Specification of Medical Processes in Accordance with International Standards and Agreements

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Abstract

Models of healthcare processes and workflows to support continuity of healthcare are an important research topic in medical informatics. The research topic is driven by the necessity to enable systems interoperability, to see the consistency of clinical data recorded in electronic health records and understand retrospectively the clinical pathways that led to these data. In this workshop paper, we propose a processes meta-model and evaluate its potential usability in healthcare by modelling the healthcare concepts and models from the ISO 13940 (system of concepts to support continuity of care). Our meta-model is developed according to the software design patterns principles, enabling to formally specify knowledge in machine-readable form at run-time and also preserving the history of these specifications. We believe our work contributes to federated interoperability (without common models and standards) of healthcare information systems utilizing executable meta-models that can map healthcare data at the semantic (medical knowledge) level even at run-time.

Keywords – electronic health record, federated interoperability, clinical knowledge modelling, multi-layer process, health care workflow

1. Introduction

While healthcare costs are rising every year, governments and society constantly push hospitals to reduce their costs and improve efficiency. The current situation is further complicated by the fact that information systems in healthcare institutions have semantically heterogeneous data models, and the data files are unstructured. Since most medical institutions use their own standards, they are not interested in changing to another standard, and as a result, terminology between medical institutions is not consistent, which poses a significant barrier to interoperability. It is unwise to create a system based on a unified approach since it is impossible to expect all medical institutions will follow the same standards. Because of this, we work for the interoperability of federated systems and have developed ABC4HEDA, which is a Single Underlying Model [1] and software that enables the data owners to manage personal health records in a transparent and secure way. The syntax, semantics, & pragmatics-based three-level modelling is in use. ABC4HEDA holds all the data in the archetypes and archetype patterns (A&AP) based model (syntax). The A&AP model forms a domain-specific language (DSL) for specifying (not programming) all the existing and future developed medical standards and protocols declaratively (even at run-time) in an unambiguous and machine-readable form.

There is no semantic data model that can describe medical workflows and processes by restricting ourselves to a more narrow problem. As of now, there has been a significant effort made to store medical records electronically (EHR), yet the stored information does not reveal, for example, the reason why a blood sample was taken, why a drug was administered, or why treatment was administered. EHRs make it difficult for healthcare workers to determine clinical data consistency and understand in retrospect the clinical pathways that led to them. In the previous paragraph, we proposed a project that did not initially include a process model. The process model was developed as part of Dr Gunnar Piho's PhD thesis [2]. By abstracting Arlow and Neustadt's [3] client relationship management archetype pattern, the dissertation proposes a business process archetype model.

Our objective in this paper is to demonstrate how ABC4HEDA, developed based on best coding practices, is relevant to healthcare and can be used to specify the medical process. Given that ISO 13940 (system of concepts to support continuity of care) can describe medical processes and ABC4HEDA can specify required business processes, it is essential to validate that medical processes based on ISO 13940 can be stored in this processes meta-model. Therefore, the system requirements are vi-

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sualised using object diagrams, where the ISO 13940 term represents an instance, and the meta-models archetype represents a class. Using an object diagram is a type of static structure diagram that shows a complete or partial view of the structure of a modeled system (objects and their relationships) at a specific time.

2. Methodology

The methodology of this paper is Design Science [4], where the research object of this qualitative research is the design process. In the first step, we analyse information systems. We examine each concept scheme clause, taking into account both its definition and its related classes, based on the structure of the ISO 13940. The second step is systematic assessment, monitoring, and coordination of requirements. When the necessary steps are completed, the final results are validated by communicating with domain experts.

