Towards Specification of Medical Processes According to International Standards and Semantic Interoperability Needs

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Abstract: Models of healthcare processes and workflows to support the continuity of health care are an essential research topic in medical informatics. This research topic is driven by the necessity to enable systems (including semantic) interoperability, to see the consistency of clinical data recorded in electronic health records (EHR) and to understand retrospectively the clinical pathways that led to these data. We propose a process meta-model and evaluate its usability by modelling the healthcare concepts and models from the ISO 13940 (system of concepts to support continuity of care) standard. Our meta-model is developed according to the software design patterns principles, enabling the formal specification of knowledge in a machine-readable format and preserving the history of these specifications. Our work contributes to the federated interoperability of healthcare information systems (healthcare enterprise applications), utilising executable meta-models that can map healthcare data at the semantic (medical knowledge) level, even at run-time.

1 INTRODUCTION

Health care is evolving from episodic (symptom-triggered) health care towards a continuous, preventive healthcare approach (EIC, 2022). There is a need for continuous and unified access to health data not limited to a particular episode of a specific health case at a particular health institution (health data silos). A significant effort has been made to store medical records electronically (EHR). However, the stored information does not always reveal the context or the reason behind taking a blood sample, administering a drug or using a particular treatment.

The current practice of EHR makes it difficult for healthcare workers to determine clinical data consistency and understand clinical pathways, especially in secondary use cases (e.g. medical science and clinical research) of EHRs, where data users know neither the patient nor the context, as physicians do in EHR primary use cases (diagnosis and clinical care). While governments and society constantly push hospitals to reduce costs and improve efficiency, healthcare costs rise yearly. One possible cost-reducing strategy is wise health data digitalization towards beneficial secondary usage (PWC, 2009). However, this task is complicated because information systems in healthcare institutions have semantically heterogeneous data models and approximately 80% of medical data are unstructured (Negro-Calduch et al., 2021).

According to Chen et al., three architectural approaches to enterprising interoperability exist: integrated (based on a common format), unified (based on a common standard) and federated (no common format; instead, parties accommodate each other on the fly) (Chen et al., 2008). We rule out integrated and unified approaches because of historical software development; most medical institutions use their in-house-specific standards or at least in-house versions of national and international standards. It is common knowledge that software systems developed by independent parties tend to be semantically heterogeneous even when based on the same standards (Halevy, 2005; Mocan et al., 2009). This heterogeneity is because standards always have room for interpretation. The redesign and redevelopment of these systems is too risky and costly. Instead, we strive for the federated approach, where (semantic) interop-

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erability of systems (Ciampi et al., 2013; Tu et al., 2016) is achieved by adjudicating each party's semantic inconsistencies continuously. For this, we are developing ABC4HEDA (Archetype-based Computing for Health Data), which is a Single Underlying Model (Meier et al., 2019) and software that enables Electronic Health Record (EHR) management in a transparent, secure and semantically coherent way. By archetype, we mean a business archetype that "*is a primordial thing that occurs consistently and universally in business domains and business software systems*" (Arlow and Neustadt, 2003), not the archetype term as utilized by the openEHR (Beale, 2002) and ISO13606 (ISO, 2019) standards.

ABC4HEDA aims to contribute to more interoperable and consistent healthcare data. It is developed based on software engineering best practices and proposes a theoretically "standard-ignorant" approach to the federated semantic interoperability of clinical data models. By "standard-ignorant", we mean an approach similar to computing, infrastructure and platform-ignorant (independent) approaches, where no unified standard is defined and third parties can specify the standards, taxonomies or terminologies they use declaratively. This paper evaluates whether the process meta-model in ABC4HEDA is applicable in the healthcare domain by testing whether it can be used to declaratively specify the healthcare process of the ISO 13940 (system of concepts to support continuity of care) standard (ISO, 2015).

Our approach has been explained in (Piho et al., 2010a; Piho et al., 2010c; Piho et al., 2011; Piho et al., 2012; Piho et al., 2014), evaluated in real-life applications (Piho et al., 2010b) and analysed on the basis of HL7 RIM (reference information model) and openEHR RM (reference model) (Piho et al., 2015) as well as LOINC (Raavel et al., 2022) and HL7 FHIR (Randmaa et al., 2022) interoperability tests.

