in seven of its profiles.
IHE's XDS Medical Summary for referral and discharge is also being built upon HL7's CCD.

8.2.2.1 Implementation Guides Using CCD

There are CDA implementation guides that make use of CCD templates. These include:

- CDA for Consult Notes, Release 1 (see link to CDA Implementation Guide),
- CDA for Operative Notes (see link to CDA Implementation Guide)
- CDA for History and Physical
- Quality Reporting Document Architecture
- CDA for Procedure Notes

8.2.2.2 Use of HL7 CDA in IHE profiles

HL7 Clinical Document Architecture and CCD are currently used in Medical Summaries (XDS-MS), Emergency Department Referral (EDR), Exchange of Personal Health Record Content (XPHR).
There are Trial Implementations for Emergency Department Encounter Summary (EDES), Antepartum Record (APR), Labor and Delivery Record (LDR), Functional Status Assessments (FSA), Immunization Content (IC), Patient Plan of Care (PPOC), EMS Transfers of Care (ETC)
Since 2010 a Perioperative Plan of Care, a Post-Partum Visit Summary, a Newborn Discharge Summary, and a Perinatal Workflow have been available.

Relevance to EMPOWER:
The various CDA/CCD templates defined by IHE could provide useful "building blocks" for mapping HIS/EHR data to CDA. Furthermore, the XPHR profile defines an interface between an EHR system and a PHR system, both of which play a role in EMPOWER. Therefore, XPHR is of special interest to the project.

8.2.3 IHE Patient Care Coordination Technical Framework

IHE Patient Care Coordination (PCC) Technical Framework[89] domain was established in 2005 to deal with integration issues that cross providers, patient problems or time. It deals with general clinical care aspects such as document exchange, order processing, and coordination with other specialty domains. PCC also addresses workflows that are common to multiple specialty areas and the integration needs of specialty areas that do not have a separate domain within IHE.
In PCC Technical Framework the following profiles are defined:

- Cross Enterprise Sharing of Medical Summaries Integration Profile (XDS-MS), including Medical Summary Document Content (MS) specification
- Emergency Department Referral (EDR)
- Exchange of Personal Health Record Content (XPHR)

In addition to these, a number of supplements are provided to the PCC Technical Framework for Trial Implementation:

- Antepartum Profiles
- Care Management (CM)
- CDA Content Modules Supplement
- Emergency Department Encounter Summary
- eNursing Summary (ENS)

[89] http://www.ihe.net/pcc/committees/index.cfm

- Immunization Content (IC)
- Labor and Delivery Profiles
- Newborn Discharge Summary (NDS)
- Patient Plan of Care (PPOC)
- Perinatal Workflow (PW)
- Postpartum Visit Summary (PPVS)
- Query for Existing Data (QED)
- Reconcilitation of Diagnoses, Allergies and Medications (RECON)
- Request for Clinical Guidance (RCG)
- Transport Record Summary Profiles (includes the following profiles)

In EMPOWER we are particularly interested in the Care Management Profile, as the basis of interoperability architecture of Care Planner implementation.

8.2.3.1 IHE Care Management Profile

The Care Management Profile (CM)[90] supports the exchange of information between HIT systems and applications used to manage care for specific conditions. More and more, special purpose care management systems are used to support wellness programs, public health monitoring, tracking of immunizations and infectious diseases, and to manage the care of patients with chronic diseases such as diabetes and cancer. Care management systems collect data used to manage care, provide decision support, communicate with patients and providers, and supply other tools to assist in the delivery of care. The successful management of care resulting from the use of these technologies results in improved patient outcomes, reducing the overall cost of care provided to patients. Examples of these systems include Chronic Disease Management Systems, Cancer and other Disease Registries and Immunization Information Systems. In order to manage patient care using these systems, hundreds of data points are routinely monitored and gathered for a patient, covering a wide variety of clinical data. Furthermore, the data needed varies based upon the condition being managed.

Current practice involves the creation of ad hoc interfaces to pass this information from each health care application to the care management system. Given the large number of applications involved, conditions which can be managed in this fashion and the number of data points necessary to manage each condition, it is not practical or cost effective to design one-off interfaces for the many conditions that could benefit from the application of a care management system.

To remedy this, IHE CM profile provides a publish-subscribe based approach: a mechanism to issue a query from a Clinical Data Consumer to a Clinical Data Source. That query uses standardized objects defined by the HL7 Care Record and HL7 Care Record Query Draft Standards for Trial Use (DSTU), using templates described in this PCC Technical Framework. The Clinical Data Consumer sends the query, and the source system sends back anything new that it receives and that matches the criteria. This query is maintained indefinitely and the source system continues sending everything that arrives until the requesting system cancels it.

90 http://www.ihe.net/Technical_Framework/upload/IHE_PCC_Care_Management_CM_Supplement_TI_2008-08-22.pdf

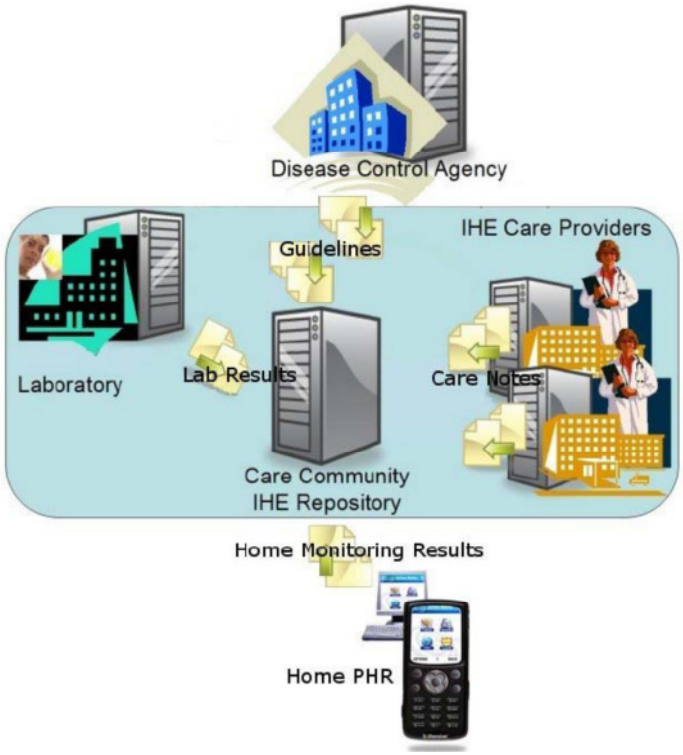

Figure 29: Care Management Architecture Overview

Actors in PCC Profile:

- **Content Creator:** The Content Creator Actor is responsible for the creation of content and for the transmission to a Content Consumer.
- **Content Consumer:** A Content Consumer Actor is responsible for viewing, import, or other processing of content created by a Content Creator Actor.
- **Clinical Data Consumer:** A clinical data consumer makes use of clinical patient data.
- **Clinical Data Source:** A Clinical Data Sources maintains patient information about vital signs, problem and allergies, results from diagnostic tests (e.g., Lab, Imaging, or other test results), medications, immunizations or historical or planned visits and procedures.
- **Guideline Manager**: The guideline manager actor is responsible for managing the guidelines used to create care plans, and for communicating those guidelines to other systems.
- **Care Manager:** The care manager actor is responsible for supporting the management of the care of patients with respect to a specific health condition. It gathers information about the care provided and on the current health status of the patient. A Care Manager actor may be designed for management of a single condition, such as management of Diabetes, or it may be a general purpose system supporting management of multiple conditions.

Transaction Definitions for PCC:

- **Query Existing Data:** Request information about recent patient information, used to obtain vital signs measurements, problems and allergies, diagnostic results, medications, immunizations, or procedures or visits relevant for a patient. The query may request information about some or all of the above topics, or may request information on a specific topic, or one entered for a specific encounter or date range.
- **Guideline Notification:** The Guideline Notification transaction reports the content of new and/or updated guidelines to interested parties. The purpose of this transaction

is to alert systems that need to act on clinical guidelines to the availability of new guidelines.

- **Request Guideline Data:** The Request Guideline Data transaction supports the capability of systems to query the contents of an identified guideline.
- **Care Management Data Query:** The Care Management Data Query transaction supports the capability of systems responsible for monitoring the health status and care provided to one or more patients to request that information from systems that may have it.
- **V3 Care Management Update:** The V3 Care Management Update transaction supports the capability for systems that have information about the health status and care provided to one or more patients to share that information with external systems that need to monitor that information using profiles of HL7 V3 Care Record standard messages.
- **V2 Care Management Update:** The Care Management Update transaction supports the capability for systems that have information about the health status and care provided to one or more patients to share that information with external systems that need to monitor that information using specific profiles of HL7 V2 standard messages.

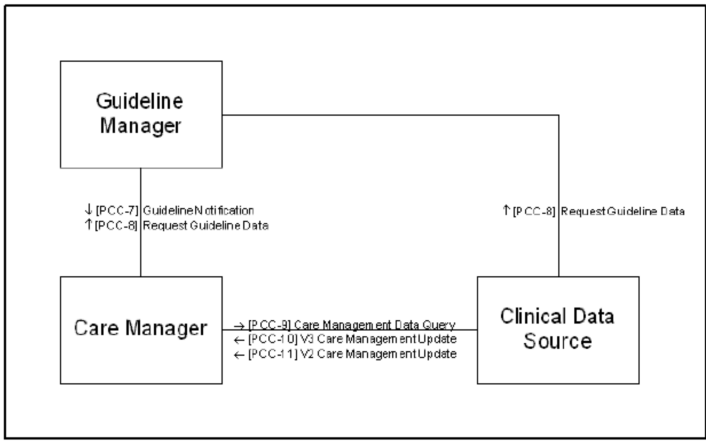

Figure 30: Care Management Actor Diagram

Relevance to EMPOWER:

In EMPOWER, the interoperability architecture for sharing EHRs and PHRs of the patients is based on the implementation of IHE CM Profile. In particular, the EMPOWER PHR plays the Care Manager Role, while the EHR Framework implements the Clinical Data Source role.

8.3 ISO 13606

The international standard ISO 13606[91] - Health Informatics -- Electronic Health Record Communication was originally developed by the European Committee for Standardization[92]. In 2008 it was adopted as an international standard by the International Organization for Standardization. It aims to enable interoperable exchange of health data between electronic health record (EHR) systems. The specified information architecture makes use of a reference model in combination with archetypes. It takes a so called „dual model approach“, that separates the medical knowledge from the technical concerns.

8.3.1 ISO 13606 Reference Model

The ISO 13606 reference model captures the global characteristics of medical records. It defines generic building blocks for aggregating health record components and for collecting the context information required to meet ethical and legal requirements. A hierarchical structure accommodates the separate parts reflecting the organization of medical records. The single building blocks are specified as follows. EHR_EXTRACT is the top-level container for the complete patient EHR or parts thereof. FOLDER is an optional organization element that divides content into compartments. COMPOSITION represents an encounter or document that may contain SECTIONs that provide clinical headings. The ENTRY represents a clinical statement that has ELEMENTs, i.e. the concrete data values that may be contained within CLUSTERs for organizing data structures like tables. All the building blocks within an EHR_EXTRACT have common attributes including a persistent unique identifier, a clinical name labelling each part, a standardized coded concept and the identifier of an archetype node.

[91] ISO EN 13606 http://www.iso.org/iso/catalogue_detail.htm?csnumber=50120
[92] CEN- European Committee for Standardization, Technical Committee 251
http://www.cen.eu/CEN/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/Pages/Standards.aspx?param=6232&title=CEN/TC+251

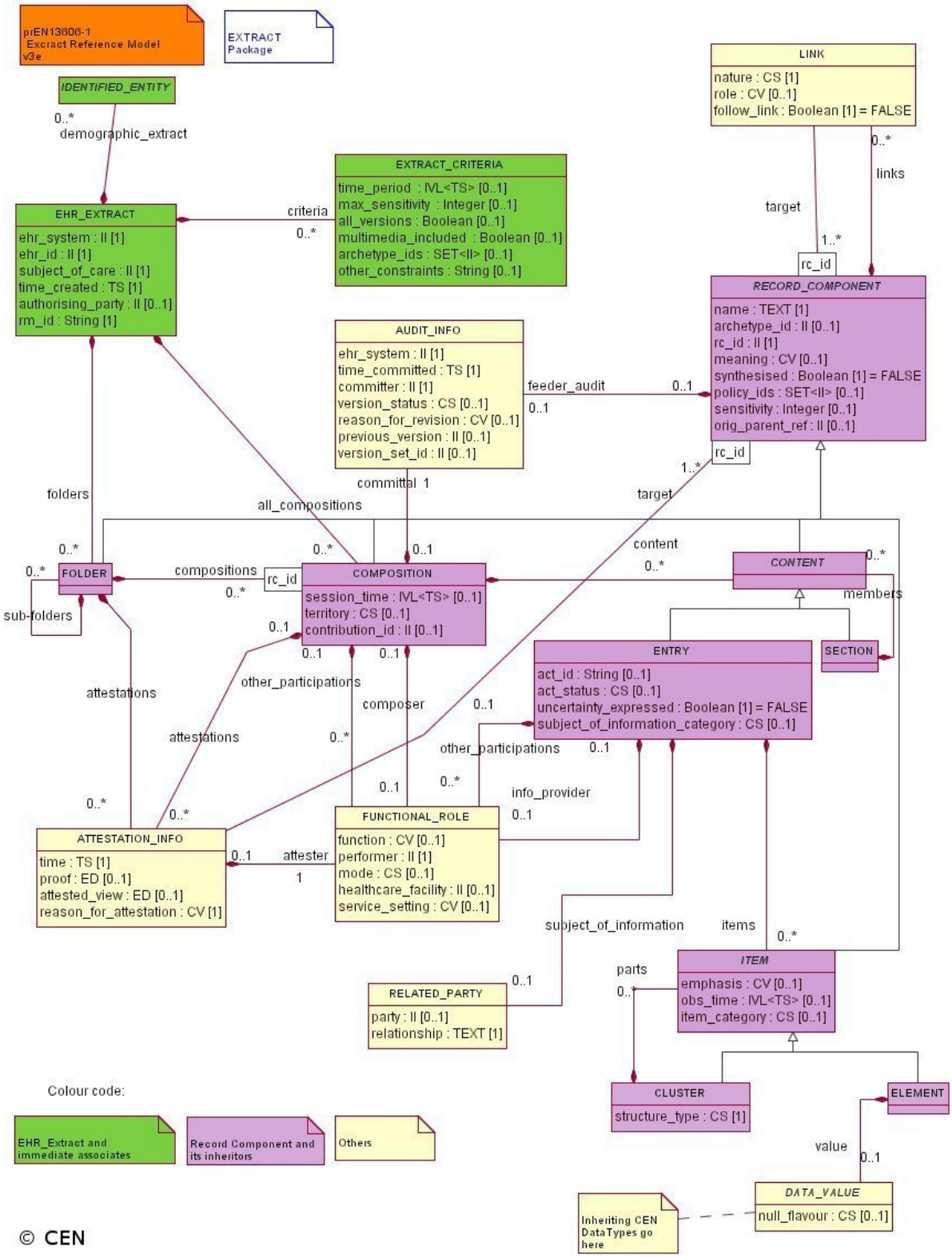

Figure 31: ISO 13606 Reference Model

8.3.2 ISO 13606 Archetype Model

This generic information model, that is suitable for all kinds of data and data structures within an EHR, is complemented in the knowledge domain. The archetype model provides meta-data used to define patterns for the specific characteristics of clinical data. Archetypes are formal definitions of combinations of the building blocks defined by the reference model for

particular clinical organizations or settings. They express distinct clinical concepts by specifying a particular hierarchy of record components and define or constrain names and other relevant attribute values, data types and value ranges. The Archetype Definition Language (ADL) is a formal syntax for the definition of archetypes. It provides a general description of the concept specified and includes terminology bindings and translations. Archetypes deliver meta-data and precise definitions of the diverse, complex and frequently changing concepts in clinical practice and, thus, facilitate semantic interoperable EHRs [Garde 2007]. Based on this principle any part of a medical record can be interpreted faithfully even if the structure and nature of the clinical content had not been agreed in advance. This is of special interest when sharing health records across institutions, for aggregating life-long personal health records or for connecting decision support systems [Stroetmann 2009].