As a preliminary step towards meeting this work's objectives, ABC4HEDA meta-models were refined with unit and acceptance tests. About 120K lines of source code (including tests) has been written in the C# programming language, and 45% of this code consists of automated unit and acceptance tests to ensure 100% code coverage. Several design patterns have developed over the years in software development that we apply in our code, and they are helpful because they improve the efficiency and quality of the resulting software. Therefore, the architecture and coding practices are clean, and approximately 12% of the code is pure POCO (Plain Old CLR Object) (similar to the POJO (Plain Old Java Object)), which forms the computable domain model for the A&AP. Approximately 3% of the code implements repository and unit of work patterns for the platform-independent data persistent infrastructure. In this part, the Entity Framework Core as an O/RM (object-relational mapper) is in use. However, due to clean code and a clean architecture approach, the mapping can easily be replaced by another mapper (e.g. object-JSON) if needed. Approximately 40% of the code uses the latest ASP.NET Core and provides infrastructure and UI features for the management and operation. E.g., it allows for writing medical knowledge specifications in a declarative manner and therefore enables specification of the medical standards & other commonly used or custom-made specifications. Also, in case needed, this part allows replacing the ASP.NET Core quickly with any other framework that supports web presentation patterns.

The theory of this proposal lies in domain engineering, design patterns, and SUM principles. Two principal patterns, item description pattern and evolving systems pattern, are illustrated respectively in Figure 1 and Figure 2. According to the item description pattern, every concept (e.g., product, procedure, person and organisation, role and relationship, order, and rule) in this A&AP-based SUM meta-model has a specifiable run-time type (e.g., *ThreadType* and *ProcessType*, shown in Figure 1).

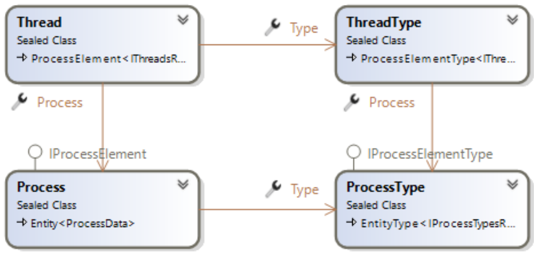

Figure 1: The item description pattern

Consider a situation where some clinical guideline specifies how and in what order particular healthcare actions should be performed. Suppose, for example, that medical science is evolving and the existing guidelines are revised. In the future, if they can perform some different kinds of healthcare actions, then it is necessary to change the information system. Instead of convening a team of developers to implement such changes to system requirements, entity types and specific rules can be added. In this way, since the requirements can be specified while the application is running, making changes is more secure, updating the source code is not required, and the application does not need to be restarted, so healthcare providers can continue working at the same time. The Zachman framework [5] enables us to formalise business aspects according to needs, also at run-time by asking what, how, who, where, when, and why questions.

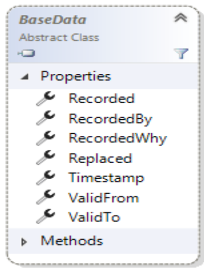

Figure 2: The systems evolving pattern

According to the systems evolving pattern (shown in Figure 2), every item and item type in the system, in addition to the *ValidFrom* and *ValidTo* date-time attributes for the items lifetime, includes also attributes (*Recorded*, *RecordedBy*, *RecordedWhy*, and *Replaced*) solely for the items recording, integrity, transparency and history preserving purposes. If an error occurs during the change of requirements and afterwards, the system does not work correctly, it is possible to trace the changes to a well-designed change management system. For every record in the system, we know who, when & why either entered, updated, or deleted a record. This information is globally immutable because of the global timestamp, and if needed, the previous data can be restored.

3. ISO 13940

The ISO 13940 standard, often referred to as ContSys, "*defines a system of concepts for different aspects of the provision of healthcare*" [6, p. 1]. According to this standard, the core business in healthcare is the interaction between subjects of care and healthcare professionals. Interactions such as these occur during healthcare/clinical processes, which explains why this International Standard takes a process-oriented approach.

The international standard contains definitions for approximately 150 concepts and their inter-relations using UML (Unified Modelling Language). The concepts cover the following eight topics healthcare actors, healthcare matters, activities, process, healthcare planning, time, responsibilities, and information management. The concepts give a basis for both content and context in healthcare services, and in practice, the standard is aimed to be used whenever healthcare information requirements are specified.

