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Towards the interoperability of computerised guidelines and electronic health records: an experiment with openEHR archetypes and a chronic heart failure guideline

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Abstract. Clinical guidelines contain recommendations based on the best empirical evidence available at the moment. There is a wide consensus about the benefits of guidelines and about the fact that they should be deployed through clinical information systems, making them available during clinical consultations. However, one of the main obstacles to this integration is the interaction with the electronic health record system. With the aim of solving the interoperability problems of guideline systems, we have investigated the utilisation of the openEHR standardisation proposal in the context of one of the existing guideline representation languages. Concretely, we have designed a collection of archetypes to be used within a chronic heart failure guideline. The main contribution of our work is the utilisation of openEHR archetypes in the framework of guideline representation languages. Other contributions include both the concrete set of archetypes that we have selected and the methodological approach that we have followed to obtain it.

Keywords: Clinical guidelines, knowledge modelling, openEHR archetypes, guideline representation languages, reusable components.

1 Introduction

Clinical guidelines are defined by the U.S. Institute of Medicine as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” [1]. Guidelines contain recommendations about different aspects of clinical practice, such as diagnosis tests or interventions to perform. These recommendations are based on the best empirical evidence available at the moment. Thus, the use of guidelines has been promoted as a means to control variations in care, reduce inappropriate interventions and deliver more cost-effective care, among others.

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Despite some discrepancies, there is a wide consensus about the benefits of guidelines and about the fact that guidelines should be deployed through clinical information systems, making them available during clinical consultations [2]. Current guideline systems include reminder systems and increasingly more complex systems representing the whole of guideline procedural knowledge. In any case, there must be some interaction with the clinical information system, in general, and with the electronic health record (EHR) system, in particular, to obtain and share all the relevant information.

In recent years, clinical guidelines have become the focus of many researchers in the areas of Artificial Intelligence and Medical Informatics. Significant contributions in these areas include a variety of languages for the representation of guidelines (see [3], [4]). Recently the focus of attention has shifted from the representation of guidelines to the integration of guideline systems in realistic healthcare settings [5]. Despite these efforts, the interaction with EHR systems remains as one of the main obstacles for the interoperability of guideline systems within clinical information systems [6]. Features such as the use of standards for shared EHRs, both for querying EHR data and generating EHR orders from guideline recommendations, are not directly supported in the current guideline representation languages.

One of the main initiatives with regard to EHR standards is the openEHR architecture [7]. It is the culmination of over 10 years of work at international level, aiming to harmonise and converge with other health standards. The concept of archetype plays a central role in openEHR. It was originally defined by Beale in 2001 [8]. An archetype is a formal (yet flexible), reusable, and composable model of a domain concept.

In this paper we take a step towards the interoperability of electronic guidelines, investigating the utilisation of openEHR archetypes jointly with one of the existing guideline representation languages. Concretely, we describe our experiences in designing a collection of openEHR archetypes intended for use within a guideline for the management of chronic heart failure modelled in PROforma.

The paper is structured as follows. First, section 2 summarises the approach and describes some related work. Next, section 3 gives details on the openEHR framework. After that, section 4 introduces the methodological aspects of our archetype design experiment, and section 5 presents the results thereof. Finally, section 6 includes some concluding remarks as well as references to future work.

2 Guideline representation incorporating openEHR archetypes

2.1 Outline of the approach

We investigate the utilisation of openEHR archetypes in the framework of guideline representation languages, with the purpose of facilitating the interaction with EHR systems. A possible approach is viewing the guideline as a representation with archetype-enabled fragments in strategic points where interactions with

other systems should occur, typically in patient data queries and/or physician order generation. This approach should be applicable regardless of the specific features of the guideline representation language in question (such as decision model, etc, see [3], [4] for a description of the main features), since all guideline languages inevitably allow for the representation and use of (more or less complex) patient data and medical actions. On the other hand the openEHR framework incorporates elements for the description of this kind of concepts, namely observations, evaluations and instructions (see section 3 for more details).

The utilisation of openEHR archetypes within an electronic guideline as a mechanism for the interaction with EHR systems requires several steps. In the context of a concrete guideline, firstly, it is necessary to design a collection of archetypes suitable for the decision support tasks carried out in the guideline. Secondly, it is necessary to ensure that the guideline model is compliant with these archetypes, making the appropriate changes otherwise. Discrepancies may occur at this stage e.g. due to the fact that guidelines are often modelled without regard to the interaction with EHR systems. Finally, it must be ensured that the connection with the target EHR system (or clinical database) via the designed archetypes is feasible. In this paper we concentrate on the first aspect, studying the design of an archetype collection for use in a concrete guideline. In accordance with the above approach and for the sake of reusability, the work has been done without considering any specific EHR system.

