Extraction of standardized archetyped data from Electronic Health Record Systems based on the Entity-Attribute-Value Model

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Abstract

Objective: The ISO/EN 13606 Electronic Health Record architecture standard permits semantically interoperable exchange of Electronic Health Record data by using archetypes to define the structure and semantics of Electronic Health Record contents. Practical implementations of the ISO/EN 13606 standard have been scarcely reported on, and none of the publications describes in detail an efficient technique of archetype-compliant data extraction from an Electronic Health Record system. We address this research issue in the present report, and focus on a specific class of largely research-oriented Electronic Health Record systems which are internally based on the Entity-Attribute-Value Model.

Method: We propose an approach for extracting data described by archetypes from an Entity-Attribute-Value based Electronic Health Record system in an ISO/EN 13606-conformant manner. The approach is based on mapping from the structure of exported source documents to the archetype. It is implemented via standard XML technologies.

Results: We tested our approach on an Electronic Health Record system employed for clinical research at the Medical University of Vienna. Using test data defined by three different archetypes, source documents were successfully extracted as archetype-conformant ISO/EN 13606 Electronic Health Record extracts.

Conclusions: Electronic Health Record data may be effectively extracted from Entity-Attribute-Value based Electronic Health Record systems using the suggested approach. As a prerequisite for applying our approach, the internal data model of the Electronic Health Record system and the archetype must overlap in a way that a semantic mapping between them is possible. The system must further provide an XML interface which permits the export of the source documents in conventional format. The export must include data and metadata that are mandatorily postulated by the archetype and the ISO/EN 13606 Reference Model.

1 Introduction

Cross-organizational electronic health record (EHR) communication, which enables authorized healthcare providers to access all relevant patient data regardless of where the data were created, will constitute a key component of future health care. The European Union acts as a political driving force behind this vision, and underlines its corresponding commitment by naming the "interoperability of EHRs" in its *eHealth action plan* as one of the goals to be strived for by member states [1]. As a consequence most European countries, Austria being one of them, are planning, or already working on, the implementation of a national EHR system [2; 3]. The next goal – which is also pursued for a limited domain by the epSOS project [4] funded by the European Commission within the Seventh Research Framework Programme (FP7) – will be to achieve interoperability of the individual national solutions.

According to a recent literature review of HL7`s *EHR Interoperability Work Group*, a distinction is made between three levels of interoperability [5]:

- *Technical (syntactic) interoperability* focuses on the transference of data rather than their meaning. It aims to neutralize the effects of distance.

- *Semantic interoperability* communicates meaning and hereby aims to ensure that the communicated information is understood in exactly the same way by the sender and the recipient.

- *Process interoperability* primarily deals with methods for the optimal integration of computer systems into actual work settings. It aims to coordinate work processes.

The ISO/EN 13606 EHR architecture standard provides a framework for achieving interoperable EHRs [6; 7]. It is based on the dual model approach, which combines two kinds of models – the Reference Model and archetypes – to represent EHR contents [8].

The *Reference Model (RM)* defines a set of generic classes from which any EHR content may be composed. It can be characterized as a communication model, i.e. a sending EHR system transforms the content to be exchanged from the system's internal data model to the RM and the receiving EHR system transforms it back to its own internal data model. A common RM, to which sender and receiver map their internal

data models when exchanging data is essential to achieve technical (syntactic) interoperability [9].
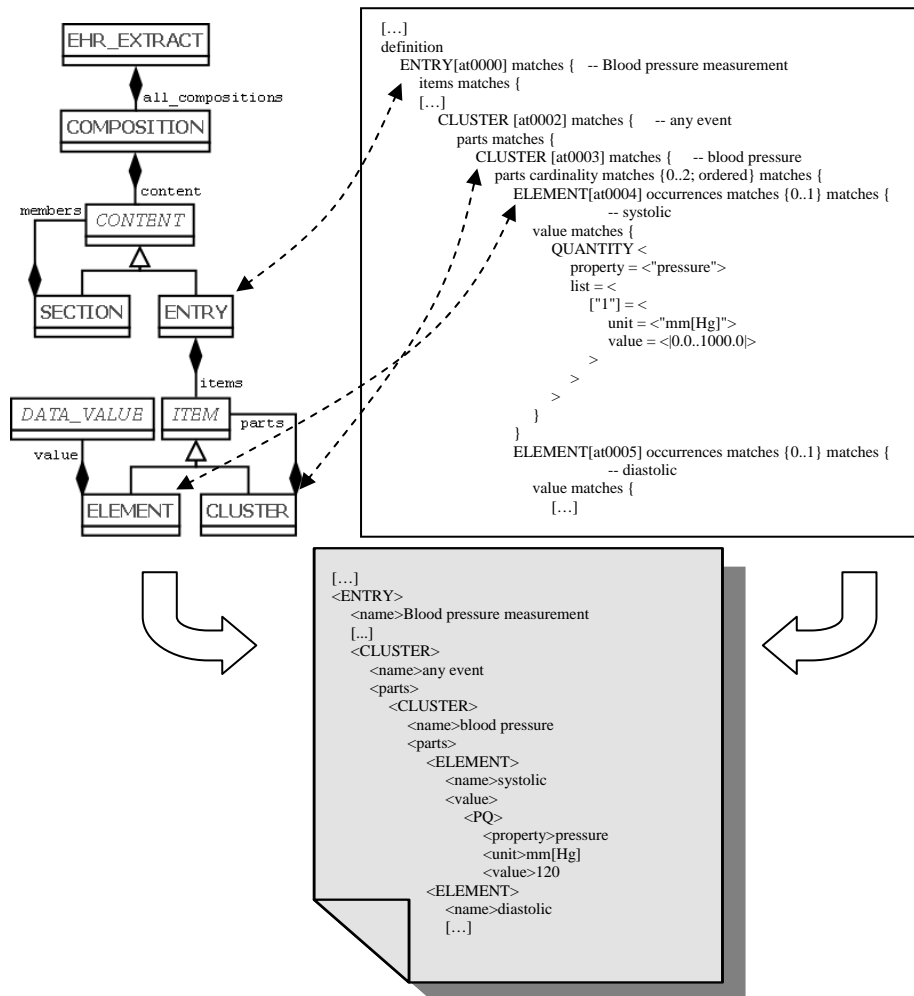

Figure 1: Sketch of the dual model approach. EHR contents (at the bottom, in XML format with closing tags omitted) are instances of a Reference Model (RM) (upper left, fragment of the ISO/EN 13606 RM in UML format) and obey the structural and semantic prescriptions of archetypes (upper right, fragment of a ISO/EN 13606 archetype that was derived from the openEHR "blood_pressure.v1" archetype[1] according to ISO/EN 13606-3 in the Archetype Definition Language (ADL) format). The archetypes refer to classes of the RM and constrain them.

