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1st Faculty of Medicine

PhD Thesis Summary
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Clinical Content Harmonization of Electronic Health Record

Harmonizace klinického obsahu elektronického zdravotního záznamu

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Contents

Abstract

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This PhD thesis deals with the possibilities of clinical content harmonisation in electronic health records (EHR). In the first sections, the current state of the art in the field of EHR and other related fields is summarised, as well as that of the tools supported by current software technologies and the results of research in the field of medical informatics. The work is focused on analysis of obstacles in sharing medical data and on proposals of steps for overcoming these obstacles. Next, the utilized tools, modelling approaches, standards and coding systems used during the research are summed up. In the following sections the methods pointing to achieving harmonized clinical models are elaborated on and resulting clinical concepts mappings, supporting tools, developed EHR systems and semantic interoperability platforms are presented. In the conclusion these results are discussed and some future work is proposed.

Keywords: electronic health record, semantic interoperability, clinical content, harmonization, HL7, archetypes

Abstrakt

Název: Harmonizace klinického obsahu elektronického zdravotního záznamu
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Tato disertační práce se zabývá možnostmi harmonizace klinického obsahu v elektronickém zdravotním záznamu (EZZ). První část mapuje současný stav výzkumu v oblasti EZZ a příbuzných oborů, nástroje podporované nejnovějšími softwarovými technologiemi a aktuální výsledky výzkumu na poli biomedicínské informatiky. Dále následuje analýza překážek zabraňujících sdílení medicínských dat a návrhy jejich řešení. Práce shrnuje veškeré nástroje, modelovací přístupy, standardy a kódovací systémy použité během výzkumu. Další část práce se zabývá metodami aplikovanými v procesu harmonizace klinických modelů a popisuje výsledky v podobě mapování klinických konceptů, podpůrných nástrojů, vyvinutých systémů EZZ a platforem pro sémantickou interoperabilitu. Závěr práce nabízí celkové shrnutí výsledků výzkumu a jejich diskusi, stejně jako výhled do budoucnosti.

Klíčová slova: elektronický zdravotní záznam, sémantická interoperabilita, klinický obsah, harmonizace, HL7, archetyp

1 Introduction

It is becoming common today that data are recorded in an electronic form. The reason for this is not only an easier manipulation and faster communication of the data but also the fact, that their sender and recipient might be a computer application. Electronic health record (EHR) builds on these premises. It is a crucial part of patient's healthcare documentation, serving as a basis for personalized healthcare based on knowledge and medical guidelinesand thus contributing to a more complex, effective and safer healthcare.

EHR, as described in [1] is "a longitudinal, electronic repository of information collected during a patient's encounters with healthcare providers and services such as medical history, results of physical examinations, progress notes, laboratory data and imaging reports."

The difficulty with EHRs is that they are naturally distributed among various healthcare providers who have treated the patient during his or her life. The records at each healthcare provider within both, the patient's home country and abroad, are for various reasons in different formats. Their interoperability is thus limited which prevents the healthcare providers from disposing of a complete record of patient's health status and from the ability to treat him optimally.

This obstacle can be reduced by the adoption of a standard or at least a mutual mapping between the standards (terminology definitions, the definition of data structures, the definitions of communication). There exist some well-known standards such as CEN EN 13606 and HL7, openEHR approaches, as well as terminologies such as SNOMED CT, ICD-10 [2], UMLS [3]. Unfortunately, they have not yet been universally accepted and implemented and thus individual countries and even individual vendors have a number of their own local standards.

In order to enable the communication between particular healthcare providers, so-called "semantic interoperability" is desired. A very concise definition of semantic interoperability is provided in [4]:"Semantic interoperability is the ability of information systems to exchange information on the basis of shared, pre-established and negotiated meanings of terms and expressions".

The semantic interoperability has 4 prerequisites [5]: standardised EHR reference model, standardized service interface models, a standardized set of domain-specific concept models and standardized terminologies.

The problem of clinical content harmonisation has similar objectives: unambiguous semantics of a common information model connected to international nomenclatures and ontologies. We can say that apart from the technical realisation of communication between systems, the harmonisation of clinical content of the participating systems is all that is necessary for their semantic interoperability.

2 Obstacles and Aims of the Thesis

Obstacles can occur on various levels of communication. Here are summed some of the recognised significant obstacles to interoperability in the healthcare system:

- *Different sets of collected values.*
  Description: The main reason of this issue is the big amount of HIS providers, who do not cooperate on the technological level and are thus unable to agree on

common set of collected values. Another reason of this obstacle are hospital-specific conventions and habits in healthcare provision.

- *Lack of detailed semantic description of collected values.*
  Description: Collected values describe basic anthropometric information about patient, medication list, allergies, results of laboratory exams but nothing more. The rest of patient's records is usually a free text because no suitable set of values has yet been agreed on.
- *Using isolated coding systems to describe semantics.*
  Description: Commonly used standard for healthcare data interchange is DASTA. In this standard the National Coding List of Laboratory Items is used.
- *Natural language is being used in the healthcare documentation.*
  Description: More convenient for a user is to express the state of patient's health in free text form. The main motivation for such a habit is freedom in data entry.
- *Free text reports, i.e. lack of structured data.*
  Description: This obstacle is closely connected with the previous one and is mainly caused by adherence to historical practice.
- *The lack of real motivation to exchange clinical data in structured form.*
  Description: Lack of motivation is caused by the whole healthcare system. eHealth solutions are still not deployed in real life, insurance companies do not motivate general practitioners (GPs) to reuse data, GPs do not trust foreign data sources, etc.