2.2 Related work

There exist several initiatives that seek the integration of EHR systems with decision support systems (DSSs) in general, and with guideline systems in particular. The KDOM framework by Peleg et al. [9] and the MEIDA architecture by German et al. [10] constitute remarkable examples among these initiatives.

The KDOM (Knowledge-Data Ontological Mapper) framework furnishes an ontology of mapping patterns that can be used to link the medical concepts and patient data items in a guideline to EHR database fields. The actual mappings are defined in terms of a virtual EHR schema which is based on a subset of the HL7 Reference Information Model (RIM), to facilitate the linking to heterogeneous EHR systems. In addition, EHR database views are defined and stored as RIM instances such that queries are performed on these RIM views instead of on the specific EHR database. The mapping ontology is the main constituent of the KDOM framework. It provides constructs for the description of one-to-one mappings (i.e. one data item to one database field) but also for one-to-many ones combining several fields or even previously defined mappings. In this way, complex mappings corresponding to abstract guideline concepts can be defined.

The MEIDA (Medical Database Adaptor) framework seeks facilitating the reuse of DSS knowledge bases across different institutions. For that purpose it provides methods and tools for establishing mappings between a DSS knowledge base (KB) and specific clinical databases. The proposed solution consists in editing the KB to embed the necessary standard terms, on one hand, and mapping

the database schema and fields to a virtual EHR schema and standardised terms, on the other hand. The virtual schema that the authors use is based on the RIM of the HL7 version 3 standard. Besides, the standard terms come from several medical vocabularies, such as LOINC and ICD-9-CM.

Overall, our approach is similar to the ones of the KDOM and MEIDA platforms, dealing with the interaction between EHR systems and guideline systems (or DSSs) using standards. In regard to the details of the proposed solutions, we share with KDOM the view that abstraction knowledge plays an important role and thus must be considered in such a framework (although we have not done it yet). A distinctive feature of our approach lies in the utilisation of openEHR archetypes, instead of the virtual schemas based on HL7 RIM used in MEIDA and KDOM. This is a key difference since clinicians are the main actors in the development of openEHR models, which ensures both the medical and the technical validity thereof [11].

3 The openEHR framework

As mentioned before, the openEHR architecture is one of the main initiatives in regard to EHR standards. The ultimate aim of openEHR is making shared EHRs possible [12]. A key aspect of the architecture is the separation of clinical knowledge, described using archetypes, from the information or recording model, referred to as the reference model. Thanks to this two-level modelling openEHR systems should be in a better position to quickly incorporate changes in clinical concepts. This is due to the fact that clinical knowledge is stored separately in archetypes, such that changes in this knowledge can be tackled with archetype modifications alone.

An openEHR archetype is a model or pattern for the capture of clinical knowledge. It is a machine processable specification of a domain concept in the form of structured constraints and based on the openEHR reference model. An archetype extensively describes the structure and content of a clinical knowledge concepts such as “diagnosis” or “blood pressure”. In principle archetypes have been defined for wide reuse, however they can be specialised for adaptation to local singularities.

An archetype includes all the relevant attributes about a specific clinical concept, according to clinicians’ criteria. In this sense, archetypes constitute maximal data sets. Additionally, archetypes include information important for the interpretation of the data (in the ‘State’ part) as well as information about how the data was collected (in the ‘Protocol’ part). Figure 1 shows the archetype “blood pressure” as an illustration.

There are three main categories of archetypes, namely:

1. Compositions, or thematic archetypes, which correspond to usual clinical documents, such as “medication list” or “encounter”.
2. Sections, or organisational archetypes, which correspond to document parts and are used to facilitate human navigation of the EHR, e.g. “SOAP” and “conclusion”.

