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Towards a HL7 based Metamodeling Integration Approach for Embracing the Privacy of Healthcare Patient Records Administration

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ABSTRACT

HL7 is a standard developed to support the exchange of information related to the medical field across institutions from the same country or from different countries. This standard provides mainly a framework to sustain the data exchange at the application / technical layer and the thereby minimize the importance of business / organization information. This is contradictory to the arising requirements dictated by the information security governance which claims the access rights to be only provided where there are business justifications. In this context, the paper aims at extending HL7 with a responsibility perspective in order to enhance the access rights considering organization constraints. Therefore, the paper firstly proposes an integration of both models and secondly provides an innovative HL7 XML format which supports new business related information framework defined around the notion of responsibility.

Categories and Subject Descriptors

H.2.7: Security, Integrity, and Protection.

General Terms

Management, Measurement, Performance, Design, Reliability, Experimentation, Security, Standardization, Verification.

Keywords

HL7, Shared Healthcare Record, Access Rights Management, Patient Record Privacy, Responsibility modelling.

1. INTRODUCTION

In many European and worldwide countries, the management of the inhabitants' healthcare related data is essential, for the patients firstly that do not have to worry about the handling of the information related to its treatment, for the healthcare practitioners secondly that have easily access to a complete,

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accurate and up to date information regarding the patient, for the healthcare professionals such as Medicare¹ (or health insurance companies) that can easily process the reimbursement, for the governmental and Ministry of Health which may profit of the interoperability between the healthcare actors to reduce the administration and healthcare management overhead.

Despite the many advantages of such an integrated approach, the development of a country size system for sharing information between huge and heterogeneous range of users is challenging. Among the multiple challenges the management of the interoperability between heterogeneous solutions, the management of the access rights to confidential healthcare patients record, the respect and compliance of/with the regional, national and international patient privacy law and regulation, the efficiency of the solution in term of performance, the innovative facet of such an approach combining legal framework, domain-driven rules, and organizational context (evolving environment, internationalization, high availability requirement, mobile access to information through mobile devices, etc.) are crucial.

In Grand-Duchy of Luxembourg, the *Agence eSanté*² is the public organization that has been set up in order to support the Luxembourgish government to ensure a better use of information in the field of health and medico-social sector, to guarantee better coordinated care of the patient and to support the exchange of information among the stakeholders by setting up an electronic health record infrastructure. The latter enhancement has for main objective to contain and share a *patient's health-related medical information named DSP*³ with whom it may concern and respecting the security rules that have been set up for the platform eSanté. This DSP is managed by the patient and/or by his/her trusted healthcare professional (e.g. his/her médecin référent - primary care physician). The platform proposes others services such as a directory of health professionals, the provision of a shared virtual workspace, or making available medical office management software. At the moment, the access to the DSP is provided and managed based on the healthcare professional, the therapeutic relationship and the patient choice. In no case, an administrative employee is allowed to access the patient's record. This is explained in figure 1 using red arrows. To access information, a user is associated to a role and the information is accessible only to the user playing this role. This access model is

¹ <https://www.medicare.gov>

² eSante Agency - <http://www.esante.lu/>

³ Dossier de Soins Partagé – Shared Healthcare Record

judged as pragmatic but weak in terms of accuracy. Indeed, providing access to a patient file must be justified not only to a doctor because he is doctor, but also because he has responsibilities related to the treatment of the patient, e.g. to make a diagnostic, to provide drugs, and so forth. Given the above weaknesses, the Public Research Centre Henri Tudor has decided to elaborate an innovative solution to face these challenges. Therefore, a new approach is going to be defined based on an twofold alignment among firstly the concrete *responsibilities* that employees from the healthcare institutes need to perform and the generic metamodel for patient record exchange named *Specification Of the General CDA Document Header (SGCDH)*⁴ and secondly, an alignment between those generic responsibilities and the concrete application layer of the healthcare institutes, such as already performed in [4].