The recent overview of how the ISO 13940 concepts are understood and applied in healthcare systems is analysed in [7]. This standard is seen as a domain description applicable to all healthcare provider procedures. Even though it is designed to support the care process, the standard does not define it, nor does it have any regulatory impact on care delivery.

The recent overview outlines how the standard defines the usage contexts for Clinical Element Models (CEM), like problem lists, health issues, and health issue threads. CEMs are similar to detailed clinical models and archetype models, and are used to model 'assertive' information, e.g., "to assert that the patient has [x]." These assertions can be expressed in multiple contexts, such as discharge diagnoses, cause of death, complication of surgery, problem list. Transformation of the assertive information between contexts using should ideally be lossless. The work discusses the importance of having an "implementation layer", which means that the logical models are not compiled directly into the artifacts used in an implemented system, but instead "implementation models" would be used as a buffer between the logical models and the system implementation. This would allow not only context-dependent transformations of the assertive information, but would also allow implementation-specific transformations like performance optimization.

As the contexts enumerated in this standard should be universally applicable, it can be seen that this approach has the potential to be used for integrating assertive clinical information also on an inter-organizational level. The research also points to successful results, where incorporating organizational context into the information model allowed the authors to integrate elements from different data sources with identical meaning, facilitate the definition of Data Quality metrics regardless of the overall level of analysis required for reuse, and also incorporate clinical researchers into the construction process. As a result of contextualising the data with the ISO 13940 concepts enabled the replication of the methodology and its use in multi-centre population studies, even with different organizational contexts.

4. Process archetype pattern

Process archetype pattern [2], shown in Figure 3, is designed by abstracting Arlow and Neustadt's [3] client relationship management archetype pattern. It describes the dynamics of the processes through a series of reports and feedback. More reports from trusted and different parties give a better picture of the whole process as a dynamic phenomenon. Planning business processes can also be accomplished with the business process archetype pattern. By comparing actual reports (feedback on what has happened in the past), expected future reports, and plans (business processes that we hope to accomplish in the future), we can monitor the adequacy and reality of the plans and adjust the plans if necessary.

The important aspect is to ensure that information is consistent across layers and, similarly to Lagos [8], our business processes are modeled as sequences of communications. Most of the ABC4HEDA software model is based on Arlow & Neustadt business archetypes, which allows responding to all the questions in the Zachman framework. While A&N business archetypes don't define a specific pattern for managing business processes, they describe how to manage relationships between parties through a CRM (Customer Relationship Management) archetype pattern. In a similar manner but with further development of the pattern, we have created the business process archetype pattern on top of the party relationship archetype pattern.

A healthcare professional's position in their field may change, but concerning the meta-models, it is essential to note that we emphasize the relationships and roles of all relevant parties. The term party relationship refers to the semantic relationship between two parties within which each plays a particular role. Consequently, every binary relationship between precisely two parties can be broken into two or more binary relationships. Thus, multiple healthcare professionals may have multiple patients.