Archetypes define the structure and semantics of EHR contents. For each EHR content, such as a blood pressure measurement or a pain symptom, a corresponding archetype specifies how the EHR content should be composed from instances of the RM. In other words the archetype acts as a "construction plan" (see Figure 1). The idea is to keep the RM stable as a solid basis for EHR software developers and, at the same time, permit

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[1] See http://www.openehr.org/knowledge/

newly evolving medical knowledge to be easily integrated by means of the separate archetype layer.

By specifying the structure of individual EHR contents and providing an interface to medical terminologies within their *ontology section*, archetypes are an important means of achieving semantic interoperability between the different communicating EHR systems. To examine the practical applicability of archetypes and so-called "templates" (the latter representing groupings and refinements of archetypes for local applications), the British National Health Service (NHS) initiated several studies in the last three years, and drew positive conclusions in this regard [10-12].

Some existing systems - which we will report on in section 4.1 - utilize the dual model approach. However, very few of them actually implement the ISO/EN 13606 standard and none of the publications describes in detail an efficient technique of data extraction from an EHR system as a valid and archetype-compliant instance of an RM. In this report we present an approach to extract data from an EHR system as an ISO/EN 13606 RM instance, which satisfies the constraints prescribed by archetypes. As the ISO/EN 13606 EHR architecture is similar to the openEHR architecture, the latter could have served as an alternative basis for our work. We decided to rely on the ISO/EN 13606 EHR architecture because, in contrast to openEHR, it has been accorded the status of an official standard. Further, the openEHR specification[2] of the EHR extract information model is still under development.

According to ISO/EN 13606-1 and ISO/TR 20514 [13], an instance of the ISO/EN 13606 RM is named an *EHR extract*. In the present report we will use the term *archetyped EHR extract* for a set of EHR data that constitute a valid instance of the ISO/EN 13606 RM and additionally comply with an archetype[3].

A simple way to create an archetyped EHR extract could be to instantiate the RM from the EHR system's data and then to derive a corresponding archetype from the resulting EHR extract "on the fly" (which could be done straightforwardly). This is not what we intend. Instead, we presume a scenario in which source EHR data have to be extracted

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[2] See http://www.openehr.org/svn/specification/TRUNK/publishing/architecture/rm/ehr_extract_im.pdf

[3] Actually an archetyped EHR extract will frequently comply with more than one archetype. In the following we assume that there is always one "root" archetype, which may include other archetypes via slots.

and made compliant with *predefined* archetypes. We call an archetype *predefined* if it was developed and published in advance by an external party, ideally in standardized form by an organization that adheres to the principles of domain knowledge governance [14].

Our overall goal is to contribute to the cross-organizational semantic interoperable communication of EHR data based on archetyped EHR extracts. Within the communication network, each EHR system typically uses an individual internal data model. For the exchange of data, the data are transformed from their internal model to the model of the archetyped EHR extract and vice versa. This presupposes that the internal data models are generic enough to cover the model of the archetyped EHR extract. According to [15], the model of the archetyped EHR extract, which merges the prescriptions of the archetype and the RM, and the internal data models must possess a common "modeling safe zone". In this zone the internal data models of the communicating systems and the model of the archetyped EHR extract overlap in a way that a semantic mapping between them is possible. This also includes the terminologies used in the different models.

Our work focuses on the extraction of archetyped EHR extracts from EHR systems. We have not yet implemented the import of archetyped EHR extracts into an EHR system. As the source of data extraction, we will focus on a specific category of EHR systems, namely systems based on the so-called "Entity-Attribute-Value" (EAV) data model. This data model is the basis of several largely research-oriented EHR systems such as [16-18] because of the benefits of its generic design [19; 20]. EAV and conventional database modeling were compared in [21], and guidelines for the application of the EAV model have been provided. As we will show in section 2, the characteristics of the EAV model affect the design of the EHR extract generation approach. Besides satisfying the specific requirements of the EAV data model, our suggested approach provides several general benefits which render it attractive for non-EAV, i.e. conventionally modeled EHR systems as well.

We will demonstrate our approach by using the ArchiMed system as the source from which EHR data are extracted. ArchiMed [22], which was developed at the Medical University of Vienna (Center for Medical Statistics, Informatics and Intelligent

Systems), may be categorized as an EAV-based *local EHR system* storing its patient data within *shareable EHRs* according to ISO/TR 20514[4]. One of its features is that it supports electronic data capture based on forms which may be interactively designed within the system [23].

One of the basic conditions of our approach was to use standard technologies to implement the extraction of EHR data. This permitted us to use powerful tools which should be widely available for practically any platform. Tool support was also one of the reasons why Lopez and Blobel suggested the application of UML Profiles to map data models of EHR systems to standardized health information models [24]. Simultaneously, we decided to base our approach on XML standards, such as XML Schema and XSLT, because XML is the primary standard for data exchange and is backed by a versatile range of tools.

This paper has been structured as follows: In section 2 we describe an approach for the extraction of EHR documents from an EHR system as archetyped EHR extracts. In section 3 we present the results of applying our approach to EHR system documents that conform to three different archetypes. In section 4 we report on previous publications concerning the dual model approach and describe our experiences relating to the application of ISO/EN 13606 and our approach. Finally, we present our conclusions in section 5.

2   Methods

Our goal is to generate archetyped EHR extracts from source documents. The term *document* here refers to a form filled in with data. In Figure 2 for example, a document for the form *Demographics* is shown, consisting of the data *20* and *m* for the variables *Age* and *Gender*. The main tasks to achieve our goal are (a) to transform the documents from their internal data model within the EHR system to the data model prescribed by the archetype, and (b) to transform the terminology used within source documents to the

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[4] Until the present time, EHR information within ArchiMed could be shared between different clinical disciplines as well as between different applications at a single EHR node. Both of these features are characteristics of a *shareable EHR*. As EHR information can be further shared as EHR extracts between different EHR nodes, records within the ArchiMed system have now achieved the status of *Integrated Care EHRs*.