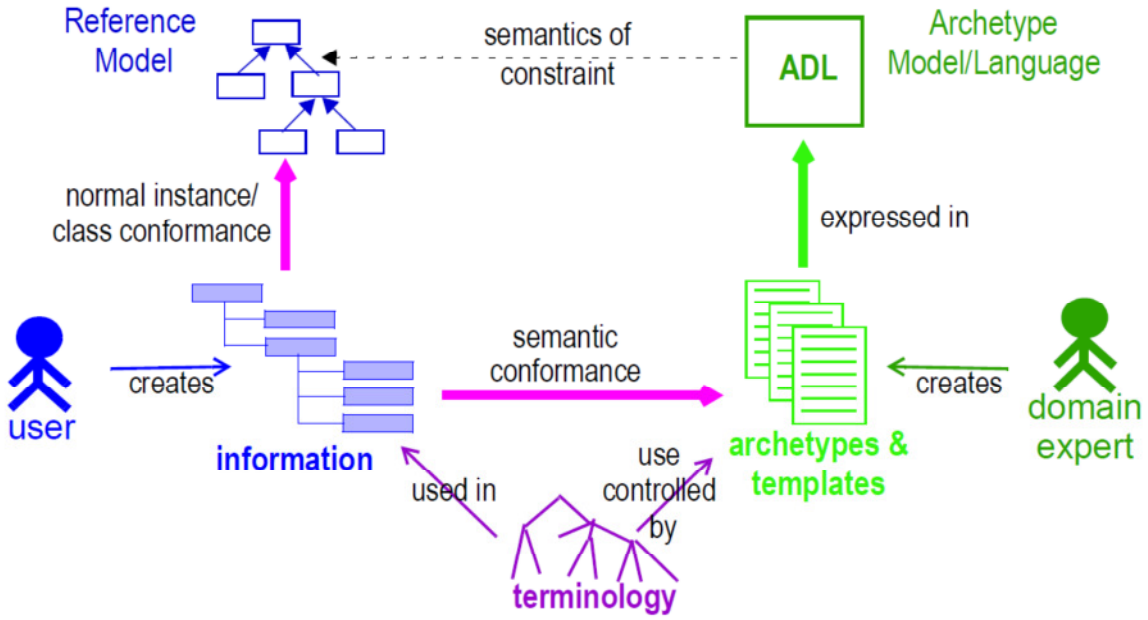

Figure 32: Archetype Meta-Architecture[93]

8.3.3 OpenEHR Specifications

OpenEHR is an open standard specification that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs) based on ISO 13606. The openEHR specifications are maintained by the openEHR Foundation, a not for profit foundation supporting the open research, development, and implementation of EHRs.
The project deliverables include requirements, abstract specifications, implementation technology specifications (ITSs), computable expressions and conformance criteria.
The abstract specifications consist of the Reference Model (RM), the Service Model (SM) and Archetype Model (AM). The first two correspond to the ISO RM/ODP[94] information and computational viewpoints respectively. The latter formalises the bridge between information models and knowledge resources[93].

[93] S. Heard & T. Beale. (eds.) (2007). openEHR Architecture Overview, http://www.openehr.org/svn/specification/BRANCHES/Release-1.0.2-candidate/publishing/architecture/overview.pdf
[94] http://www.rm-odp.net/

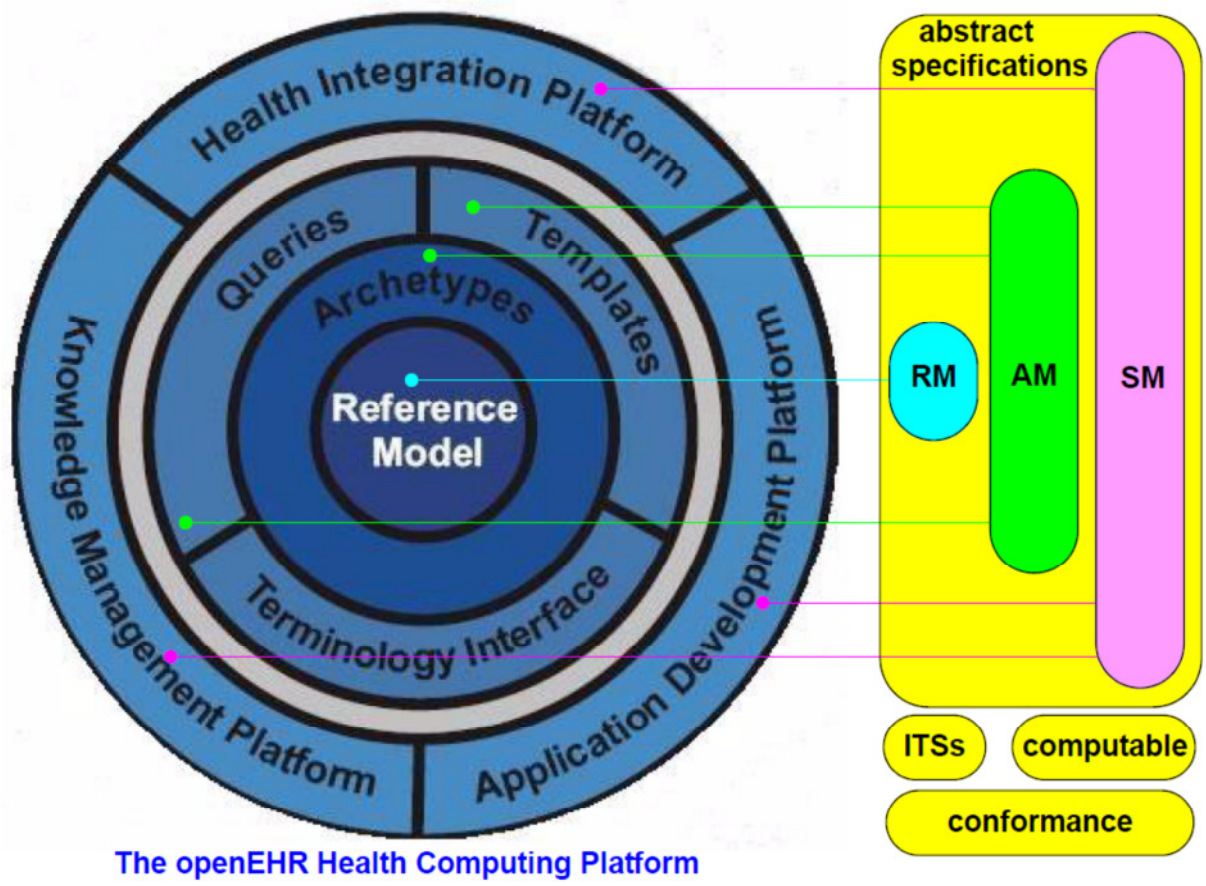

Figure 33: openEHR Specifications in relation to the Health Computing Platform

8.3.4 OpenEHR Clinical Knowledge Manager

OpenEHR facilitates the development of structures and terminologies to represent health data. These information models ideally are publicly available for used in health information systems and are developed and maintained by the user community. OpenEHR in this respect provides a repository called Clinical Knowledge Manager. At the moment different instances[95] exist at openEHR[96] itself (counts 288 archetypes), at NEHTA[97] (counts 83 archetypes) and in Sweden[98] (counts 60 archetypes).

Relevance for EMPOWER:
The standard-based services of the Patient Empowerment Framework will support semantic interoperability by utilizing appropriate standards from the HL7 and IHE Profiles in combination with ISO 13606 information models. The Empower services will collect data from various sources like the health professionals EHR, monitoring devices and personal health applications – the ISO13606/OpenEHR specifications facilitate the exchange and integration of heterogeneous data in this context.

[95] http://en.wikipedia.org/wiki/OpenEHR
[96] http://openehr.org/knowledge
[97] http://dcm.nehta.org.au/ckm/
[98] http://sllocean.karolinska.se/ckm/

8.4 Archetypes and Detailed Clinical Models

The ISO 13606 Archetypes define the medical concepts and thus ensure semantic interoperability that is needed for precise and reliable interpretation of medical data within an EHR. Archetypes deliver meta-data (e.g. data on the adequate application of the archetype, references and terminology bindings) that consistently define the divers, complex and frequently changing concepts in clinical practice and, thus enable precise processing and correct interpretation of data that is exchanged across institutions or even across countries.

8.4.1 Existing Archetype Developments

Archetypes are developed by various initiatives. The **National Health Service (NHS)** started in the year 2007 together with Ocean Informatics a project for the evaluation of the potential of archetype modelling for structured medical records and interoperability. As a result an evaluation report[99] was published and a series of clinical archetypes were defined for the domain of paediatrics. The NHS has developed and used openEHR archetypes and templates as a formal way of capturing clinical content requirements. In a pilot, around 220 archetypes and 40 templates were developed in the maternity and emergency department specialties. By end 2008, the number of archetypes was around 1000. The archetypes are available at an online repository[100] [101] that was not updated since then.
The Technical University of Valencia is investigating the collection and sharing of information and knowledge within a network for clinical research in the **ResearchEHR** project. This initiative is continuing former studies[102] concerning the development of a platform for standardized and semantic interoperable clinical data exchange that provided already several system components like an archetype editor that supports mapping to legacy data. In this context so called integration-archetypes are used for the linkage of routine systems to the standard-based platform. Furthermore archetypes for the EpSOS[103] datasets (Patient Summary, ePrescription und eDispensation) were defined.

Variable	EN13606 Name	EN13606 Class	Data Type
-	Allergies	CLUSTER	-
Allergy	Allergy	CLUSTER	-
Onset date	-	CLUSTER.obs_time	IVLTS
Allergy description+ Id code	Allergy description	ELEMENT	CODED_TEXT
Agent + Id code	Agent	ELEMENT	CODED_TEXT

ADL code:

```
CLUSTER[at0010] occurrences matches {0..*} matches {  -- Allergy
    parts cardinality matches {2..2; unordered; unique} matches {
        ELEMENT[at0011] occurrences matches {1..1} matches {  -- Allergy description
            value matches {
                CODED_TEXT[at0050] occurrences matches {1..1} matches {*}  -- CODED_TEXT
            }
        }
        ELEMENT[at0013] occurrences matches {1..1} matches {  -- Agent
            value matches {
                CODED_TEXT[at0052] occurrences matches {1..1} matches {*}  -- CODED_TEXT
            }
        }
    }
    obs_time existence matches {0..1} matches {
        IVLTS[at0046] occurrences matches {0..1} matches {*}  -- IVLTS
    }
}
```

Figure 34: Example of an epSOS Archetype in tabular and ADL form[104]

[99] http://www.connectingforhealth.nhs.uk Report!!!
[100] http://www.openehr.org/svn/knowledge/BRANCHES/dev-uk-nhs/trunk/archetypes/gen/html/index_en.html
[101] http://my.openehr.org/wsvn/knowledge/templates/dev-uk-nhs
[102] http://www.linkehr.com
[103] http://www.epsos.eu
[104] epSOS Deliverable 3.5.2 Appendix G - CEN EN13606 Technical Specifications

The **openEHR** foundation aims to consolidate the efforts for archetype development at a single focus point and therefore maintains the CKM platform for sharing and disseminating archetypes development results to a broad audience. CKM supports a public review scheme that classifies the archetype definitions according to their maturity until they reach the status published. Most of the definitions are not finalized and still have draft status (*at chapter 8.3.4* OpenEHR Clinical Knowledge Manager *you find the web addresses of different CKM instances*).
The Swedish government has decided on the use of ISO 13606 as a base standard for national health data communication, where openEHR will be used for definition of clinical models, terminology integration and for implementations[105].
In Australia the NeHTA (National e-Health Transition Authority) has clinical data groups based on openEHR methodology and currently investigates the transformation from openEHR to HL7 CDA. Queensland Health is running an openEHR-based repository that manages discharge summaries. Victoria Health uses openEHR at the state cancer registry
The **EHR-Arche**[106] project of the Medical University Vienna models archetypes for collecting observations by physicians treating diabetes patient. The work aims to support the users of an EHR in looking up information that is relevant in a certain context. Thereby document metadata is combined with an information model based on archetypes in order to provide search facilities that fit to the user's needs.
These initiatives follow different approaches for the definition of archetypes. Either archetypes are specified based on the ISO 13606 reference model, or on the extended openEHR reference model. Where LinkEHR[102] wants to provide a tool that is able to work with several reference models. In addition there are the HL7 RIM based models and other less advanced ones like CCR. This shows that there is a certain diversity existing that produces certain incompatibilities amongst existing initiatives.

8.4.2 Detailed Clinical Models

The Detailed Clinical Models (DCM)[107] started as a project within HL7 in 2008. They aim to develop a structured way of describing clinical content that is understandable for both healthcare providers and IT-specialists. DCMs can be used independent from an implementation in a certain technical format. In DCMs medical knowledge, data specifications and terminology are combined on a meta-level that is independent from specific standards or technology [Goossen Review 2010]. The DCM methodology is addressed by the ISO NWIP 13972 - Quality Requirements and Methodology for Detailed Clinical Models which give the following description: "Detailed Clinical Models are small items of clinical, preventive and care information that are well defined and for which knowledge, data definition, vocabulary binding, and information model for use in information and communication technology are standardized and reusable over domains, purposes, standards and implementations". In other words a DCM specifies the data elements and attributes of clinical concepts, including the possible values and types of attributes, and relationships needed to express these definitions in a way that is understandable to both clinical domain experts and technical experts. Moreover the comprehensive inclusion of terminologies enables data elements to be linked to concepts present in multiple terminologies. This way DCM has the capability of modelling a multitude of precise items of clinical information and thus facilitates transformations between different data modelling approaches (e.g. HL7 CDA and ISO 13606 Archetypes) without loss of meaning [Goossen Bridging HL7 2010].

[105] http://www.openehr.org/shared-resources/usage/government.html
[106] EHR-Arche http://www.meduniwien.ac.at/msi/arche/
[107] http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models

Relevance for EMPOWER:
Archetype based information models for diabetes related ODLs will be developed particularly with regard to self-management and action planning. Using this flexible approach to knowledge models facilitates the creation of new disease management scenarios without locking the business logic or workflows into any specific EHR, PHR or PHA.
The emerging standard for Detailed Clinical Models will be evaluated and tested. DCMs will be examined as a means to decouple information modelling from the EHR standard used for implementation. This is of special interest for the inclusion of clinical guidelines and helps to build a framework that is modular and at the same time coherent.

8.5 PHR Interoperability

8.5.1 Standards for Domain Modelling useful for PHR

How can we define domain models in the PHR? One possibility is to base the models on the data exchange standards, CCD or CCR. A mapping between the HL7 CCD exchange document and the PHR domain model would be the likely solution. Microsoft HealthVault defines their domain schemas using XSD schema language, however, the main problem is that both static knowledge and dynamic should be defined – a domain driven design of the PHR might be a better approach.
The standard ISO13606 is the basis of the openEHR information model and architecture[108] for EHRs. The openEHR includes domain model and rule language called the Archetype Description Language (ADL), which is a domain specific language to describe a domain model and rules One goal of the openEHR community is to empower the domain experts to collaborate and define archetype clinical domain models which any institution or department can use (for details see 8.4).

8.5.2 PHR and EHR Document exchange standards

These are standards for exchanging snapshots of patient health records between PHR and EHR Systems.

8.5.2.1 Data exchange issues

Consistency Issues affect not only HL7, but any data exchange solution between EHR and PHR. HL7 V3 - The question is posed: Messages or Documents. Why and when to use messages or documents. This is applicable to IHE XPHR and CCR as well regarding consistency of data across EHR and PHR systems.[109]
Should HL7 Messages or Documents (CDA) snapshots be considered? It is critical to understand the life cycle of health data snapshots -the issues about importing them into a PHR system need to be understood. There is a consistency problem if the original data is changed or removed. In contrast, messages could be managed better than whole documents across PHR and EHR systems. Documents, however, seem to bet the preferred means of exchanging snapshots between PHR and EHR systems. For example, RIM data in an imported CDA document cannot be maintained.

[108] openEHR architecture and information model
http://svn.openehr.org/specification/TRUNK/publishing/architecture/rm/ehr_im.pdf and
http://www.openehr.org/specifications/spec_strategy.html
[109] http://www.ringholm.de/docs/04200_en.htm

8.5.2.2 CCR - ATSM Continuity of Care Record

Site: http://www.ccrstandard.com,
Wiki http://wiki.medpedia.com/Continuity_of_Care_Record_%28CCR%29_Standard

The Continuity of Care Record (CCR) standard is a patient health summary standard, widely used for secure, computable, electronic capture and transfers of personal health data from one health IT system to another (e.g. EHRs) and to and from these to personal health record (PHR) applications. CCR is an "older" standard, but considered simpler and more readable according to Google. This standard is actively used in products, including Google Health's CCR subset. The HL7 Continuity of Care Document (CCD) includes harmonisation to CCR. There are numerous applications[110] that support CCR based software and because of the CCD, a wider range of applications supports this standard.
Google CCR and the Google Health API:

- PHR – supports a subset of ATSM CCR as Google profile gCCR
- CCR reference http://code.google.com/apis/health/ccrg_reference.html
- Java libraries for CCR XML http://code.google.com/p/ccr4j/,
- CCR with Google GData

Relevance to EMPOWER:

Despite the existing support for CCR in a number of commercial PHR systems, for the EMPOWER project the use of CCD (see next section) and the IHE XPHR specification derived from CCD seems to be a more appropriate choice. CCD is a mapping of the CCR structure to CDA syntax, and since CDA syntax will also be used by the project to expose EHR data, the use of CDA would provide a common ground for both EHR and PHR data imported into EMPOWER. CCR remains relevant, however, as a reference model describing a base dataset (summary) of the most relevant clinical information about a patient.

