Archetype Modeling Methodology

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ABSTRACT

Clinical Information Models (CIMs) expressed as archetypes play an essential role in the design and development of current Electronic Health Record (EHR) information structures. Although there exist many experiences about using archetypes in the literature, a comprehensive and formal methodology for archetype modeling does not exist. Having a modeling methodology is essential to develop quality archetypes, in order to guide the development of EHR systems and to allow the semantic interoperability of health data. In this work, an archetype modeling methodology is proposed. This paper describes its phases, the inputs and outputs of each phase, and the involved participants and tools. It also includes the description of the possible strategies to organize the modeling process. The proposed methodology is inspired by existing best practices of CIMs, software and ontology development. The methodology has been applied and evaluated in regional and national EHR projects. The application of the methodology provided useful feedback and improvements, and confirmed its advantages. The conclusion of this work is that having a formal methodology for archetype development facilitates the definition and adoption of interoperable archetypes, improves their quality, and facilitates their reuse among different information systems and EHR projects. Moreover, the proposed methodology can be also a reference for CIMs development using any other formalism.

ABBREVIATIONS:

ADL: Archetype Definition Language

AM: Archetype Model

AMM: Archetype Modeling Methodology

CIM: Clinical Information Model

RM: Reference Model

1. INTRODUCTION

Accurate and comprehensive specification of information structures of Electronic Health Record (EHR) systems is a major objective in the medical informatics field. Researchers, developers, and governments have provided different methodologies, standards, and regulations, in their attempt to formalize the documentation of health care activities and data generated in the clinical domain, and to make it semantically interoperable [1–6]. One of the main problems is dealing with the complexity and diversity of health information. In the search for solutions for this problem, three main artefacts emerged: EHR reference models, clinical information models (CIMs), and medical terminologies or ontologies [7].

EHR reference models define generic data structures to represent the common characteristics of health data. They do not provide a complex and detailed model to deal with specific data, but a generic framework to store and process any kind of EHR data. Examples are the standards HL7 CDA [8], ISO 13606 – Part 1 [9], or openEHR Reference Model [10].

CIMs define data structures for specific scenarios of use. In this paper, CIM is used as the generic term that encompasses any clinical domain-oriented specification defining how to organize clinical information, and how to use it inside an EHR system, EHR repository or for EHR communication. Archetypes, templates, detailed clinical models, profiles, or resources are examples of different CIM technical approaches used by existing EHR standards and specifications.

Medical terminologies and ontologies help in defining and organizing the vocabulary and relationships between concepts used in the medical domain. They provide mechanisms for the formalization of the model of meaning of EHR systems [11].

An example of the concurrent use of the three artefacts is the dual model architecture [12]. The dual model architecture has gained recognition during the last decade as an important contribution towards semantic interoperability of the EHR. ISO 13606 standard, openEHR specifications and the Clinical Information Modeling Initiative (CIMI) [13] are examples of adoption of the dual model architecture.

A dual model architecture defines two different models. First, a generic Reference Model (RM) designed to represent the most basic properties and structures of any EHR. Second, an Archetype Model (AM). Archetypes define specific information structures to store or transfer data between EHR systems, i.e. archetypes are a particular implementation of CIMs. Finally,

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terminologies are used together with the RM and the archetypes to provide an unambiguous definition of the semantics of the data structures and coded data values.

As we will explain in the next section, two of the aforementioned artefacts already have mature methodologies guiding their development. EHR reference models, when implemented as software, follow existing software engineering and logical database definition methodologies [14–20]. There are also several development methodologies for creating terminologies and ontologies [21–25]. However, CIMs, and in particular archetypes, lack a well stablished methodology for their development, as concluded in a previous study [26].

Clinical experts are usually in charge of developing archetypes in the scope of a local, regional or national EHR project, where archetypes provide a formal description of the clinical information to be used or shared. The benefits of using an archetype modeling methodology are twofold. First, the methodology helps in the coordination of the development team, and provides a set of tools and strategies to ease and accelerate the development process. Second, it facilitates that archetypes created by different teams can be reused. Following ad hoc methodologies, archetype authors might produce archetypes that are only usable in their own projects, but not in other contexts. New archetypes might overlap, or be incompatible with existing ones. This is the result of considering archetype creation as a craft rather than an engineering process. To mitigate this problem, we need to provide archetype authors with specific and formal rules that guide archetype development and governance. A clear archetype modeling methodology is needed to define reusable and sound archetypes.

1.1. Objective

The objective of this paper is to describe a formal methodology for the modeling of archetypes, which encompasses best practices in the literature and the experience in related areas, such as software engineering and ontology definition. The methodology shall facilitate the creation of archetypes by clinical experts.

2. BACKGROUND

A characteristic of archetypes is to act as a mediator or interface between implementations of EHR systems, and medical terminologies. They are able to combine, in a single artefact, the specification of information structures, and their semantic description through medical terminologies. For example, a blood pressure archetype specifies the data elements that can be registered in the EHR (i.e. systolic and a diastolic values, both measured in

mmHg, and greater than or equal to zero). At the same time, the blood pressure archetype incorporates the semantic definition of the data elements by adding mappings to medical terminologies (i.e. the archetype structure is mapped to SNOMED CT concepts 75367002 |Blood pressure (observable entity)|, 271650006 |Diastolic blood pressure (observable entity)|, and 271649006 |Systolic blood pressure (observable entity)|). Due to this close relationship, and in order to achieve meaningful results when building archetypes, archetype modeling methodologies should be aligned to the modeling of software, terminologies and ontologies.

Table 1 provides a short summary of methodologies that influence the design of an archetype modeling methodology. A more detailed description of the activities covered by each type of methodology is included in the following sections.

Methodology domain	Resulting artefact	Scope of the modeled artefact	Example artefacts	Example methodologies
Software modeling	Data model	Model of the basic data structures of the EHR	ISO 13606 Reference Model OpenEHR Reference Model	Software engineering methodologies, data base methodologies, IEEE 1074 standard, ISO/IEC 12207 standard…
CIM modeling	Clinical Information model	Model of the domain-oriented information structures	ISO 13606 archetypes OpenEHR archetypes	Only partial experiences are found in the literature without describing the development methodology in detail
Ontology modeling	Concept model	Model of meaning including medical	SNOMED CT ICD-10 LOINC	UPON, On-To-Knowledge, TOVE, IDEF5, METHONTOLOGY…

		vocabularies, concept definitions and their relationships		

Table 1. Summary of modeling methodologies and their domain of use

2.1. Clinical information modeling methodologies

In a previous work [26] the authors published a systematic review of CIM development methodologies found in over 50 published papers. The conclusion of the systematic review was that a unified modeling methodology does not exist. Most of the existing CIM developments shared a similar approach, although only in few cases the authors clearly described the methodology followed. The identified common phases included the scope definition, the analysis of the information covered in the specific domain, the design of CIMs, the definition of implementable specifications, the validation of CIMs, and their publication and maintenance.