The rest of this paper is structured as follows. In Section 2, we explain the methodology we have utilized. Sections 3 and 4 briefly overview the ISO 13940 standard and Process Archetype Pattern, respectively. Section 5 specifies the healthcare process from the ISO 13940 standard in the domain-specific language based on the Process Archetype Pattern meta-model of ABC4HEDA. We analyse and discuss the presented results in Section 6 and conclude the paper in Section 7.

2 METHODOLOGY

Consider a situation where a clinical guideline specifies how and in which order the particular healthcare activities should be performed. And consider that medical science is evolving and the guideline is revised. Based on this revision, the healthcare institution has to change its practices; therefore, it is necessary to also change the information system to support the new guideline. However, as the historical data are based on the old guidelines, the new system must now support both versions.

Instead of convening a team of developers to implement such changes to the information system, in the ABC4HEDA approach, changes are specified declaratively while the application is running. Changes can be rolled back, updating the source code is not required and the application does not need to be restarted for healthcare providers to proceed with work and utilise the new guideline.

ABC4HEDA makes use of syntax, semantics and pragmatics-based three-level modelling (Bjørner, 2006). All data and knowledge are stored in an archetype and archetype pattern(A&AP)-based model (syntax – what we write) (Piho, 2011). These archetypes and archetype patterns have been designed (Piho et al., 2010c) according to the Zachman Framework (Zachman, 1987) by asking (and answering) *who* (involved actors and their roles), *what* (products and services), *when* (date and time), *where* (location), *why* (rules) and *how* (processes) questions. This paper evaluates the business process (*how*) meta-model.

The A&AP model forms a domain-specific language (DSL) (Fowler, 2010) for specifying (not programming) all existing and future developed medical knowledge (taxonomies, ontologies, standards, protocols, etc.) declaratively (even at run-time) in an unambiguous and machine-readable format (semantics – what we mean). This DSL is to be applied in a particular healthcare information system for specifying (pragmatics – how we use) the healthcare terms and concepts in use in that particular healthcare organisation.

The two principal patterns in use – the item description pattern (Coad, 1992) and the evolving systems pattern (Oei et al., 1994) – make our meta-model dynamically evolvable and semantically interoperable despite model changes. In line with the first pattern, every concept in the ABC4HEDA meta-model has a type that is specifiable during run-time (Figure 1, right). And in accordance with the second pattern, meta-data is stored for the transparency and history preservation purposes of the items (Figure 1, left). So, in case of a mistake or an error during a change in requirements, it is possible to trace and roll back the system. Consequently, ABC4HEDA supports second-order evolution (Oei et al., 1994) in such a way that changes in semantics (meaning of data, knowledge about data), which would generally require a change in meta-models (e.g. database layout, classes in software), are converted to first-order evolution of data because both the data and their semantics (meaning, knowledge) are presented in the same manner.

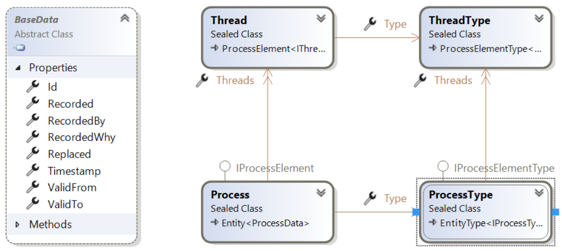

Figure 1: Evolving systems (left) and item description.