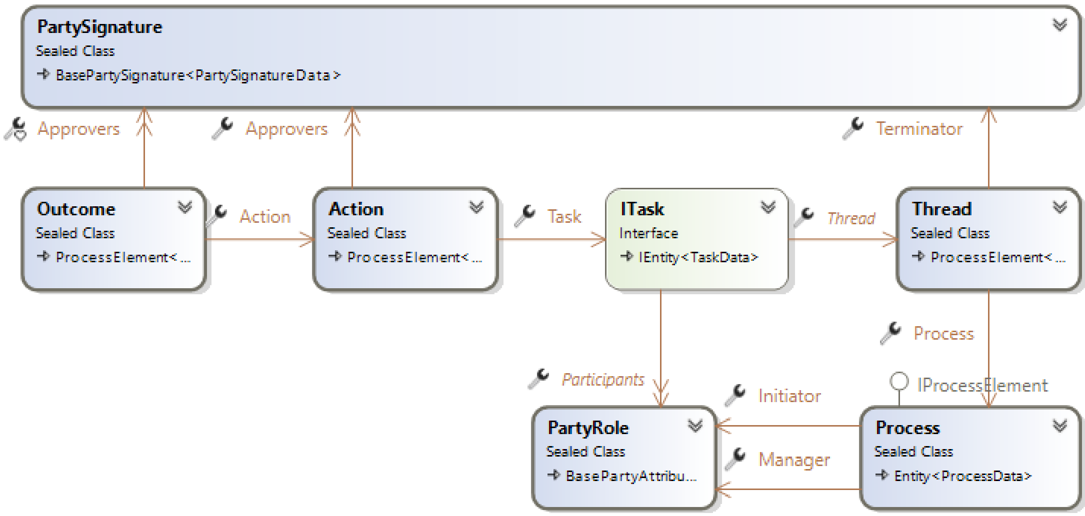

Figure 3: The business process archetype pattern

Healthcare professionals can hold multiple positions or roles during their term of office. When changing roles, for example, a GP registrar becomes a General Practitioner, the party is assigned a new role on the date of employment using the *ValidTo* attribute. Similarly, when one of the roles has been completed, the *ValidTo* attribute will be added, according to aforementioned systems evolving pattern.

The process archetype pattern strongly correlates with the party relationship archetype pattern. A business process always describes a relationship between two parties. One party is conditionally in the role of supervisor (consumer) and the other in the role of reporting party (provider). Each *Task* is a relationship between the parties involving at least two roles. The task archetype of the process archetype pattern, shown in Figure 4, illustrates the usage of the item description pattern by Coad [9]. Although mainly it describes the relationship between the two parties, many others can participate, and all parties can be changed using constraints (*RelationshipConstraint*) and rules (*RuleSet*). In addition, *TaskRouting* enables to transfer of the *Task* to another party.

Each business process consists of one or more subprocesses (*Thread*) described by a type (*ThreadType*). The allowed sub-processes of a business process are specified in the business process type (*ProcessType*). One and the same business process can contain more than one subprocess (*Thread*), and each sub-process can consist of more than one *Task*. Each *Task* can include one or more *Actions*, and each *Action* can have multiple *Outcomes*. Business processes always have an *Outcome*, which is reflected in the company's accounts (or to clarify the results in a medical facility, then in the patient's medical record or in the results of laboratory tests). For this reason, each *Outcome* might also be registered according to the patterns of the inventory or order archetype, similarly to Berry [10].

Business processes often require approval of certain activities, which can only be approved by authorized parties. Such confirmations use the party signature (*PartySignature*) archetype. Estonia, for example, has five different types of licenses for providing various medical services under the Health Care Services Organization Act. Intelligibly, there must be legal coordination between the parties. The activity license signed by a responsible party grants permission to provide health care services on the activity site at that business location.

Because business processes are different and can often be changed, the business process archetype is manageable. By using the rule (*RuleSet* and *RuleContext*) archetypes, we can formally describe and manage the various business requirements used in business processes.

5. Specification of medical processes

System requirements are represented in this chapter as object diagrams, such that ISO 13940 terms are instances and ABC4HEDA meta-models archetypes are classes. The description of the terms is based on the ISO technical document [6].