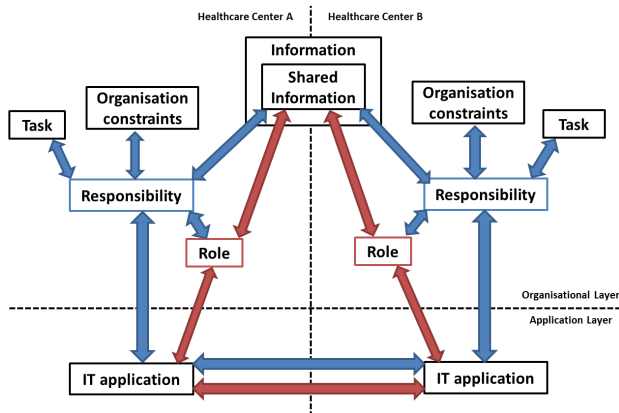


Figure 1. Synoptic mapping highlights

This new approach is represented with blue arrows in figure 1. As suggested, the access to the information is related no more only to the role played by the user, but by its real responsibilities which are themselves function of the role, the tasks to be achieved, and potential organizational constraints. With this approach, we aim at semantically enhancing the alignment among the organizational artefacts and the applications that supports their realization, and thereby, the access to the information manipulated by this layer. This paper firstly presents the research method in the next section, then it turns to the presentation of the initial model (namely ReMMo) and the eSanté healthcare institutes' models. In Sec.4, we introduce the extension of the eSanté model with ReMMo and in Sec. 5, we analyze the usability of the alignment by means of a prototype that sustains the deployment of inference rules. In Sec. 6 we provide an overview of the related works and in Sec. 7 we conclude the paper and suggest perspectives for future works.

2. Research method

Hevner et al. [1] explains that the design science paradigm seeks to extend the boundaries of human and organisation capability by creating new and innovative artefacts. The research that we tackle through this paper concerns the improvement of the alignment between the eSanté platform and the information system of healthcare institutes. Through this research, we aim to strengthen the organisational capability of these institutes by enhancing the care provided to the patients. Practically, the research aims to

design a new artefact to model and formalize the responsibilities of the employees related to healthcare services. Hence, we acknowledge that the research may plainly be considered in the scope of design science [2] and more specially, the action design research method (ADR – [3]), as explained by Sein et al. The action design research method has for objective to strengthen the connections between the practitioners and the end-users (the healthcare institutes) and the researchers (the CRP Henri Tudor) by combining *the building, intervention and evaluation (BIE) activities*. Accordingly, the method advocates for a continual evaluation of the problem and the built artefact in order to ceaseless adjust the artefact elaboration with real usage settings.

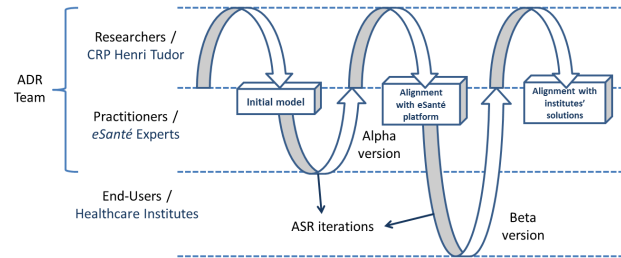


Figure 2. ADR life cycle, adapted from [3]

The ADR method's advantage is that it allows considering the end-users requirements all along the definition and elaboration of the artefact which, as a result, allows elaborating artefact in environment where requirements are subject to evolution. Along the research, given that the realization of this alignment has been informed by theories, we consider that we are in an *IT-Dominant BIE Generic Schema* [3] such as represented in Figure 2. In this schema, a first innovative artefact is created by the researcher and alpha versions are iteratively generated in a limited organizational context. In a second step, the more mature artefact is evaluated in a wider organizational setting and beta versions are shaped with the end-users. Applied to our research, a first mapping between the initial model (namely the Responsibility metamodel) and the eSanté platform model will be realized in laboratory environment. Afterwards, this mapping will be applied in a concrete organizational setting and will be evaluated and refined with experts of the domain. This second step corresponds to the elaboration of an alpha version (illustrated in Figure 2). During this step, the requirement for the alignment of the eSanté platform and the healthcare institutes will be enriched with the specifications dictated by the experts, such as, among other legal and national regulations (elaboration of the alpha version). The third step of the iteration consists in elaborating a final version of the artefact considering the requirements of the end-users (the last requirements evolution). During this final stage, the pragmatic requirements of the end-user are going to be considered. Those requirements includes among other additional organisational rules. It corresponds to the elaboration of the beta-version of the Sein et al. approach.