3 ISO 13940:2015

The ISO 13940:2015 standard "*defines a system of concepts for different aspects of the provision of health care*" (ISO, 2015, p. 1). It states that the core business of health care is the interaction between the patient and healthcare actors. The standard uses UML (Unified Modelling Language) diagrams to define around 150 concepts and their interrelations across eight domains: healthcare actors, healthcare matters, activities, processes, healthcare planning, time, responsibilities, and information management. The standard does not have any regulatory impact on care delivery, but rather gives a conceptual basis for describing both the content and the context of healthcare services. We use the standard as a common healthcare domain model, which, according to the software triptych principle, "*from domain model via requirements to the software*" (Bjørner, 2006) is wise to use whenever the requirements for information systems are analysed. A review (Kankainen, 2021) analysing how the ISO 13940 concepts have been understood and applied in literature found two relevant use cases of the standard. The first use case (Oniki et al., 2014) collected information contexts (discharge diagnosis, cause of death, complication of surgery, problem list, etc.) from the standard and used them in data transformation; the same assertive information is displayed differently in individual contexts. The work discusses the importance of having an 'implementation layer', which means that the logical models are not compiled directly into the artefacts used in an implemented system; instead, 'implementation models' are used as a buffer between the logical models and system implementation. Such a technique allows context-dependent transformations of the assertive information and implementation-specific transformations for performance optimisation. The second use case (García-de León-Chocano et al., 2015) exploited the fact that the contexts enumerated in the ISO 13940 standard hold universally across cultural, national and organisational borders. Contextualising their data quality metrics with the ISO 13940 standard enabled them to replicate their methodology at a cross-organisational level.

4 BUSINESS PROCESS ARCHETYPE PATTERN

A large part of the ABC4HEDA model is based on business archetypes (Arlow and Neustadt, 2003), which allow us to respond to all the questions in the Zachman framework. While Arlow & Neustadt do not define an archetype pattern for business processes explicitly, they describe how to manage relationships between parties through a customer relationship management archetype. With some amendments to their pattern, we have created the business process archetype pattern (Figure 2) by generalising their party relationship archetype (Piho, 2011).

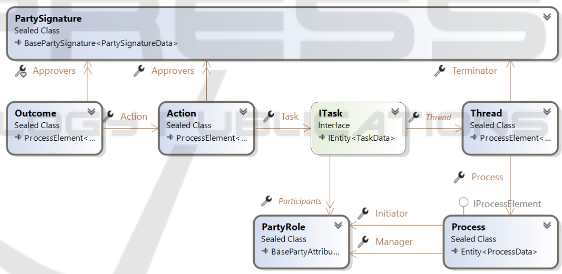

Figure 2: Business process archetype pattern.

In a similar fashion to a film being a series of static pictures, the process archetype pattern specifies the processes' dynamics through an ordered set of reports and feedback from the process. More reports and/or feedback give a better overview of the entire process as a dynamic phenomenon. The same pattern can be used for business process *planning* by replacing actual reports and/or feedback with expected reports and/or feedback. By comparing the actual with the expected, we can monitor the adequacy of the plans.

The central part of our business process archetype pattern is the task archetype (Figure.3). A task is a party relationship between two party roles and allows us to model multiple simultaneous roles, e.g. in terms of a family member, a person can simultaneously be a parent and a spouse, or a daughter and a sister.
This modelling approach combined with the afore-

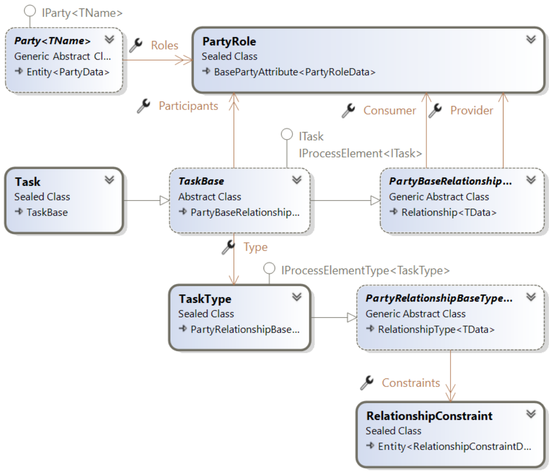

Figure 3: Task archetype.

mentioned patterns for item description and systems evolution makes it possible to define new role and relationship types at run-time. Additionally, it allows us to keep information consistent in ABC4HEDA, which, according to Lagos et al. (Lagos et al., 2018), is a crucial aspect of information models and systems.