terminology prescribed by the archetype. In section 2.4 we describe how the second point is addressed. In the following, we will concentrate on the first point, i.e. the transformation from the internal data model to the archetype data model.
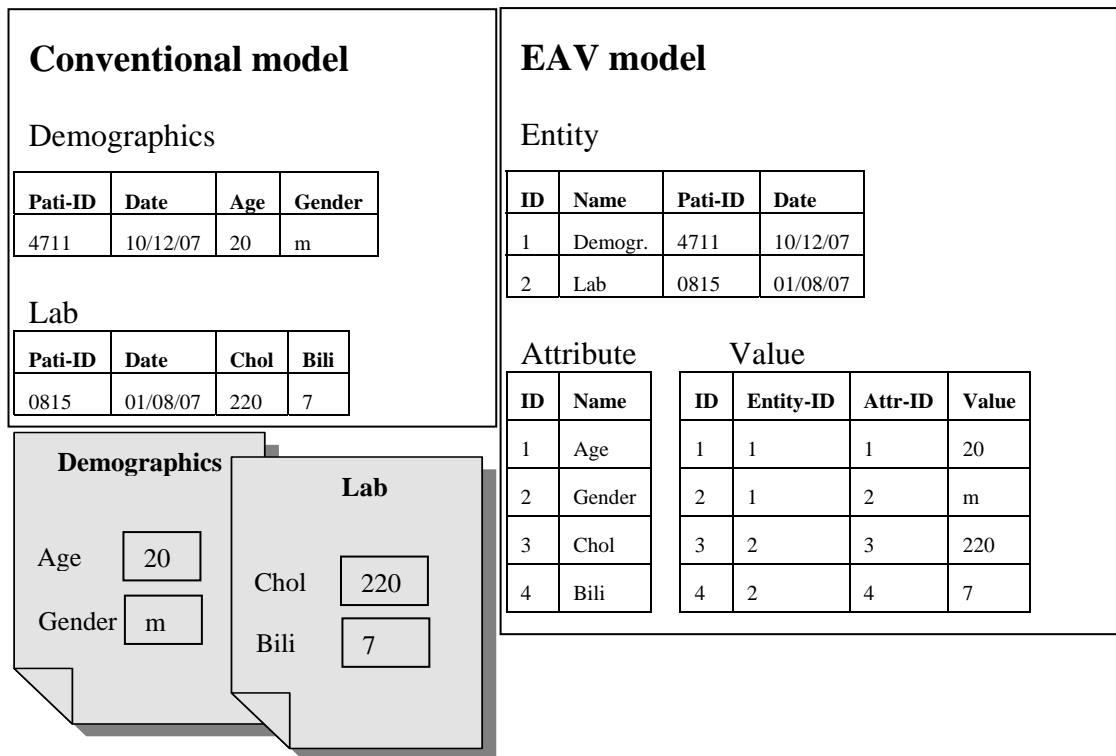
Conventional model

Demographics

Pati-ID	Date	Age	Gender
4711	10/12/07	20	m

Lab

Pati-ID	Date	Chol	Bili
0815	01/08/07	220	7

Demographics

Age [20]

Gender [m]

Lab

Chol [220]

Bili [7]

EAV model

Entity

ID	Name	Pati-ID	Date
1	Demogr.	4711	10/12/07
2	Lab	0815	01/08/07

Attribute

ID	Name
1	Age
2	Gender
3	Chol
4	Bili

Value

ID	Entity-ID	Attr-ID	Value
1	1	1	20
2	1	2	m
3	2	3	220
4	2	4	7

Figure 2: Comparison of conventional and EAV design of a relational database for two documents of forms *Demographics* and *Lab*. Form headers, which would include the Patient-ID and the document date, are omitted in the forms for reasons of simplicity. In a conventional model each form is stored in an individual table, documents correspond to table records, and variables correspond to table columns. An EAV model, however, is based on a fixed set of generic tables, which store all data.

An obvious approach is to define a direct mapping from the EHR system's database table representing the form to the archetype. LinkEHR-ED is a tool that provides this functionality for conventionally modeled relational databases [25; 26]. It allows the individual columns of the table representing the form (compare left side of Figure 2) to be mapped to the corresponding nodes of an archetype. The documents are retrieved from the records of the same table. Similarly, common tools for transferring data between relational databases and XML documents (see [27] for a list of products) typically anchor the mapping on tables and individual columns.

However, these tools cannot be used for databases conforming to the EAV model. In the EAV model the documents of all forms are stored in a common set of generic tables (compare right side of Figure 2). Metadata are used to represent forms. Different models

for these metadata have been suggested which usually entail an extension of the "basic" EAV model shown in Figure 2. Examples include adding a *Data_Field* and *Form* table [22], a *Form* and a *Group* table [19], or a *Class* table [28]. To generate archetyped EHR extracts one could define a mapping from the particular representation of the form variables (e.g. the rows of table *Data_Field* in [22]) to the corresponding archetype nodes, retrieve the respective data from the *Value* table using a model-specific query and finally transform them to a conventional structure. Depending on how the metadata are modeled, however, this would require individual solutions for different systems.

To achieve a generally applicable solution, we chose an approach which anticipates the transformation of the data to a conventional structure. This step is usually provided as a standard feature by EAV-based EHR systems within their export interfaces. They typically transform source documents to a conventional structure before delivery, as most tools for processing exported data (e.g. statistical analysis packages) require this format for their input. The exported conventionally structured source document represents an entry point, which decouples our approach from individual metadata models of different EAV-based EHR systems. To generate archetyped EHR extracts we map the structure of the exported source document, i.e. the form to the archetype.

As we decided to base our approach on XML standards, we emanate from the archetyped EHR extract being represented as an XML document. An obvious approach then is to also export the source document from the EHR system as an XML document and map it to the archetyped EHR extract via an XSLT script. Several tools[5] exist that allow the XSLT script to be automatically generated from a visual mapping between XML schema descriptions of the source document and the archetyped EHR extract. The XML schemas describing the source document respective the archetyped EHR extract will be called *source schema* respective *target schema* in the following.

Besides EAV-modeled EHR systems, the suggested approach may also be attractive for conventionally modeled EHR systems, as (a) it can be realized by means of standard XML tools, (b) it does not require access to the internal database tables, which may not always be available, (c) the target schema can also be used to validate an archetyped EHR extract for compliance with its archetype (see section 2.1), and (d) the target

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[5] E.g., Stylus studio (http://www.stylusstudio.com/) and Mapforce (http://www.altova.com/)

schema displays the hierarchical structure of the archetyped EHR extract which should be helpful for users who lack prior knowledge of archetypes and the RM but are familiar with the XML technology.

2.1 Overview of our approach

Our approach for extracting archetyped EHR extracts from EAV-based EHR systems can be summarized as follows:

1. Design a form within the EHR system that allows the data prescribed by the archetype to be captured. This step may be omitted if the data prescribed by the archetype – at least all mandatory archetype nodes must be covered – are already available within the EHR system as legacy data and if it is semantically correct to unite these data under the common context of the archetype. See section 4.3 for a discussion of the latter issue.

2. Generate the source schema that describes the source document to be exported. See section 2.2 for the details of this step.

3. Generate the target schema that describes the archetyped EHR extract. See section 2.2 for the details of this step.

4. Map the source schema to the target schema to transform source documents to archetyped EHR extracts. See section 2.4 for the details of this step.