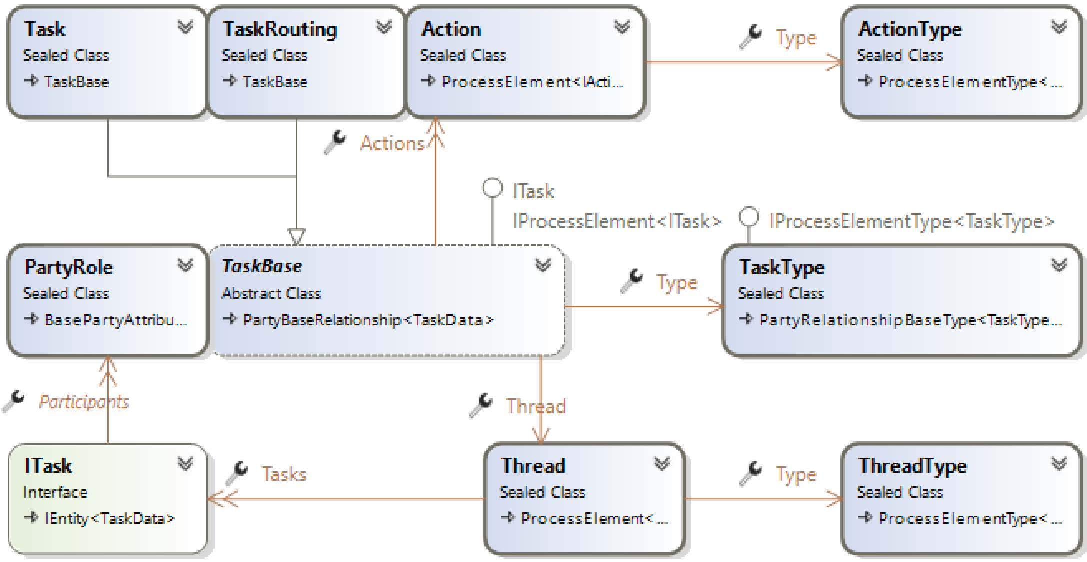

Figure 4: The task archetype pattern

The core of a patient's treatment is a dynamic, personalised care plan (shown in the Figure 5). In the business process model, it is described as a *Task*, which includes several links to other elements in the process model and in the ContSys terminology. Multiple care plans can address multiple health threads. The ISO standard describes a health thread as a defined association between healthcare matters as determined by one or more healthcare actors. In the process model, we consider this as a health care episode, which means this is described as a *Thread*. The first episode of healthcare may be related, for example, to a family doctor, where activities related to the patient's complaints and medical history result in a referral. If the family doctor determines that their health concern requires the involvement of a more specialised doctor, then laboratory examinations result in specialised medical care. Then medical history and endoscopy result in a referral to the hospital, and finally, the medical history and surgery result in hospitalisation. All of this is covered in a series of interconnected episodes of health care or health threads.

The care plan and health thread can be planned by adding health threads to the care process and care plans to the health thread. According to ContSys terminology, healthcare planning is the part of the management of healthcare activities that involve the development or modification of a care plan. In the ABC4HEDA process model, this healthcare planning is a specific *Process*.

Care plans are implemented by at least one organisation or person participating in healthcare. In the process model, the parties are defined in terms of their roles (*PartyRole*) or signatures (*PartySignature*). We discuss the existing party archetype and one of its shortcomings at the end of the chapter.

The care process is started by a health issue related to a subject of care as identified by one or more healthcare actors. As an example of care process, a person with the role of a patient might be enrolled in a hospital until he or she is discharged. In the first *Thread*, the patient is taken to an emergency room and undergoes a medical examination. Therefore, this health issue is one *Outcome*, which has been identified by one party during the *Action* of a medical examination.

After admission to a hospital, a patient may go through a number of different *Threads* once specific procedures are conducted and it is determined to which department the patient should be referred. Each *Thread* is related to a specific problem that will be dealt with at the hospital clinics and centers. Recall that business process components have a transfer option, such that the ambulance center can transfer patients to the internal medicine department, or they can be sent home if minor patient concerns are resolved. Therefore, a sub-process is linked to a specific department, such as surgery, internal medicine, independent inpatient nursing, intensive care, or obstetrics. *Tasks* are specific procedures that will be completed on a patient, such as examinations, diagnoses, and treatments. A particular *Task* is made up of several *Actions*, each leading to a different *Outcome*.