Tasks (e.g. an appointment) are grouped into threads (e.g. patient's clinical examinations to determine a possible diagnosis), and threads are grouped into processes (e.g. a patient's stay in hospital). A task contains one or many actions (e.g. measuring blood pressure), and each action may have one or many outcomes (e.g. both systolic and diastolic value of a blood pressure). All the process archetype elements (process, thread, task, action and outcome) have declaratively specifiable types that can be added during run-time. For certain activities, business processes often require approval that can only be given by authorised parties. For example, Estonia has five licences for providing various medical services under the Health Care Services Organisation Act. Legal co-ordination must take place between the parties, which is made possible using the party signature archetype (*PartySignature*). Finally, *TaskRouting* allows tasks to be transferred between parties (e.g. a change in treating physician).

5 SPECIFYING THE ISO 13940 SYSTEM OF CONCEPTS

In this section, we specify the concepts and relationships from the ISO 13940 standard using the domain-specific language of the ABC4HEDA meta-model described above. Unified Modelling Language (UML) object diagrams are used for visualisation. In the object diagrams, the ABC4HEDA meta-model terms are pictured as classes (types), and the ISO 13940 standard concepts are pictured as objects (type instances).

5.1 Specifying the Care Plan

The core of a patient's healthcare process in ISO 13940 is the dynamic, personalised care plan that encompasses the activities, goals and objectives related to a health issue (Figure 4). The 'care plan' is modelled as a *Task* in the ABC4HEDA business process meta-model (domain-specific language). In ISO 13940, multiple 'care plans' can address multiple 'health threads', where a health thread is a defined association between healthcare matters as determined by one or more healthcare actors. In ABC4HEDA, we model health threads as *Thread*. The 'care plan' and 'health thread' are organised by adding health threads to the healthcare process and adding care plans to the health thread. According to ISO 13940, the care plan is the result of 'healthcare planning' and it is 'healthcare activity management' that changes the statuses of healthcare activities in the care plan. In ABC4HEDA, healthcare planning is a *Process* and a change in the status of activities is modelled using the *ActionStatus*. Care plans are applied by 'healthcare actors' – either organisations or persons participating in health care. In ABC4HEDA, healthcare actors are defined in terms of their roles (*PartyRole*) or signatures (*PartySignature*). The healthcare process is set in motion by a health issue identified by one or more healthcare actors. An example of a healthcare process is a patient's stay at a hospital until discharged. During the stay, the patient can undergo many 'health threads' (*Thread*). Each *Thread* is related to a specific problem that will be dealt with in hospital clinics and centres. A 'referral' in the ISO 13940 standard is the movement of a 'healthcare commitment' between 'healthcare professionals'. The same is accomplished by *TaskRouting* in ABC4HEDA.

Activities in a care plan can be arranged to comply with a 'clinical guideline'. 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 other tasks (healthcare appointments), clinical guidelines are modelled by specific types of activity (*ActionType*). These guidelines make up checklists for the patient's care path, similarly to Nan (Nan et al., 2015). Additionally, a 'care plan' can be based on a 'core care plan', which provides reusable content and structure for a specific set of circumstances. We model core care plans as *Threads* specified by *ThreadType* in

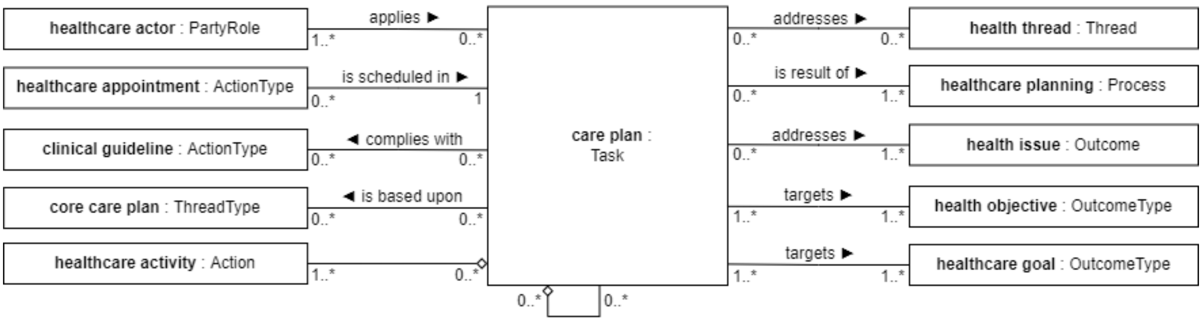

Figure 4: ISO 13940 care plan in ABC4HEDA domain-specific language.

the ABC4HEDA process model. A care plan aims to fulfil a 'health objective', and the activities it carries out target 'healthcare goals' that contribute to the objective. How the goals and objectives can be used for evaluation is described below in the section on healthcare activities.