This thesis aims at the following issues: study the latest achievements in the field of EHR, software technologies and other outcomes of the medical informatics research; identify the obstacles in medical data sharing; analyse the clinical content included in healthcare documentation in the field of cardiology or dentistry; annotate the semantics of clinical content in the given field by means of established terminologies; describe the formalised clinical content in given field by openEHR archetypes and finally test the communication possibilities of the created archetypes via communication standards.

3 Methods and Materials

3.1 EHR Approaches and Classification Systems

The openEHR Foundation is a not-for-profit company, limited by guarantee. Its founding shareholders are University College London, UK and Ocean Informatics Pty. Ltd., Australia. This foundation responded to a need for continuity of research conducted formerly in European and Australian projects (1992-2003): GEHR (1992-1994, supported by the Advanced Informatics in Medicine initiative), Synapses (1995-1998), Synex, Medicate and 6-winit (2001-2002).

The efforts of the openEHR Foundation concentrate on creating well-formulated clinical requirements; rigorous development, implementation and evaluation methodology for systems; common information model for the record and promoting the evolution towards high quality and cost-effective EHR solutions offered. Finally, it concentrates on empirical evaluation of systems performance against clinical requirements.

One of the fundamental contributions of the openEHR Foundation to the research of this thesis are the openEHR clinical content models which are known as archetypes and templates. Archetypes are the foundation building blocks at the clinical concept level; templates aggregate and constrain the archetypes to create context-specific clinical content for use in direct patient care. With the notion of archetypes the 2-level modelling approach is introduced. Archetypes, openEHR templates and the 2-level modelling methodology will be described later.

Another approach to EHR is a MUDR EHR. This EHR system is an implementation [6] of MUltimedia Distributed Record proposed at the EuroMISE Centre as a 3-layer application. The main contribution of the MUDR EHR was the separating the knowledge from the patient data. The knowledge base consists of knowledge trees and each tree is build of knowledge nodes. Each edge connecting two knowledge nodes specifies its own type, which enables to create a more complex structure similar to ontology. Patient data are stored using data-files organised in tree structure. Each data-file was linked to a knowledge node that determined its meaning and a datatype. This PhD thesis mostly employed the data modelling technique proposed by the MUDR EHR, which was applied in the field of dentistry.

MUDRLite EHR was also developed at EuroMISE Centre [7] in 2005. The motivation of creation such an EHR was filling the gap in deployment possibilities of the MUDR EHR. The MUDRLite EHR was designed to be less complicated and only comprises two layers – database and user interface combining the application logic.

The extensibility was mainly achieved by introducing an XML-based language (MLL - MUDRLite Language) for describing the user interface, which completes similar task as the HTML language, defining the look of a web-page. The most important features of the MUDRLite EHR exploited in this thesis was its data models defined directly as relational database schemas and the special element of the MLL language enabling external components to extend the functionality of the MUDRLite EHR.

Clinical terminologies have close relation to the clinical content stored in EHR. One of the most popular one is SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms). According to [8] it is a comprehensive clinical terminology, originally created by the College of American Pathologists. It aims to contribute to the improvement of patient care through underpinning the development of systems to accurately record health care encounters and to deliver decision support to health care providers [9].

The main contribution of SNOMED CT terminology to this thesis is its acceptance by professionals and a huge range of covered domains and institutional mechanisms enabling its translation to various languages (not in Czech yet).

3.2 Communication Standards

The HL7 is a non-for-profit, ANSI-accredited standards developing organization (SDO) 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 [10].

The HL7 is also a name for some of the standards developed by HL7 organization. Namely it refers to HL7 version 2.x and version 3 messaging standard. The abbreviation HL7 stands for Health Level Seven, which refers to the seventh level, i.e. application layer, of the ISO/OSI reference model [11].

European standards are represented here by EN 13606 (EN – Europäische Norm). It is a multipart standard named "Health Informatics – Electronic health record communication" and consists of the following parts: 1. Reference model, 2. Archetypes interchange specification, 3. Reference archetypes and term lists, 4. Security and 5. Messages for exchange.

This standard was released in 2007 by Technical Comittee CEN/TC251 "Health informatics" and supersedes the former version ENv 13606 [12]. Its scope is to specify the communication of part or all of the EHR of a single identified subject of care between EHR systems. However, this standard is not intended to specify the internal architecture or database design of EHR system (EHR-S) [13].

In the scientific literature many references to the harmonization process can be found. However, not all harmonization activities are connected with the aim of this thesis. Two different approaches can be distinguished: harmonization of standards in healthcare and harmonization of clinical content in an EHR. The harmonization of clinical content is what this thesis is concerned with.

3.3 National Efforts

Sharing and reusing the data among different institutions in the Czech healthcare environment is at relatively low level. The majority of healthcare information systems in the Czech Republic communicate with each other using a national communication standard called DASTA [14], which is based on the national nomenclature called National code-list of laboratory items [14]. DASTA is specialized mainly in transfer of requests and results of laboratory analyses. Its current version is XML based and provides also the functionality for sending statistical reports to the Institute of Health Information and Statistics of the Czech Republic [15] and limited functionality of free text clinical information exchange. Unfortunately, the DASTA has almost no relation to international communication standards and is not suitable for our research.