[110] CCR Applications list http://www.ccrstandard.com/ccrstandardimplementationsanddeployments

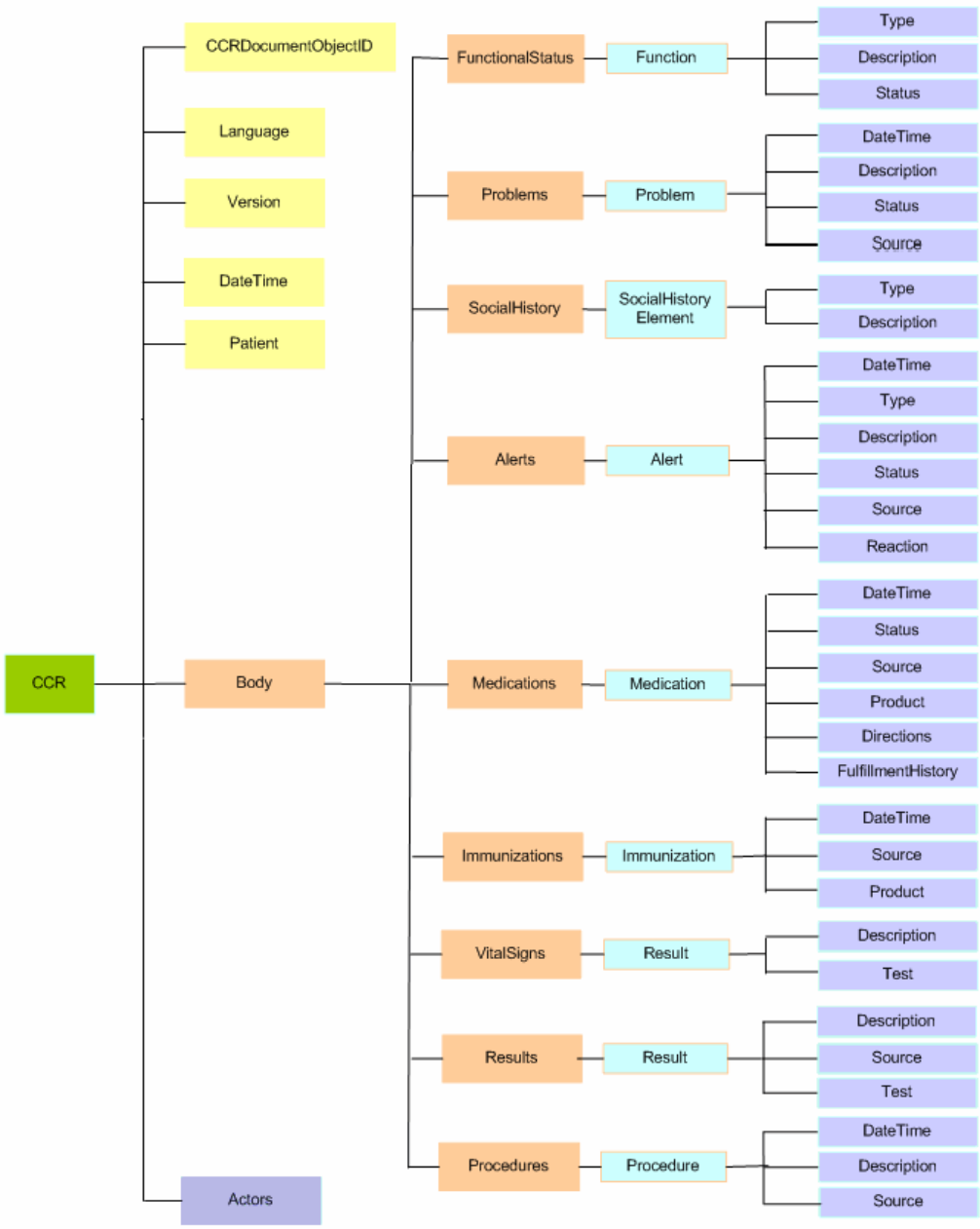

Figure 35: Google subset of CCR

8.5.2.3 CCD – HL7 Continuity of Care Document

The CCD represents a complete implementation of CCR that provides a rich clinical data representation. Many products do try to support the import of data format as CCR or CCD. Many products do support CCR, especially since it preceded the CCD. For example, the ATSM includes a report about Google Health support of a subset of CCR[111].

The CCD is an XML-based standard that specifies the structure and encoding of a patient summary clinical document. It provides a "snapshot in time," constraining a summary of the pertinent clinical, demographic, and administrative data for a specific patient. The primary objective of the CCD is to foster interoperability among PHRs, EHRs, Practice Management Applications (PMA), etc. as a means to improve patient care.

The CCD is essentially the CDA implementation of ASTM's Continuity of Care Record (CCR). The CCD is a harmonized format for the exchange of clinical information, whereby the HL7 and ASTM integrated the ASTM CCR and the HL7 CDA. It can be described as

[111] ATSM announcement regarding CCR and Google Health http://www.astmnewsroom.org/default.aspx?pageid=1418

both a CDA implementation of the ASTM Continuity of Care Record (CCR) and an implementation guide for patient summary data based on CCR using the HL7 Clinical Document Architecture (CDA). The summary of patient data includes a patient's administrative and clinical information, and are composed of sharable CDA templates that describe clinical "data models" such as lists of medications, allergies, vitals, history, care plan, etc. One interesting comparison might be made to the OpenEHR standard ISO/EN 13606 for clinical domain model specifications.
The CCD provides a set of templates representing parts of a medical summary record. These templates are essentially modules that can be reused in other CDA document types, thereby enhancing interoperability across systems. Templates include, for example, family history, vital signs, family history, care plan, etc.

- Types of clinical data: lists of medications, allergies, test results, patient problems
- Types of administrative data: of patient demographics, insurance, registration data
- Examples:
  - Microsoft HealthVault[112]
  - CDA Validation Guidelines [113]
  - Indivohealth[114]

Relevance to EMPOWER:

CCD becomes relevant for EMPOWER where health related data captured or maintained by the patient him/herself needs to be included into the follow-up process. Here CCD provides an interoperable definition that permits the transfer and import of such data into the EMPOWER core.

8.5.3 Exchanging Healthcare Data

8.5.3.1 ONC: Nationwide Health Information Network

ONC[115] – Office of National Coordination for Health information (USA)
NHIN[116] provides resources to support the secure exchange of health information using standards and tools. NHIN resources include specifications to create systems and tools for interoperability from the site's Inventory of Tools. In Figure 36Figure 41: Nationwide Health Information Network (NHIN) the diagram indicates how various systems connect PHRs, EHRs and other systems to the NHIN gateway. NHIN uses HL7 standards/specifications and references IHE profiles. Furthermore, it provides software that facilitates the uptake of the standards NHIN promotes. Communities focus on specific problems together rather than forcing companies to reinvent basic services. Relevant for EMPOWER, the NHIN CONNECT project provides interoperability related open source software.

[112] http://blogs.msdn.com/familyhealthguy/archive/2008/10/23/awkward-turtle.aspx
http://msdn.microsoft.com/en-us/healthvault/bb968871.aspx
[113] http://xreg2.nist.gov/cda-validation/downloads.html
[114] http://www.lhncbc.nlm.nih.gov/lhc/docs/published/2008/pub2008036.pdf
[115] ONC Office of the National Coordinator
http://healthit.hhs.gov/portal/server.pt?open=512&objID=1200&parentname=CommunityPage&parentid=1&mode=2&in_hi_userid=10741&cached=true
[116] NHIN http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&cached=true&objID=1142

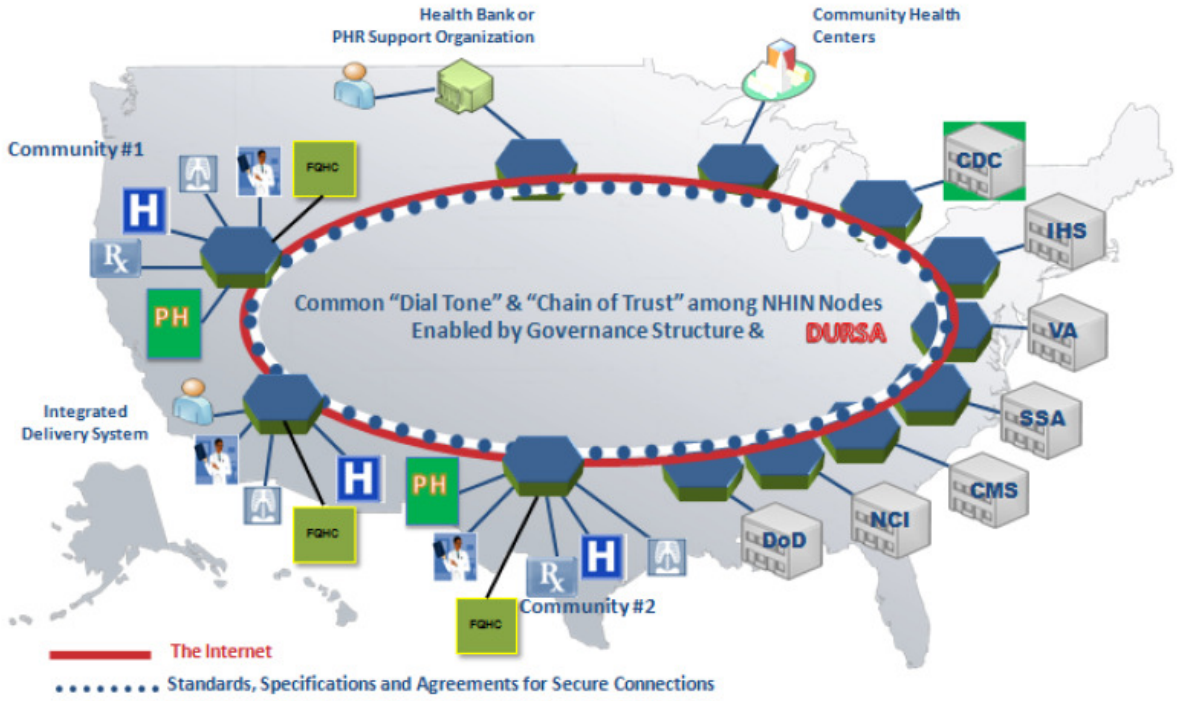

Figure 36: Nationwide Health Information Network (NHIN)

Relevance to EMPOWER:

As described above, NHIN is primarily a national U.S. initiative, but the open source tools provided by the initiative could be relevant for EMPOWER and are discussed below.

8.5.4 Special Topics for Interconnectivity/interoperability

One of the most challenging issues for a project where more modules (frameworks, application) are involved the interconnectivity between the parts. The next sections will briefly describe some of the most popular State of the Art solutions that might help EMPOWER in the software architecture design, especially relevant for interoperability software design and Open Source software choices involving existing interoperability frameworks.

8.5.4.1 JCA

JCA is the acronym Java (Enterprise) Connector architecture and it defines an interface between Enterprise Information Systems (EIS) and Enterprise Containers (EJB container and WEB container). EIS is the generic term for any information system including: relational databases, message oriented middleware, CORBA, legacy systems, etc. The JCA is the ideal solution for connecting heterogeneous systems even if the system(s) API is vendor agnostic and the products behind the API are always proprietary. The next figure tries to in a very simplify way to show how an EIS can connect to an application server – "the plug" represents the JCA. On this level is important to notice that the JCA is generic (the plug look the same) and it can be used with several EISs.

The JCA provides a full palette of enterprise specific features such as transaction, security, connection management; most of these features are provided in a transparent way from the user perspective. The JCA is applicable to any resource that needs to be integrated in to the system in a transacted secure and scalable manner. Most of the existing enterprise system are able to use JCA conform techniques.

One of the base components of the JCA is the Resource Adapter; its main purpose is to define a unified collection of contracts between and application server and EIS. The next

diagram exemplify this, various contracts (Application, System, etc.) are sum up in a Resource adapter.

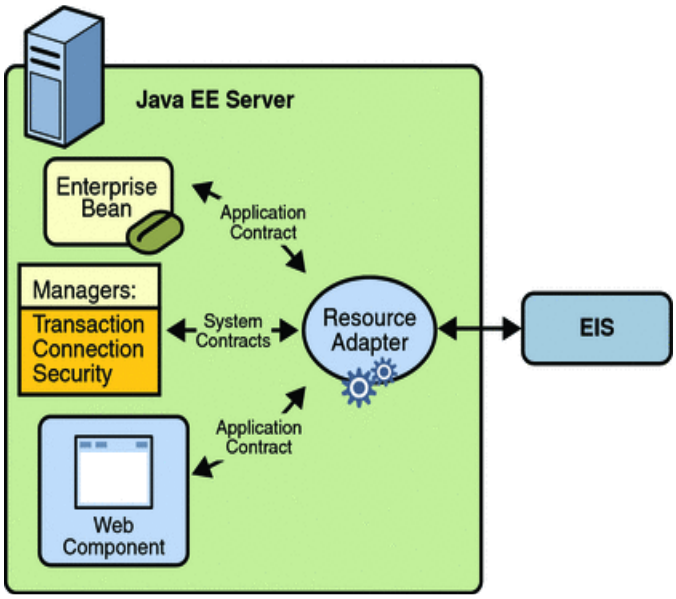

Figure 37: Sum of EE server contracts involved in a Resource Adapter

Another interesting feature from the JCA is the SPI (Service Provider Interface) – this is a generic interface (which emphases the component replacement feature) used to integrate enterprise specific features like: transaction, security and connection management of an Application Server with those of a EIS. An application server represents a framework (or an environment) designed to execute efficient processes and flows; all enterprise systems are based on an application server.
In a very idealistic way these two components can describe the perfect system, the Resource Adapter sums the contracts (between the server and the EIS) and the Service Provider Interface wrap them in enterprise conform operation (transaction, security, etc).
Another interesting aspect about the JCA is the way resources (and/or tools) are accessed, the JCA defines a generic way to access resources (and/or tools) the Common Client Interface (CCI). The CCI ensures that each Application Server can supply tooling to support any and all JCA -compliant EISs. Some of its features are:

- Definition of a remote function-call interface that focuses on executing functions on an EIS and retrieving the results
- A simple, powerful, and extensible API
- Consistency with various facilities defined by the J2SE and J2EE platforms
- Independence from any specific EIS
- The CCI consists of classes and interfaces for the abstraction and manipulation of connections, interactions, records, and connection metadata.
- JCA Advantages:
- Well documented (examples, tutorials).
- Various implementations – supports for a lot of EIS.
- Expect to become a standard (at least for the EE world)
- JCA Disadvantages:
- Too generic, specific needs requires specific implementations
- High complexity – it is not appropriate for simple things.
- Requires advanced JEE knowledge.

- The main source of documentation is :
  http://java.sun.com/j2ee/connector/overview.html

8.5.4.2 MOM and JCA

Another interesting case related with JCA is the combination of MOM and JCA. MOM is the acronym for Message Oriented Middleware. In a very wild sense a MOM system is third party used to connect together two (or more) other parties via messages. Because JCA allows connections any kind of EIS (which is JCA conform) the two involved parts can also be connected with any other EIS. This kind of flexibility allows you to build powerful product by using (combining) existent one. For example, a message producer sends messages to an consumer and the consumer is only able to store the messages. A third module is able to notify registered used using SMS. If the third module is a JCA conform one can be integrated in the upper described relation and enrich the actual functionality.
More, the MOM system are able to connect not only java products, it can use any other available messaging system (i.e. SOAP, email, CORBA messaging, proprietary messaging systems used in ERP (SAP, PeopleSoft, etc), legacy messaging systems, etc.).
More about message oriented middleware: http://java.sun.com/products/jms/

8.5.4.3 ESB

The MOM architecture can be easy integrated in to an ESB (Enterprise Service Bus). The ESB enhance the messaging featured describe in the previous sections make them more powerful. The interconnectivity degree is higher than the one from MOM (see diagram). Because the application logic tends to increase the ESP provides a message oriented query language.

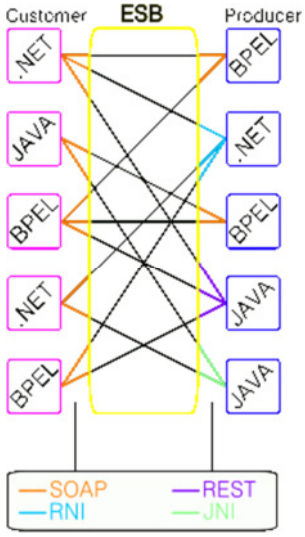

Figure 38: Enterprise Service Bus

The ESB has an open source implementation named OpenESB and until now it was integrated in NetBeans (Java IDE), the IDE allows the developer to define business rules and workflows using a graphic interface.
More information: http://wiki.open-esb.java.net, http://soa.netbeans.org/,

8.5.4.4 Mule

Mule is a lightweight java ESB framework; its purpose is to provide the user to connect its application with a large variety of EIS systems.

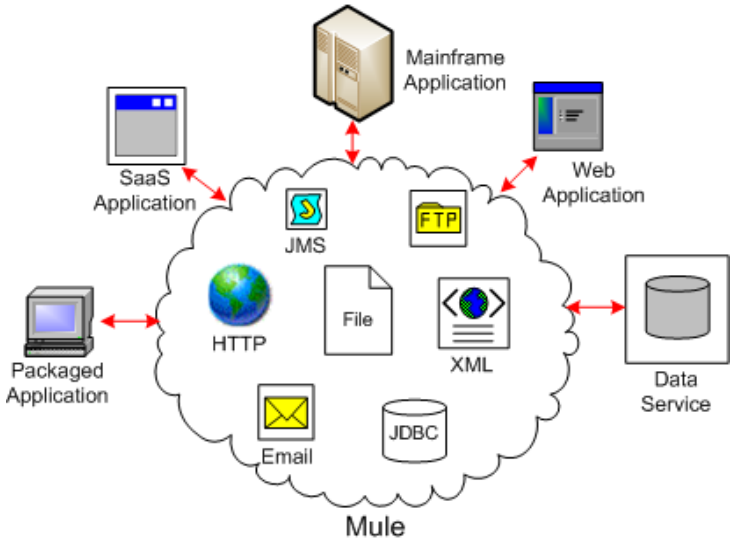

Figure 39: Mule and its connectivity features

The main Mule advantages are its lightweight nature which makes it applicable on many kinds of business (frameworks) and the Service Oriented Architecture (SOA) architecture that enhances integration. SOA defines a set of design rules used to build loosely integrated services. Beside this Mule is compatible with most of the actual application server and EIS.
More information about: http://www.mulesoft.org/

8.5.5 PHR Interoperability Frameworks

PHR medical data exchange – how to exchange patient data between PHR and EHR systems?
The best practice would best to reuse an Interoperability framework especially if a community is active and will remain focused on addressing interoperability using standards, especially with respect to HL7 and IHE profiles.
The following are notable interoperability frameworks or PHRs that are relevant to EMPOWER.