As a prerequisite for applying our approach, an EHR system must satisfy the following conditions:

- As explained in section 1, the target schema, which merges the prescriptions of the archetype and the RM, and the internal data model of the EHR system must overlap in a way that a semantic mapping between them is possible.

- Besides the data and metadata which are mandatorily prescribed by the archetype, an archetyped EHR extract must also contain those metadata that are mandatory according to the ISO/EN 13606 RM. From the latter, the EHR system must provide the id of the source EHR, the id of the patient, the id of the committing person, the ids and labels of the individual data items, and the time points at which the data were originally committed. The id of the originating EHR system, the id of the RM, the id of the committing EHR system, and the attributes ENTRY.uncertainty_expressed,

RECORD_COMPONENT.synthesized, as well as CLUSTER.structure_type may be supplied by constant values (compare section 2.4). The time point when the EHR extract was created may be determined during the extraction process.

- The system must provide an XML interface which permits the export of the source documents in conventional format. Besides the mandatory archetype data and metadata, the export must include those mandatory RM metadata, which cannot be supplied by constant values (see above).

2.2   Creation of the source and target XML schemas

Using standard XML tools, we automatically derive[6] the source schema from the source document, which is exported from the EHR system in XML format. If the EHR systems provides a generic XML schema that describes the output of its XML export interface, this may also be used as the source schema.

For the creation of the target schema, we examined two variants:

a) Generic target schema: Here, one could for example use an XML schema pendant of the RM, to which any archetyped EHR extract obviously must be compliant. This would be appealing, as no archetype-specific target schema would have to be designed. However, we identified two kinds of problems caused by generic target schemas. First, it does not permit the expression of arbitrary sequences of RM-classes that might be prescribed by an archetype (e.g. an ENTRY "a" containing ELEMENT "x", CLUSTER "y", and ELEMENT "z" in this particular order). Second, the target schema is so generic that it cannot be used to validate an archetyped EHR extract for compliance with its archetype.

b) Specific target schema: Here, the strategy is to derive a schema from each archetype that precisely describes the structure of the archetyped EHR extract. In this case the target schema is specific enough to validate an archetyped EHR extract for compliance with its archetype [29]. Besides, the hierarchical structure of the archetyped EHR extract becomes explicit. This should be particularly

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[6] The automatic generation of a schema from an XML document is typically supported by XML tools, such as XML-Spy (http://www.altova.com/).

helpful for users who lack prior knowledge of archetypes and the RM but are familiar with the XML technology.

We chose variant (b) due to its above mentioned advantages. The drawback that a specific target schema has to be created per archetype is alleviated by the fact that this step can be automated [30].

2.3 *How to satisfy the unique particle attribution constraint rule*

A problem we had to solve when developing the target schema was how to satisfy the *unique particle attribution constraint rule*. This rule requires an XML schema to be defined in a way that it is always possible to unambiguously associate an instance element in an XML document with a schema element, without having to consider the instance element's content or structure. As archetypes frequently prescribe sequences of instances of the same RM class (e.g., the openEHR "blood_pressure.v1" archetype prescribes a sequence of different pressure types, each expressed by means of the RM class ELEMENT, as shown in Figure 1), this rule would be violated in an XML schema that is straightforwardly derived from such an archetype (see example in Figure 3).

This problem was first reported in [31], where the applicability of XML schemas for representing archetypes was examined with the goal of validating an XML-formatted EHR extract against the XML schema version of an archetype. Besides the afore-mentioned sequences of the RM class instances prescribed by an archetype, violations of the unique particle attribution constraint rule were also found in those cases in which archetypes restrict the values of a data field to being from a set of values having complex data types. We avoid violations of the unique particle attribution constraint rule in both cases by introducing "virtual specializations" for ambiguous schema elements, as will be described in the following paragraphs.

Another problem reported in [31], namely the representation of archetype "slots" within an XML schema, is irrelevant in our case. Archetype slots allow a nesting of archetypes. According to the ADL, the coarse-grained archetype may reference the fine-grained archetype via wild-cards. Tun and colleagues state that it is not possible to define a hierarchy of complex types within the XML schema for the fine-grained archetypes,

which permits them to be instantiated in more than one coarse-grained archetype. This problem is irrelevant in our case for the following reason: As our goal is to generate an archetyped EHR extract from a concrete EHR system document, optional components originating from archetype slots do not occur within the document. Instead, the selection of the desired component was already made when the document was created. Therefore, the target schema in our case already holds concrete instantiations for archetype slots, i.e. each archetype slot is replaced in the schema by one fine-grained archetype which was selected from the permitted wildcard pattern when creating the source document.

To satisfy the unique particle attribution constraint rule within the target schema, we name the schema elements according to specializations of the RM classes, which express the classes' semantics as defined within the archetype. For instance, the structure of systolic and diastolic pressures in Figure 3 would be prescribed by the schema elements named "ELEMENT_Systolic" and "ELEMENT_Diastolic", i.e. rows 01 and 10 would be replaced by <xs:element name="ELEMENT_Systolic" minOccurs="0"> respective <xs:element name="ELEMENT_Diastolic" minOccurs="0">. This is done for each node in the archetype that constrains a class of the RM.

```
[…]
01 <xs:element name="ELEMENT" minOccurs="0">
02    <!-- systolic -->
03    <xs:complexType>
04       <xs:sequence>
05          <xs:element name="name">
06             <xs:simpleType>
07                <xs:restriction base="xs:string">
08                   <xs:enumeration value="systolic"/>
09          <xs:element name="value" type="QUANTITY"/>
10 <xs:element name="ELEMENT" minOccurs="0">
11    <!-- diastolic -->
12    <xs:complexType>
13       <xs:sequence>
14          <xs:element name="name">
15             <xs:simpleType>
16                <xs:restriction base="xs:string">
17                   <xs:enumeration value="diastolic"/>
18          <xs:element name="value" type="QUANTITY"/>
[…]
```

Figure 3: XML schema fragment (closing tags are omitted) that was straightforwardly derived from the blood-pressure archetype (only the systolic and diastolic pressure components are shown in the schema) depicted in Figure 1. The schema violates the unique particle attribution constraint rule, as it is unclear whether an instance element <ELEMENT> within an XML document is associated with the "systolic" or the "diastolic" schema elements without considering the contents of the <name> element. The <name> element originates from a corresponding attribute in the RECORD_COMPONENT class of the RM. Several other attributes and data types have been omitted in the schema for reasons of simplicity.