5.2 Modelling the Healthcare Process

ISO 13940 defines the 'healthcare process' (Figure 5) as transforming the patient's health. It has an input health state and an output health state. How the health state can be observed and assessed is described in the section on healthcare activities. The healthcare process can be evaluated by 'healthcare process evaluation', where requirements are systematically assessed against the healthcare processes. The ABC4HEDA meta-models evaluate the compliance of the process using *RuleContext*.

For each healthcare process, a 'healthcare mandate' is required. ISO 13940 defines this as a directive based on either 'informed consent' or 'legal authorisation' and a 'healthcare actor' accepting 'healthcare commitment'. In the ABC4HEDA meta-models, parties have legal capacity (*PartyCapacity*) to perform specific activities.

The entire process model yields a holistic health record, which is a data repository regarding both the health and the health care of the patient. This health record consists of entity types, along 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*.

5.3 Modelling the Healthcare Activity

The healthcare activity model is shown in Figure 6. The management of activities within the care plan was detailed in the above care plan section and not repeated here. In the ISO 13940 standard, a 'healthcare activity' targets a 'healthcare goal', just like the care plan aims to meet the overall 'health objective'. A healthcare activity is assessed by the healthcare evaluation, which refers to the process of evaluating various aspects of healthcare operations. In our ABC4HEDA meta-model, when there is a need to review 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 the healthcare activities outlined in the care plan. In this sense, a healthcare activity is connected to a healthcare commitment. According to ISO 13940, 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, the activities included in the *Task* require the approval (*PartySignature*) of both the originator and the recipient.

ISO 13940 also outlines 'automated health care', 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', as detailed in the next section. The healthcare activities provided to the patient require at least one of these resources, and at least two parties are involved in a patient's health-related *Task* at any given time.

5.4 Modelling the Healthcare Resource

Health care and its activities need resources (Figure 7). 'Healthcare personnel' is modelled as *Person* and the 'point of care', i.e. the location at which direct healthcare activities are performed, is an *OrganisationUnit*. One shortcoming in the party archetype pattern is that a *Party* can also be considered a resource that is consumed or used during the process. As such, it is likely that the addition of an abstract device to meta-models will be necessary in the future in order

Figure 5: Model of healthcare process using ISO 13940 terms and ABC4HEDA entities.

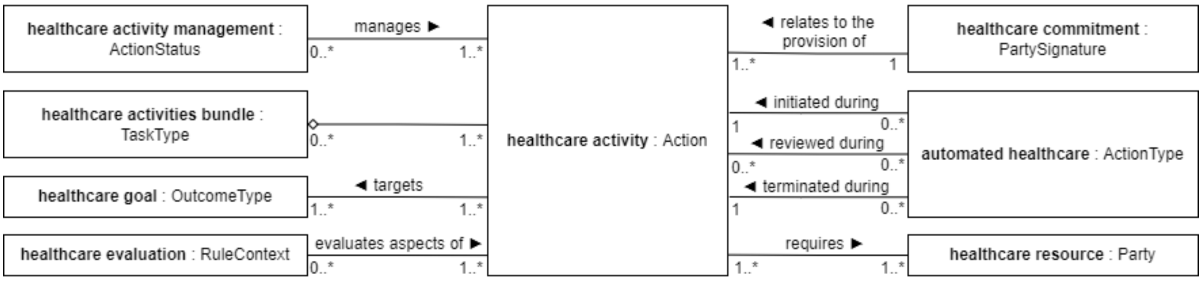

Figure 6: Model of healthcare activity using ISO 13940 terms and ABC4HEDA entities.

to describe, for instance, automated medical devices.