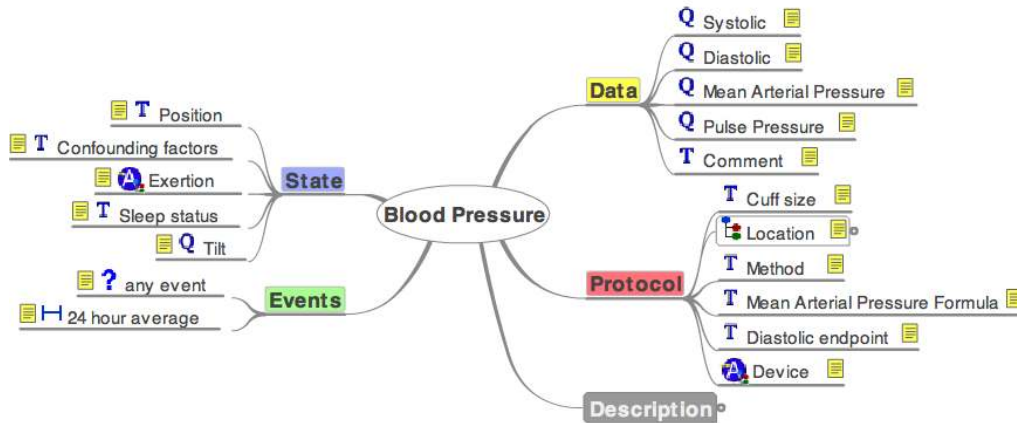


Fig. 1. openEHR archetype for the “blood pressure” concept (diagram taken from the openEHR Clinical Knowledge Manager web repository [13]).

3. Entries, or descriptive archetypes, which are the most common and medically relevant archetypes. Four types of entries can be distinguished: observations, evaluations, instructions, and actions. This categorisation stems from the typical iterative problem-solving process used in Medicine: a problem is solved by making observations, making assessments, prescribing actions or instructions to perform next (which can be further investigations and/or interventions), and executing these instructions.

By design archetypes are language and terminology independent. An archetype developed in English can be translated, interpreted and viewed in another language and the structural and content information remains the same. On the other hand, archetypes are terminology-neutral, since there is no single terminology which describes the variety of medical terms used in clinical information systems. Instead, archetypes may have bindings to one or more terminologies, defined as mappings from the archetype local term to terminology codes.

4 Methodological aspects

We have carried out an experiment consisting in designing a collection of openEHR archetypes intended for use within a guideline for the management of chronic heart failure (CHF). As described before, the motivation for this experiment is studying the feasibility of using archetypes as a means to solve the interoperability problems of guideline systems and EHR systems.

Concretely, we have worked with the guideline for the diagnosis and treatment of CHF developed by the European Society of Cardiology (ESC) [14].

According to the ESC, there are at least 10 million patients with heart failure in the countries it represents. The prognosis of heart failure is poor, hence the importance of a correct patient management. The ESC CHF guideline had been previously modelled in PROforma [16] as part of a project aimed at the development of an electronic care plan for the treatment of comorbidities [15]. The PROforma model of the CHF guideline is a medium-sized structure (e.g. it consists of 54 tasks) of a significant complexity. The latter has to do with the complexity intrinsic to the pharmacological treatment of heart failure.

According to our approach, consisting in viewing the guideline as a representation with archetype-enabled fragments in points where interactions with the EHR system occur, special attention must be paid to PROforma elements such as enquiry sources and actions. Enquiries represent points where data need to be obtained from the user or an external system, and actions represent procedures that need to be executed in the external environment [16]. Although these syntactic elements are specific to PROforma, the medical concepts they hold are characteristic of the guideline and therefore they can be shared with other implementations of the same guideline, and possibly with other guidelines in the same domain. This ensures a high potential for reuse of the archetypes to develop from these concepts.

4.1 Archetype repository

We have used as starting point the archetypes from the openEHR Clinical Knowledge Manager (CKM) [13], which is a web-based repository allowing for archetype search, browse and download. Archetypes in the CKM have been created by independent domain experts, mainly clinicians and computer scientists, and then they have been released to the community as open source and freely available content. Before publication, archetypes undergo an iterative review process to ensure that they cover as many use-cases as possible and thus constitute a sensible maximal data set. This review is carried out by a combination of clinicians and content experts with varying expertise and from different geographical provenance.

According to openEHR the main categories for the description of clinical concepts are observation, evaluation, instruction and action. This categorisation is related to the way in which information is created during the care process: an *observation* is created by an act of observation, measurement, or testing; an *evaluation* is obtained by inference from observations, using personal experience and/or published knowledge; an *instruction* is an evaluation-based instruction to be performed by healthcare agents; and an *action* is a record of the interventions that have occurred, instruction-related or not.