In terms of the RM, a schema element <xs:element name="ELEMENT_Systolic"> corresponds to what we call a "virtual subclass" ELEMENT_Systolic of the RM class ELEMENT. The virtual subclasses are named according to the RM classes from which they are derived, concatenated with the *text* attribute[7] of the corresponding item within the *term_definition* section associated with the class instance in the ontology section of the ADL archetype. The RM class from which the virtual subclass is derived is explicitly given by the corresponding RM class constraint within the archetype.
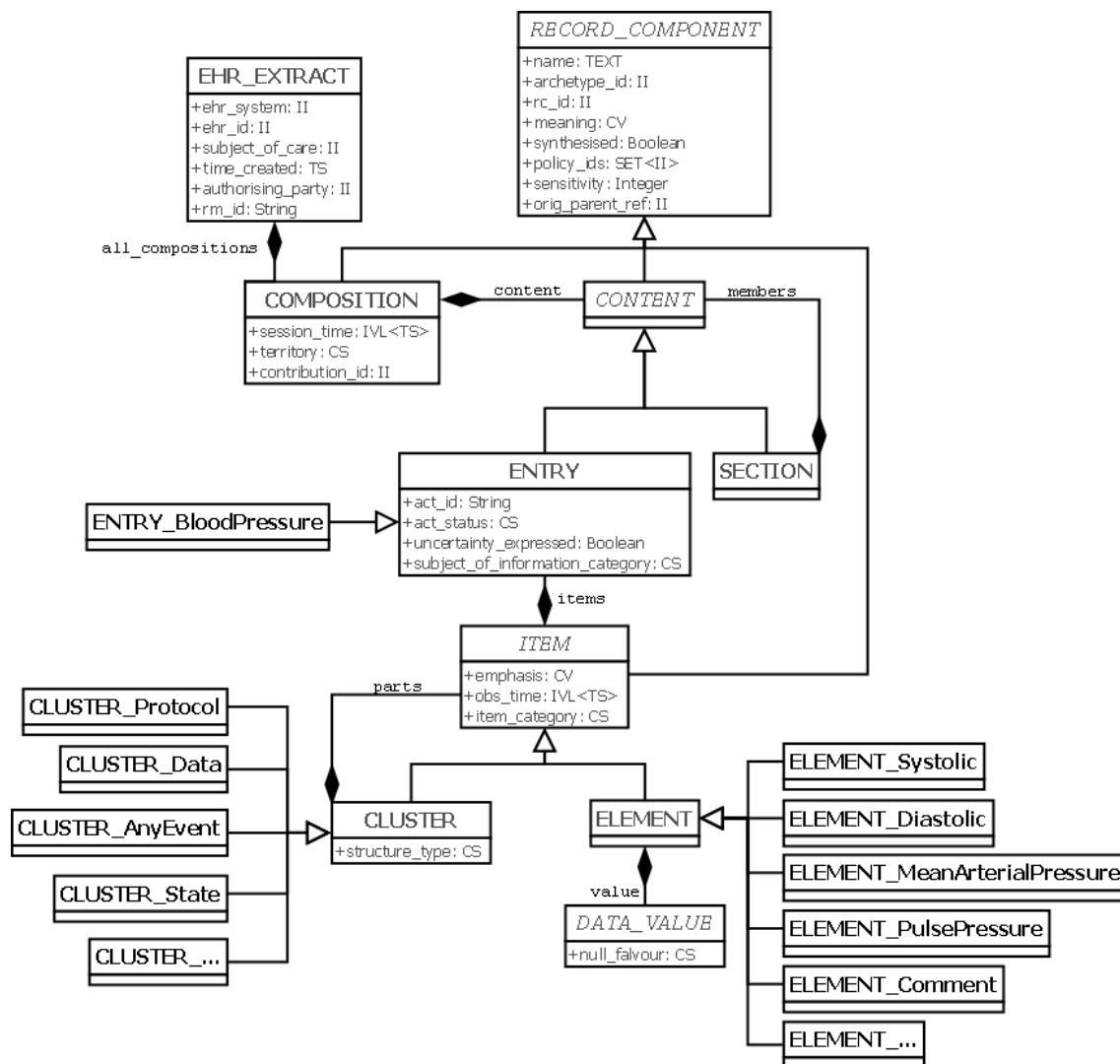

Figure 4: Fragment of the ISO/EN 13606 RM that is temporarily extended by several virtual subclasses originating from a ISO/EN 13606 archetype that was derived from the openEHR "blood_pressure.v1"

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[7] Our algorithm, which automatically derives the target schema from an archetype actually appends the archetype node identifier (e.g., *at0004* for systolic pressure in Figure 1) to the RM class names to create the names of virtual subclasses. In the context of this paper we use the *text* attribute instead as it is more expressive for the reader.

archetype according to ISO/EN 13606-3. The original RM classes are colored gray; the classes in black are the virtual subclasses.

Obviously, the virtual subclasses inherit all attributes and relations from their superclasses. We term these classes "virtual" because they are disposed in the final step of the transformation process by typecasting the instance elements that instantiate them back to the original RM classes. Thus, the virtual subclasses only appear temporarily in the EHR extract during the transformation process. Their sole purpose is to permit valid XML schema representations of archetyped EHR extracts[8]. Figure 4 shows a fragment of the ISO/EN 13606 RM that is "temporarily extended" by several virtual subclasses.

2.4   Mapping the source and target schemas

The source and target schemas can be conveniently mapped by means of standard XML mapping tools. This is typically well supported, allowing XML schema elements to be visually mapped, which results in an XSLT script describing the mapping. Using the underlying XSLT mechanisms it is further possible to convert terminologies or units that are prescribed by the archetype but are offered differently to the user via the EHR system form (see Figure 5).
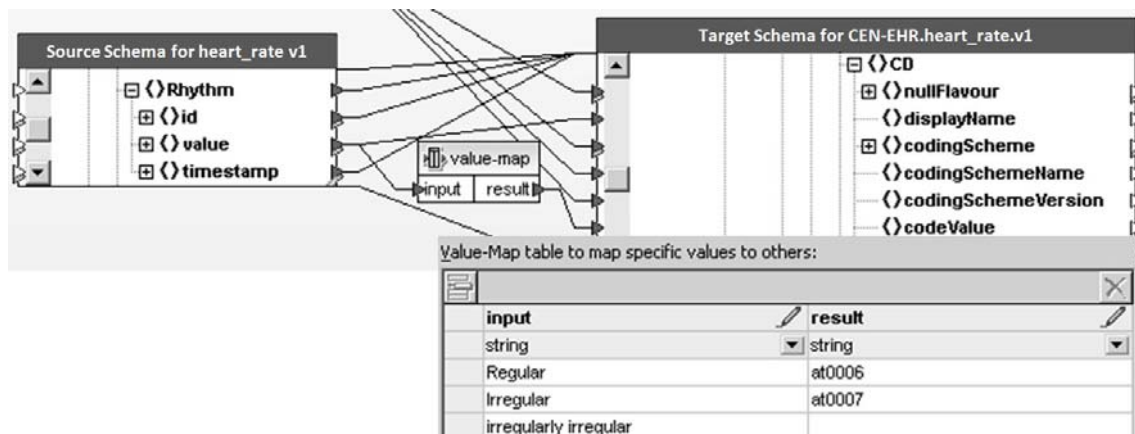