4 Results

This section presents the results of the clinical content harmonisation research. First, modelling of clinical content using Minimal Data Model for Cardiology (MDMC) [16] is presented. In order to fix the semantics of its concepts, these were mapped to coding systems, which is described in Section 4.1. Then the MDMC was transformed (see Section 4.1) into HL7 v3 RIM derived classes, thus producing Local Information Models (LIM), enabling the implementation of HL7 v3 based communication. MDMC concepts were also paired with existing archetypes (see Section 4.1) to test the exchange of clinical information via openEHR solutions.

In the sections 4.2 and 4.3 developed EHR-Ss for dentistry and cardiology are described. They fill the gap in the Czech healthcare environment lacking structured EHRs.

Next, formal models comparison and synchronisation was implemented (see Section 4.4). The ability to compare and possibly synchronise given formal models is inevitable during the clinical content harmonisation process. A universal tool for this purpose was developed and named Schemagic. User interface of this tool was implemented and the system was extended to support MUDR KB trees and openEHR archetypes.

Various approaches to semantic interoperability achievement are shown in order to validate the possibilities of utilisation of the CC modelled in MDMC and mapped by means of conding systems, HL7 RIM and openEHR archetypes. One solution is based on HL7 v3 messaging and is described in Section 4.5. The other utilises openEHR architecture and is summarised in Section 4.6. Finally, an attempt to define an archetype modelling methodology is discussed in Section 4.7.

4.1 Modelling the Clinical Content

Modelling of the clinical content was based mainly on the MDMC. In order to test the clinical data exchange between two different EHR-Ss based on MDMC and the other one using HL7 v3 standard or openEHR archetypes, it was necessary to create an equivalent representation of the clinical content described by the MDMC using methodologies defined by each of these approaches.

Concepts of the MDMC were mapped to the coding systems mainly in order to ease the development of equivalent representations of the MDMC utilising the `code` attribute of HL7 v3 RIM classes or openEHR Archetypes' term bindings. The mapping process was performed manually by author because of the complexity of finding matching concept code to given concept from the MDMC. These concepts originally named in Czech had to be translated into English before the mapping process started. After that SNOMED CT Core Concepts file and LOINC DB file were searched for equivalent concepts names. This search was performed by the author in cooperation with medical doctors.

After the process of mapping clinical concepts of the MDMC on established coding systems, it was necessary to create refined models based on HL7 v3 RIM in order to examine the possibilities of the HL7 v3 standard in structured medical data exchange. These refined models were named Local Information Models (LIM) and its main purpose was to work as a first step for developers of the particular EHR into the HL7 v3 world. The author's task was to create LIM classes representing clinical content defined by ADAMEKj application (Section 4.3).

To show that the HL7-solution is not the only one, the openEHR archetype repository (CKM) was searched for archetypes covering the same field as MDMC concepts. The search process was performed manually by the author, since there is no stable mapping (stored in a repository) of archetypes on any coding systems. English equivalents (or their fractions) of clinical concept names were entered into the resource search section in the CKM.

4.2 EHR in Dentistry

4.2.1 MUDRLite EHR with the DentCross Component

The first practical implementation of the MUDRLite system was realised in the area of dentistry. The main part of the user interface is represented by a so-called DentCross. It

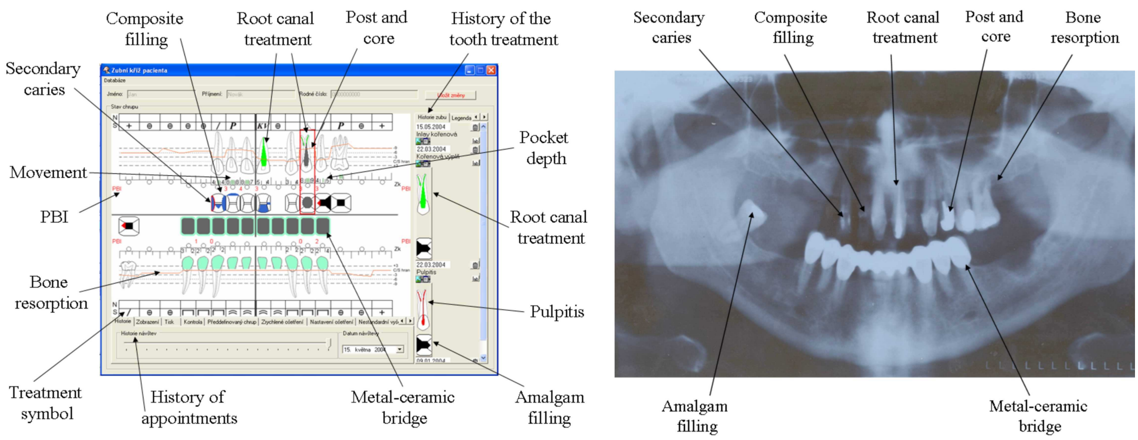

Figure 1: DentCross Component and its comparison to orthopantomogram.

is implemented as a stand-alone library that was developed for the MS .NET Framework platform. For the end-user the DentCross component looks similar to a dental orthopantomogram (Figure 1).