Resource management and funding for health care are shown in Figure 7, and both items needed to describe them are available in the meta-models. For example, a *Party* is needed to fund healthcare resources, and said *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 DISCUSSIONS AND CONCLUSION

In ABC4HEDA, around 120K lines of source code have been written in C# programming language, and 45% of this code consists of automated unit and acceptance tests to ensure 100% code coverage. The architecture and coding practices are clean and approximately 12% of the code is pure POCO (Plain Old CLR Object), which forms the computable domain model for the A&AP. Approximately 3% of the code implements a repository and unit of work patterns for the platform-independent data-persistent infrastructure. The Entity Framework Core as an 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, if necessary. Approximately 40% of the code uses the latest ASP.NET Core (also replaceable) and provides infrastructure and UI features for management and operation by allowing medical knowledge specifications to be written in a declarative manner, therefore enabling specification of medical standards & other commonly used or custom-made specifications.

ABC4HEDA follows the federated approach to the interoperability of systems without establishing rules and protocols. This standard's ignorance is achieved by separating data and knowledge. Rather than enforcing standards, ABC4HEDA allows clinical knowledge to be specified declaratively at runtime. By preserving the history of both data and knowledge, the integrated systems may evolve independently and safely.

We described how the ABC4HEDA meta-model is capable of encoding terms from the ISO 13940:2015 (system of concepts to support continuity of care) standard. The terms covered all domains: healthcare actors, matters, activities, processes, planning, time, responsibilities, and information management.

The necessary work behind the meta-model was done by selecting the clinical guideline for a stroke patient's journey created during a design sprint at North Estonia Medical Centre and devised by the master's students of Tallinn University of Technology. Several treatment plans were outlined on the patient's journey, and the Estonian Health Insurance Fund provided us with a more detailed description of the treatment plans. Throughout the research, the process model was validated by experts.

We evaluated the usability of the ABC4HEDA meta-models and software using its domain-specific language to specify the ISO 13940 terminology declaratively. The ISO 13940 standard takes a

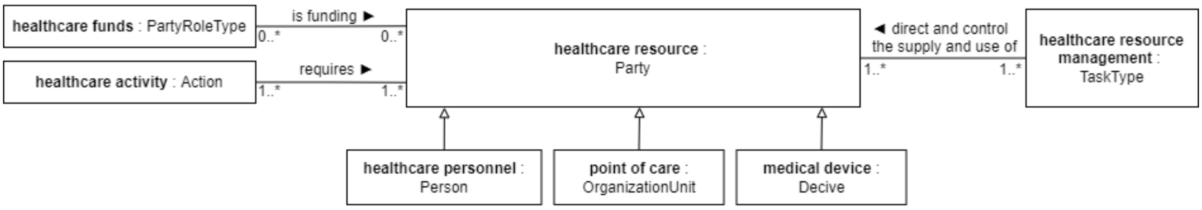

Figure 7: Model of healthcare resource using ISO 13940 terms and ABC4HEDA entities.

process-oriented approach and postulates the interaction between patients and healthcare professionals as the essential aspect of healthcare processes. The system requirements based on ISO 13940 were visualised and validated using object diagrams.

Our proposed process meta-model contributes to the semantic interoperability of federated systems and the inclusion of more quality healthcare data in primary (care and diagnoses) and secondary (medical science and research) use cases. Notably, the contextualisation dimension of data quality (Aerts et al., 2021) is increased, as all clinical data in ABC4HEDA are modelled as process outcomes, which keeps the content of data (e.g. blood pressure) linked to its context (e.g. the activity of measuring blood pressure and the reason for performing the activity).

Our process meta-model describes the dynamics of business processes as a series of conducted and reported tasks as relationships between parties. Process planning follows the same pattern and allows us to evaluate the planned with the achieved.

Future work involves validating the order and party role archetype patterns. The integration of ABC4HEDA with more healthcare standards and clinical research standards must also be proven before the entire business logic can be validated.

AUTHORS' CONTRIBUTION

TS wrote the manuscript with support from KK, GP and TK. GP designed ABC4HEDA. TS and two other bachelor's students (Rainer Randmaa and Kaur Matthias Ravel) under the supervision of KK, TK and GP implemented ABC4HEDA. GP and PR supervised the project and paper writing.

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