Figure 5: Fragment of the mapping between a source and a target schema. The latter is derived from the archetype CEN-EHR-ENTRY.heart_rate.v1 which, amongst other features, prescribes that the ELEMENT *Rhythm* may hold a code from the set {*at0006, at0007, at0008*} with corresponding display names {*Regular, Irregular, Irregularly irregular*}. In the EHR system form the display names are offered to the user and stored in the *value* attribute of element *Rhythm* (see corresponding structure in the source schema). The display names are directly mapped to the *displayName* attribute of the corresponding

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[8] Note that the temporary extension of the RM with the virtual subclasses originating from archetype constraints on RM classes actually corresponds to a temporary transition of the dual model approach to a single model approach – RM and archetype are united in a single virtual model.

instance of data type CD in the target schema. The display names are further converted to the appropriate codes via a mapping table to populate the attribute *codeValue*.

Some metadata prescribed by the archetype (e.g. a code value "OE-01" prescribed for attribute *meaning* of an ENTRY which indicates that the latter holds observational data) or by the RM (e.g. the id of the RM) typically do not appear on the EHR system form and thus also not in the source schema. The corresponding elements in the target schema then have to be supplied by suitable constant values. In some cases even complete archetype nodes may be omitted in the form. As an example, node *at0002* of Figure 1 may be visually omitted, even though its sub-nodes *at0004* and *at0005* are represented as input fields in the form. For the element corresponding to node *at0002* in the target schema, the attribute *synthesised* (see RM class RECORD_COMPONENT in ISO/EN 13606-1) is then set to *true* to indicate that the schema element has no corresponding pendent in the originating EHR.

The mapping from the source schema and the constants to the target schema is stored as an XSLT script. This script is then applied to the source document in order to transform the latter into an archetyped EHR extract. Finally, the virtual subclasses' instances within the archetyped EHR extract are typecasted to the original RM classes by means of a simple XSLT-based renaming script.

3 Results

As the first step, we manually derived three ISO/EN 13606 archetypes[9] from three existing openEHR archetypes "openEHR-EHR-OBSERVATION.dimensions.v1", "openEHR-EHR-OBSERVATION.body_weight.v1", and "openEHR-EHR-OBSERVATION.heart_rate.v1". The conversion of an openEHR archetype to an ISO/EN 13606 archetype consists of mapping the more specific classes of the openEHR RM referred to in the former, to the more generic classes of the ISO/EN 13606 RM referred to in the latter. Corresponding mapping prescriptions are given in section 7.2 of ISO/EN 13606-3.

For the archetype design we used Ocean Informatics' open source ADL Workbench[10].

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[9] http://www.meduniwien.ac.at/msi/mias/models/CEN-EHR-ENTRY.[dimensions, body_weight, heart_rate].v1.adl

[10] https://wiki.oceaninformatics.com/confluence/display/TTL/ADL+Workbench

This tool checks whether the archetypes are specified in valid ADL and provides a well arranged tree view of the archetypes' structure. Note that this step is actually not part of our method; it is merely a preparatory step that became necessary because ISO/EN 13606 archetypes are not yet publicly available. The time taken to develop the ISO/EN 13606 archetypes was between four and eight hours per archetype, depending on the complexity of the openEHR originals.

To record the data prescribed by each archetype, we manually created corresponding forms within the ArchiMed system. If the archetype contained a slot, we "filled" it with a concrete "sub-archetype" (compare section 2.3). If the inclusion/exclusion criteria of the slot permitted several sub-archetypes, we chose one of them, depending on what data the form should allow to record. For the three archetypes mentioned above, this was the case for the archetype "dimensions". Using ArchiMed's flexible form design tool [32], the creation of each form took about two to four hours.

Sample source documents were created within ArchiMed by filling in the forms with data. The documents were then extracted from ArchiMed's database as XML documents using an export interface of the system. No manual effort was required for the extraction step.

From these XML documents, we automatically derived the source schemas as described in section 2.1. Besides making sure that the source document was fully documented so that all schema elements in the source schema would be generated, we did not have to manually intervene in the source schema generation process. Consequently, this step also did not require any manual effort.

For each archetype we automatically derived a target schema as described in section 2.1. The target schema is conformant to an existing XML schema [33] of the RM. It includes all mandatory attributes and relations from the RM (e.g., attributes rc_id and $name$ are mandatory for each RM class and relation $committal$ is mandatory for class COMPOSITION in ISO/EN 13606). We do not include optional attributes of RM classes in the target schema which are not constrained by the archetype. We assume that these optional attributes are not needed in an archetyped EHR extract as they were deliberately not mentioned in the archetype. If the archetype contains slots, they are replaced in the target schema with schema representations of those "sub-archetypes"

that were selected during the form creation process. Target schemas are automatically derived from archetypes, no manual effort is required for this step.

Source and target schemas for the archetypes were then visually mapped as described in section 2.4. We used Altova's Mapforce[11] for this purpose. The mapping process took about four to eight hours per archetype.

By means of the XSLT script resulting from the mapping, the exported XML document was transformed to an archetyped EHR extract that includes virtual subclasses. In the final step, the virtual subclasses were automatically typecasted to the original RM classes. The resulting archetyped EHR extract is conformant to the RM and can be validated by an existing XML schema [33] of the RM. No manual effort was required for the transformation and typecast.

4   Discussion

In section 4.1 we report on previous publications concerning the application of the ISO/EN 13606 standard and the dual model approach. Section 4.2 describes our experience relating to the application of ISO/EN 13606. In section 4.3 we comment on what we have learned during the application of our method.

4.1   Related work

In [34] Martinez and colleagues describe a patient monitoring system that communicates data from an intensive care unit to an EHR server as ISO/EN 13606 EHR extracts. The data are derived from medical devices and transformed from an XML-based ISO/IEEE 11073-conformant format to ISO/EN 13606 EHR extracts using XSLT. As in our system, XML schema is used to validate the EHR extracts although it is not clear whether they are validated against an archetype or against the RM only.

Martinez-Costa and colleagues have focused on representing archetypes in a way that allows their semantic management and processing similar to functionalities known from the Semantic Web domain [35]. They propose to use the Web Ontology Language (OWL) instead of ADL for the representation of archetypes, as this would allow more

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[11] http://www.altova.com/

efficient implementation of semantic activities such as comparison, classification, selection and consistency checking of archetypes. For this purpose they present a method for transforming archetypes represented in ADL and based on the ISO/EN 13606 RM into an equivalent OWL representation.