This component is fully interactive and enables recording fully structured dental information. A dentist can choose among about 60 different actions, treatment procedures or tooth parameters. The features of the component include the support of various forms and shapes of teeth, the exact position of a tooth, impacted teeth, agenesis of a tooth, primary and secondary caries etc.

The database layer of this tool is implemented using MS SQL server. The stored clinical content is based on dental knowledge base prepared by experts, which was transformed by the author into relational database schema consisting of almost 50 tables. The information recorded in a graphical form accelerates dentist's decision-making and it enables a more complex view in suggesting an evaluation.

4.2.2 Voice-controlled Data Entry in the Dental EHR

Interconnection of Automated Speech Recognition (ASR) module developed at the Department of Cybernetics, University of West Bohemia in Pilsen [17] and the DentCross component of the MUDRLite EHR resulted in an application called DentVoice. The junction of voice control and graphical representation of the dental arch makes hand-busy activities in dental practice easier and more comfortable thanks to minimization of the contact with a computer.

The prototype application consists of the DentCross component with the integrated TCP/IP client of the ASR server and the voice commands (discrete speech) definition file. Voice commands can be divided in two groups: global manipulating commands (4 commands) and context dependent commands (33 groups).

The DentCross component was successfully tested by students of the 1st Faculty of Medicine of Charles University in Prague and the DentVoice application was deployed in November 2007 for testing at the Department of Paediatric Stomatology at the Motol University Hospital.

4.2.3 Temporomandibular Joint Disorders Recorded in MUDRLite EHR

A knowledge modelling tool from the MUDR EHR application suite was used to create a specialized TemporoMandibular joint Disorder (TMD) Knowledge Base. This knowledge base contains more than 80 concepts and extends the former Dental Knowledge Base.

In order to create MUDRLite forms, concepts from the TMD Knowledge Base had to be transformed in a relational database model. The user interface and application for TMD was encoded into MLL in MUDRLite EHR, thus creating user forms interconnected with database layer.

This application consists of 3 main parts. In the first part basic patient facts (name, id number, date of birth etc.) can be found, which helps in orientation. The second part consists of a list of events sorted by dates. Third part consists of subjective patient problems, anamnestic datas, results of investigation, diagnosis statement and therapy recommendations. This part is the most important and represents all TMD data about the particular patient.

This application serves as a complex information source for the TMD treatment and is part of the whole system supporting decision making in the therapy of TMD [18].

4.3 EHR in Cardiology – MUDRLite2 and ADAMEKj

The MUDRLite EHR suffered from limitations of user interface capabilities and the gradually rising complexity of the MLL Language. Thus, modern programming technologies were searched to replace MUDRLite's weaknesses and preserve its benefits. MUDRLite2 was proposed as succesor technology to MUDRLite. Its fundamental parts are Hibernate [19], Spring Framework [20] and Spring Rich Client Project (Spring RCP) [21].

The first part is a high performance object/relational persistence and query service. Its task, among others, is to map application's domain objects to tables in the object/relational database. The second part, the Spring Framework, provides automated configuration and wiring of application objects. The latter, the Spring RCP, is used to build a user interface. The Spring RCP is based on Java Swing; its main advantage is providing an elegant way to build highly-configurable, GUI standards following rich-client applications.

Enterprise programming technologies offer well-balanced ratio of Java programming (Spring RCP) vs. creating XML configuration files (Hibernate, Spring Framework). This resultes in still simple configurability by XML files while complex parts written in Java are developed using standard application development tools, like Eclipse or netBeans IDE.

The ADAMEKj application is a pilot implementation of MUDRLite2 and it evaluates the benefits of used technologies. It is a two-tiered application consisting of the data layer and the user interface. The domain model of the application is based on MDMC and consists of 67 tables. The user interface was inspired by the former ADAMEK application [22]. A big focus was put on the acceptance of it by its users, i.e. physicians that were closely involved in the whole development process.

An integral part of each EHR is its communication with other systems. ADAMEKj is capable of communicating utilizing HL7 v3 messaging standard. The process of data interchange implemented using HL7 v3 standard is described in more detail in Section 4.5.

4.4 Formal Models Comparison and Synchronisation

Under the term formal or formalised models we understand UML models (e.g. class diagrams), E-R models, data dictionary representation in a database, etc. Here, openEHR archetypes describing clinical content and MUDR knowledge base trees representing structure of collected variables will be considered as such formal models.

The structure and extensions of the Schemagic tool will be described in more detail in the following text (see also [23]). It was designed to compare and synchronise formal models. To achieve its universality these models had to be described using structures defined by Schemagic. The names of these structures are inspired by the original aiming of the tool to relational databases (db objects, db machine, db connection and schema handle). The Schemagic tool together with its documentation can be found at WWW pages [24].

Schemagic was a command line oriented application and lacked the user interface. This was improved by the development of the application called SchemagicCenter. It covers following features of the Schemagic tool:

- creating, viewing and editing definition files (dbobjects, machines, connections, schema handles and plugins),
- executing all steps of the schema loading, comparison and synchronisation process in a wizard style or each step separately,
- browsing the tree structure of the loaded formal model instance,
- viewing so-called diff tree, which is a result of the comparison step,
- syntax-highlighted viewer of the synchronisation result of relational schemas – the SQL script.