In the case of archetype modeling, the most relevant reference is the openEHR data modeling approach (ODMA) [27], a five step methodology used by some archetype authors. However, only a sparse description of the methodology steps is found in the literature. There is no detailed information about the complete methodology workflow, the expected inputs and outputs of each step, or about the required participants during the modeling process. Moreover, ODMA is focused to the development of openEHR archetypes and its tooling ecosystem, and not a generic archetype modeling methodology. All these factors limit the applicability of ODMA by other archetype authors.

2.2. Software development methodologies

Software development methodologies and software engineering provide a reliable reference for developing archetypes from a technical perspective. Archetypes are part of the software specifications of EHR systems since they constrain a particular object-oriented RM, i.e. a model that can be implemented in systems to store and communicate data instances. Thus, there is a direct relationship between archetypes and technical implementations of information systems, which in turns implies a relationship between archetype modeling and software development.

There are many software development methodologies. For example, the traditional waterfall model [14], the incremental build model [15], the spiral model [16], or the more recent

agile software development methodologies [17]. Beyond their specific differences, they share common development phases: requirements analysis, functional and technical design, implementation, testing and installation. Several standards have formalized the process of software development. One of them is the IEEE 1074 standard for developing a software project life cycle process [18]. It provides a basic common framework to be followed by any specific software development methodology. Similarly, the ISO/IEC 12207 standard [19] establishes guidance for software life cycle processes, activities and tasks during the development, operation, maintenance and disposal of software products.

It is also worth mentioning logical database modeling [20], whose objective is to define the most optimal and detailed data model of a database. This includes identifying entities, their attributes, relationships between the entities, and normalizing the data model. These activities are also relevant for archetype modeling.

2.3. Ontological modeling methodologies

There are several examples of ontology development methodologies. For example, the United Process for Ontologies (UPON) [21], On-To-Knowledge [22], TOVE project [23], IDEF5 [24], or METHONTOLOGY [25].

The objective of these methodologies is to provide guidelines about the specification, conceptualization, formalization and implementation of ontologies. They share the following phases:

1. Specification of the scenario and scope, mentioned in all the analyzed methodologies [21–25]. This phase establishes the purpose, context, and scenarios of use of the ontology to be developed.
2. Knowledge acquisition, mentioned in [21,22,24,25]. It includes the collection of relevant data, documentation and existing ontologies in order to analyze, and refine the ontology requirements.
3. Conceptualization. It consists on the structuration of the domain knowledge in terms of concepts, attributes and relationships. It also includes the development of a terminology or glossary of terms for the ontology. All the analyzed ontology methodologies include this phase.
4. Implementation. In this phase, the ontology is encoded using a formal language such as OWL. It requires the use of a development environment with editors, syntactic analyzers, and validators that help in detecting inconsistencies or redundant knowledge. Again, all the studied methodologies include this phase.

5. Evaluation, mentioned in [21,22,24,25]. The evaluation phase guarantees that the ontology is fit for purpose, and that it meets all the initial requirements. It may also evaluate the syntactic and semantic quality of the ontology.

In addition to these activities, only one methodology [22] mentions the application of the ontologies and their future evolution and maintenance. It is also the only one to mention the tools and participants in the ontology development process.

3. METHODS

The methodologies described in the background section were used as an initial reference for our development. Learning from existing good practices in modeling clinical information models, information structures, and ontologies helped in setting the initial main phases of our archetype modeling methodology. This helped to align our archetype modeling methodology to the modeling of other health information artefacts. Since all these artefacts work coordinately inside information systems, it is recommendable that they follow the same design principles.

We adapted the methodology to the specific needs and characteristics of archetypes, and their development process. We present a comprehensive list of requirements covered by the methodology. These requirements are inherent to the archetype approach, as described in [12].

- Archetypes are built according to an underlying RM. Archetype authors must take into account the underlying structure and the contextual information already supported by the RM when creating archetypes.
- Ensure that the archetypes represent all or most of the information required in the proposed scenarios of use.
- Facilitate the creation of reusable archetypes. An archetype definition should be sufficiently generic to be reusable in other scenarios. Afterwards, archetypes can be modified by specialization and versioning in order to meet specific requirements.
- Coordinate the concurrent use of archetypes and terminologies. Terminologies are used to define the semantics of the archetype structure itself, and to define the valid values for coded data. Guidance on how to combine archetypes and terminologies should be provided.

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- Support the participation of technical and clinical specialist in the modeling process. Building archetypes is a multidisciplinary task. It requires the participation of experts on the medical domain and experts on the technical standards used. An archetype development methodology should define the role of the participants.

- Templates are particular types of archetypes for specific use cases. While archetypes provide generic and reusable definitions of the information model, templates define specific configurations of archetypes. The definition of templates has to be covered by the methodology.

Additionally, we can find the following requirements in the literature.

- Guarantee archetype quality [28]. *Menárguez-Tortosa et al.* [29] analyzed the quality of existing archetypes and concluded that "around 1/5 of archetype specializations contain modeling errors, the most common mistakes being related to coded terms and terminological bindings. […] This result reinforces the need for making serious efforts in improving archetype design processes".

- Establish the relationship between archetype modeling and archetype governance. Archetype governance includes the set of policies, actions, and tools to ensure that archetypes can be identified, stored, searched, and that they can evolve to meet new requirements. The relationship between archetypes, and between archetypes and other semantic EHR resources (terminology value sets or clinical guidelines for example) has to be properly managed to guarantee an ecosystem of quality interoperability assets [30,31]. Although this paper does not cover archetype governance, it wraps our archetype development methodology proposal.

The methodology described in the following section is the result of years of practical development of archetypes in regional and national EHR projects. The development of the methodology is based on an iterative trial and error approach. Each implementation experience served to learn about the limitations of the methodology that triggered the definition of improved versions.