There is an aggregation link between a care plan and

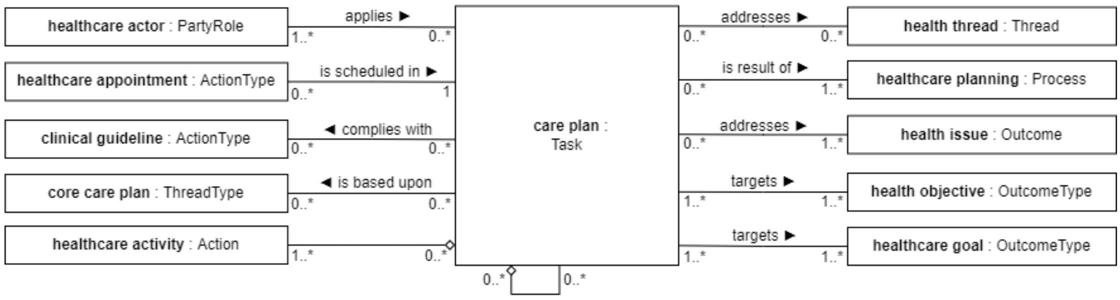

Figure 5: A model of care plan using ISO 13940 terms and ABC4HEDA entities

a specific healthcare activity, shown in the Figure 5. A component can exist independently of its aggregate in this type of relationship. So, for example, a core plan may contain several healthcare activities, and if those activities were removed, a care plan would continue to exist. Toward the end of the chapter, we discuss healthcare activities in more detail, along with their interrelationships.

If necessary, the patient will be scheduled for a healthcare appointment many times during the treatment. In our process model, this is an *Action* of a specific *Task* defined by *ActionType*, and one of the results or *Outcomes* may be, for example, to agree on a new admission. Specific activities in a care plan can be put together using one or many clinical guidelines. The ISO 13940 standard describes a clinical guideline as a systematically developed statement designed to assist healthcare actors in making decisions about healthcare activity related to specified health issues. Just like healthcare appointments, clinical guidelines are based on specific types of activity (*ActionType*). These guidelines make up checklists for the patient's care path, similarly to Nan [11].

It is possible to create a variety of care plans using a variety of core care plans, which provide reusable content and structure for a specific set of circumstances. This core care plan is one type of a specific *Thread* (*ThreadType*) in the process model.

The care plan is designed to achieve one or more of the desired healthcare objectives for at least one set of health activities that meets health needs. In addition, the care plan also aims to accomplish at least one of the desired healthcare goals that contribute to the achievement of the health objective. In the process model, both of these ContSys definitions can be described as a type of a specific *Outcome* (*OutcomeType*).

The core plan also has a self-aggregation relationship so that some object instances may be related to other instances of the object. In other words, all elements of the process model are ordered and linked, which means there are many care plans in one health thread, many activities in the care plan, etc.

It is also important to note that the care plan is planned in the healthcare process, shown in the Figure 6, which describes a set of interrelated or interacting healthcare activities which transforms inputs into outputs. In the business process model, this is designed using types. The ISO standard also defines that the healthcare process is based on the patient's health, where the patient's input health state is a health state at the initiation of the healthcare process, and the patient's output health state is a health state when a healthcare process ends. Different healthcare procedures reveal the results of the activities, but if some results are related to specific measurements, then these measurements are described by the patient's body metrics (*BodyMetric*).

For each healthcare process, a healthcare mandate is required. The ISO standard defines it as a directive based on commitment and either informed consent or legal authorization, defining each actor's responsibilities and rights in this healthcare process. In the meta-models, parties can have a legal capacity (*PartyCapacity*) to perform specific activities. For example, an organization has the authority to be a medical institution, and a person has the authority to provide health care.

The healthcare process should be assessed by the healthcare process evaluation, where requirements are systematically assessed against the healthcare processes. The ABC4HEDA meta-models evaluate the compliance of the process with the *RuleContext*.