The SchemagicCenter tool is based on Java environment and is independent on operating system in the same way as the Schemagic tool.

The extensions of the Schemagic tool were accomplished using the editing features of the SchemagicCenter. However, configuration files contain among others class names for classes like connection factories, database object loaders, database object comparators etc. In order to extend the Schemagic tool to support MUDR knowledge trees and openEHR archetypes, these classes had to be programmed using a Java IDE tool (e.g. Eclipse).

4.5 Semantic Interoperability Platform based on HL7 v3 Messages

In this section an approach to semantic interoperability among heterogeneous EHR systems based on HL7 v3 standard is described. The research presented here was done in the frame of the ITDCSH project and was published in [25]. The primary result of this project was a proposal of a semantic interoperability platform (SIP) (Figure 2).

In [26] the author describes the difference between the human semantic interoperability and computable semantic interoperability (CSI), and states four necessary but not the only conditions (the "four pillars") for establishing the CSI:

1. a common information model that spans all domains of interest,

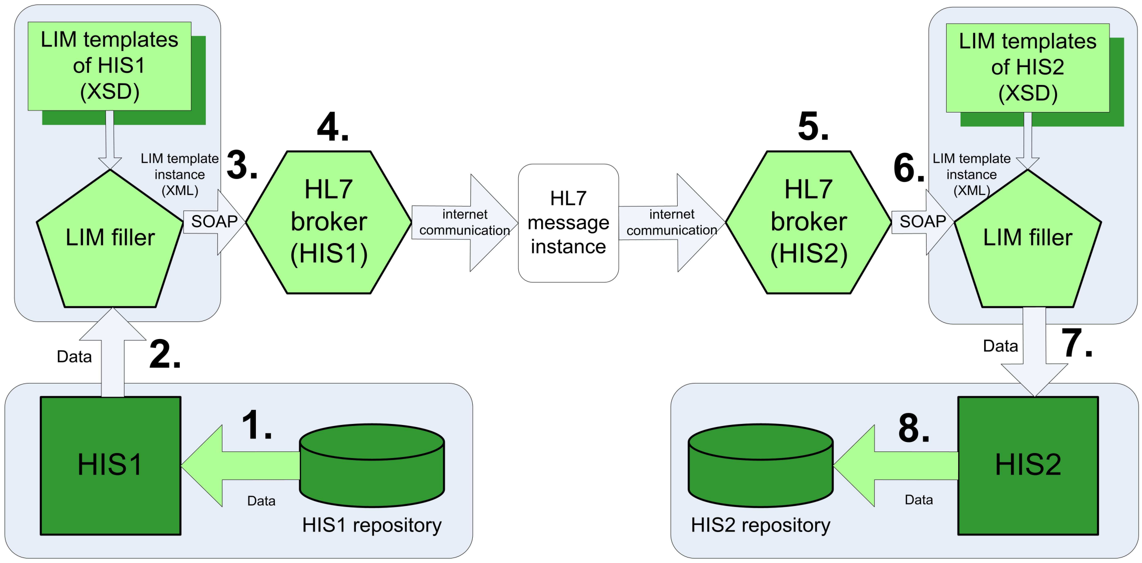

Figure 2: Proposal of a SIP based on the international communication standard.

2. unambiguous semantics of each transferred data element defined by its data type,
3. usage of vocabulary – binding the information models to domain-specific terminologies,
4. a formal top-down message development process with restricted optionality.

To meet the conditions of semantic interoperability (1.-4.), the following steps were performed:

1. The first condition addresses the usage of a common model. The "world of HL7" introduces the Reference Information Model (RIM). In this solution, the information stored in the incorporated EHRs was modeled by creating the Local Information Models (LIMs). Its classes are derived from the core classes of RIM. This approach represents a slight diversion from the general HL7 v3 message development process, which is discussed later.
2. The second condition was fulfilled by using the data types defined by HL7 v3 for all attributes in the LIM model. An important role was played by the data type "coded with equivalents" (CE) and its derived subtypes, allowing us to connect the concepts from our model with given code-lists.
3. The third condition requires the usage of vocabulary. Concepts from LIMs (based on MDMC) had to be mapped to a code-list that is supported by HL7. The Logical Observation Identifier Names and Codes (LOINC) [27] coding system was used as the preferred one, since it contained a significant subset of concepts used in LIM models. The remaining concepts were encoded by the SNOMED Clinical Terms (SNOMED CT) [9] and ICD-10 [2].
4. The last condition requires using a strict methodology. HL7 v3 provides methods for defining data interchange structures using only RIM elements bound to domain-specific values. After preparing the LIM models and their binding to the coding

systems, tree-like structures from the LIM (LIM templates) had to be derived as the next step in the process of the message definition. Each LIM template represents one integrated part of the EHR the LIM describes, e.g. physical examination, medication and ECG data. The HL7 HMD [28] and LIM templates serve the same purpose, i.e. they define the hierarchy, sequence and optionality of classes specified in HL7 R-MIM (Refined Message Information Model) and the LIM, respectively.

LIM fillers and HL7 broker components were developed to support data transformations of a given HIS.

The HL7 broker is a fundamental part of our solution. For the EHR-S, the attached HL7 broker serves as a gateway to the world of HL7 v3 and separates it from details of HL7.