4. RESULTS: ARCHETYPE MODELING METHODOLOGY

We present an Archetype Modeling Methodology (AMM) that formally defines the common phases and good practices to follow when developing archetypes. The methodology also covers two fundamental aspects for the success of archetype development: the selection

of the group of people participating in the modeling process, and the need of using design guidelines to guarantee the consistence of the outcomes.

4.1. Work group

Success of archetype modeling depends on the group of people involved in the process. Archetypes can be used in multiple settings, potentially serving multiple healthcare specialties. A good archetype design team should include, at least, health professionals providing knowledge about different domains of use, experts in clinical terminologies, and technical professionals who are familiar to the RM and the archetype tooling. The following members should be part of the archetype modeling group:

- Group leader. Person in charge of coordinating the work of the group and responsible of governing the archetype modeling process. Preferably, the group leader should have a clinical profile, with also some technical skills and knowledge of the archetype development process. Archetype modeling requires reaching a consensus and harmonization of different needs and opinions. The group leader has to make a decision when discrepancies arise between the team members, to facilitate agreements between them.

- Clinical experts. They are the main responsible for providing inputs to the modeling process. They have to define the scope of the archetype, to collect information requirements, to document the sources of knowledge and references used, and to select the information items to be included in the archetype. In addition, they decide the structural organization of the information items, and the applicable data constraints.

- Terminology experts. Optionally, terminology experts provide inputs related to the use of terminologies in combination with archetypes. They are in charge of defining the semantic binding between the archetype structure and terminology codes. In addition, terminology experts are in charge of defining value sets used in coded information elements.

- Technical experts. Optionally, technical experts with expertise in EHR standards and EHR systems implementation can participate in the modeling process. Technical experts provide insights on the existing information systems. They also provide advice about difficulties or possible limitations for the implementation of the archetypes using a specific RM, and they can develop the final formal specification of archetypes.

- Multidisciplinary clinical support team. Additionally, a multidisciplinary group of clinicians from different knowledge areas should collaborate with the work group. They support the information gathering process and the evaluation process of the resulting archetypes, although they might not directly participate in the modeling process.

4.2. Selection of the Reference Model

In order to work with archetypes it is essential to choose the RM that will be the basis for their definition. Only ISO 13606 and openEHR work natively with archetypes. However, it has been demonstrated that it is possible to apply the dual model methodology to other standards, such as HL7 CDA or CDISC ODM [32]. Each of the RMs has its own technical characteristics and scope. The needs of the working scenario have to be studied to select the most appropriate standard in each case. However, it is possible that the RM is already decided by the local or organizational regulations.

4.3. Design guidelines

A design guideline describes the general rules, best practices, and common agreements to ensure a consistent development of archetypes at a national, regional or organizational level. Archetype design guidelines specify common rules on how to name archetype nodes, how to create commonly used data structures, or how to specify the preferred reference terminologies. Guidelines may also describe the policy followed to achieve consensus during the development of archetypes. In addition, the use of appropriate tools such as archetype editors [32,33] can support the development process of archetypes and facilitate the achievement of a consistent modeling. Following design guidelines facilitates the maintenance, reuse and interoperability of archetypes in broader contexts. The group leader is in charge of developing new guidelines, or selecting existing ones. Members of the work group should be familiar with the guidelines before defining archetypes.

4.4. Methodology phases

AMM is a 5-phase methodology that covers the modeling process of archetypes, from the requirements analysis, to the publication of the result archetypes. The phases are analysis, design, development, validation, and publication. The phases are divided into activities. Each activity includes a description of the tasks, the needed inputs, expected outputs, the tools used, and the participants. The only specialized software needed is an archetype editor, which facilitates the archetype implementation phase.
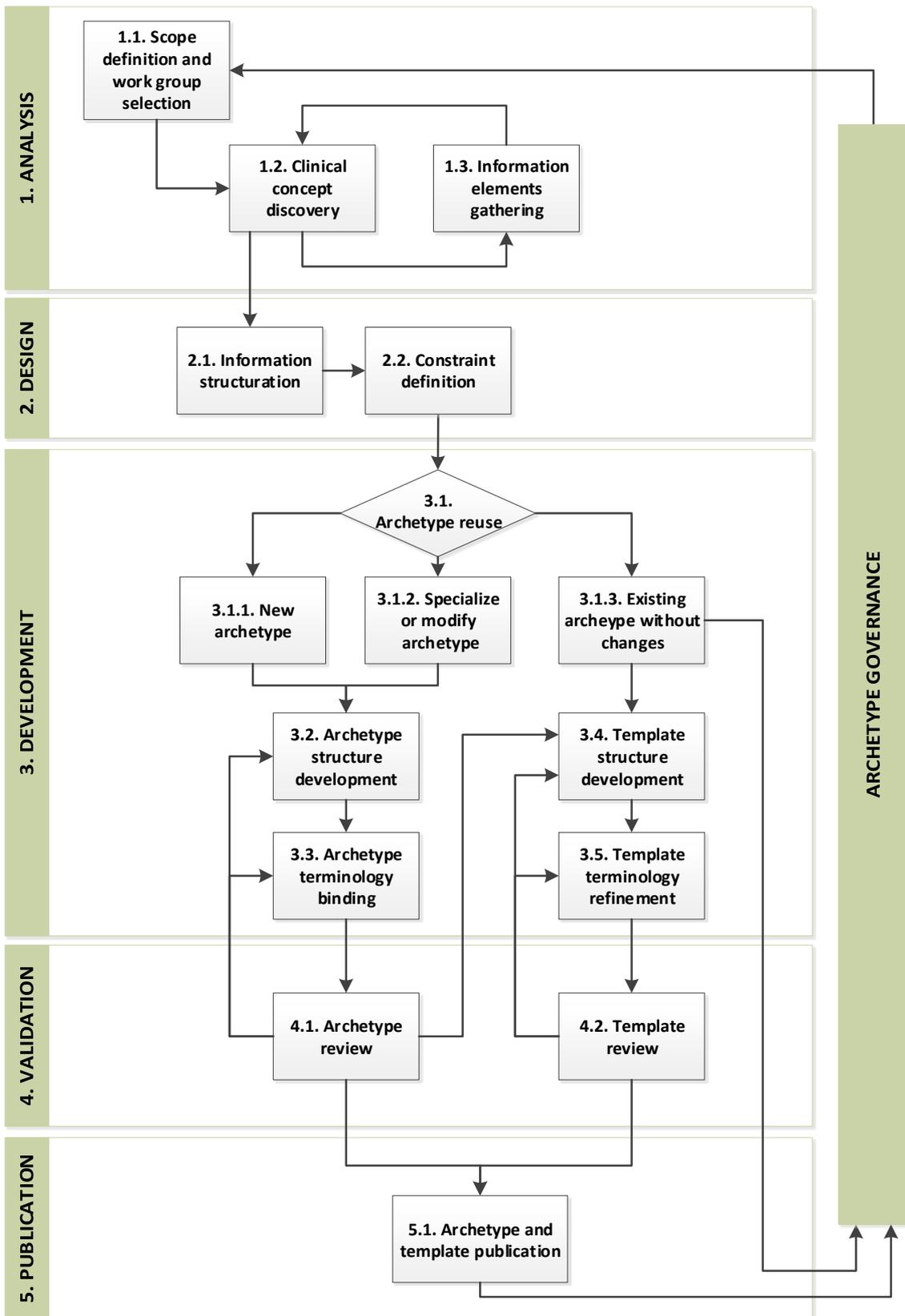
Figure 1. Graphic summary of the Archetype Modeling Methodology workflow