The whole process model gives us a health record, which is a data repository regarding the health and healthcare of a subject of care. This health record consists of entity types, together with entities. Entity types are the planned treatment activities with the expected results, and entities are (immutable) protocols of correct *Action* and the associated *Outcomes*.

A more detailed illustration of healthcare activity is shown in the Figure 7. It is connected to healthcare activity management, an element of care management in which the status of activities in a care plan (*Task*) is changed. For example, in the ABC4HEDA context,

Figure 6: A model of healthcare process using ISO 13940 terms and ABC4HEDA entities

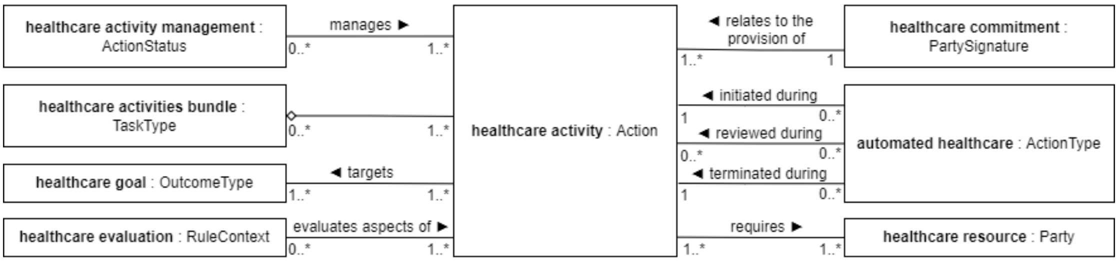

Figure 7: A model of healthcare activity using ISO 13940 terms and ABC4HEDA entities

activities included in a *Task* can be updated using the *ActionStatus*.

There is also an aggregation link between health activities and the health activities bundle. This bundle is a collection of health activities. In the meta-models, this is defined as the number of type-specific activities within the *TaskType*.

A specific activity aims to ensure the intended purposes of the healthcare activity are met, just as a care plan aims to meet its healthcare goals. Furthermore, a particular healthcare activity is assessed by the healthcare evaluation, which refers to the process of evaluating various aspects of healthcare operations according to the ISO standard. In the meta-models, when there is a need to evaluate external evaluations or contracts, the rules can indicate what is needed, and the context of the rules (*RuleContext*) indicates what meets the desired goals and what does not.

Previously, it was pointed out that different mandates are needed for healthcare activities outlined in the care plan. In this sense, a healthcare activity is connected to a healthcare commitment. According to the ISO standard, this refers to the party's acceptance of a healthcare mandate to which the healthcare mandate is assigned. In order to begin any activity and to meet that condition, activities included in the *Task* require the approval (*PartySignature*) of both the originator and the recipient.

The ISO standard also outlines automated healthcare, which is one type of *Action* (*ActionType*) initiated by a responsible healthcare actor and thereafter delivered by an automatic medical device. The actor as well as the medical device both represent healthcare resources. The healthcare activities provided to the patient require at least one of these resources, and there are always at least two parties involved in a patient's health-related *Task*.

As previously mentioned, care plans are implemented by at least one organization or individual in the healthcare field. Therefore, both are represented in the Figure 8. One specific healthcare personnel is defined as a *Person*, and the location where direct healthcare activities are performed is the *OrganizationUnit*. According to the ISO standard, the party archetype pattern has the shortcoming that *Party* can also be considered a resource that is consumed or used during the process. As such, it is likely that in the future, it will be necessary to add some abstract type of device to meta-models to describe, for instance, automated medical devices.

Resource management and funding opportunities for healthcare are also shown in the Figure 8, and both items needed to describe them are available in the meta-models. For example, a *Party* is needed to fund healthcare resources, and that *Party* may have a role in funding (*PartyRoleType*). In addition, the management of healthcare resources can be performed by a specific type of *Task* (*TaskType*).