- NHIN CONNECT
- IPF: Open eHealth Integration Platform Framework
- Mirth Connect
- Tolven PHR
- Indivo PHR connection services

They provide a basis for connecting systems and EMPOWER's participation in a particular community. This would be advantageous to all, rather than attempting to start from scratch. Alternatively, one might reuse an existing PHR system's interoperability layer, or create an interoperability framework from scratch based on the IHE profile for XPHR.

8.5.5.1 NHIN CONNECT

Site: http://connectopensource.org/about/what-is-CONNECT
Characteristics: interoperability framework for health care**License**: open source
Interoperability services / standards: CONNECT supports the Nationwide Health Information Network (NHIN) is based on HL7 and IHE standards.
Additional services: security, authentication
Comments for developers:
Description – CONNECT is based on the NHIN[116] specifications for health information data exchange and standards.

Three primary elements make up the CONNECT solution:

- The **Core Services Gateway** provides the ability to locate patients at other organizations, request and receive documents associated with the patient, and record these transactions for subsequent auditing by patients and others. Other features include mechanisms for authenticating network participants, formulating and evaluating authorizations for the release of medical information, and honoring consumer preferences for sharing their information. The NHIN Interface specifications are implemented within this component.
- The **Enterprise Service Components** provide default implementations of many critical enterprise components required to support electronic health information exchange, including a Master Patient Index (MPI), XDS.b Document Registry and Repository, Authorization Policy Engine, Consumer Preferences Manager, HIPAA-compliant Audit Log and others. Implementers of CONNECT are free to adopt the components or use their own existing software for these purposes.
- The **Universal Client Framework** contains a set of applications that can be adapted to quickly create an edge system, and be used as a reference system, and/or can be used as a test and demonstration system for the gateway solution. This makes it possible to innovate on top of the existing CONNECT platform.

Figure 40: NHIN CONNECT Overview

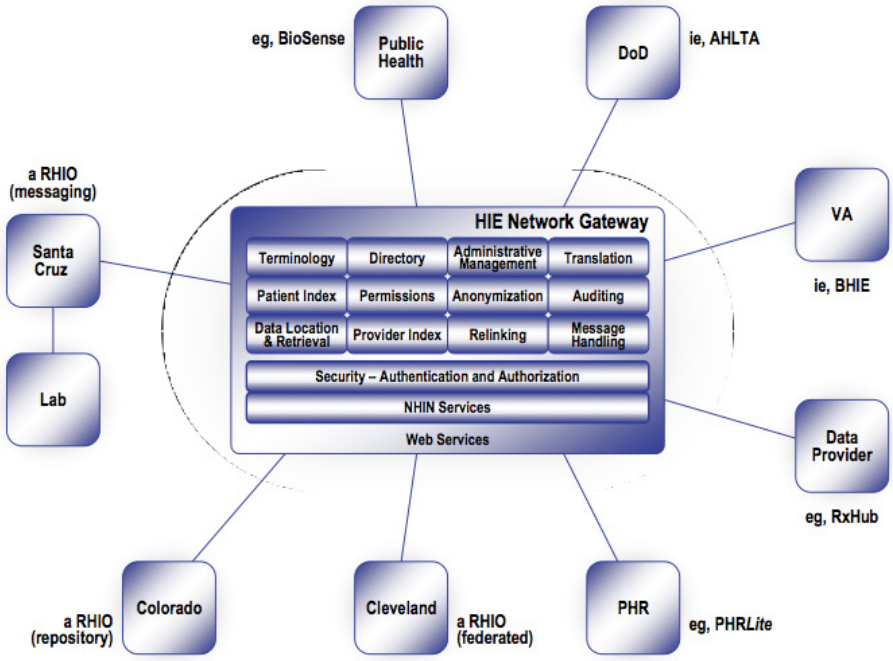

Figure 41: Nationwide Health Information Network (NHIN)

Developer resources:

- FAQ http://connectopensource.org/about/faq

Relevance to EMPOWER:

NHIN Connect provides a number of software tools that might be used as “building blocks” for the EMPOWER implementation. Of particular interest are the Master Patient Index and the Audit Log.

8.5.5.2 Open eHealth Integration Platform Framework (IPF)

Site: http://gforge.openehealth.org/gf/project/ipf/, http://openehealth.org/gf/project/ipf-tools/,
Characteristics: online PHR / standalone PHR interoperability services / interoperability framework for health care
License: open source, Apache
Interoperability services / **standards**: HL7 messaging Use Case

Additional services:
Comments for developers: domain specific languages based on Groovy, Java
Description – IPF addresses interoperability for HL7 related Use Cases and EHRs. Regarding PHRs, the IHE profile for XPHR will be addressed and seems to be in progress. IPF is based on Apache Camel[117], an integration framework based on Enterprise Integration Patterns[118] (EIP). Extremely important is the health developer community involved with IPF and it is quite active.

Developer resources:

- Very useful Developer Workshop Videos[119] from ICW Developer Network presents an extensive developer's workshop on the Open eHealth IPF framework
- Tutorial for HL7 processing[120]
- IPF Tutorials
- Introduction http://architects.dzone.com/articles/introduction-open-ehealth
- http://repo.openehealth.org/confluence/display/ipf/IPF+Tutorials#IPFTutorials-Firststepstutorial
- http://repo.openehealth.org/confluence/display/ipf/IPF+Tutorials;jsessionid=C97A4CEE84ED68CE69A98E8B6B40D8F6
- http://repo.openehealth.org/confluence/display/ipf2/First+steps+tutorial
- http://repo.openehealth.org/confluence/display/ipf2/First+details+tutorial
- The Open Health Foundation provides a suite of tools and components destined to the eHealth industry. Most important to EMPOWER is the Integration Platform Framework (IPF) tools. IPF is not a singular product it is a suite of products; some of the most important are:
- Open eHealth Application Platform - used to create new health care domain application
- Open eHealth Development Tools – tools used to build (health care domain) applications
- Open eHealth Integration Platform Tools – platform dependent tools (e.g. OSGI)
- An important aspect of IPF is the support for OSGI (Open Services Gateway Initiative). The Equinox OSGI framework is used for the IPF tools. OSGI is an open standard organisation with its main purpose to define how components and services are packed together and how they are published (the definition is naïve, but the scope and purpose of the OSGI is beneath the purpose of this document). All the other enumerated products are using a very simplistic way of packing and publishing – most of them are simple jars or enchanted jars if the product must be deployed in an Application Server, this may fulfil single projects needs but if you want that your product is part from a project/service suite then you need to fulfil the OSGI rules. This makes the IPF tools special – they are OSGI conform and they allow you to build OSGI conform bundles. A bundle is a package that contains components and services, the package uses the OSGI rules.
- The IPF is based on Apache Camel, thus it follows the SOA architecture – and this enables it to communicate with all the other SOA end points. Furthermore, from the development point of view, IPF provides its own development environment based on the Eclipse IDE.
- Apache Camel Integration Framework supports IPF

117 Apache Camel http://camel.apache.org /
118 Enterprise Integration Patters (EIP) http://camel.apache.org/enterprise-integration-patterns.html
119 ICW Developer workshop for IPF http://www.channels.com/episodes/show/4734744/Using-HL7-Processing-Capabilities-of-the-Open-eHealth-Integration-Platform-in-the-Implementation-of?
120 IPF Hl7 processing http://repo.openehealth.org/confluence/display/ipf2/HL7+processing+tutorial

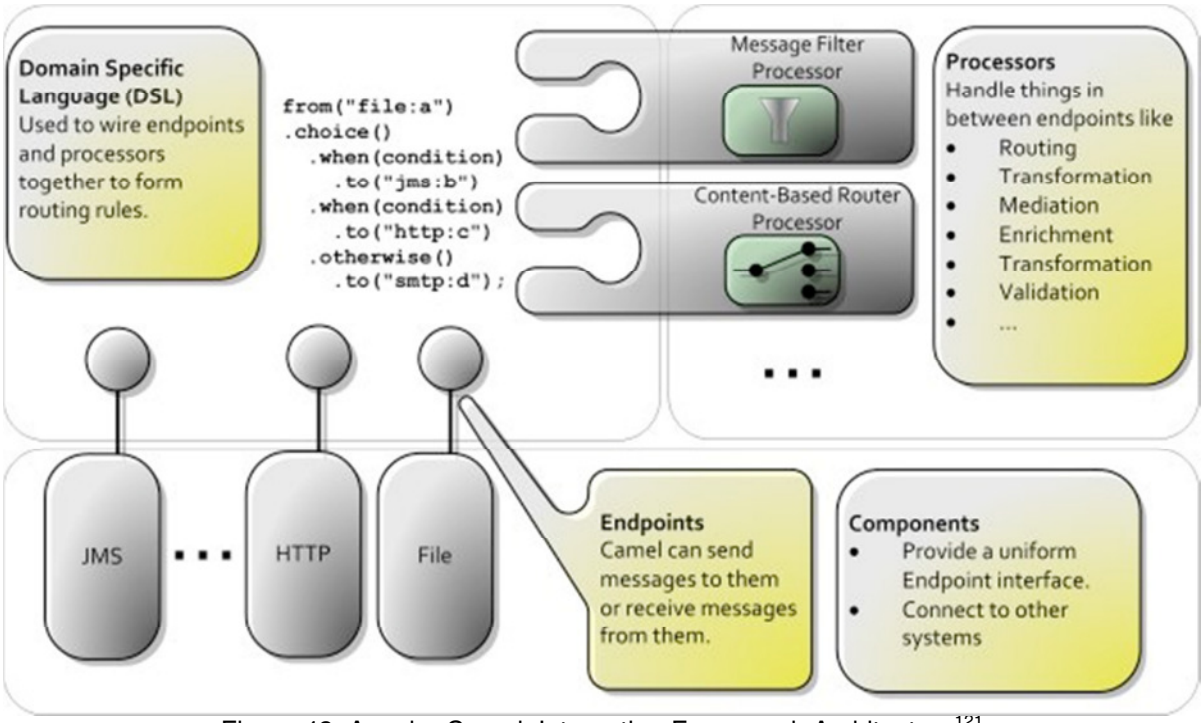

Figure 42: Apache Camel Integration Framework Architecture[121]

Apache Camel is rule based routing & mediation engine which can be integrated into full ESB container, a message broker or a web services smart client. Camel might be described as a small embeddable ESB because it includes common ESB services such as transformation, mediation, monitoring, orchestration, smart routing[117].
Important characteristics:

- provides implementations of common Enterprise Integration Patterns (EIPs)
- enables connectivity to a many types of endpoints (transports) and APIs
- flexible wiring of endpoints to Camel processor components using Domain Specific Languages (DSLs). A processor component is an extension point for adding connectivity to other systems.
- DSLs can be written in several languages, such as Java, Scala, PHP, Ruby, Javascript ,etc
- OSGi bundles
- SOA – Services Oriented Architecture
- Integration with IDEs (Integrated Developer Environment)

Relevant for EMPOWER:

Interoperability framework based on Apache Camel that could provide to EMPOWER solid SOA, OSGi based building blocks. The concrete implementations of Enterprise Integration Patterns are attractive.

Community has implemented HL7 Use Cases and continued work on IHE profiles.

Active open source community related to HL7 and IHE

[121] Apache Camel Architectural Diagram http://architects.dzone.com/articles/apache-camel-integration

8.5.5.3 Mirth Project - Mirth Connect and Mirth Exchange

Site: http://www.mirthcorp.com/community/overview,
http://en.wikipedia.org/wiki/Mirth_(software)
http://www.mirthcorp.com/community/mirth-connect
Characteristics: interoperability framework for health care
License: open source, MPL (check additional licenses from 3rd party tools); Mirth Meaningful Use Exchange product for CCD interoperability is a commercial product.
Interoperability services / **standards**: Mirth Connect: Standards supported CDA, CCR.
General list: HL7, EDI, XML, NCPDP, DICOM, and Delimited Text) and protocols (such as LLP, JDBC, and FTP). Java Connectivity Architecture (JCA)
Additional services: Mirth Project provides components *for health applications (PHR, etc)*; additional services beyond the interoperability stack are provided depending on the components used from the Mirth project. (For example, services that act/react to data flowing through the interoperability layer – monitoring, messaging and alerts, filtering, transformation, routing). Additional appliances can be added on top of Mirth Connect
Comments for developers: modular, portable.
Description – Mirth is an open source project that uses most of the concepts defined before to provide routing, filtering, and transformation of messages between health information systems over a variety of protocols (like LLP, Database, and FTP) with support for numerous standards (such as HL7, XML, and DICOM). The actual Mirth implementation is based on Mule even more, thus we can assume that the Mirth follows the ESB architecture inheriting in this way most of the characteristics enumerated in the previous sections.

The Mirth project includes a number of subprojects that can be combined, including Mirth Connect, Mirth Exchange, Mirth Results.

- Mirth Connect (Figure 43) is an open source health care integration engine and specifically provides an HL7 interface engine. Many standards are supported as described in the template. Mirth Connect Channels are the common sharable connectors implemented in this framework. Connectors are also a feature found in Google Health, Indivo and HealthVault as a means to facilitate interoperability with particular systems. This seems to address the possibility that systems are either not fully compliant to standards or simply do not support them.
- Webinar: www.mirthcorp.com/webinars/mirth-connect-webinar
  www.mirthcorp.com/webinars/mirth-connect-webinar-part-1-mirth-connect-overview
  www.mirthcorp.com/webinars/mirth-connect-webinar-part-4-mirth-connect-demonstrations
- Mirth Exchange[122] (Figure) is used on top of Mirth Connect:
- Mirth Exchange provides a platform for implementing and disseminating standards-based open source interoperability solutions. These solutions are meant to help simplify the integration of legacy HIT systems,
- Mirth Results - Organize and aggregates clinical data across multiple sources
- Mirth Meaningful Use Exchange (Figure)
- www.mirthcorp.com/products/mirth-mux
  Joining systems with the United States National system NHIN[122]

This is built over Mirth Connect and Mirth Exchange to provide data exchange based standards such as the Continuity of Care Document (CCD) for exchanging patient data between systems.

[122] Mirth Project – Interoperability framework – Mirth Exchange http://www.mirthcorp.com/community/mirth-exchange

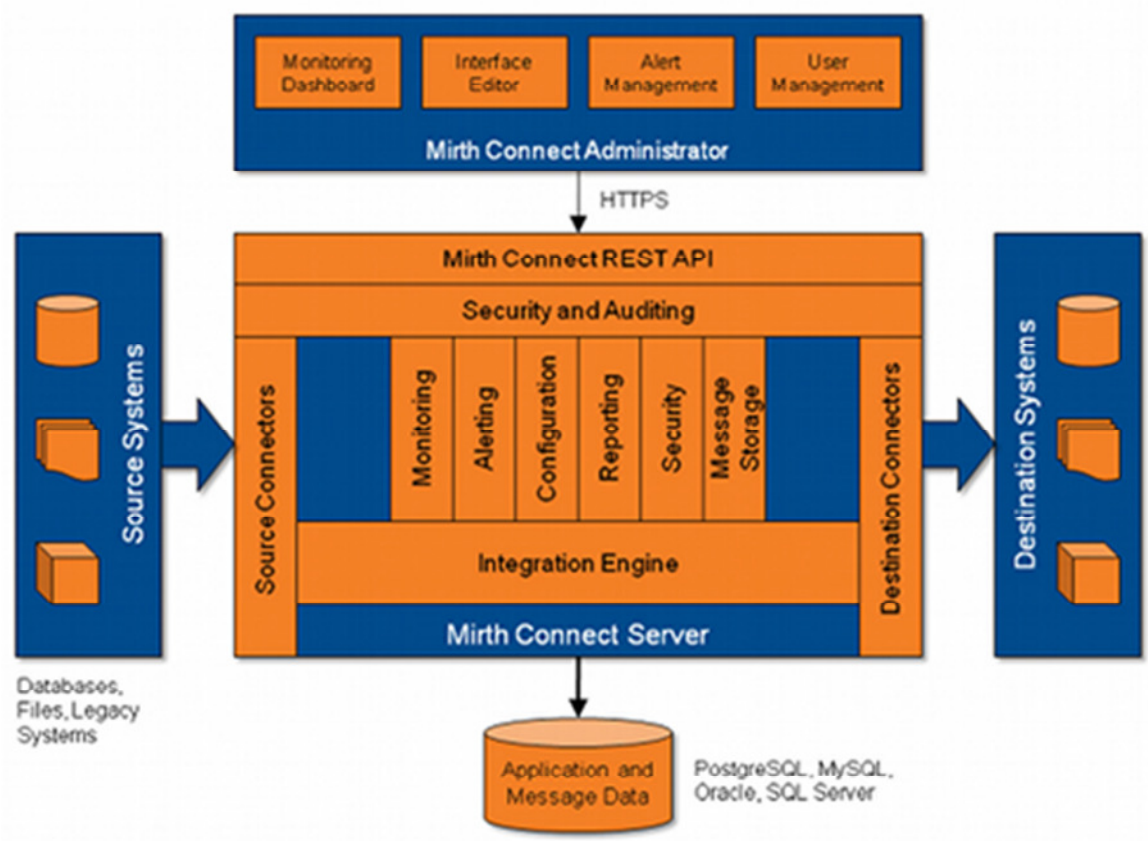

Figure 43: Mirth Connect Architecture Overview

Figure 44: Mirth Exchange

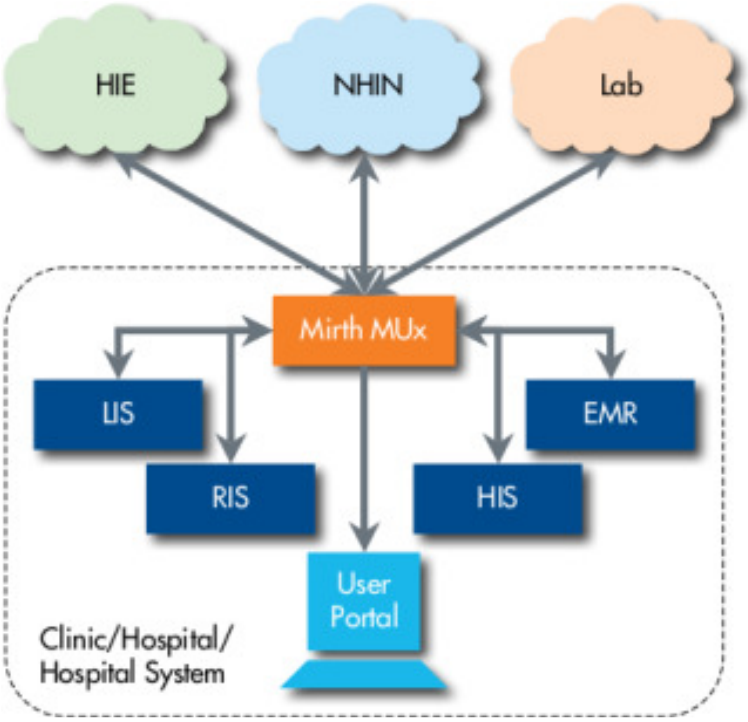

Figure 45: Mirth MUx - Meaningful Use Exchange

Relevance for EMPOWER:

Extensive interoperability framework could be basis for EMPOWER.