Smith and Kalra examine in [36] the possible application of EHRs in complementary and alternative medicine. They showed that patient records from homeopathy practices can be represented as instances of the ISO/EN 13606 RM. They originate from handwritten notes of six different homeopathy practices and translate them into ISO/EN 13606-conformant EHR extracts. The goal is to model each set of original notes as faithfully as possible with an EHR extract. Standardization of patient records from homeopathy practices via archetypes was not performed although it has been mentioned as a desirable future goal.

As mentioned earlier, our target schema can be used to validate archetyped EHR extracts, i.e. check them for conformance with the corresponding archetype. The benefits of using XML schemas instead of rules for the validation of exchanged medical data in Turkey's national health information system have been stressed by Kabak and co-workers [37]. Originating from the HL7 CDA standard [38], they define different types of "transmission schemas" as XML schemas and hereby extend the original CDA data model in similar fashion as we did. The transmission schema instances are also typecasted to the original CDA model via XSLT scripts.

The following two publications are similar to our work in some respects and are therefore compared to our approach in greater detail.

Two projects to investigate the value of the dual model approach for extracting data from a clinical information system and from two different information systems of general practitioners have been described in one study [39]. These projects, which came to a positive conclusion concerning the afore-mentioned research question, may be compared to our work as follows: (1) They use openEHR as the target EHR architecture while we use the ISO/EN 13606 standard. (2) They use custom-made archetypes derived from the existing source data which they plan to extract. In contrast, we use predefined archetypes. We think this better reflects the general goal of exchanging data based on standardized archetypes whose authorship and maintenance conform to the

appropriate regulations [9; 14]. (3) Analogous to the authors, we use XML to format the extracted data. (4) Similar to them, we use XSLT to transform source data to archetyped EHR extracts. To avoid the tedious coding of the XSLT, we automatically generate the latter from a mapping between two XML schemas (see section 2.4), which may be visually specified by means of standard XML tools. (5) Their source data are stored in a less structured form than that of the archetypes and therefore have to be partly placed in free text comment fields in the archetype. In contrast, source data within our EHR system are highly structured and can thus be transformed to an archetyped EHR extract, the content of which can be processed in a fully mechanical fashion.

In [40] Munoz and co-workers report their development of a server that supports the storage and exchange of archetyped EHR extracts conformant to ISO/EN 13606. Their work may be compared to ours as follows: (1) They focus on the development of a central server that mediates between communicating EHR systems. For this purpose it receives and stores archetyped EHR extracts and delivers them on request. The ISO/EN 13606-server fulfils a similar task as the *IHE Cross-Enterprise Clinical Document Sharing Integration (XDS) profile* [41]. The systems differ in that XDS stores EHR data in federated repositories in a format agreed upon within an affinity domain whereas the ISO/EN 13606-server stores them centrally in a relational representation of the RM. In contrast to Munoz and colleagues, we focused on a method to extract ISO/EN-conformant archetyped EHR extracts from an EHR system that internally uses a proprietary data model. This aspect has not been covered in [40]. In the latter study, the "starting points" are the archetyped EHR extracts. However, our work complements theirs insofar as archetyped EHR extracts generated by an EHR system according to our method may be exchanged with other EHR systems on the basis of their server framework. (2) Similar to our approach, the authors used XML schemas to validate the correctness of EHR extracts. However, they do not mention whether EHR extracts are checked for conformance with archetypes or the RM only.

4.2   *Experience concerning the application of ISO/EN 13606*

Our experience concerning the application of ISO/EN 13606 was generally very positive. The RM was well suited to represent the clinical data we wished to extract from our EHR system. It provided appropriate classes for each form component used

within our EHR system to structure clinical documents. During the implementation of EHR extracts and archetypes, however, we encountered a few aspects for which the standard did not provide sufficient details for unambiguous implementation:

Part one of the standard states that the attribute *archetype_id* of class RECORD_COMPONENT should be populated with the identifier of the archetype node (e.g., the *Blood pressure measurement* node in Figure 1 is associated with the identifier *at0000*) to which the component corresponds. What remains unclear is where one should store the identifier of the archetype itself, of which the node is a part. As node identifiers are only unique within their archetype, the archetype identifier is essential to distinguish node identifiers of different archetypes for EHR extracts that are conformant to more than one archetype. We chose an implementation strategy that is analogous to the use of the comparable attribute *archetype_node_id* of openEHR's RM class LOCATABLE. The openEHR *Common Information Model specification* states that the attribute should contain the archetype identifier in the case of an EHR extract component that corresponds to an archetype root point [42]. Nodes of the same archetype must then correspond to subcomponents in the EHR extract, each holding the corresponding archetype node identifier.

Part one of the standard requires each RECORD_COMPONENT to hold a unique identifier in its mandatory attribute *rc_id* by which it is referenced in the originating EHR system. The same class also contains a Boolean attribute *synthesised* that must be set to TRUE if the RECORD_COMPONENT was "artificially" created to comply with the standard but does not have a corresponding node in the EHR from which it was extracted. If the RECORD_COMPONENT does not exist in the originating EHR, however, it also cannot be referenced in the originating system. As the *rc_id* is a mandatory attribute, we had to populate it with dummy identifiers in case of synthesised RECORD_COMPONENTs.

As mentioned in section 3, we had to convert openEHR archetypes to ISO/EN 13606 archetypes. Part three of the standard provides a conversion guide from openEHR RM classes to ISO/EN 13606 RM classes, which unfortunately does not explain which data types should be selected. For example, the *data* attribute of the openEHR class OBSERVATION should be converted to an instance of the ISO/EN 13606 class

CLUSTER. The latter's attribute *meaning* should hold the value "<Data> OE-04", which obviously represents a code-text pair. However, the authors fail to mention which of the possible data types such as CODED_TEXT, CD or CV of CEN/TS 14796 [43] should be used. Furthermore, although the codes are explicitly defined in ISO/EN 13606-3 which therefore is the coding scheme, we had to populate the attribute *codingScheme* present in all previously mentioned data types with a self-defined Object Identifier (OID), as no official OID has yet been defined for ISO/EN 13606-3.

4.3 Experience concerning the application of our method

When designing a form to collect the data prescribed by the archetype, in some cases the prescribed data structure may be deeper than what can be represented by the components of the EHR system form. If those archetype nodes that had to be omitted in the form do not require user input, they may be supplied from constant values (compare section 2.4). This solution is inapplicable, however, when the archetype nodes that cannot be represented within the form require user input. For instance, an ENTRY archetype may prescribe a CLUSTER that holds a collection of repeating ELEMENTs for user input. In the ArchiMed system we would represent this as a form holding a table, where each ELEMENT is allotted a separate column in the table. According to the RM, one of the CLUSTER's parts could be another CLUSTER, in turn holding ELEMENTs for user input. This would correspond to a table column containing additional tables within each cell, and cannot be implemented in an ArchiMed form. In other words, some archetype nodes requiring user input possibly cannot be represented by a form of a given EHR system. On the other hand, one may argue that the data prescribed by an archetype should be obtainable in a reasonable way in a form. For an archetype containing structures such as the above mentioned example, this probably is not the case from the form usability point of view. The archetype's design should therefore be scrutinized.