Phase 1. Analysis

The modeling process starts when a promoter, usually a health professional or organization, requires building archetypes to support the information used or registered in a specific domain. The objective of the analysis phase is to delimitate the scope, requirements and use cases of the clinical domain to be modeled. An additional objective is to identify the coarse-grained clinical concepts involved, and gather relevant information for the design phase. Figure 2 shows a simplified example of the results of this analysis phase in the form of a mind map representing medication information.
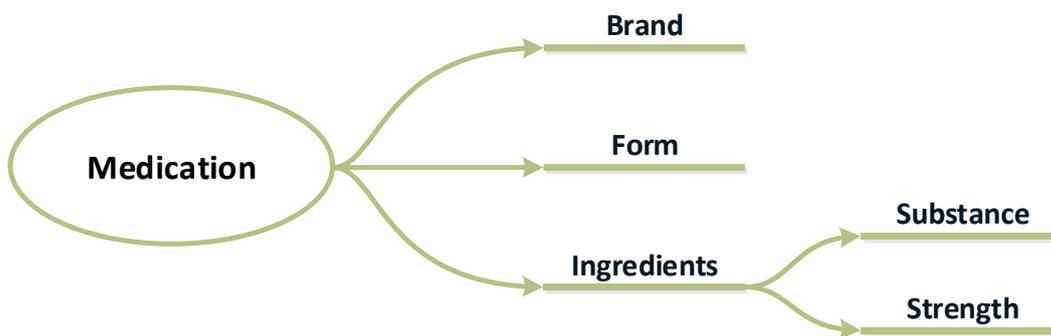

Figure 2. A mind map can easily represent the set of concepts and information elements discovered during the analysis phase

- Activity 1.1. Scope definition and work group selection
    - o **Inputs**: A request for modeling clinical information in a specific domain.
    - o **Outputs**: Initial analysis document. It includes, at least, the scope of the work, the expected uses of the information, the involved information systems and care settings, and the list of members of the work group.
    - o **Description of the activity**: The first task is the definition of the precise scope of the archetypes. A limited scope may result in a set of archetypes only usable in a very particular scenario. A broad scope may end in a large set of archetypes defined simultaneously, hindering the overall definition process. The promoter and the leader of the modeling work have to define precisely the limits of the scope and use cases to be covered. Then, the members of the work group are selected with a multidisciplinary perspective. The participation of experts in the domain of study is essential to gain specialized knowledge about the requirements, but it is also important to incorporate experts from other fields that can offer new perspectives over the problem under study. Finally, it is convenient to

provide a first list of information systems and care settings where the archetypes are expected to be used.

- o **Participants**: Promoter of the modeling process, group leader.
- o **Tools**: Text editor.

- Activity 1.2. Clinical concept discovery
    - o **Inputs:** Document with the analysis of the scope, requirements, and use cases for the archetypes.
    - o **Outputs:** Document with the list of clinical concepts involved in the scenarios of use, including the name of each clinical concept, and a short description of it.
    - o **Description of the activity:** The objective is to provide a name and describe all the clinical concepts that are relevant for each use case. Clinical concepts are generic groups of related information involved in the modeled scenarios of use. They do not necessary have a one-to-one match to the archetypes designed in the next phase, which may be influenced by the internal architecture of the selected RM. Multiple archetypes can potentially be derived from a single concept during the design phase. The set of identified clinical concepts must cover the complete scope and requirements defined in activity 1.1.
    - o **Participants:** Group leader, clinical experts.
    - o **Tools:** Text editor, spreadsheet, mind map.

- Activity 1.3. Information elements gathering
    - o **Inputs:** Document with the list of clinical concepts.
    - o **Outputs:** Document with the list of information elements associated to each clinical concept.
    - o **Description of the activity:** The objective of this activity is to collect the list of specific information elements associated to each clinical concept. Information elements are atomic clinical data items registered in the EHR or used in the modeled scenario. Clinical experts' knowledge and expertise is essential to analyze existing documentation, bibliography, data entry forms, data interchange messages, data structures (databases, information systems, etc.) related to the scope of each clinical concept. They have to decide which data is needed at different healthcare levels (primary care, specialized care, emergency care, clinical research, etc.), or requested by different users or roles (clinicians, nurses, researchers, administrative staff,

etc.). The result will be a collection of information elements that will be part of the archetype definition.

- o **Participants:** Group leader, clinical experts.
- o **Tools:** Bibliography, documentation of existing information systems, text editor, spreadsheet, mind map.

Phase 2. Design

Once the scope of the modeling process is clear, and the clinical concepts and information elements involved are identified, the information has to be organized and structured. The constraints on data values are also defined. Figure 3 shows the simplified design table for the medication archetype.