Java Connectivity Framework is utilized.

The architecture is simple and easy to extend.

It provides a user interface for the administrative tasks.

Supports most of the actual database systems (Apache Derby (default), PostgreSQL, MySQL, Oracle 10+, MS SQLServer, and MS SQLServer)

It is based on an existing community

Negative: CCD support is part of a commercial product

8.5.5.4 Tolven PHR – Dataflow Architecture, RIM Templates

Site: http://www.tolven.org
Characteristics: standalone PHR interoperability services of the Tolven PHR system
License: open source
Interoperability services / **standards**: CCR, HL7 RIM lab results; UMLS integration
Additional services: additional services beyond interoperability
Comments for developers: -
Description – The Tolven PHR's interoperability architecture is of interest for developers; please see the rule-base dataflow architecture (Figure 46: Tolven Data Flow Architecture)
Developer resources:

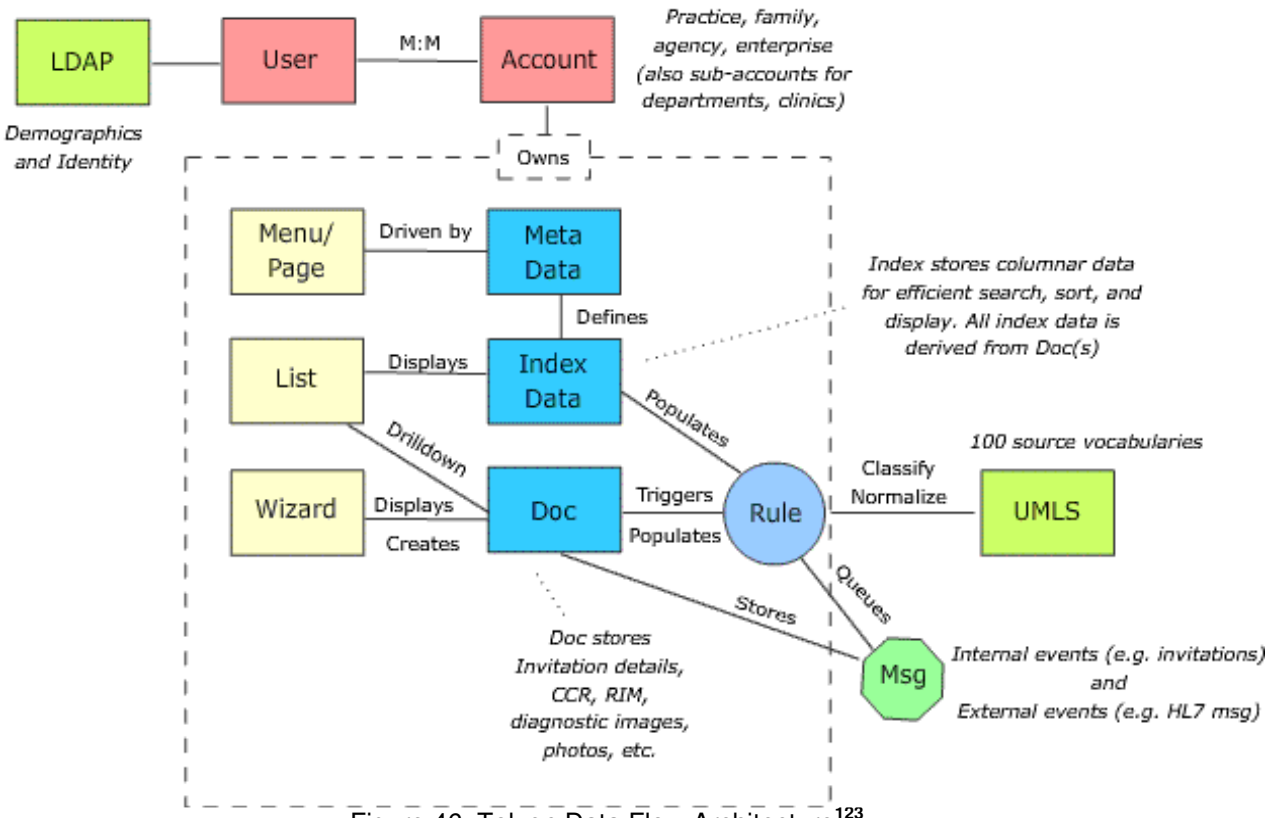

Figure 46: Tolven Data Flow Architecture[123]

Tolven Templates http://www.tolven.org/architecture/briefs/templates.html
Rules and their application http://www.tolven.org/architecture/briefs/rules.html

Relevance for EMPOWER:

Tolven Data Flow Architecture is of strong interest to the architecture of the PHR system and interoperability layer. Available tools should be further investigated during prototyping

8.5.5.5 Indivo PHR Connection Services

Site: http://www.indivohealth.com
Characteristics: standalone PHR interoperability services
License: open source**Interoperability services / standards**: Provides API and tools for connecting EHRs. Provides connectors for common PHR systems (Google Health, HealthVault, Drosia). Possible support of CCR using a Subscription Agent
Additional services:
Comments for developers: modular
Description – We make note of the Indivo Interoperability layer for use by developers to further explore connection and interoperability services implemented by PHR.
Developer resources: See Indivo PHR description

Relevance to EMPOWER:

Indivo could be used for enhancing the EMPOWER PHR system in Task 5.1.

[123] Tolven Data Flow Architecture http://www.tolven.org/architecture/briefs/dataflow.gif

8.6 Terminology Standards

Terminologies are a collection of terms or concepts with subsumption relationships between them, which are used to build a classification hierarchy of concepts. Terminologies provide a framework within which communities can communicate and express ideas in a consistent manner and facilitate unambiguous information share [Bechhofer 1997]. Medicine has a long tradition in structuring its domain knowledge through terminologies and coding schemes for diseases, medical procedures and anatomical terms such as LOINC[124], SNOMED[125], ICD-10[126]. In addition to these, there are terminology servers enabling access to multiple terminologies, provide a metathesaurus, and provide mappings among different terminologies. Examples of such systems are UMLS[127] and NCI EVS[128.]

Relevance to EMPOWER: Medical coding systems are used in several messages and documents in EMPOWER, e.g. EHR/PHR instances. EMPOWER will not impose usage of a specific coding system; instead, it will support usage of several coding systems even in a single EHR document. EMPOWER will implement a Code Mapping API whose interface conforms to HL7 Common Terminology Services (CTS) and the core mapping functionality is supported by UMLS Metathesaurus. For example, it will be possible to translate a coded term in SNOMED CT to its counterpart in ICD10 immediately.

8.6.1 LOINC

Logical Observation Identifiers Names and Codes (LOINC)[129] is a universal standard for identifying laboratory observations and clinical results. Since its inception, it has expanded to include not just medical and laboratory code names, but also nursing diagnosis, nursing interventions, outcomes classification, and patient care data set.

Relevance to EMPOWER: LOINC will be relevant for providing semantic interoperability of data extracted from the HIS/EHR.

8.6.2 SNOMED CT

The Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)[130,] developed and promoted by IHTSDO[131], is considered to be the most comprehensive, multilingual healthcare terminology in the world. It contains a systematically organized computer processable collection of medical terminology covering most areas of clinical information such as diseases, findings, procedures, microorganisms, and pharmaceuticals. It allows a

124 Logical Observation Identifiers Names and Codes, http://www. regenstrief.org/loinc/
125 The Systematized Nomenclature of Medicine Clinical Terms, http://www.snomed.org/snomedct_txt.html
126 International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10), Second Edition, WHO, Geneva, Switzerland, 2005, http://www.who.int/whosis/icd10/
127 Unified Medical Language System (UMLS), http://www.nlm.nih.gov/ research/umls/
128 https://cabig.nci.nih.gov/concepts/EVS/
129 Logical Observation Identifiers Names and Codes, http://www. regenstrief.org/loinc/
130 The Systematized Nomenclature of Medicine Clinical Terms, http://www.snomed.org/snomedct_txt.html
131 The International Health Terminology Standards Development Organisation, http://www.ihtsdo.org/

consistent way to index, store, retrieve, and aggregate clinical data across specialties and sites of care. SNOMED CT is a compositional concept system based on Description Logic[132], which means that concepts can be specialised by combinations with other concepts.

Relevance to EMPOWER:

SNOMED CT will be relevant for providing semantic interoperability of data extracted from the HIS/EHR.

8.6.3 ICD-10

The International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10)[133] is a coding system of diseases and signs, symptoms, abnormal findings, complaints, social circumstances and external causes of injury or diseases, as classified by the World Health Organization (WHO)[134.] It is used to classify diseases and other health problems recorded on many types of health and vital records including death certificates and health records. In addition to enabling the storage and retrieval of diagnostic information for clinical, epidemiological and quality purposes, these records also provide the basis for the compilation of national mortality and morbidity statistics by WHO Member States. Especially, Turkey supports ICD 10.

Relevance to EMPOWER:

ICD 10 is a rather course-grained encoding primarily intended for statistical purposes and reimbursement procedures. However, as baseline information it is available in most patient records.

8.6.4 UMLS

The Unified Medical Language System (UMLS)[135] is a controlled compendium of many medical vocabularies, also providing a mapping structure between them. It is composed of the following three main knowledge components:

- The Metathesaurus forms the base of the UMLS and it comprises over one million biomedical concepts and five million concept names, all of which are from over a hundred controlled vocabularies and classification systems such as ICD-9, SNOMED and LOINC. The purpose of the Metathesaurus is to provide a basis of context and inter-context relationships between these various coding systems and vocabularies to provide a common basis of information exchange between the variety of clinical systems.
- The Semantic Network is designed to categorize concepts in the UMLS Metathesaurus and provide relationships among the concepts. It has 135 semantic types and 54 semantic relationships.

132 Description Logics, http://dl.kr.org/

133 International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10), Second Edition, WHO, Geneva, Switzerland, 2005, http://www.who.int/whosis/icd10/

134 World Health Organization, http://www.who.int/en/

135 Unified Medical Language System (UMLS), http://www.nlm.nih.gov/ research/umls/

- The SPECIALIST Lexicon contains syntactic (how words are put together to create meaning), morphological (form and structure) and orthographic (spelling) information for biomedical terms.

Relevance to EMPOWER:

UMLS's most relevant aspect for EMPOWER is the metathesaurus, which can be used to map terms from one terminology to another given that an exact match, mapping or generalization is possible.

9 Security & Privacy Mechanism

Working with personal health data, EMPOWER must adopt high-quality standards for its security and privacy mechanism. Patient data and resources must be securely protected against unauthorised disclosure as well as unauthorised or improper modifications, i.e. data integrity must be guaranteed. On the contrary, data access for legitimate users must be ensured at any time to deliver a useful service. This trade-off between security and usability[136] needs to be overcome.
Serious state-of-the art PHR-like systems (see Chapter 7.3) or ODL apps (see Chapter 10.1) provide both an acceptable use policy (AUP, or terms of use) and a privacy policy. However, users of such services must accept the policies (which may even change without notice) if they want to use it. In some cases the user can at least modify the data which is exposed to other users and the service provider.

To improve this situation, classical role-based access control mechanisms (RBAC) have been recently extended with temporal authorisation or hierarchical role models. A generic approach on access control is possible through the use of an elaborated context-based security model, allowing the user to enhance privacy by the specification of multiple constraints (temporal, spatial, emergency case, etc.) in which other users or services may access sensitive data. Based on the constraints, each user is enabled to formulate comprehensive privacy policies, instead of just accepting one single policy as provided by the service.

In the following sections, available state-of-the-art standards and technologies are collected and described that support the design of a useable system that is secure and privacy-aware.

9.1 Basic requirements for privacy-aware data processing

By providing an e-Health service like EMPOWER, data processing of personal information is part of the core business. As summarised in an article by Bizer in 2007 [Bizer 2007], privacy-aware processing of personal data requires the accordance with the following seven basic principles:

- **Lawfulness**: Processing of personal information must be compliant with a legal regulation, a contract, a labour agreement or the explicit consent of the person concerned.
- **Consent**: For a valid consent, the person concerned must be comprehensively informed and it must be ensured that the consent was given voluntarily.
- **Limitations on use**: Use of personal information must be limited to a specific purpose, for which they have been collected. This also means that the purpose needs to be explicitly mentioned when receiving the consent from the person concerned.
- **Necessity**: Data processing needs to be limited as necessary to reach the required purpose.
- **Transparency**: The collection and processing of personal information must be transparent to the person concerned.
- **Security**: Privacy can only be reached if data processing, communication and storage are done in a secure way.
- **Supervision**: Data processing must be permanently supervised, both internally and externally.

[136] http://jnd.org/dn.mss/when_security_gets_in_the_way.html

Relevance to EMPOWER:

These principles are relevant for EMPOWER both, for designing the prototype implementation and for selecting third party (open source) products and technologies to be included in the prototype. Finally, they will be relevant for the creation of EMPOWERs privacy policy.

9.2 Relevant Industry Standards, Laws and Directives

Data protection of personal data is also entitled by the legal frameworks in all European countries based on the EC data protection directive 95/46/EC[137], which goes under a major reform within 2012[138]. It must be noted, that the result of this reform may strongly influence the applicability of EMPOWER results towards possible product rollouts. As previously mentioned the legal basis is the first principle in designing a privacy-aware application.

Furthermore, several industry standards with special focus on information security and privacy are available, like ISO/IEC 27000-series, Common Criteria ISO/IEC 15408, ISO/TS 25237:2008, etc. While those standards are not that important for the design of a research prototype, they will become relevant once EMPOWER results are to be exploited in products from the industrial project partners.

Currently on-going, WG4 in the ISO Technical Committee 215 and WGIII in the CEN Technical Committee 251 focussing on security and privacy related issues in the standardisation of the interoperability between eHealth systems. They work together under the umbrella of the Joint Initiative Council[139]. Their results are considered important and need to be further followed by the EMPOWER consortium.

Relevance to EMPOWER:

However, it is not the objective of EMPOWER to develop a new Privacy & Security Framework, while it will apply state-of-the-art technologies in order to enable such functionalities to the user. Finally, a privacy-by-design approach is required from the beginning of the project. This includes that the patient has personal control over his own information, and by default all data needs to be considered as private as long as the patient does not pro-actively share his information.

[137] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:NOT

[138] http://ec.europa.eu/justice/data-protection/index_en.htm

[139] http://www.jointinitiativecouncil.org/

9.3 Standardised Privacy Policy specification languages

As previously mentioned, web services usually specify their privacy policies, often in written form (in prose). To make them comparable and machine readable, the W3C and the OASIS group made efforts in standardisation initiatives to provide policy specification languages (e.g. WS-Policy[140], XACML[141], P3P[142]).
WS-Policy provides a general framework for policy specification for both, the provider and customer (in web-services terms also called "consumer"). Having this two-party approach, a web-service interaction can only be initiated, if the policies of both partners fit together. The policies itself can be defined in the Extensible Access Control Markup Language (XACML) which include requirements of the other party (e.g. what role the consumer must have) and capabilities of the service which are provided once all requirements are satisfied. One possibility to describe such capabilities is for example the W3C P3P policy statement, or the Enterprise Privacy Authorization Language (EPAL)[143]. Finally, a positive result of such negotiation is only achieved when all assertions between consumer and provider are matching. The resulting policy is called "mutually acceptable policy".
The following example of a privacy policy in the eHealth domain which can be expressed in EPAL is available on IBMs EPAL web-site[144]:

- "Members of a group of doctors can read protected health information for medical treatment if the doctor is the patient's primary care physician and the transaction is logged for seven years."