The CKM website gathers a community of individuals interested in fostering the development of openEHR archetypes. The number and specificity of available archetypes differs significantly among categories, probably because the archetypes are developed according to individual interests. Some examples of available archetypes are shown next. Within the observation category, in the CKM we can find e.g. the archetypes `blood pressure`, `body weight` and

microbiology. We also find specialisations of `body weight`, namely `adjusted body weight` and `body weight at birth`. Within the evaluation category we find e.g. `triage evaluation`, and `diagnosis`. In the instruction category we can find e.g. `medication order`, `imaging request`, `healthcare service request` (with the specialisations `laboratory test request` and `referral request`), and so on. Finally, in the action category we can find e.g. `medication action` and `imaging investigation`.

4.2 Archetype methodology

Strictly speaking there is no documentation that can be used as a guide for archetype building and utilisation, probably due to the novelty of the openEHR approach. An exception is the methodology sketched by Leslie&Heard [17]. According to these authors the steps to be performed in archetype design are, for each subject/activity/task:

1. Identify clinical concepts. In this step all the different concepts involved in the subject must be identified, making clear whether it is a single concept or is it made up of multiple concepts. For this purpose the authors recommend using mind maps as a tool, both to identify individual concepts and detect and solve any overlap.
2. Identify existing archetypes. In this step it is necessary to investigate the archetypes available in repositories, in our case the openEHR CKM, and select the best candidates for reuse. In case the candidate (or candidates) is a maximal data set for the purpose under consideration, it should be used as it is; otherwise changes would be required in the selected archetype.
3. If necessary, create new archetypes. In case there is no archetype suitable for the concept in question, a new archetype should be created. The procedure for archetype creation, according to the authors:
 - (a) Gather the content.
 - (b) Organise the content, identifying e.g. purpose, data elements, and coding/terminology issues.
 - (c) Choose the archetype class, namely: *entry*, for clinical concepts of the categories described above; *composition*, for documents; or *section*, for document parts.
 - (d) Build the archetype, with the substeps: name the archetype, select the structure, add data types, add constraints, add meta data, and add terminology.
 - (e) Publish the archetype.

Leslie&Heard methodology concentrates on the creation of new archetypes and does not provide indications for archetype modification in general and for archetype specialisation in particular. This is somehow surprising since archetypes are designed to reflect as many use-cases as possible, leaving room for the required specialisations.

For the purposes of our experiment, in which archetype specialisation is expected to play an important role, we have followed the methodology below:

1. Review the guideline to determine all the clinical concepts to be archetyped. In PROforma this roughly amounts to filtering the concepts included as enquiry sources, actions, and decision candidates.
2. Create a mind map to identify the separate clinical concepts and to detect possible overlaps, according to the indications of Leslie&Heard methodology.
3. Classify the above concepts into the clinical concept categories of openEHR.
4. For each concept, search the CKM repository for suitable archetypes in the corresponding category:
 - (a) if an archetype is found, determine whether it should be used as it is or whether it should be specialised.
 - (b) if no archetypes are found, specify a new archetype following Leslie&Heard methodology.
5. Create the required archetype specialisations and/or new archetypes using a specific-purpose tool (e.g. Ocean Informatics¹ open-source archetype editor).
6. Validate both archetype specialisations and new archetypes, with the help of clinical experts.

Notice that this simplified methodology will be further developed as we proceed with the rest of the activities necessary for guideline system-EHR system coupling (see section 2.1). For instance, we are aware that important information on data abstraction can be collected during the process of concept identification (in step 2). With this aim, the mind maps we use are not limited to concepts in the electronic guideline but rather include related concepts obtained from the guideline text (and other sources), and show abstraction relations. Abstractions can take several forms, e.g. logical or temporal expressions based on one or more data items. This is a crucial step since guidelines very often operate on data abstracted from lower-level EHR data.

5 Results

Next we describe the results of applying the above methodology to the design of a collection of archetypes to be used as part of an electronic guideline for the management of CHF. Except for the two last steps, i.e. archetype specialisation/building and archetype validation, all the steps have been fulfilled.

1. Review of the guideline to determine all the clinical concepts. In order to identify the clinical concepts necessary to support CHF management, and hence requiring archetypes, we have used as starting point the PROforma model of the guideline. As sketched before, we have focused on the PROforma elements enquiry, decision and action. Thus, data sources within enquiries suggest a related concept, e.g. *echocardio results* led to the corresponding concept “echocardio results”. Similarly, decision candidates and actions suggest some related concept. In this step we have identified 33 guideline concepts in total.