Archetype description						
Name	Medication					
Description	Information about a medication					
Recommended use	Used together with medication prescription and administration instructions					
Leader						
Participants						

Archetype design					
Information element	Description	Mandatory	Repeateable	Class/Data type	Domain
Medication name	Commercial brand	Yes	No	Free or coded text	
Generic name		Yes	No	Coded value	SNOMED CT
Form	Presentation. E.g. tablets	Yes	No	Coded value	SNOMED CT
Active ingredients	Add one group per each ingredient	No	1..*	Organizer	
Substance name		No	No	Free or coded text	
Strength		No	No	Physical quantity	>0, UCUM
Additional details		No	No	Free text	

Figure 3. Example of a design table created during Phase 2

- Activity 2.1. Information structuration
  - o **Inputs:** Document with list of clinical concepts and information elements.
  - o **Outputs:** Document with the archetype structural design.
  - o **Description of the activity:** An aggregation of the information elements is needed to create meaningful archetypes. Aggregations might correspond, or not, to the originally identified clinical concepts. For example, two different clinical concepts may not have much sense as standalone archetypes, and may be modeled as part of the same archetype. Each designed archetype will have a name, purpose, the list of information elements included, and how they are structured and organized. It is recommended, although not mandatory, to be as much aligned as possible to the RM chosen for the final implementation. Each RM imposes a basic

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structure for the data with a particular meaning and purpose. For example, ISO 13606 defines Compositions, Sections, Entries, Clusters and Elements as the basic building blocks of the information structures. Data structures should be compliant with the underlying RM. It is also possible to design the archetype in a generic way, without specifying RM classes, and only include the RM structures during the following development phase. The results of the activity will be the main reference to build the final archetypes.

- o **Participants:** Group leader, clinical experts.
- o **Tools:** Text editor, spreadsheet, mind map.
- Activity 2.2. Constraint definition
  - o **Inputs:** Document with the archetype structural design.
  - o **Outputs:** Document with the complete archetype design specifications, including data constraints for each information element.
  - o **Description of the activity:** The archetype structure is refined by including information about the constraints applicable to data elements, such as occurrences, cardinality, or data types of each element. Data constraints applicable to data values are also specified: ranges for numerical values, valid alternatives or fixed values for texts and string values, or lists of terminologies that can be used to record data for coded values. The constraints and classes defined by the underlying RM could be considered, for example to decide the data types of each information element.
  - o **Participants:** Group leader, clinical experts.
  - o **Tools:** Text editor, spreadsheet, mind map.

Phase 3. Development

The development phase, is focused on the creation of the actual archetypes, using the appropriate technology and tools, such as the Archetype Definition Language (ADL) [34], archetype editors, and terminology services. New archetypes might be created, or existing ones might be reused or adapted if needed. Local configurations of archetypes (templates) might be also created in order to fit specific requirements. Figure 4 shows a medication archetype, as the result of the development phase.

ENTRY [at0000] - Medication {1}
- ELEMENT [at0001] - Medication brand {1}
  - CODED_TEXT [at0002] - CODED_TEXT {1}
- ELEMENT [at0003] - Generic name {1}
  - CV [at0004] - CV {1}
- ELEMENT [at0005] - Form {1}
  - CV [at0016] - CV {1}
- CLUSTER [at0006] - Active ingredients {1..*}
  - ELEMENT [at0008] - Substance name {1}
    - CODED_TEXT [at0015] - CODED_TEXT {1}
  - ELEMENT [at0009] - Strength {1}
    - PQ [at0012] - PQ {1}
- ELEMENT [at0010] - Additional details {0..1}
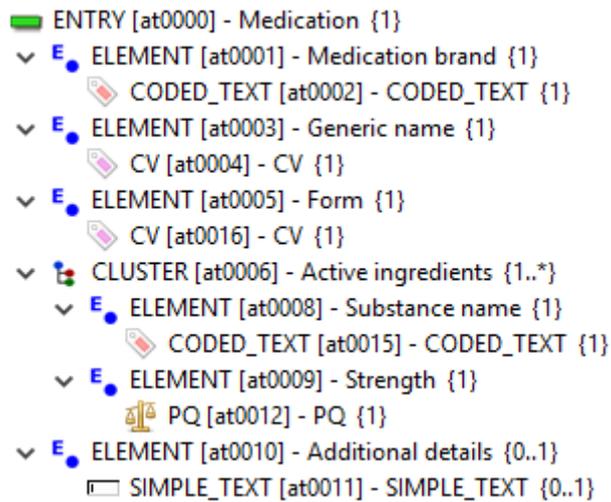 - SIMPLE_TEXT [at0011] - SIMPLE_TEXT {0..1}

Figure 4. Information structure of a medication archetype implemented in ISO 13606. Each of the nodes of the archetype, and the coded values, can be internally bound to terminologies.

- Activity 3.1. Archetype reuse
  - **Inputs:** Document with the complete archetype design specifications.
  - **Outputs:** List of existing reusable archetypes, either completely or needing modifications, and new archetypes to be developed from scratch.
  - **Description of the activity:** The aim of this activity is to select the set of reusable existing archetypes, and list the new ones to be defined. Archetypes related to the scope of our modeling scenario were probably studied during the phase of Analysis, since they are also a source of information and knowledge. It is probable that some existing archetypes fit in our information models with no additional changes (activity 3.1.3). If it is not the case, new archetypes can be created (activity 3.1.1), or adapted by specialization or versioning (activity 3.1.2). Not all the information present in the archetype design specification may become part of the final archetype, as the RM usually already contains most of the common contextual information related to the health care process. Technical experts will identify which information elements do not have to be represented explicitly in the archetype structure.
  - **Participants:** Group leader, technical experts.
  - **Tools:** Archetype repositories.
- Activity 3.2. Archetype structure development

o **Inputs:** Document with the complete archetype design specifications, list of existing and reusable archetypes, and list of new archetypes to be developed.

o **Outputs:** Set of archetypes implemented in a formal archetype definition language.

o **Description of the activity:** This activity is executed for each of the archetypes to be developed or adapted. Archetypes can be implemented using a specific formal language such as ADL. It facilitates defining all the constraints and structure of an archetype using a well-defined syntax. To ease the implementation process, specific tools such as an archetype editor can be used. In this activity, it is required to be strictly compliant with the RM selected. Building an archetype starts by choosing its root class. The root class will limit the valid nested information elements, which will be structured and constrained according to the RM. This includes deciding about the best matching between the information model specifications and the classes and structures imposed by the RM. All constraints over data values have to be included in the archetype implementation. In addition, a name and description of all information elements using natural language has to be provided. The metadata of the archetype (authors, expected use, keywords, etc.) should be also defined. Clinical experts trained in the use of archetype editors and knowledgeable about the RM can perform the structure specification activity. However, given the complexity of health standards and RMs, it is recommendable that technical experts in the RM participate in the development.

o **Participants:** Clinical experts, technical experts.

o **Tools:** Archetype editor.