In todays networked world, per-application or per-service based privacy is not anymore enough to sustainably protect users privacy, because personal data is distributed and stored (because of data retention policies) on multiple places. To extend the above mentioned approaches recent projects like the PrimeLife project[145], also supported by W3C, explicitly focus on the privacy protection in such distributed information environment with the ultimate goal to support the users in maintaining a life-long privacy.

The IHE (see Chapter 8.2) also defines a "Basic Patient Privacy Consents" (BPPC) profile[146] that requires patients to provide their consent acknowledgements. One possible approach to implement this profile is the use of the mentioned XACML. One of the project partners already shares experience on this approach in their white paper "Implementation Experiences on IHE XUA and BPPC"[147].

Relevance to EMPOWER:
The described policy specification languages show a promising approach to the privacy preservation problem in the health sector, but the complexity of the sector directly affects the applicability of such languages. Currently they are not yet widely adopted in eHealth applications. For the health domain, IHE developed the BPPC profile that and can be implemented by using XACML. Such approach makes this topic relevant to the EMPOWER scenario.

[140] Web Services Policy 1.5 – Framework, http://www.w3.org/TR/WS-Policy/
[141] OASIS Extensible Access Control Markup Language Technical Committee, http://www.oasis-open.org/committees/xacml/
[142] Platform for Privacy Preferences (P3P) Project, http://www.w3.org/P3P/
[143] Enterprise Privacy Authorization Language (EPAL 1.2), http://www.w3.org/Submission/2003/SUBM-EPAL-20031110/
[144] http://www.zurich.ibm.com/pri/projects/epal.html
[145] http://www.primelife.eu/
[146] http://wiki.ihe.net/index.php?title=Basic_Patient_Privacy_Consents
[147] http://www.srdc.com.tr/publications/2006/XUA-BPPC.pdf

9.4 Secure Communication with SSL/TLS

Basis for data integrity and data privacy is the use of a secure communication channel.

TLS and SSL have been designed to provide secure communication over the Internet. Transport Layer Security (TLS) is the successor of SSL (secure socket layer). The most recent protocol version is 1.2, which is described in the proposed standard RFC5246[148]. Communication, e.g. in client/server applications, using TLS is designed to provide privacy by preventing eavesdropping and to ensure message integrity. TLS requires a reliable transport protocol (such as TCP), but is independent from application layer protocol (like HTTP, SMTP, IMAP). Multiple free open-source TLS implementations are available[149], making this standard easy to deploy also in heterogeneous environments.

TLS is based on the notion of digital certificates. A certificate is a digital form of identification that is usually issued by a certification authority (CA) and contains identification information, a validity period, a public key, a serial number, and the digital signature of the issuer. For authentication purposes, a TLS client or server uses an X.509 certificate to provide another party with strong evidence that attests the identity of the party that holds the certificate and the corresponding private key.

Relevance to EMPOWER:

TLS should be the minimum requirement to be used when exchanging personal eHealth data through Internet Protocol (IP) networks. Therefore the EMPOWER prototype needs to be designed for an easy support of TLS, which will be enabled when real patient data is communicated over public networks.

9.5 Audit Logging and “Break-the-glass” policy

In medical environments, data access in emergency situations may be required without explicit consent of the patient. The so called “break-the-glass” phenomenon is an established and practically applied pattern that may be used to overrule predefined access control policies. The usual approach in such event is to address this challenge with leveraging audit mechanisms to monitor and enable retrace of data access in emergency situations.

The **Audit Trail and Node Authentication (ATNA)**[150] Integration Profile from IHE establishes security measures which, together with the Security Policy and Procedures, provide patient information confidentiality, data integrity and user accountability.

OpenATNA[151] is an implementation of an Audit Record Repository supporting RFC 3881[152] audit messages over BSD Syslog as well as RFC 5424-5426[153] (UDP and TLS). It can be used for audit logging according the ATNA Integration Profile as described in the IHE wiki.

However, the break-the-glass solutions always represent a weak point in the system and are in turn one of the first targets for attackers or misuse. This problem has been also identified

[148] http://tools.ietf.org/html/rfc5246
[149] http://en.wikipedia.org/wiki/Comparison_of_TLS_Implementations
[150] http://wiki.ihe.net/index.php?title=Audit_Trail_and_Node_Authentication
[151] https://www.projects.openhealthtools.org/sf/projects/openatna/
[152] http://tools.ietf.org/html/rfc3881
[153] http://tools.ietf.org/html/rfc5424, http://tools.ietf.org/html/rfc5425, http://tools.ietf.org/html/rfc5426

by the TAS³ EU project (see chapter 9.7), introducing a state variable for the emergency situations that must be set before "break-the-glass" access is allowed. The already mentioned PrimeLife project approaches this issue by proposing an exception-based access control mechanism, defining separate policies for planned and unplanned exceptions.

Relevance to EMPOWER:

Audit Logging is a definite requirement for the EMPOWER project. In accordance to HL7 standards implementation of ATNA, or the use of OpenATNA would be sufficient. The maintenance of additional state variables to limit breaking-the-glass access would also be beneficial.

9.6 Technologies for Identity Management and Access Control

Multiple solutions for identity management, user authorisation and access control exist, many of them providing also support to the single sign-on (SSO) problem. They are partly overlapping, but they are mainly serving different purposes. In the following possible options for implementing ID management are listed. It should be noted that there is a general conflict of interest between having a globally unique IDs for every person (like social insurance number, personal email-address, etc.) and privacy. Special-purpose IDs linked together with an optional ID mapper as proposed by the TAS³ project can provide a convenient solution.

9.6.1 OpenID

OpenID is a free and open identity technology, providing "Authentication-as-a-Service", which basically enables a single-sign-on authentication for multiple services with shared user credentials. One of the main advantages of OpenID is that it follows a decentralised approach so an OpenID service can be established locally and afterwards be connected to other OpenID providers in a second step.
The OpenID specification is open and available on the OpenID website[154]. Large web-sites like Google, Yahoo!, PayPal or IBM use and provide OpenID, meaning that accounts on their services can be used to access other resources within the OpenID network.
A more complex alternative to OpenID has been developed by the Kantara initiative[155], which targets on harmonisation and bridging between different identity approaches.

9.6.2 OAuth

OAuth is an open protocol that allows a secure API authorisation for of applications that can be web-based, desktop or mobile applications. Using OAuth, a user can enable application to access personal data from another service.
The OAuth 1.0 protocol has been defined in the IETF Standard RFC5849[156]. The standardisation of Version 2.0 is in progress. OAuth implementations in multiple languages are available[157]. The main difference from OAuth to OpenID is that the latter just forwards a certificate from the identity provider showing that this user has a valid account, while OAuth requires the identity provider to already provide a valet key for the service that should be accessed.

[154] http://openid.net/developers/specs/
[155] http://kantarainitiative.org/
[156] http://tools.ietf.org/html/rfc5849
[157] http://code.google.com/p/oauth/

9.6.3 SAML

The Security Assertion Markup Language (SAML)[158] is an XML framework for exchanging authentication and authorisation information, usually between separated security domains. SAML is specified by the OASIS Security Services Technical Committee. SAML defines XML-based assertions, protocols, bindings, and profiles.
SAML is for example implemented by Shibboleth[159] together with additional privacy functionality that allows controlling the attributes released to each application.
OASIS Web Services Security TC describes how to use SAML with SOAP[160]. Regarding REST services, developers must investigate this issue regarding new specifications or best practices[161].

9.6.4 WebID and WebAccessControl

WebID[162] and WebAccessControl[163] are two standard defined by the W3C to enable the user managing their identities on the web. While WebID enables a uniquely identification of users, WebAccessControl is a decentralized system for allowing different users and groups various forms of access to resources where users and groups are identified by HTTP URIs. These standards are e.g. employed by the Linked Media Framework (LMF) that bundles central Semantic Web technologies to offer advanced services. LMF is developed at SRFG and can act as a linked data backend framework for EMPOWER. In order to make it usable for eHealth applications using personal data, a permissions framework is required. The LMF has currently a permissions module based on WebID and WebAccessControl under development which can be expected to be completed within the runtime of EMPOWER. Both technologies may be adopted in EMPOWER even without LMF.

Relevance to EMPOWER:
Multiple Technologies for ID management and access control are available. The topic is closely related with the interoperability/interconnectivity topics as described in Section 8.5.4. Therefore the technology adopted for EMPOWER needs to be done in conjunction with the design of the PHR interoperability framework.

9.7 Integrated Security Solutions

Several (open-source) products are available that provide an integrated solution of the already described technologies. For providing a proof-of-concept prototype as planned to be done in EMPOWER, re-use of existing implementations is essential compared to building a complete implementation from scratch. Therefore, we also analysed some of the existing access control platforms for their applicability in EMPOWER.

[158] http://saml.xml.org/
[159] http://www.shibboleth.net/
[160] SAML & SOAP https://www.oasis-open.org/committees/tc_home.php?wg_abbrev=wss
[161] SAML & REST http://www.sdtimes.com/WHY_YOU_SHOULD_BROKER_RESTFUL_WEB_SERVICES_WITH_SAML/By_FRANCOIS_LASCELLES/About_REST_and_SAML_and_SECURITY/34309 and http://sberyozkin.blogspot.co.at/2011/11/saml-claims-based-authorization-for-jax.html
[162] http://www.w3.org/wiki/WebID
[163] http://www.w3.org/wiki/WebAccessControl

9.7.1 Forgerock Tools : OpenAM, OpenDJ, OpenIDM, OpenIG

Suite of tools to support Authorization, Authentication, Identity management and Entitlement and Federation software[164].

OpenAM
OpenAM provides open source Authentication, Authorization, Entitlement and Federation software. Through OpenAM, the community actively continues development of OpenSSO.

OpenAM provides core identity services to simplify the implementation of transparent single sign-on (SSO) as a security component in a network infrastructure. OpenAM provides the foundation for integrating diverse web applications that might typically operate against a disparate set of identity repositories and are hosted on a variety of platforms such as web and application servers. Features include:

- SSO, LDAP via OpenDJ, secure directory server
- SAML V2 a standard for exchanging authorization information across different systems
- Authentication - Validation of digital identity
- Authorization - Includes enforcement of access policies on network resources
- Web Single Sign-On (SSO)
- Federated identity
- Supports SSO, LDAP via OpenDJ,SAML V2
- Security Assertion Markup Language(SAML)
- OpenAM provides open source Authentication, Authorization, Entitlement and Federation software. Through OpenAM, the community actively continues development of OpenSSO.
- Includes OpenDS directory server

The software package supports Security Assertion Markup Language (SAML) version 2, a standard for exchanging authorization information across different systems. It also includes a new monitoring framework, and directory server, - OpenDS.

OpenIDM is an open standards based identity management solution. In addition to being open source, OpenIDM offers high flexibility in business process handling.A user interface combined with a workflow engine.

- Identity Management
- Workflow Engine, UI

OpenDJ
The OpenDJ open source directory services, includes secure directory server, built-in data replication, client tools, and an LDAP SDK.

- LDAPv3 compliant directory service,
- Directory Service Markup Language (DSMLv2) compliant directory service
- Stores identity data securely; secure directory server
- Supports different levels of authentication and authorization.
- Protects passwords through encryption and extensive policies.
- Configuration changes are audited and archived.
- Complies with LDAPv3 and DSMLv2 standards

[164] http://www.forgerock.org/index.html

- OpenDJ DSML gateway enables applications accessing directory data through DSMLv2[165].

Open Identity Connectors
The Open Identity Connectors Framework and Toolkit (OpenICF) for development of Connectors. Connectors provide a consistent generic layer between applications and target resources[166].

OpenIG
The Open Identity Gateway (OpenIG) is a high-performance reverse proxy with specialized session management and credential replay functionality;it extends both federated and traditional single sign-on to all web applications.

Open Identity Gateway
The Open Identity Gateway is a reverse proxy server with specialized session management and credential replay functionality. It extends both federated and traditional single sign-on to all web applications.OpenIG works together with OpenAM to integrate Web applications without the need to modify the target application or the container that it runs in[167].

9.7.2 CAS-Server

CAS is an authentication system originally created by Yale University to provide a trusted way for an application to authenticate a user.
CAS[168] provides enterprise single sign-on service:

- An open and well-documented protocol
- An open-source Java server component
- A library of clients for Java, .Net, PHP, Perl, Apache, uPortal, and others
- Integrates with uPortal, BlueSocket, TikiWiki, Mule, Liferay, Moodle and others
- Community documentation and implementation support

9.7.3 Java Security Mechanisms

Although not a ready integrated solution, the available Java security mechanisms should be mentioned in this section, as Java provides many of the required security features that are necessary to implement software architectures with integrated privacy and security. As at least some of the EMPOWER components will be based on Java, a variety of security features and mechanisms can be easily integrated, like authentication and authorisation (JAAS), generic security services (Java GSS-API), encryption (JCE), or secure communication (JSSE). These mechanisms are made available in Java EE through component containers (or application servers). Current application servers like Apache Tomcat, Glassfish or JBoss implement the Java EE Security specification, which make them possible candidates to be used in EMPOWER.

[165] http://www.forgerock.com/opendj.html http://en.wikipedia.org/wiki/OpenDJ
[166] http://openicf.forgerock.org/
[167] http://openig.forgerock.org/
[168] http://www.jasig.org/cas

9.8 Related EU-projects

Privacy and identity management are a major topic an many EU-funded research projects. Within FP7 work programme a dedicated thematic area on trust and security is open, where multiple research projects are funded. A complete list of the projects is available on the Cordis website[169]. Some, which are of specific interest for EMPOWER are:

- **PrimeLife** will resolve the core privacy and trust issues pertaining to challenges like how to protect privacy in emerging Internet applications or how to maintain life-long privacy. Its long-term vision is to counter the trend to life-long personal data trails without compromising on functionality. We will build upon and expand the sound foundation of the FP6 project PRIME that has shown privacy technologies can enable citizens to execute their legal rights to control personal information in on-line transactions.
- **PICOS** (Privacy and Identity Management for Community Services) was a privacy-related project focussing on mobile communities. The developed approaches and concepts, like Profile Management or Consent Management can be applied also to the EMPOWER scenario.
- The Trusted Architecture for Securely Shared Services (**TAS^3**)[170] project's objective is to develop a trusted infrastructure to support the responsible security and privacy management of information in a world of ever increasing mobility of people and information. The project is organized in a user-centric manner that is designed to foster user trust and acceptance while allowing for more robust and beneficial use of the information in a controlled and accountable manner.

10 User environment for Diabetes Patients

10.1 Applications supporting Diabetes Patients[171]

Name	Logo	Functionality description	Supported devices / OS
Glucose Buddy		This app lets the user record blood glucose levels and note the time of day—such as "before breakfast" or "during activity." Users can view trend graphs, interact in the Glucose Buddy forums, and record insulin injections, exercise, and food eaten. They can also sync their phone to an online account to manage their data on Glucose Buddy's website	**iPhone, iPod Touch, iPad**
WaveSense		Meter manufacturer AgaMatrix's app lets users log blood glucose levels and type in personal notes. They can record the amount of insulin injected and the number of carbohydrates eaten, and view one-, three-, seven-, 14-, 30-, and 90-day trends in graph or chart form. High, in-range, and low readings are color coded in the logbook. Users can also e-mail their stats to family or their doctor. The app comes loaded with about 50 diabetes-related videos.	**iPhone, iPod Touch, iPad**
Vree		The Vree app (free for a limited time, but $1.99 after that) from Merck lets users log her blood glucose, exercise, weight, blood pressure, and food and medication intake. A home status page allows her to scroll through graphs and e-mail them to her doctor. The app has a database of common foods (including restaurant meals) but only allows users to build sandwiches and salads to personal specifications. Tips and articles on weight loss, nutrition, exercise, and type 2 diabetes are stored within the app. The medication field doesn't make tracking insulin doses possible.	iPhone, iPod Touch, iPad
OnTrack		With this app, the user can log and graph her blood glucose level as well as food intake, blood pressure, weight, exercise, pulse, A1C results, body fat percentage, and medications. For each entry, the user can add personal notes. Results can be exported via e-mail to the user's medical team.	Android phones
Lose It		This app enables users to track their weight loss, daily food intake, and exercise. It is possible to add meals as you eat them (from a list of common foods, brand-name foods, and restaurant meals, or personal recipes) and watch the sliding scale climb toward a daily calorie limit. The user can record exercise	iPhone, iPod Touch, iPad

[171] Information presented in this section originates from the mobile app markets (itunes, android market, etc).