¹ See <http://www.oceaninformatics.com/>.

Table 1. Summary of results.

Entry	Guideline concept(s)	Concept(s)	openEHR archetype(s) ^a
Observation ^b	angioedema	angioedema	√...exam.v1
	cough	cough	√...exam.v1
	ECG_etc_results	ECG results, Xray results, Nat. pept. results	√...ecg.v1, √...imaging.v1, ~...lab.test.v1
	echocardio_results	echocardio results	√...imaging.v1
	fluid_retention	fluid retention	√...exam.v1
	postMI	postMI	√...story.v1
	recentMI	recentMI	√...story.v1
	state_revision_action	revision 24-48h. after treat.	√...exam.v1
Evaluation ^c	ACEI.intolerant.decision	ACEI intolerant	√...exclusion-medication.v1
	assess_CHF_action	assess CHF aethiology & type	√...problem-diagnosis.v1
	atrial.fibrillation	atrial fibrillation	√...problem-diagnosis.v1
	bronchial.hyperreactivity	bronchial hyperreactivity	√...problem-diagnosis.v1
	CHF.decompensation	CHF decompensation	√...problem-diagnosis.v1
	ECG_etc_results, echocardio_results	HF diagnosis	√...problem-diagnosis.v1
	fluid_retention	fluid retention	√...problem-diagnosis.v1
	hyperglycemia_unbalance	hyperglycemia unbalance	√...problem-diagnosis.v1
	hypoglycemia_unbalance	hypoglycemia unbalance	√...problem-diagnosis.v1
	improved.HF	improved HF	√...problem-diagnosis.v1
	infection	infection	√...problem-diagnosis.v1
	stage_decision	determine NYHA class	√...problem-diagnosis.v1
	state_revision_action	revision 24-48h. after treat.	√...clinical_synopsis.v1
	stenosis	renal artery stenosis	√...problem-diagnosis.v1
	still_symptomatic	still symptomatic HF	√...problem-diagnosis.v1
symptoms_severity	symptoms severity	√...problem-diagnosis.v1	
Instruction ^d	ACEI.action	ACEI medication	√...medication.v1
	aldosterone_antagonist_action	aldosterone antagonist medication	√...medication.v1
	ARB_action	ARB medication	√...medication.v1
	betablocker_action	betablocker medication	√...medication.v1
	cardiac_glycosides_action	cardiac glycosides medication	√...medication.v1
	CHF_fortnightly_follow_up_plan	14-days follow-up	√...follow.up.v1
	CHF_non_pharma_treatment_plan	no pharmacological treat.	~...non_drug_therapy.v1
	diuretics_action	diuretics medication	√...medication.v1
	ECG_Xray_Nat_peptides_action	ECG, Xray, Nat. pept. test	~...procedure.v1, √...imaging.v1, ~...request_lab_test.v1
	echocardio_action	echocardiography	√...imaging.v1
inotropic_support_action	inotropic support therapy	√...medication.v1	

^a Legend: √ archetypes used as they are, ~ requiring specialization.

^b Observation names have the prefix **openEHR-EHR-OBSERVATION**.

^c Evaluation names have the prefix **openEHR-EHR-EVALUATION**.

^d Instruction names have the prefix **openEHR-EHR-INSTRUCTION**.

An exception to the above general rule are the enquiries requesting an input from the physician where several options are acceptable according to the guideline. An example is *ARB_introduction*, which is a yes/no value that reflects the physician decision regarding the use of ARB drugs² as part of the therapy. This kind of enquiry sources do not correspond to established clinical concepts and therefore have not been considered for archotyping.

2. Creation of a mind map to identify separate clinical concepts. We have used a mind map to better visualise the concepts identified in the previous step, and also to make explicit the relationships among them. Here we have made use of on-line medical resources, in addition to the records of the interviews with the experts held during the modelling of the CHF guideline. As mentioned before, the mind map not only includes the concepts in the electronic guideline but also related concepts obtained from additional information resources.

An important guiding principle is explained next. If as a result of guideline execution some piece of information is relevant enough to be stored in the EHR system, then there must be necessarily an archetype for it, even though the electronic guideline does not explicitly model it. A notable example is an evaluation concept to represent whether the patient has CHF or not, which was not modelled in the guideline.