- Activity 3.3. Archetype terminology binding

o **Inputs:** Set of implemented archetype information structures.

o **Outputs:** Set of archetypes bound to terminologies.

o **Description of the activity:** Medical terminologies provide the semantics of archetypes. Archetypes are bound to terminologies in two ways. First, the model meaning binding or term binding, where a descriptive code is assigned to each information element of the archetype. Second, the value set binding or constrain binding, where valid value sets can be assigned to coded information elements. It is usually necessary to use specialized

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systems such as terminology servers, to help in building and managing value sets. An in-depth description of the work to be made with terminologies and how to create usable value sets aligned to archetypes is out of scope of this paper, but there are many references in the literature [11,35–38].

- o **Participants:** Terminology experts, clinical experts, technical experts.
- o **Tools:** Archetype editor, terminology services.

- Activity 3.4. Template structure development
    - o **Inputs:** Set of archetypes.
    - o **Outputs:** Set of templates.
    - o **Description of the activity:** Templates are a special type of archetypes that further constrain them for a particular setting. In other words, templates are archetypes configured for a local use, and not intended for general reuse. A template represents the most specific requirements of the initial scenarios of use. Templates focus on the usability of the information model rather than in its genericity and interoperability. The process of defining templates includes selecting existing archetypes and put them together in a broader information model (usually at the level of clinical documents). In a template, information elements that are not needed in a local scenario are removed. Other information elements may be further constrained.
    - o **Participants:** Clinical experts, technical experts.
    - o **Tools:** Archetype editor.

- Activity 3.5. Template terminology refinement
    - o **Inputs:** Set of templates.
    - o **Outputs:** Set of templates with refined terminology bindings.
    - o **Description of the activity:** Templates can also refine terminology bindings. For example, in a particular template, a subset of the valid codes for an information element can be defined. Standard terms can be adapted to local vocabularies in use by the final users and systems.
    - o **Participants:** Terminology experts, clinical experts, technical experts.
    - o **Tools:** Archetype editor, terminology services.

Phase 4. Validation

The aim of the validation phase is to ensure that archetypes and templates meet the initial needs and requirements. The validation phase includes identifying errors, inconsistencies,

absences of information, or misleading specifications. If errors are found, archetypes or templates have to iterate again over the previous development phase.

- Activity 4.1. Archetype review
  - **Inputs:** Set of archetypes.
  - **Outputs:** Set of validated archetypes or list of needed changes. It will require a new iteration of the development activities.
  - **Description of the activity:** Automatic review and validation of archetypes is possible to some degree. It includes the validation of the information structure with regard to the underlying RM, and the consistency of terminology bindings [29]. However, an additional functional validation should be performed to check if archetypes are fit for purpose. Final users of the archetypes should be responsible of the functional validation. To facilitate the validation activity, technical complexity of archetypes and RMs models should be hidden as much as possible. This can be achieved by using alternative archetype representations, automatically generated from the specification, such as mind maps or data entry forms. If the participation of a selected group of final users is not possible, the multidisciplinary clinical support team can be responsible of the validation activity. Every comment or error notification about the archetypes should be registered, tracked and adequately resolved before deploying the archetype.
  - **Participants:** Group leader, clinical experts, multidisciplinary clinical support team, selected final users.
  - **Tools:** Archetype editor, issue-tracking system.
- Activity 4.2. Template review
  - **Inputs:** Set of templates.
  - **Outputs:** Set of validated templates or list of needed changes. It will require a new iteration of the development activities.
  - **Description of the activity:** This activity is equivalent to activity 4.1, but related to the review of templates. The same recommendations apply here, although the participation of end users is even more important, since templates will be closer user interfaces, and to the real implementation inside EHR systems.
  - **Participants:** Group leader, clinical experts, multidisciplinary clinical support team, selected final users.

Phase 5. Publication

The last phase of the methodology is the publication of archetypes and templates. The objective is to make them available for EHR systems developers, and to facilitate their reuse for creating new or specialized archetypes. Publication of archetypes and templates is closely related to archetype governance.

- Activity 5.1. Archetype and template publication
  - o   **Inputs:** Set of archetypes and templates.
  - o   **Outputs:** Published archetypes and templates.
  - o   **Description of the activity:** Publication of archetypes and templates means making them available to any user or system. The formal definition of archetypes (ADL) should be downloadable, editable and reusable. In some cases, the developers may apply restrictive or commercial licenses to archetypes. In that case, archetypes cannot be considered as part of an interoperable ecosystem, but only as a documentation of a particular implementation. Archetypes and templates in development (drafts) can be published in order to open them to a public review process, but in that case they have to be properly identified [39] and users should be warned about the potential risks of using those definitions in a real implementation.
  - o   **Participants:** Group leader.
  - o   **Tools:** Archetype repository.

A complementary phase: archetype governance

Archetype modeling is a process executed in the context of a broader governance process. Archetype governance is responsible, among other tasks, of maintaining published archetypes available, receiving change requests or new requirements, deciding about the deprecation or obsolescence of archetypes, or starting a new archetype modeling process.

Archetype governance can be also the best time for the localization of archetypes, i.e. the translation of archetypes to different languages. Translations should ideally be part of the development phase, but it is a costly process. It would be extremely difficult to translate archetypes to all existing languages at the same time. Moreover, during the development phase, archetypes could suffer modifications. Translation of archetypes involves a different group of

participants, with a major importance of linguists rather than clinical experts. Therefore, the translation of archetypes fits better in the governance process.

Governance use some tools and resources already used during the modeling phases, such as archetype repositories, and issue tracking systems. They help in recording and following-up new requirement requests or the notification of errors found on archetypes or templates.

5. APPLICATION

Development and testing of the AMM were performed simultaneously, based on an iterative trial and error approach. We used initial versions of AMM in small projects, where we could apply the methodology and test its practical value. The participants in the projects could accelerate the archetype creation process by applying the methodology, and define internal protocols to coordinate the development teams. Each of these projects provided insights on needed modifications and refinements of the methodology, which were tested in successive larger projects. The final version of AMM presented in this paper is a result of all these experiences. In this section, we summarize two relevant projects that contributed in formalizing the methodology.