The vendors of the EHR-S only need to specify the LIM templates based on their LIM models describing their database structure and to implement a simple SOAP client to push, poll and process LIM messages from/to the HL7 broker. Besides the LIM templates, the vendors must upload all internally used enumerations with appropriate descriptions to our web-based vocabulary mapping tool.

Querying in our solution is based on the HL7 storyboards. As an example of such a storyboard, one from the "Patient Administration" domain called "Patient Registry Find Candidates Query" (artifact code PRPA_ST201305) was implemented to search for the patient's administrative data.

Queries that are produced by the incorporated EHR-Ss and passed to the HL7 broker are composed of "empty" LIM templates with only some attributes containing values, which are recognized as the parameters of a query.

Our solution enables composing the queries to all the domains covered by the LIM templates. The HL7 broker executes the appropriate storyboard that leads to the acquisition of the data queried by the LIM filler module.

Figure 2 shows that both EHR-Ss communicate without any human intervention. They are controlled by queries placed by the user of EHR-S initiating communication. In this way, the **automated interactions between these systems** were achieved.

An important feature of our solution is the introduction of LIM models and LIM templates. The HL7 broker enables composing the queries to all the domains covered by the LIM templates. All the necessary information about the given clinical domain is covered by the configuration file of the HL7 broker. Consequently, the **clinical domain independency** and **configurability** criteria are fulfilled.

The **extensibility** of the solution was achieved by using the international communication standard and introducing the HL7 broker. The communicating systems do not need to know anything about the data structure of their counterparts. The new communicating EHR-S can be added after accomplishing the following steps: the creation of the LIM describing information stored in the EHR, deriving the LIM templates from the LIM model, the implementation of a transforming module (e.g. LIM filler) for data conversions between the EHR database and the LIM templates, and finally the creation of the HL7 broker's definition file specific to the new EHR-S. The **openness** of our solution was provided by making our results available to all interested parties.

4.6 Clinical Data Interoperability Based on the openEHR Approach

In the previous section, an approach to SIP based on HL7 v3 standard was presented. During the implementation process the complexity of the HL7 v3 standard emerged as a problem, which supported an idea of proposing an alternative SIP based on an openEHR approach.

The experiment was conducted in order to compare the communication schema based on HL7 v3 messages with the data exchange using openEHR archetypes and extracts [29]. The main motivation for accomplishing such a comparison were the difficulties encountered during implementation of the communication among EHR-Ss using HL7 v3 messages. The main shortcoming was the usage of HL7 balloted storyboards. Storyboards describe the dynamic aspect of the communication and define the factual form and thus the content of messages is exchanged. And here emerges the main problem. HL7 storyboards are "short-message" oriented, which was not exactly matching our needs. The nature of our communication was rather document-oriented, which caused complicated transfer of LIM messages (e.g. physical examination) via several HL7 v3 messages originating in several storyboards.

The use of openEHR extracts on the other hand makes the data exchange straightforward. The data compliant with defined LIM templates were more suitable for openEHR extracts than for HL7 v3 messages, i.e. the task was to transfer "documents" rather than short messages. Another possible solution would incorporate HL7 CDA documents [30], which might be a future work for the next research project.

The solution based on the openEHR approach had to fulfill the computable semantic interoperability conditions summarised on p. 13 in the same manner as the HL7 based solution did.

1. the openEHR archetypes used in this solution were gathered from the CKM repository, which only contains archetypes based on the openEHR reference model. This fulfills the first condition of using the common information model that spans all domains of interest.
2. The unambiguous semantics of each transferred data element was described by data types defined by the openEHR Foundation in the document "Data Types Information Model" [31].
3. The usage of vocabulary was satisfied by utilising the mapping done on MDMC and several coding systems in Section 4.1. MDMC concept codes were used to fix the semantic meaning of concepts in an archetype via its ontology section.
4. A formal message development process is described in the "Extract Information Model" [29]. Apparently the openEHR approach does not use messages, but rather so-called EHR extracts are used for transporting of clinical data among EHR-Ss.

The main advantages [32] of the openEHR approach are the functional and semantical interoperability. The functional interoperability represents the correct communication between two or more systems. This is also covered by other approaches like HL7 v2.x. The openEHR approach also offers the semantic interoperability.

In the following text, steps leading to creation of an EHR with the Harmonised Clinical Content (HCC) will be proposed. Concepts of the clinical content of an EHR are usually "hiden" in the object model, database schema or in meta-models developed during the information system creation. These clinical concepts had to be extracted from the information models and upgraded to a higher level of modelling hierarchy, thus enabling the clinical content to be manipulated explicitly, allowing for a harmonisation claims. The process of enabling the creation of EHRs with HCC has following steps:

1. **map clinical concepts** to an international coding system or ontology (SNOMED CT, LOINC, etc.),
2. **find archetypes** in a repository or knowledge base that sufficiently cover encoded concepts,
3. **underlying reference model** may be openEHR RM or HL7 v3 RIM thanks to OWLmt Mapping Engine [33] that is capable of transforming one to another one by using pre-defined mappings.

An `openEHR-EHR-SECTION.physical_examination.v1` archetype was created using the Ocean Archetype Editor tool. This archetype was developed to be a root archetype of composed openEHR template (OET). The archetype is derived from the SECTION class from the openEHR Reference Model. The slots in this archetype were filled with suitable archetypes found in CKM. Finally, concepts covered by archetypes slots were encoded in the ontology section by codes from SNOMED CT.