The design of a new form will not be required, if the data that are mandatorily postulated by the archetype are already available as legacy data within the EHR system. Optional archetype nodes for which no data are available do not present a problem. In this case, the corresponding elements in the target schema are simply ignored in the mapping process as there are no corresponding elements in the source schema from

which they are supplied. Whether nodes of the archetype may be supplied with legacy data originating from *different* source documents depends on whether it is semantically correct to unite the contexts of these documents under the common context defined by the archetype. As an example, an ENTRY archetype may specify what data to collect in the course of a particular *single* observation. If these data should be supplied by different source documents it must be checked whether they can still be seen as belonging to a single observation. In the positive case, the target schema would simply be fed from a set of source schemas, one for each source document.

The more specific the source schema describes the structure of the source document, the simpler it can be mapped to the target schema. As an example, two ELEMENTs x and y prescribed by an archetype could be represented as two variables x and y with corresponding data in the source document. If the source schema describes these variables with two separate schema elements x and y, they can be easily mapped to the corresponding schema elements ELEMENT_x and ELEMENT_y in the target schema. The source schema may, however, also describe both variables with a single generic schema element *variable* containing a subelement *label*, which can hold the values x and y. In this case, the element *variable* would have to be mapped to ELEMENT_x as well as to ELEMENT_y in the target schema. Which of the two elements in the target schema is supplied by a concrete content of element *variable* would then have to be decided by checking the contents of its subelement *label*. Although the corresponding conditional mapping can still be done, it is more laborious than mapping from a source schema that describes the structure of the source document more specifically.

The ISO/EN 13606 RM includes two classes that represent "choices" within an EHR extract; the abstract class CONTENT may be substituted by the concrete classes ENTRY or SECTION, and the abstract class ITEM may be substituted by the concrete classes CLUSTER or ELEMENT. In the target schema, CONTENT for instance could naturally be represented as an abstract complex type, which is referred to from a schema element *content* within the complex type COMPOSITION, according to the relation *content* in the RM. Its two concrete subclasses could be derived from the abstract type by extension. However, this type of XML schema design impedes a visual mapping of the source and target schema, as suggested in section 2.4. Abstract complex types cannot be visually expanded in standard XML mapping tools, which precludes the

complex types derived from them to be mapped. This problem can be avoided if the schema element representing the relation to an abstract class does not refer to the abstract class itself but directly to a choice of its concrete subclasses. For example, the schema element *content* within the complex type COMPOSITION could contain a choice of complex types SECTION and ENTRY, both derived from a complex type CONTENT.

In our approach we focused on the generation of an archetyped EHR extract for each individual document within the EHR system. Although this results in valid EHR extracts, it does not utilize the full capabilities of the ISO/EN 13606 RM. According to ISO/EN 13606-1, an EHR extract contains a part of, or all of the EHR of a single patient. If we assume that a patient's EHR consists of a set of documents, our method should also be able to integrate these documents in the form of different COMPOSITION instances within a single EHR extract. This might be achieved by integrating the archetypes which describe the different documents within an overarching archetype. From the latter a comprehensive target schema may then be derived to which the different source documents would be mapped. Alternatively, archetyped EHR extracts describing individual documents could be merged in a separate final processing step. We did not, however, examine these approaches yet in detail.

5 Conclusion

In this report we have presented an approach for the extraction of ISO/EN 13606-conformant archetyped EHR extracts from EAV-based EHR systems. It is based on mapping from the structure of exported source documents to the archetype. The required transformation is implemented via an XSLT script which can be automatically derived from a visual mapping between two XML schemas describing the source document respective the archetyped EHR extract. Our approach may also be attractive for conventionally modeled EHR systems due to its advantages stated below. As a prerequisite for applying our approach, an EHR system's internal data model and the model of the archetyped EHR extract must overlap in a way that a semantic mapping between them is possible. The system must further provide an XML interface which permits the export of the source documents in conventional format. The export must

include data and metadata that are mandatorily postulated by the archetype and the ISO/EN 13606 Reference Model.

Advantages of our approach are that (a) it can be realized by means of standard XML tools, (b) it does not require access to the internal database tables, which may not always be available, (c) the XML schema describing the archetyped EHR extract can also be used to validate an archetyped EHR extract for compliance with its archetype, and (d) the XML schema displays the hierarchical structure of the archetyped EHR extract which should be helpful for users who lack prior knowledge of archetypes and the RM but are familiar with the XML technology.

Limitations of our approach are that (a) a specific XML schema has to be created for each archetype, (b) the XML schemas describing the source document respective the archetyped EHR extract have to be manually mapped, and (c) if the data prescribed by the archetype do not already exist as legacy data, new EHR system forms have to be manually designed to collect them.

To resolve the first limitation we developed a tool that automatically derives an XML schema from an archetype. Further, we are examining an alternative approach which would avoid manual form design and mapping for the most part. In this approach EHR system forms will automatically be derived from archetypes. When generating the form components, it will be recorded for each component to which archetype node it corresponds. Based on this mapping, documents collected via the generated form could be immediately extracted as archetype-conformant EHR extracts in the final step.

Acknowledgements

Authors' contributions

All authors made substantial contributions in the following domains
- Conception and design, acquisition of data, or analysis and interpretation of data

- Drafting the article or revising it critically for important intellectual content

- Final approval of the version for publication

Georg Duftschmid is responsible for the integrity of the work.

Statement on conflict of interests

None of the authors has any conflict of interests relating to the work presented here.

Summary table

What was already known on the topic:
- Cross-organizational EHR communication will constitute a key component of future health care.

- The ISO/EN 13606 EHR architecture standard provides a framework for the communication of EHR data. It employs the archetype-based dual model approach to achieve semantic interoperability.

- The EAV model is frequently used by research-oriented EHR systems for internal organization of the EHR data.

What this study added to our knowledge:
- Tools for the extraction of ISO/EN 13606 archetype-conformant EHR data from a conventionally modeled EHR system cannot be used for EAV-based EHR systems. These tools expect each form to be represented as an individual table and documents to be represented as the records of these tables. This is not the case for EAV-based EHR systems.

- Instead source data may be exported from the EAV-based EHR system as XML

documents and then transformed to ISO/EN 13606 archetype-conformant EHR

data via standard XML technologies and tools.

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