The first version of AMM was stablished in 2011 in the regional EHR project of Valencia, Spain. The project objective was to develop a multi-purpose, archetype-based, clinical research database, aggregating clinical data from five million people. We did a requirements analysis, and developed the specifications of the contents of the research database in the form of ISO 13606 archetypes and HL7 CDA templates. During the analysis phase, only selected clinical experts from the regional health service participated. This resulted in the definition of very specific and hardly reusable archetypes, and showed the need of incorporating a multidisciplinary team of experts. We also learned about the need of developing a conceptual model first, instead of working directly with archetypes implemented in any of the two standards. Otherwise, the continuous changes in the archetypes would have made the project unsustainable. This also allowed avoiding the limitations imposed by EHR standards in design time. Finally, we learned about the importance of defining the information structures before working with the terminological aspects of the models to ease the development process. A terminology server was deployed to managed terminology subsets and mappings independently of the management of archetypes.

Between 2015 and 2017, the authors participated in the National Unified Electronic Health Record project (HCEN) for the National Health System of Uruguay. The aim of the project

was to build archetypes and implementation specifications of six clinical documents for the National Unified EHR system. The modeled documents were Patient summary, Primary care outpatient note, Hospital emergency service note, Non-centralized emergency service note, Discharge summary, and Dentistry note. We applied all phases of AMM, including a governance policy and a management system for the resulting archetypes.

The work group was composed by all the suggested profiles of AMM: a clinical group leader, a clinical experts group, a multidisciplinary clinical support team from the National Health System, a terminology expert in SNOMED CT, and a group of technical experts in HL7 CDA, and ISO 13606. All the members participated during different phases of the development, and covered all needs of the project. An additional group of final users of the developed specifications also participated to evaluate the results. This kind of final users was a valuable addition to the work group.

In Phase 1 (requirements), clinical experts studied existing documentation related to the use case. They included specifications from existing projects such as the Spanish National EHR specifications, the European epSOS specifications, openEHR archetypes, and the HL7 CDA Implementation Guide for IHE Health Story Consolidation.

In Phase 2 (design), clinical experts designed the information models correspondent to the six clinical documents. To facilitate this task, a template spreadsheet was designed to document the information elements. The spreadsheet allowed including the set of information elements, their naming, their structure, their data types (numbers, texts, dates, coded values…), their cardinality, and the applicable data constraints or code subsets.

In Phase 3 (development), technical experts converted the information model specifications into formal and standardized archetypes. They defined 41 ISO 13606 archetypes, 6 HL7 CDA implementation guides, and sample HL7 CDA data instances. The terminology expert defined SNOMED CT subsets to populate the possible values of coded information elements such as procedures, allergies and diagnosis. In addition, the terminology expert, with the support of the clinical experts, selected the appropriate terminological codes to map and describe the semantics of the information structure of the archetypes. A lesson learned was that it is important to maintain a continuous collaboration between technical and terminology experts during the whole development process. Such a collaboration minimizes the inconsistencies while developing archetypes that are bound to terminologies.

In Phase 4 (validation), we designed mockup data entry forms to simulate the data registry process in real clinical environments. Six health institutions, 60 health professionals and

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more than 120 patients participated in the evaluation process. The overall evaluation of the designed documents was positive, although they also provided suggestions and possible modifications for future revision of the archetypes.

In phase 5 (publication), all the generated materials and specifications, including the information model specifications, the ISO 13606 archetypes, and the HL7 CDA implementation guides were published in a governance system [40].

The project scope was limited to the definition of clinical and technical specifications of the six mentioned clinical documents. It will be responsibility of local health information systems implementers to include the new specifications into their future software developments.

6. DISCUSSION

In this paper, we have presented a formal methodology to guide the definition and implementation of archetypes. The adoption of archetypes and dual model architectures is entering into its maturity. However, in order to achieve a robust and stable archetype-based environment, it is fundamental to have a clear modeling methodology.

Archetype-based semantic interoperability requires using standard RMs, and medical terminologies to attach semantic descriptions to information structures. This would be enough to guarantee the faithful exchange and reuse of data and models among heterogeneous systems in a full semantic interoperability scenario. However, the lack of a homogeneous methodology for defining archetypes, and for governing them, burdens real semantic interoperability. Without such a methodology, different people or organizations might create different and incompatible archetypes for the same purpose. Archetypes might overlap or leave out portions of the information, limiting their reusability.

This work provides a standard methodology for archetype development. In order to measure the success of the methodology, we can analyze how well it covers all the aspects related to the development process, how much it follows established good practices, and which degree of adoption it reaches.

AMM can be compared to existing development methodologies of related areas, specifically, methodologies for the development of CIMs, software and ontologies. Table 2 shows a summary of this comparison.

Archetype modeling methodology	Development of clinical information models	Development of software	Development of ontologies
Analysis	Scope definition Selection of experts Analysis of domains	Identification of needs Functional requirements Technical requirements	Specification Knowledge acquisition
Design	Design	Architecture design Functional design Technical design	Conceptualization
Development	Definition	Implementation	Implementation
Validation	Validation	Testing	Evaluation
Publication	Publication	Installation	Application

Table 2. Comparison of AMM to CIM, software and ontology development methodologies

1. Analysis. All methodologies include a first phase related to the analysis of the general domain, the study of the specific use case, and the identification of requirements. In the case of development of CIMs, it includes the clear definition of the scope of use of CIMs. It also includes the analysis of the domain to acquire information of the existing systems and solutions. In the case of software development, the requirements are technical (related to implementation and performance issues) and functional (related to the inputs, outputs and behavior of the system). In the case of ontologies, the requirements phase establishes the objective and scenarios of use of the ontology. Finally, in AMM, this phase also includes the identification of clinical concepts and information elements.

2. Design. The goal is to completely describe and organize the contents identified during the analysis phase. The design phase of AMM, CIMs and ontologies is very similar. In software development, design is slightly different, since it covers three aspects: architecture, functional and technical design. It includes not only the information specifications, but also the expected behavior of the software and the global context of execution. In other words, software design covers a bigger scope than the design of archetypes.

3. Development. It is the process of actual development of the archetypes in a formal language. In the AMM it includes the development of the information structure and constraints using ADL language. The development phase also includes the selection of the controlled vocabularies (i.e. terminologies or value sets) used by the models. CIMs

definition phase has similar objectives. There are more differences with software development phase. The result of archetype development is a type of specification expressed in a formal language computable by EHR information systems. In contrast, the result of software development is the working system itself.