Additionally, in this process it became apparent that many guideline concepts in fact correspond to two different clinical concepts, typically observations and evaluations. For example, for the guideline concept *echocardio results* two concepts must be considered: a concept to hold the results of an echocardiography and a concept to represent the medical assessment of these results. Moreover, in many cases the guideline refers to a concept about a medical assessment but the observations/tests on which the assessment is based are not explicitly mentioned. This indicates an abstraction, as described in section 4.2. An example is the concept *hyperglycemia unbalance* which is based on a glucose blood test, among other things. Another example is *ACEI intolerant*, related to cough and angioedema, among other concepts.

3. Classification of clinical concepts into openEHR categories. At this point we have determined the type of entry for each different clinical concept, in preparation for the next step. Obviously, we have taken into account the guiding principle described above, and also the twofold consideration of certain guideline concepts both as observations and evaluations.

In this step we have identified a total of 40 archetypable concepts. The two first columns of table 1 show the results of the process up to this step.

4. Search the CKM repository for suitable archetypes. From the concepts of the previous step, we have used the search&browse utilities of the CKM repository to identify the most suitable archetypes. With this aim, we have used the documentation part of archetypes, specially the sections on purpose, use and misuse.

² Angiotensin receptor blockers.

Table 1 shows the results of this step. For clarity issues the table does not include the category document/composition, and hence the concept “patient discharge” is not listed.

We have found more or less specific archetypes for all of our concepts. In total 15 different archetypes have been selected for use in the CHF guideline. For simplicity, this number only includes the entry categories (observation, evaluation, instruction and action) and the composition one. The most frequent archetypes are `openEHR-EHR-EVALUATION.problem-diagnosis.v1` and `openEHR-EHR-INSTRUCTION.medication.v1`. We consider that the majority of the archetypes could be used as they are, and that only 5 of them would require specialisation. Although these results still have to be validated with the help of medical experts, we regard them as a very positive finding concerning the usability of openEHR archetypes.

6 Conclusions and future work

There is a general consensus about the fact that clinical guidelines should be deployed using some computer support and that this support should be integrated within the clinical information system, to take full advantage of the potential benefits of guidelines. However, currently one of the main obstacles to this integration is the interaction with the EHR system.

With the aim of solving the interoperability problems of guideline systems, we have investigated the utilisation of the openEHR standardisation proposal in the context of one of the existing guideline representation languages. Concretely, we have designed a collection of archetypes to be used within a CHF guideline. The main contribution of our work is the proposal itself, consisting in the utilisation of openEHR archetypes in the framework of guideline representation languages. Other contributions include both the concrete set of archetypes that we have selected and the methodological approach that we have followed to obtain it.

Most of the work has consisted in the identification of the clinical concepts involved in the guideline and the selection of suitable openEHR archetypes. The task has been more complex than expected because of the mismatch between the guideline concepts and the clinical concepts available in the openEHR repositories. A plausible explanation for this is that in most cases electronic guidelines are modelled as independent objects without taking into account deployment issues such as the interaction with EHR systems. To solve this problem we advocate for a completely different approach, namely modelling guidelines using EHR standards as a guide.

On the tool side, the openEHR repository has proven to be very useful in our experiment. Its web-based platform provides very powerful search&browse utilities and includes all sort of descriptions including e.g. tabular views, conceptual maps, etc. In addition, the documentation view includes very useful sections describing the purpose of the archetype, use or typical usage, and misuse or cases in which the archetype should not be used (with hints on which one to use instead). All this information refers to clinical aspects rather than to technical ones, which

is of great help for guideline modellers without a clinical background. On the archetype side, a very positive finding is the high percentage of reuse.

As future work, we plan to proceed with the experiment by validating the archetype design and specification with the help of clinicians, and using an archetype editor to actually create the required archetypes and specialisations. Important aspects related to these tasks will be the validation of the abstraction knowledge elicited during the concept identification step, as well as the adequate documentation of archetypes with this knowledge. With regard to the next steps to make possible the interaction between a guideline system and an EHR system, outlined in section 2.1, the most important issue to solve is the choice of technologies. With respect to the knowledge representation language to use, we have not yet ruled out representation languages different from PROforma, with execution engines that might be suitable for the kind of interactions used in the openEHR framework. Concerning the connection with the target EHR system, we are studying platforms allowing for a smooth interaction based on openEHR.

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