Once having the archetype describing exchanged data ready, the actual data transportation can be established. The openEHR approach distinguishes various types of Extracts [29]. For this experiment the `EHR_EXTRACT` was used.

The components used in the experiment as well as the data flow are depicted in Figure 3. The former LIM Filler module attached to ADAMEKj EHR creates the LIM message containing data about a physical examination. The LIM message is then transformed by XSL templates into the EHR Extract conforming to the `openEHR-EHR-SECTION.physical_examination.v1` archetype, described in the previous section. Both the LIM message and the EHR Extract instance are encoded in XML. The XML form of the EHR Extract is realised as a dADL language serialised into XML as described in [34]. The EHR Extract instance is sent via SOAP to the former HL7 Broker, which was reconfigured for the purpose of this experiment. The HL7 broker then sends the EHR Extract instance to the recieving system. In this experiment the HL7 broker does not transform the openEHR Extracts in any way. It serves as an inbox/outbox for the communicating EHR-S.

4.7 Archetype Modelling Methodology

Within the frame of research in the EuroMISE Centre, a MUDR KB tree based on concepts of the MDMC was created. Another KB tree was created for the domain of dentistry. MUDR KB trees can be considered as some kind of ontologies, because they comprise vertices interconnected with various kinds of edges. The tree structure is formed only by the edge of the *superior* type. From the modelling point of view, MUDR KB trees do not depend on any kind of implementation technology. After creation of the KB tree in the MUDR Knowledge Base Editor tool, it can be imported to MUDR or it can serve as a

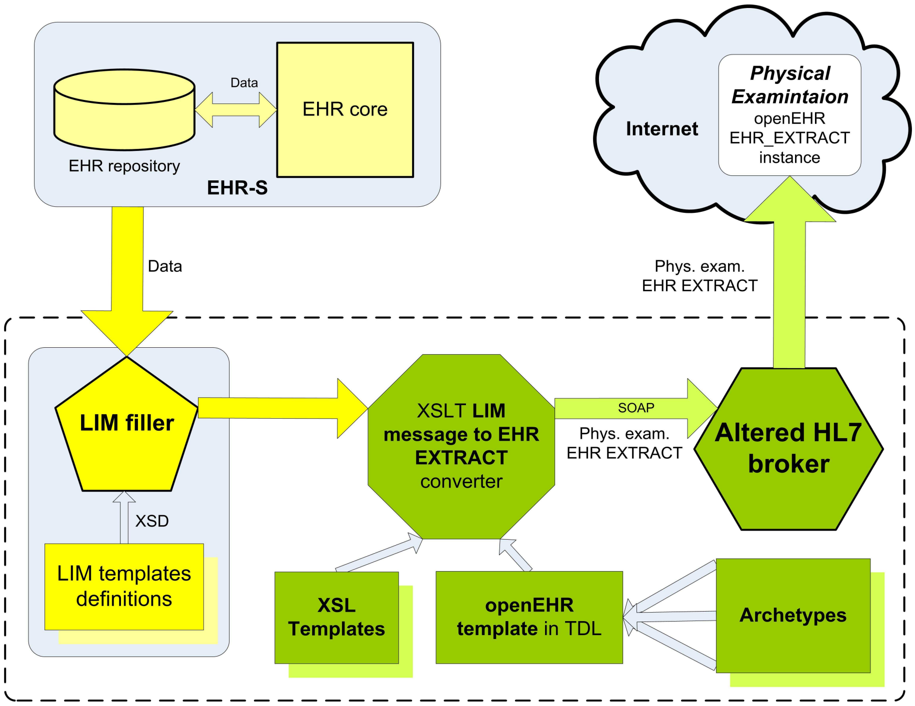

Figure 3: New communication schema based on openEHR templates and archetypes.

basis for further modelling process. Hence, the process of enabling the creation of EHRs with harmonized clinical content formulated on page 17 can be extended by the *ontology creation* step at the beginning of the process.

Although the ontology creation process can end up with various ontologies describing more or less the same domain, they can be aligned and merged [35] thank to the research conducted in the field of knowledge modelling. However, openEHR archetypes do not have merging and aligning techniques developed. Nevertheless, in the frame of this thesis, an ADL archetype comparison tool was developed, which could help to compare two archetypes developed by different authors, but describing the same concept. Such a tool could be fully utilised in a standards development organization (SDO) which is in charge of managing a central archetype repository.

The archetype creating and modelling methodology cannot be defined by any research team. This should be proposed by a SDO thus enabling creation of an extensible and open centralised repository of clinical content modeled in the form of archetypes. The openEHR Foundation is approaching a solution of this task via their approval process in the Clinical Knowledge Manager containing commonly accepted clinical concepts.