		(choose from a long list of activities), graph weight loss, get reminders, and share progress on Facebook and Twitter	
Calorie Counter by MyNetDiary		With this app, the user can record meals (choose from an expansive food library that includes restaurant picks), exercise, water intake, medications, weight and measurements. Food selections include a nutrition facts label, and the app's bar code scan lets the user search for and log packaged foods. The app includes tips and articles on nutrition	iPhone, iPod Touch, iPad
Log For Life		Diabetes Quick Entry is a companion application for the subscription-based web application, Log for Life. It provides an easy way to manage diabetes log while on the go. Among its features the following are characteristic: • Quickly log glucose, carbohydrates, medication, exercise, weight, and notes • Two-way sync: syncs all data to and from logforlife.com • Historical entries view • Edit or delete any entry • View any log that you have access to through the web-based sharing system	iPhone, iPod touch, and iPad and requires iOS 3.0 or later
My Fitness Pal		The goal of this (free) app is to help a user lose weight. It tracks calories eaten (food) and burned (exercise). It has an extensive library of 1,113, 000,000 foods and restaurant items. It is not diabetes-specific so a user needs to log blood glucose to other apps.	Apple, Android, Blackberry, and Windows Phone
Insulin Calculator	 	This app calculates insulin dose based on carb intake and blood glucose values. For initial configuration it requires that the user, in cooperation with her doctor determine 3 "constants" — Carb/Insulin Ratio, Correction Factor, and Glucose Level Goal. Then, every time the app is used, the user simply enters the 2 "variables" – blood glucose measurement and the amount of carbs consumed. The app uses a formula to calculate how much insulin the user should intake. The app costs $0.99 in Apple Store, and $1.99 in Android Market	Apple and Android
The Body and Type 1 Diabetes		This is an educational app teaching the basics: what is diabetes, insulin, carbs, control. It features animated graphics and easy-to-follow steps	iPhone, iPod touch, iPad
Blood Pal Free - Glucose Tracker		Blood Pal automatically saves glucose level, relationship to the meal, and time of measurement. The user can also read all historical data in list view or chart view and email the data to her doctor	iPhone, iPod touch, iPad, requires iOS 3.0 or later

Glucose Charter		Glucose-Charter is a blood glucose, insulin and medication recording tool installed on iPhone. It helps diabetic patients manage their Diabetes, type 1 and 2. Significantly Glucose-Charter records Insulin and medications in a diary and optionally reports these to the patient's doctor every 30 days. Glucose-Charter supports self-monitoring & logging of blood glucose, insulin and other medication, known carbohydrate foods. It also includes food information display and therefore supports eating decisions. It also provides the user and her doctor with the needed record keeping.	iPhone, iPod touch, iPad, requires iOS 3.0 or later
Diabetes Companion		The dLife Diabetes Companion app is backed by the resources of a diabetes website. The dLife Diabetes Companion offers access to the essential tools necessary for managing diabetes. The app features the following: • WATCH: View over 400 videos by searching via keyword or by choosing from one of over 30 categories. The extensive video library contains cooking demonstrations, stories of real people with diabetes, and practical information. • SOLVE: Access the dLife Expert Q&A database of over 4,000 questions with responses from diabetes professionals and community members, searchable by category or keyword. • EAT: Find recipes and food information on the spur of the moment. Use the dLife Food and Recipe Lookup feature to search over 9,000 diabetes-friendly recipes and 25,000 specific foods. Recipes include ease-of-use scale, prep/cooking times, ratings, and complete nutritional information. • MANAGE – Log and track blood glucose levels and get a 360 view of diabetes management. With dLife Diabetes Companion, you can: • record carb, insulin and blood glucose data and track over time • input exercise type and exertion level • log a meal and BG levels before and after an event • easy to read reports detailing daily, weekly, and monthly BG levels • email diabetes information to family, healthcare professional or whomever the user chooses • spot low or high ranges with color-coded results • set custom target ranges, hypo-/hyperglycemic limits, and mealtime schedules	iPhone, iPod touch, iPad, requires iOS 3.0 or later

		• add tags to glucose results for food, exercise, medicine, or health issues	
Diamedic		Diamedic Diabetes Logbook offers a solution for the diabetics to record every glucose reading, insulin injection, lab result, carb intake, weight, medication and exercise workout. The app features the following: • Use the built-in insulin types, medications and exercise types or customize to reflect personal usages and preferences. • Use built-in glucose periods (before/after breakfast, etc.) or set personal ones. • Show glucose readings and lab results in mg/dL or mmol/L and weight in kg, pounds or stones. • Track basal program settings on insulin pumps. • Log items via scroller wheels or the built-in keyboard. • Graph readings, weight and lab results in multiple formats. • Use the prescription and medication refill calculators to predict refill requirements based on previous 30 days. • View all information about the current day in the Composite View. • Email information. • Exchange data with any FTP file server. • Add notes to individual log items. • Set up insulin injection templates for common shots. • Track pulse, blood pressure & temperature. • Dosage calculator.	iPhone, iPod touch, iPad, requires iOS 4.3 or later
Diabetes Pilot		Diabetes Pilot is an app for managing diabetes on iPhone or iPod Touch. It works by itself or in combination with Mac and PC software (available separately). Diabetes Pilot is designed for all people with diabetes - whether they use insulin, other medications, or just diet and exercise. Some of the app features are the following • Synchronizes record data and foods with Mac and PC software (sold separately) for easy backup, editing, import/export, and creating more elaborate reports. Data is kept under patient's control, on his or her own devices, for reliability and privacy. • Records glucose (mg/dL or mmol/L), medications, meals, exercise, blood pressure, weight, and notes about test	iPhone, iPod touch, iPad, requires iOS 3.0 or later

results or any other information that's of interest to the patient.
- Includes an integrated food database with reference information on thousands of foods. Tracks carbohydrates, calories, fat, protein, fibre, sodium, cholesterol and other nutrients.
- Graphs daily glucose readings and weight so that the patient can study trends. Copy the graphs to the patient's photo album for future reference or to send to others via email.
- If the patient uses insulin, Diabetes Pilot can estimate insulin for meals and correcting high glucose. For those who don't use insulin, Diabetes Pilot works great for tracking other medications.
- Helps the patient find trends in blood sugars. Estimates HbA1C.
- Sends reports and exports data via email. Creates reports for sending via e-mail. Exports data to a spread sheet or other software.

The following table presents the basic features of the above-described mobile apps, allowing easy comparison.

	Wavesense Diabetes Manager	Glucose Buddy-Diabetes Tracker	Blood Pal- Glucose Tracker	Glucose Charter	Diabetes Companion	Diamedic	UTS Diabetes	Diabetes Pilot	Vree	OnTrack	Los It	Calorie Counter	Diabetes Quick entry	My fitness Pal	Insulin Calculator	The Body and Type 1	Blood Pal
Graph Glucose	√	√	√	√	√	√	√	√	√	√			√		√		√
Glucose Log	√	√	√	√	√	√	√	√	√	√			√				√
Carb Log		√		√	√	√	√	√	√	√	√	√	√	√	√		
Exercise Log		√			√			√			√	√		√			
Insulin Dose Log	√	√		√	√	√	√								√		
Medication Log/ Reminder			√	√		√	√	√	√								
Email option	√		√	√	√	√		√	√	√							
Print Data		√						√									
A1C Estimator		√						√		√							
Effect of meal on glucose		√						√									
Online Manual/Help				√													
Food Database				√	√			√	√		√	√		√			
Recipe Finder					√						√	√					
Online Videos	√				√												
Sync to Online Account		√					√	√					√				

In addition to diabetes-dedicated mobile apps, several others are available dedicated to fitness and mental health monitoring. We provide below a short description of indicative such applications.

Name	Logo	Functionality description	Supported devices / OS
Runtastic		This app lets the user track runs and activities. By exploiting the mobile device built-in GPS. Further info includes distance, time, speed, calories, altitude, pace, etc.). Some of its features are the following: • Map of workouts in real-time with mobile device built-in GPS • Personal workout diary and metrics • Weekly, monthly and yearly statistics • Mapping: Detailed live mapping and historical mapping of previous sessions (Google maps) • Dashboard configuration: Display preferred statistics • Graphs: charts with altitude, pace and speed information • Performance analysis with split times • Accurate calculation of elevation gain and loss • Manual entry of workouts • Landscape mode • Possibility for sharing of info on Facebook and Twitter	**iPhone, Blackberry, Android**
FitBit Tracker and apps		Fitbit Tracker is a wireless-enabled wearable device that measures data such as the number of steps walked, quality of sleep, and other personal metrics. Fitbit apps are also available for iPhone and Android phones. Fitbit allows users to set a Food Plan for themselves on the website or the mobile app based on a weight goal. The Food Plan tool has four different intensity settings users can choose from, and gives a range of calorie consumption to aim for each day. This number updates dynamically with any activities logged on the Fitbit website or synched with the Fitbit Tracker. It also gives a projected date for the weight loss which updates as the user logs their weight.	Fitbit Tracker, iPhone, Android phones
iExercise Journal		iExercise Journal is an iPhone, iPod Touch and iPad app that helps the user track fitness activities. It monitors progress and keeps track of daily physical activities (exercises and workouts). It also includes exercise/physical activity Trends Analysis.	iPhone, iPod, iPad

Depression Journal		iDepression is an app for iPhone, iPod Touch and iPad app to help individuals keep track of depression and gather specific data including factors and events that cause depression. It also helps them track triggers and the effectiveness of medication. Some of its features are the following: • Easy and intuitive interface to record information about depression. • Enables monitoring of changes in depression over time. • Log history display allows one to view all historic data. • Supports free text notes to each log. • Custom reports - Daily, Weekly, Monthly and more. • All data is stored locally on iPhone for your privacy. • Export to Microsoft Excel	iPhone, iPod, iPad
Depression Connect		Depression Connect is an iPhone, iPod Touch and iPad app which helps people to stay connected with a large growing community of others living with depression. With Depression Connect mobile, users can follow discussions, ask questions and add comments. They can also discuss treatments, start conversations, and learn from others. Some of its features are the following: • Interaction with a vibrant community of people • Seaking for answers and support from others in community discussions • Asking questions, starting discussions, and commenting on what others say • Mood tracking: Telling others how the user is doing by posting status updates from the Activity tab • Following interesting discussions by pressing the star button • Activity feeds in order to keep track of discussions and replies • Quick search for information using categories and sorting	iPhone, iPod, iPad
Depression CBT Self-Help Guide		Depression CBT Self-Help Guide is an app for Android phones. It helps the user to manage his/her depression by understanding the factors that contribute to the symptoms. He/ she learns to manage stress by engaging in self-care behaviours in order to improve depression symptoms and mood. Some of its features are the following: • Screening test with graph to monitor severity of depressed mood • Articles about clinical depression and cognitive-behavioral therapy (CBT)	Android phones

		• 50 suggestions from CBT with a tracking feature to help focus positively and motivate • Depression Assistance Audio to help understand clinical depression • Cognitive Thought Diary to learn to challenge stressful thinking and provide positive feedback • Emotion Training Audio to learn to access calming moods or emotions • Relaxation Audios to learn deep relaxation • Password protection available • Customization of graphics	
aSleep Classic		aSleep Classic is an iPhone, iPod Touch and iPad app. It helps the users to relax and listen to sounds of nature and melodies that will help to fall asleep. aSleep is also suitable for meditation, yoga, to release the stress and so on. Some of its features include: • Password protection available • Multitasking • 47 high quality stereo sounds • Open AL Audio Engine with: • Auto Play • Adjustable volume • Adjustable speed • Resume after interruption • Accelerometer support: • "Shake to Shuffle" sound selection • Settable timer & options: • Sound fades out • Alarm • Automatically exit the application • Auto saving settings • Built-in instructions for use	iPhone, iPod, iPad
Sleep Diary Lite		Sleep Diary Lite is an app for Android phones. Sleep Diary is an all-in-one sleep cycle alarm clock that analyzes sleep patterns and help to get a better rhythm improving wellness and fitness. In conjunction with the Smart Alarm, that wakes the user in the light sleep phase, Sleep Diary can help to improve overall heath. Use of statistics report to understand sleep cycle. Simple to use. Place in the bed and press "Start". Features: • Auto saving settings • Sleep Cycle monitors movement during sleep using the phone accelerometer. • Advanced statistics and charts to help visualize and understand sleep cycle.	Android phones

		• Record entry sleep in the diary. • Smart Alarm that awakes the user in the light sleep phase. • Using Soft Alarm that gradually increases in volume is more relaxing then most alarms. • Configurable Alarms including sound & music selection, snooze time and activities. • Auto backup option to keep data safe along with export options (export data as CSV and charts) in order to further analyze personal statistics. • Resume Tracking feature allows to stop and restart the tracking within 10 minutes • Works great as an alarm & diary without tracking, if so required. • Optimized to minimize battery usage • English & German Languages Supported.	
StressFree		StressFree is an iPhone, iPod Touch and iPad app. Trains breathing to synchronize at 6 breathes per minute optimizing maximum stress relief and relaxation. Use in the car, before bed for 5 to 10 minutes. Promotes relaxation, deep quality sleep and restfulness.	iPhone, iPod, iPad
Let Panic Go		Let Panic Go is an iPhone, iPod Touch and iPad app. Designed to interrupt the cycle of thoughts and body sensations that fuel a panic attack. Some of its features include: • Automatically exit the application • Biofeedback enhanced, to help regain control over breathing • No audio necessary • visually formatted for rapid access and ease of use • Incorporates mindfulness and cognitive behavioral techniques • simple instructions with built-in training module • Guided exercise adapts to user's level of relief	iPhone, iPod, iPad
iCounselor: Anger		iCounselor: Anger is an iPhone, iPod Touch and iPad app. All material was written by a licensed psychotherapist (LCSW) with twenty-five years of counseling experience. First, it helps the user to rate his/her level of anger on a color coded scale of 0 (not angry at all/content) to 10 (enraged). Then moves on to the first set of skills, where s/he selects one of ten different calming activities to perform. If s/he is not sure	iPhone, iPod, iPad

	which skill to select, s/he has to shake the iPhone or iPod and one will be randomly chosen. After following the instructions for the calming activity, s/he selects one of ten ways to change his/her thoughts. Changing thoughts in order to change feelings is the basis of cognitive behavioral psychotherapy, the most widely practiced evidence based form of psychotherapy. After utilizing one of the thought changers, proceed to selecting one type of solution for the problem that triggered anger. After implementing the solution provided by the app, user can rate the level of anger again in order to determine if the skills chosen were effective. If the level of anger has not reduced sufficiently, user can try again, selecting a different skill set.	

Relevance for EMPOWER:
Each and every application presented in the table above features a functionality that is relevant to an extended (or less extended) set of requirements related to the EMPOWER end users and intended functionality of the EMPOWER mobile apps.

A rather common objective of all the presented apps is the support of diabetics' self-management, the provision of an interface to log vital, physical, and diet parameters, medication, etc. This is also a significant objective of EMPOWER.

What EMPOWER projects differs to, is the fact that it aims at incorporating personalized action plans as a way to help individuals handle their chronic disease. For this, a software component acting as a recommender will be built. Moreover, it aims at exploiting the information collected via (among others) the mobile apps towards building personalised action plans for dynamic self-management of the user's health, notwithstanding the fact that it will support semantic interoperability with standard based Personal Health Records. A significant feature of the EMPOWER system is that it will support different maturity levels for self-management, based on the user's profile. In addition, monitoring of mental parameters is part of the intended functionality, something that is not part of any of the above-presented applications.

As a general remark, we should note that we anticipate that the incorporation of this functionality will render the EMPOWER mobile app into an application that motivates users in using it. By doing so the project will address one of the major drawbacks of existing applications, i.e. the lack of interest about keeping on using an application after the initial enthusiasm.

The second table presented above, includes a list of smartphone apps that support mental health and well-being. Each one of them helps individuals to improve specific aspects of daily living. Studies have shown that diabetic patients have twice the risk to suffer from depressive disorder, compared to people that don't have diabetes. Stress and sleep disorders could be included in the spiral that diabetes can lead to. Mental illnesses could hamper the self-care and consequently the diabetic's therapy. Therefore, support and help could be useful anytime. The smartphone apps listed above, by no means intend to supersede the therapy provided by a specialist. They could help in a better understanding and control of the stressful situation diabetes may lead to. In conclusion, the EMPOWER system mobile app, essentially, should integrate the personalized action plan with a mental health support application, in order to enhance the diabetic therapy and ensure the patient's well-being

10.2 Multimodal Services and Interfaces

As mobile devices are taking over our lives, people become nomadic. Human-computer interaction (HCI) has to adapt and follow the emerging need for new kinds of services that work in multiple environments, device-independent. Multimodal user interfaces (MUIs) are the new trend that came along with a new lifestyle; people no longer rely only on a PC (laptop or desktop), they constantly use digital technology while on the move with devices like smart-phones and tablets.

Two major groups of MUIs have emerged, one concerned in alternate input methods and the other in combined input/output:

1. The first group of interfaces combines various user input modes beyond the traditional keyboard and mouse input/output, such as speech, pen, touch, manual gestures, gaze and head and body movements.
2. The second group of multimodal systems presents users with multimedia displays and multimodal output, primarily in the form of visual and auditory cues.

Interface designers have also started to make use of other modalities, such as touch and olfaction. Proposed benefits of multimodal output systems include synergy and redundancy. The information that is presented via several modalities is merged and refers to various aspects of the same process[172].

Those users who have difficulty with one input modality could greatly benefit from using an alternative input modality, or a combination of modalities enabled by a multimodal interface. In the case of users with visual impairments, auditory and haptic modalities offer tremendous potential for contributing to effective interaction when the visual modality is engaged, or overwhelmed [Vitense 2002].

Currently, multimodal system output is used primarily for improving the mapping between communication medium and content and to support time sharing and attention management in a variety of data-rich, real-world domains where operators face considerable visual attentional demands **Fehler! Verweisquelle konnte nicht gefunden werden.**. A critical motivator for the development of MUIs is the ongoing migration of computing and information access away from the ergonomics of desktop computing to more challenging settings including mobile devices such as tablets and smartphones, in vehicle (e.g. navigation systems), and in-home entertainment systems (set top box, wall-mounted displays). These devices generally have no real keyboard or mouse and offer limited screen real estate, making traditional graphical user interfaces cumbersome and difficult to use. Furthermore, since mobile devices are used in situations involving different physical and social environments, tasks, and users, they need to allow users to adapt their mode of interaction to the surrounding environment **Fehler! Verweisquelle konnte nicht gefunden werden.**.