4. Validation. The objective of the validation phase is to confirm that the specified model covers all requirements and use cases previously identified. It is a common phase for all the mentioned methodologies, as it can detect errors generated during the development phase, or even requirements not considered initially.

5. Publication. The publication phase has some differences between the studied methodologies. In AMM and CIMs development, it consists in publishing archetypes and templates (or CIMs) to make them available for systems that can use the new models. In contrast, a deployed software or ontology is ready for use by the final users.

In summary, AMM phases align to other methodologies. There are, of course, differences related to the specific aspects and nature of archetypes, CIMs, software, and ontologies, but they do not affect the overall approach of the methodology.

Experts involved in the development of archetypes influence their final quality. For this reason, we have provided recommendations about the members of the work group. It is important to have a multidisciplinary group of clinical experts to ensure the genericity of archetypes. They will provide clinical documentation requirements for each of their specialties. It is also important to reach an agreement on the minimum common aspects and information elements included in the archetypes. Work group members should be trained in clinical information modeling and know about the benefits of building generic and reusable models. It is essential to maintain a stable group of trained professionals in archetype modeling, and to involve them in future developments or revisions of the archetypes, to maximize the quality of archetypes.

It is important to define a realistic scope for the modeled archetypes (activity 1.1.). Archetype modeling is a costly task. In many occasions, it may be preferable to define a basic but usable archetype, rather than trying to be exhaustive including information elements that cover any clinical scenario. Archetype versioning allows us to define basic versions of the archetypes first, and then review and complete them in future iterations of the modeling process.

AMM does not impose a specific order to act when there is a need to develop multiple archetypes. In that case, we can follow three possible approaches, namely top-down, bottom-up, and middle-out.

In the top-down approach, the most generic or coarse-grained concepts and information structures of the domain under study are first identified. They are analyzed to find specific structures that can be reuse in different places. The main problem with the top-down approach is that it usually leads to archetypes dependent on the requirements of the domain of study. Archetypes are usually closer to specific local requirements, i.e. they solve problems related to specific scenarios of use, as for example the definition of the contents of clinical documents or data entry screens. Moreover, in the top-down approach designers do not usually pay much attention to the future reuse of the archetypes.

The second approach is bottom-up. It consists on identifying the most basic information structures inside the EHR, and then composing complex structures reusing the basic ones. Bottom-up approach ensures a higher level of interoperability of the archetypes, since it starts designing generic and basic structures that serve to any purpose. However, it can also cause the creation of a large number of archetypes, which are not needed in other scenarios. Moreover, it is difficult to identify basic information structures without knowing the context where they will be used.

The third possibility is to follow a middle-out approach. It is a combination of the top-down and bottom-up approaches. In this approach, clinical statements needed in our case of study or usable in other scenarios are identified. A clinical statement is as a building block of the EHR that puts together the information that a human or a machine records, related to a common clinical context. I.e. what has been done, by whom, when, where and how it was done. It corresponds to the ENTRY class in ISO 13606; the OBSERVATION, EVALUATION, INSTRUCTION, and ACTION classes in openEHR; and to the clinical statements of HL7 CDA: Act, Observation, SubstanceAdministration, Supply, Procedure, Encounter, and Organizer. Once the clinical statements are identified, we can proceed downwards, defining the details of the information structure documenting the clinical statement; or upwards, defining templates that reuse clinical statements in configurations for specific scenarios of use.

Although all three approaches can lead to successful results, our experience suggests that the middle-out approach is the most efficient. It provides a good balance between genericity and specialization. Modeled archetypes are sufficient to represent all kind of information structures, without losing their reusability capabilities. Moreover, the middle-out

approach helps in distinguishing archetypes for generic scenarios of use, from templates designed for local uses.

One of the main challenges of archetype modeling is to manage the relationship to medical terminologies. During the design phase, the boundary problem between the information model (archetypes and the RM) and the knowledge model (clinical terminologies) may appear. The same information can be often represented as part of the archetype structure or as terminology concepts. Both can be correct representations of the clinical information models, and the decision made will affect how the registered information in the EHR systems can be reused. As a recommendation, AMM requires the definition of the archetype information structure (activity 3.2) before the definition of the terminology specifications and bindings (activity 3.3). Advanced terminologies, such as SNOMED CT, include a complete conceptual model, based on formal description logics, constraining the permitted attributes and values that may be applied to each kind of concept. However, this conceptual model is not enough to represent all the epistemological and contextual information to be documented during health care. EHR data standards and archetypes provide the basic framework to represent clinical data and its context information. They also define where terminologies should be used, and thus, they help defining the scope of terminology value sets. Value sets might not be aligned to data structures if their order of definition is swapped.

Governance of archetypes is deliberately left out of the AMM. The methodology is focused on the development of archetypes to fulfill specific requirements of a use case. The evolution of archetypes, their adaptation to new requirements, and the governance of the complete ecosystem of archetypes, requires a deeper study and the development of specific strategies that are out of scope of this paper. Examples of governance of archetypes can be found in the literature [40–42].

AMM methodology describes the archetype development process. However, the AMM methodology can also serve as a basis for the development of any other type of CIM, for example HL7 CDA templates or HL7 FHIR resources. Different technologies and tools may be used in each case, but the principles of analysis, design development, validation, and publication will remain the same.

7. CONCLUSION

Using CIMs as the basis for future-proof and semantically interoperable EHR systems is not a future promise, but a reality of current EHR standards and specifications. Archetypes, templates, profiles, or resources, are different names to refer to conceptually similar, yet technical different, solutions for building CIMs. The focus of the AMM methodology is building archetypes, although the methodology can be also of interest for building other types of CIMs.

The lack of a proper archetype modeling methodology limits the definition of quality-assured and interoperable archetypes. The proposed AMM methodology has taken into account the best practices from other development domains, and adapted them to the archetype characteristics. The use of AMM in several regional and national development projects has validated and refined the methodology. Nevertheless, our aim is to provide a reference methodology. Archetype designers and developers can adapt the proposed phases to meet some specific needs of a particular development project. For example, personal or technical resources involved in modeling a national EHR would not be the same as for modeling a local information system. However, they should follow the same basic design principles.

Further work includes a deeper exploration of the bidirectional influences between archetype development and terminology development. In addition, it is of interest to study the governance of archetypes. Finally, it is necessary to develop tooling to help and guide archetype development process. Using dedicated tools for archetype definition and governance will provide an engineering framework to assure the quality of the developments.

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