6. Evaluation and discussions

The ABC4HEDA strives to ensure the interoperability of federated systems. We have developed features that allow third-party systems to use our software and toolbox

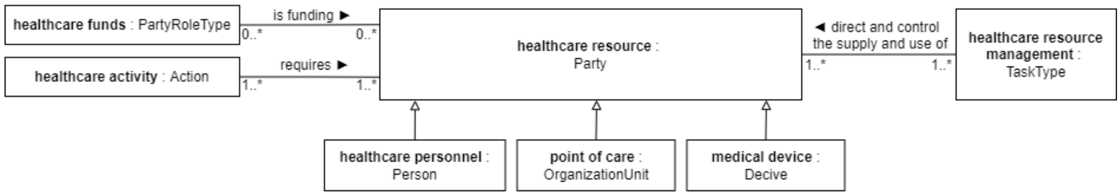

Figure 8: A model of healthcare resource using ISO 13940 terms and ABC4HEDA entities

without changing or adapting their source code. All the existing and new systems, including ABC4HEDA, can evolve and integrate with ABC4HEDA without restrictions and without coordinating their development plans and protocols. Such a standards ignorance is achieved by separating data and knowledge. Rather than enforcing standards, the system allows medical knowledge specification declaratively in a no-code or low-code way, even at run-time. By preserving history both in data and knowledge, the ABC4HEDA allows integrated systems to evolve independently.

With the help of ABC4HEDA software and meta-models, we facilitate interoperability without establishing rules and protocols. An efficient medical system also benefits from a thoughtful process model. If different systems and individual electronic records contain information about the patient, then providing further treatment, the physician needs to be able to see the patient's medical treatment process retrospectively when looking at treatment data. Business process archetype patterns are a way to address this issue. Based on the ISO standard we described this process archetype pattern in the previous chapter and covered areas such as healthcare actors, healthcare matters, activities, process, healthcare planning, time, responsibilities, and information management. Throughout the course of the research, this process model was constantly validated by experts. The validation of the hypothesis now allows us to move forward with the project.

If a patient comes to a hospital with a particular health concern, they will be treated according to the appropriate treatment guidelines. This has been considered, and the defined core care plans and treatment guidelines are incorporated into ABC4HEDA as types. This is compatible with the requirements of the item description pattern described in the previous chapters. Consequently, we searched for a specific real-life medical example to illustrate this process. In the negotiation process, we selected a stroke patient's treatment path created within the design sprint of the North-Estonian Regional Hospital created by the master's students of Tallinn University of Technology. Several treatment guidelines are outlined on the patient's journey there, but the Estonian Health Insurance Fund provided us with a more detailed description of the treatment plans. After these specific healthcare guidelines have been incorporated into the process archetype pattern, the order and party role archetype patterns must be validated. Interoperability of ABD4HEDA with other medical standards must also be proven, and then the entire business logic can be validated.

7. Conclusion

We believe that our work will positively impact the interoperability of federated systems and the provision of better healthcare services through a process model. It was necessary to realise and test the process model first in order to conduct the research. Modeled by abstracting Arlow and Neustadt's client relationship management archetype pattern, this process model describes the dynamics of processes through a series of reports and feedback. Our previous works have led us to the point where we can combine the terminology of the ISO 13940 standard with the ABC4HEDA meta-models and software. This standard suggests that the most important aspect of healthcare is the interaction between patients and healthcare professionals. Interactions such as these occur during healthcare processes. Therefore, this standard takes a process-oriented approach. System requirements based on the ISO standard were visualised and validated using object diagrams. Following validation of the model and inclusion of an example of the required treatment guidelines in the process archetype pattern, the results proved that ABC4HEDA primarily meets all the specified requirements.

Authors' contribution

Tanel Sõerd wrote the manuscript with support from Kristian Kankainen, Gunnar Piho and Toomas Klementi. All authors contributed to the final version of the manuscript. Gunnar Piho and Peeter Ross supervised the project.

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