MUIs were first seen as more efficient than unimodal interfaces (Graphical User Interfaces - GUIs); however, evaluations showed that MUIs only speed up task completion by 10%. Hence, efficiency should not be considered the main advantage of MUIs. On the other hand, MUIs have been shown to improve error handling & reliability: users made 36% fewer errors with a MUI than with a GUI **Fehler! Verweisquelle konnte nicht gefunden werden.**.

There is also a resurgent interest in MUIs coming from the industrial world. Recently, Apple filed an application for a patent approval, which is going to advance iOS devices with a new live interface that is referred to as the Multi-Modal Human Interface. The new user interface is powered by a new engine that is able to detect environmental conditions and change the operational interactivity options for users so as to maximize the iDevice's usefulness - automatically. It's also designed to reduce power drainage so that devices could be up and running longer. One example provided for in Apple's documentation is an iPad shutting down the standard iOS UI automatically in favor of one that is driven by a voice and speech recognition UI while the user is driving. Apple states that their invention covers small form

[172] Multimodal interaction from Wikipedia, the free encyclopedia, Internet: http://en.wikipedia.org/wiki/Multimodal_interaction#cite_note-0

factor electronic devices that include a processor and an interface engine in communication with the processor and a sensor coupled to the processor. The sensor is arranged to detect at least one environmental factor and pass an indication of the detected environmental factor to the processor. The processor and the interface engine cooperate to determine if an environment of the electronic device has changed, identify an updated human interface when the environment has changed, and cause the small form factor electronic device to present the updated human interface only if a level of interactivity corresponding to the updated human interface is at least greater than a threshold level of interactivity. The multi-modal human interface (MMHI) engine could provide an updated MMHI arranged to automatically maintain a pre-determined level of interactivity between a user and the electronic device. As the situation may require, being able to update the MMHI in such a way that a user could interact with an iPad (or other iOS device) without having to rely on visual indicators could be very useful. For example, it would be advantageous to not rely on visual indicators provided by display when the display isn't viewable or that using the display would adversely affect the operation of the iPad by, for example, severely reducing expected operating time at a current operating state[173].

UIs are of outmost importance in e-health applications and therefore, should be carefully devised. One major difficulty in designing a UI for an e-health application is that the user profile is difficult to be defined. First of all, an e-health application addresses two different types of users; patients and clinicians. Owing to the different needs of those two user roles there should be designed two different UIs. On the other side, users could apply to different age groups. Either patients or clinicians could be of any age, and thus, the users' adeptness to digital technology could not be predefined. On top of that, patients could have a vast range of special needs depending on the nature of their illnesses. A MUI can settle the different needs and facilitate the UI design. For example, if a user is unable to use her hands, a speech input UI could make it possible for her to use the application.

The University of Fribourg in Switzerland has developed a framework, the LoCa framework, for adaptive user interfaces for home care and smart hospital services. Their approach includes a MUI application which gives the users the freedom to use the application on any device running on Android, an open source Operating System (OS) available on a number of mobile devices. This makes it a multimodal system output application. They used model-based UIs for automated UI generation. Model-based UIs offer a promising approach to automated UI generation in a multi-device environment. UI designers develop the models upon which the UIs are based. During run-time, the UI is generated by applying a set of transformation algorithms to different types of models. Their research includes a use case scenario in a smart hospital, where each clinician is equipped with an Android smartphone with a touchscreen display. Additionally, they have access to workstations and may also use tablet PCs. The smart hospital is equipped with the indoor location tracking system Ubisense. Each room has an entertainment multimedia set for each patient, to watch TV, access the internet or listen to music. Additionally, a Hospital Information System stores the patient record of every patient. The patient record contains information including the patient's personal information (e.g. name, date of birth), current room, admission date and medical history. Patients have their heart rate and blood oxygen saturation constantly monitored. These measuring devices are registered to a specific user and have a bluetooth interface. In addition, some of the devices for measuring additional physiological parameters (e.g. glucose meter) that are carried by a nurse are also equipped with a Bluetooth interface **Fehler! Verweisquelle konnte nicht gefunden werden.**.

Another e-health application is the Diet Diary, which focuses on the design and development of an input multimodal interface used by elderly people and allows them to keep track of their daily dietary habits. The goal of the diet diary is to make people aware of their diet and give personalized advice in a usable way on how they could improve it. In order to support mobility, they developed their application to run on a PDA. Most PDAs can be operated

[173] http://www.patentlyapple.com/patently-apple/2011/12/apples-revolutionary-smart-bezel-project-gains-a-new-chapter.html

through different ways: h/w buttons, touchscreen or both. Taking into consideration that few older adults have any experience with PDAs, they chose to limit input modality to on-screen buttons. They avoided drag and drop and sliding bar interface elements because they expected that the target user group could have problems using these as consequence of potentially reduced motor skills. The output of the diet diary interface was through three different modalities: text, speech and graphics, consisting of icons and images. Textual concepts, such as diary components, food products, and nutritional elements, e.g. carbohydrates, were accompanied by images and icons. In addition, they gave advice about food intake which was accompanied by illustrations representing the same concepts. The spoken feedback was pre-recorded, because occasionally older adults have hearing problems in upper frequency range, a male Dutch native speaker with low voice was used.

During their study, they applied scenario-based approach and a within-subject design. Each participant had to complete four different scenarios, each under different conditions, which were:

1. Text input only
2. Text and speech
3. Text and graphics
4. Text, speech and graphics.

After each scenario, the participant filled in two questionnaires. Upon completion of all four scenarios, participants were required to fill in a final questionnaire by putting their interface preference, perceived quickness of use, perceived ease of use and clarity in an ordered list, rating four conditions from best to worst. In addition to issuing questionnaires they extracted data from the logs that were made during the use of the application. Logs allowed them to assess the time that the participants needed to compete each scenario, count the number of user actions and count the navigation errors made by users. Errors were defined as user actions that resulted in reaching other part of the diet diary menu structure than intended by the scenario. The results showed that the participants preferred the combination of text and graphics modalities over only text or text and speech or text, speech and graphics. Also, the users thought that the combination of text and graphics was quickest to work with over the rest of the modes of use. For perceived ease of use, the users once more gave the highest rating to text and graphics, as well as perceived interface clarity. No significant differences were found in retained diet knowledge, scenario time, number of errors and number of performed actions **Fehler! Verweisquelle konnte nicht gefunden werden.**.

A non e-health multimodal application is described by Holzapfel et al **Fehler! Verweisquelle konnte nicht gefunden werden.**. They combined different input modalities in order to facilitate natural interaction with human-friendly robots. They chose a rule-based approach on the semantic level, with a separation of the system into an application independent parser and application specific fusion rules. A major challenge was to understand different input modalities in changing environments with background noise and changing light condition, which complicates speech recognition and visual tracking. The system is designed to run on a humanoid robot in a kitchen scenario. The robot's task is to help people in the kitchen, to bring dishes, switch on lights and to put objects into the dishwasher. In the experiment the user could instruct the robot to get or bring objects and switch on or off lamps and the air conditioner. The system disambiguates object descriptions either by exact description from speech input or by disambiguation through the interpretation of pointing gestures. The experiment was performed with a stereo camera for person tracking and a head set microphone with automatic segmentation for speech recognition.

To deal with falsely detected input, integrated processing was applied. Different to pen input, it is much harder to detect when a gesture has taken place for 3D pointing gestures. Thus relying on this information is not effective. To obtain robustness, they used speech as the main modality, and gesture to resolve ambiguities, which is better suited to deal with falsely detected gestures. For redundant multimodal input, multimodal fusion improves the robustness of the system; e.g. when speech recognition errors occur.

Relevance for EMPOWER:
Undoubtedly multimodal user interfaces are becoming part of our experience with modern technology. While some modalities (e.g. touch screens) are very common in medical applications (actually the whole set of application presented in the previous section related to diabetes and diet monitoring are mobile apps running in devices with touch screens), some others are only necessary in special occasions and for special groups of users (blinds, reduced motor function, etc.). It is therefore important to clearly figure out the profile of the potential end users within EMPOWER, and then design the appropriate (multimodal) user interfaces. It is important to keep in mind that multimodality is not something that necessarily adds significant efficiency in the interaction with the applications; while for some users multimodality may render the interaction with an application funnier, for some others it may be a significant facilitator and motivation to use them. This is an issue that will be analysed in detail during the collection of the EMPOWER end user requirements and affect the design of the necessary user interfaces

10.3 Data and Trend Analysis

To provide efficient data and trend analysis functionality the medical data should be presented in the optimal way for all users of a system [van der Linden 2009]. Another requirement is that the visualization layer of the system will still be able to represent the data even if the dataset is changed. As EMPOWER solution is based on medical data storage and exchange standards the visualization layer will be capable to represent medical data, even if its structure is not known beforehand.

ISO 13606 provides modelling functionality to build medical documents of any complexity. But the medical concepts within one archetype are not semantically connected. For example if a user wants to specify a reference interval for a physical quantity (PQ) field it will not be automatically processed by an EHR system unless the system knows in advance that it must refer to the certain archetype field for a reference.
The modern trends in data visualization show that the architecture where the visual model is separated from the data model is supposed to be the optimal one [Bird 2000]. This approach is presented on Figure 47. A dual model approach allows separating medical knowledge (expressed in for example ISO 13606 archetypes) from visual knowledge and presentation layer implementation for a better flexibility and roles division.

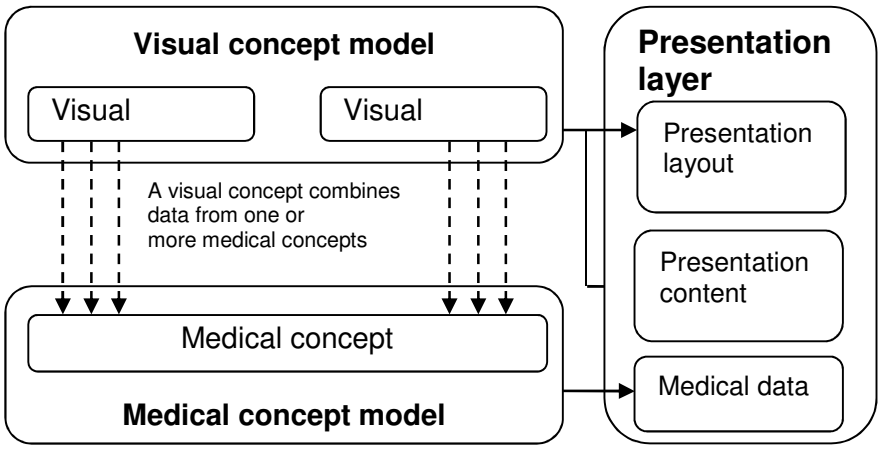

Figure 47: Dual model architecture for medical data visualization

A dual-model approach to generic presentation layer

Including screen presentation knowledge in the archetype definitions requires using nonstandard modelling features. However, this complicates the archetype processing and does not allow the visualization method to be generic. Also, introducing two different types of concepts (medical domain and presentation concept) into a single model adds complexity to the information display [van der Linden 2009].

Presentation layer model

The presentation layer model consists of:
• Visual groups to combine the medical concepts
• Widgets, the definition of a screen presentation.
• Profiles, which tailor the presentation to the local environment.
In our approach a widget is a platform-independent display unit that contains presentation knowledge for a single data type or for a combination of data types. Widgets are mapped to classes of the ISO 13606 Reference Model. There exist several types of widgets: data-oriented widgets such as: “PQ”, “Coded Text” and visual group oriented widgets such as “list”, “table” or “diagram”.

Content model

The Content model describes the content-related presentation knowledge in Visual Groups. Widgets are combined into specific (device-dependent and/or platform-dependent) visual groups. A visual group is focused on presentation of the content. The groups combine data fields from different archetypes. A Visual Group consists of a combination of widgets that are related with a set of predefined associations (i.e. one archetype field is a reference interval for another).
The proposed approach is based on the idea that a visualization layer will complete the archetype layer that represents the medical concept. The visual concepts are stored as XML files separately from the related archetypes. They define platform independent visual blocks to specify a layout for each archetype data field and group different archetype elements into visual groups. Each visual group contains a specification of visual tools that can be used to build a user interface. The archetype structure is taken into account (e.g. compositions, entries). This allows building a multi-purpose visual layer based on the ISO 13606 archetype model that will take into account the different perspectives on the medical data of doctors and patients.

The proposed approach is based on the idea that a visual layer completes the archetype layer, which represents the medical concept. The visual medical concepts define platform independent visual blocks and the layout for each archetype data field, respecting also the

archetype structure. They will be stored as XML files separate from the related archetypes to make visual medical concepts re-usable.

Trend analysis

Trend analysis considers the data derived from the different sources such as the EHR operated by a doctor, data submitted manually by the patients, data imported from the medical devices and data from other sources. To provide efficient analysis the trends must be presented to the users in the most efficient way. Standard based visualization solutions will allow visualizing data change trends. Standard based trend presentation tools can display different data if its structure is standardized. A trend visualization tool will enable users to understand the impact of vital signs and other quantitative parameters i.e. dietary or exercises options. Efficient visualization techniques will provide different views on the data change trends to satisfy the needs of different user groups (patients, doctors). This will enable patients to better understand the therapy flow. For the doctors it will reduce time reading the health record and understanding the trends of important parameters.

Relevance for EMPOWER:
Visual medical concepts will be used to provide different views on trend data, thus supporting different user perspectives, e.g. doctors/patients, and allowing the usage of multiple devices in a flexible and user-friendly way.

10.4 Feedback Mechanism

EMPOWER supports patient-centric ODL collection for empowered patients that use a PHR or PHA to feedback the patient health ODLs to the EHR systems. For example, the dietician could receive patient observations, perhaps a shared calendar reporting dietary and medication logs. Or the patient could receive an alert to execute a set of physical exercises along with instructions on how to do so via a multimodal human computer interface. This way EMPOWER will support the process and enable interaction with patients. This will be based on modelling of knowledge relating to dynamic knowledge based on rules and workflows.
It is obvious that providing feedback to diabetics will encourage them in their self-management activities. The feedback could probably be connected with suggestions for optimizing actions according to the personal Self-Management-Pathway. The feedback will be generated from the Action Plan module and its dynamic knowledge model. It is planned that alerts will be raised when critical thresholds are passed, or reminders and motivation messages will be shown when specific activities are necessary.

10.4.1 TOSCA glaucoma home monitoring

The TOSCA project developed a home monitoring service for glaucoma patients [TOSCA 2003] that was used to continuously monitor intraocular pressure. Hereby the patients' measurements are transmitted on a regular base from the self-tonometer to a central application server via telephone line. Transmitted measurements are stored and an automated check based on a rule set (see Table: Feedback Rules) is performed. This way a feedback message is generated that is immediately sent back to the measuring device.

rule	message
(IOP > TIOP + 10) OR at least 3 times in a batch (IOP > TIOP + 5)	**See Doc Today !**
(IOP > TIOP + 5) OR at least 3 times in a batch (IOP > TIOP)	**Contact Doc !**
(IOP > TIOP)	**Medication ?**
otherwise	**OK**
all checks refer to intraocular pressure values (IOP) transmitted within one batch - they are compared to the patients individual target value settings (TIOP) for a single eye	

Table: Feedback Rules

The generated response is shown on the LCD-display (see Figure 48) and gives one of the following instructions:

- OK
- Medication ?
- Contact Doc !
- See Doc Today !

Figure 48: Display of Feedback Message at self-tonometer

Optionally blood pressure can be included in the monitoring. To collect the blood pressure values an RS232 interface is available to transfer the data from the sphygmomanometer to the self-tonometer. The blood pressure values are transferred together with the intraocular pressure values.
In order to define the setting for the home monitoring a risk classification based on the glaucoma status is made and the threshold values used for the feedback message calculation are supplied by the physician. The medication is documented.
All the existing data concerning anamnesis, examinations, settings and medications can be retrieved on demand via a browser based interface. Moreover the data collected by the patient who is performing intraocular pressure and blood pressure measurements at home is accessible to the physician as well as the feedback messages that were sent to the patient. This way current and complete information needed to observe the monitoring process is provided to the health professionals.

10.4.2 Mobile Diabetes Intervention Study

The Mobile Diabetes Intervention Study [Charlene 2009] provided patients with a coaching system using mobile phones and patient/physician portals to allow patient-specific treatment and communication. Patients enter BG data, carbohydrates consumed, diabetes medications taken, and miscellaneous comments regarding diabetes self-care.
Real-time messages are sent to the patient's mobile phone providing feedback on the entered data. The feedback is driven by the values of the patient's data, the trend of any recently entered data and the physician's medication instructions for each patient. Entered data are captured in real-time in the web-based logbook. Patients may provide their health providers with printed copies of their electronic logbooks and other information because some physicians do not have access to the individual patient portal system. Patient action plans summarizing the patient-entered data and identifying possible self-management actions for improving their diabetes control are electronically sent to the patients every 2.5 months. Each patient is instructed that action plans also serve as a pre-visit summary for the patient's next office visit to their health providers.

Relevance for EMPOWER:
Providing patients with feedback messages is essential for encouraging them in their self-management activities. Feedback can be given in different ways ranging from reminders to execute planned actions to rising of alerts when critical thresholds are passed during the monitoring.
Feedback should be provided immediately (“real-time”) and ideally be complemented with suggestions for optimizing the individual actions originating from the Action Plan module.

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