5 Discussion

It turned out that at the beginning of the clinical content modelling proces, it is good to start with a statistical model, which consists of a list of collected attributes, their data types and containts (e.g. the range of values). The statistical model is then transformed by a domain expert into a formal model describing the clinical field. The final stage of the clinical model creation should comprise mapping clinical concepts to established coding

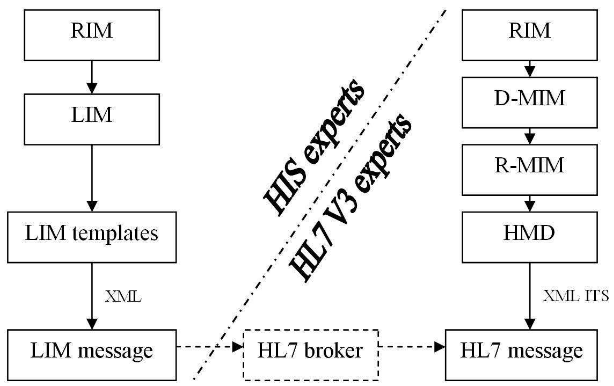

Figure 4: The messaging development process, recommended by HL7 v3 on the right and our solution on the left side.

systems in order to fix the semantic meaning of modelled concepts.

However, the CEN EN 13606 standard is gaining on popularity and is in the center of interest in various research projects [36]; in this thesis the openEHR approach was used mainly for its continual improvement and development process, better documentation and broader acceptance by experts. Since the openEHR approach is tightly related to the EN 13606, the conversion of our solution remains possible.

Introduction of enterprise programming technologies, such as Hibernate framework, into the development process of medical applications (concerning ADAMEKj EHR), resulted in shifting of the modelling procedures from the database layer to an object-oriented programming language. This approach showed that established modern tools for enterprise programming allow us to develop EHR systems of various sizes and of various degrees of universality (applications tailored to one's needs or universal sophisticated systems). ADAMEKj EHR served as a testing repository of clinical data employed in the development process of the HL7 v3 standard-based semantic interoperability platform.

EHR in dentistry stores information about the status of denture and surrounding tissues and as well as treatment procedures. Since the set of concepts describing dental defects and corresponding recovery procedures is limited and well-defined, a relatively high degree of structural exuberancy can be observed in many paper-based forms. The "natural" acceptance of data in a structured form makes the dentistry the most suitable field for the structured EHR application.

The MUDRLite EHR with interactive Dental Cross component offers a transparent record of the whole dentition and individual accomplished examinations in a concentrated form. The usage of the information collected by the interactive DentCross component may be used to support the identification in forensic dentistry is demonstrated in [37].

The development process of message interchange, recommended by HL7 v3, was altered by splitting the implementation effort between HIS developers and HL7 standard implementers (see Figure 4). This procedure seems to be more manageable for smaller developer teams than a strict adherence to HL7 v3 methodology. This modelling methodology is utilised only by developers (experts on HL7 v3) of the core component of the solution – the HL7 v3 Broker.

Using LIM models and LIM fillers resulted in considerable universality of the solution that consequently does not depend on the communication standard used (although the LIM is based on HL7 v3 RIM). This independency is supported by the fact that contemporary modern communication standards have some important characteristics in common: basic reference model, user defined models derived from that reference model using strict methodology, and finally, a kind of templates helping in creating a new message or document.

The message interchange based on EHR Extracts from openEHR is based on a simple idea – instead of rendering the definitions contained in OET as screen forms, these definitions could be used to build EHR_EXTRACT instances, which are consequently exchanged among EHR-Ss. Such a concept is close to the document interchange via HL7 v3 CDA, which, however, has one major drawback – a lower degree of data structuring.

During the research process in the area of clinical content of EHRs, the following types of content harmonisation were identified:

- Harmonisation of the content on database schema level – it involves the synchronisation of various versions of EHR from the same vendor; for this purpose the Schemagic tool was developed. Relational database schemas and MUDR knowledge trees are supported.
- Harmonisation of the development process on the knowledge level – the target of this type of content harmonisation is to converge to the state when all vendors would have access to common source of knowledge; for this purpose the knowledge repository (e.g. openEHR archetype repository) would be used. A comparison of knowledge concepts can be promoted by the extension of Schemagic supporting archetypes.
- Data interchange among EHR systems produced by various vendors – for this purpose the communication standard would be implemented, acting as a transformation tool.

6 Conclusion

The research accomplished in the frame of this PhD thesis analysed two approaches to clinical content harmonisation. The real benefits of the proposed methods can be learned only when HL7 v3 standard and/or openEHR archetypes will be widely used. The usage of the HL7 v3 is hampered by its great complexity discouraging users who have experienced a different style of work with the former HL7 v2. This fact is referenced also in some foreign studies, such as [38].

The main step for a wider use of HL7 v3 in the Czech Republic should be the implementation of functionality, which is currently provided by the DASTA national standard, the inclusion of NCLP on the list of HL7-supported code systems, or better the mapping of the NCLP to an established international nomenclature like SNOMED CT. The next fundamental step would be obtaining the translation of the international nomenclature into the Czech language.

Generally, for a wider acknowledgement of archetypes the acceptance of the EN 13606 standard may be benefitial. Moreover, extension of this standard or specifying a new one which would define archetype based EHR systems, would help broader acceptance of 2-level modelling and knowledge separating approaches.

The UMLS Knowledge Source can be exploited in clinical content mapping in the future. Further support and contribution to harmonisation of clinical ontologies are also one of the future goals. The primary objective for the future, however, should be reaching an agreement about clinical concepts used in EHR-S with well-defined semantics by means of international terminologies. Clinical content coordination demands should be addressed to the EuroRec institute via national proREC centres in order to push the idea of semantic interoperability further.

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