3. Model and metamodel descriptions

In this section, we successively present the *SDCDH* Model HL7 Luxembourg and the Responsibility metamodel named ReMMo.

3.1 SGCDH

SGCDH model has been extracted from the technical specifications of the *eSanté agency* [11] and represented in Figure 3. In the following of this section, we present the concepts which

⁴ The SGCDH is publically available at: <https://www.esante.lu/portal/fr/agence-esante/base-documentaire,224,224.html?#contentModule>

literature related to the responsibility, the review of the literature related to the accountability highlights that the responsibility is associated to accountabilities which are broadly defined as the obligation to give account to someone else under the threat of sanction(s). This responsibility is defined for a unique actor to which it is assigned. The concept of actor has already been largely defined in the literature [6] and it will not be reviewed in detail in this work. This concept of actor has been defined in *i** as an active entity which carries out actions to achieve goals by exercising its know-how. This actor may be either an employee or a business role. The employee represents a human entity which may or may not play one or more business roles and the latter represents a set of employees who share common characteristics. To realize his accountability, an actor must possess a set of capabilities and

rights to use. These capabilities are intrinsic to the actor and correspond to the knowledge, the know-how, or the attitude he possesses. The concept of right is common but is not systematically embedded in all IT frameworks. It encompasses facilities required by an actor to fulfil his accountability(ies). These rights to use are described in terms of access to a business object. This business object is a passive element (information or document) which has relevance from a business perspective and which may be used by one or many task(s). Capability and rights are components that have already been defined in the field of IT [7]. They have been introduced in ReMMo as well. Additionally, we have introduced the concept of condition which we define as a context which must be verified for the accountability to exist.

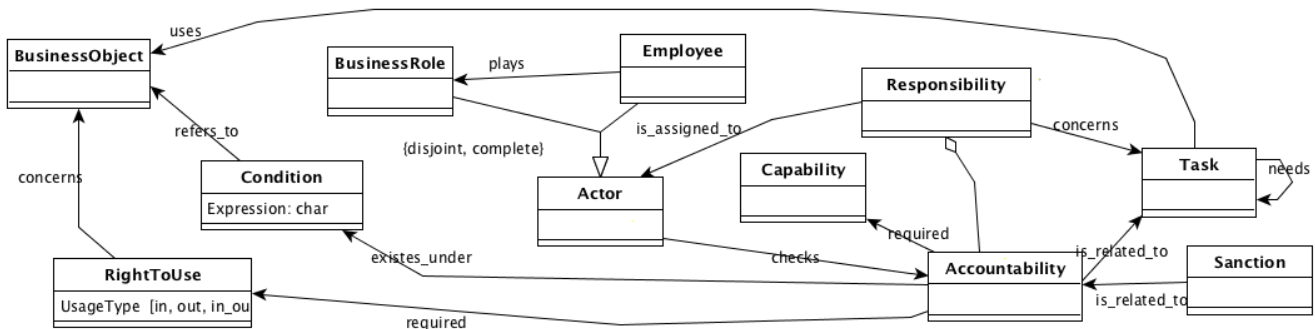


Figure 3. ReMMo concepts and relations.

4. Specification Of the General CDA Document Header model extension

4.1 Extension rules

The mapping between the *Specification Of the General CDA Document Header* model and the ReMMo aims at extending the *Specification Of the General CDA Document Header* model with a responsibility perspective. In order to integrate two metamodels, [8] explain that three types of heterogeneity need to be resolved: semantic, structural, and syntactic. The semantic heterogeneity represents differences in the meaning of the considered metamodels elements and must be addressed through elements mapping and integration rules. The elements mapping introduces a correspondence between at least one element of each of the source metamodels. According to [9], two types of mapping are conceivable: 1:1 and n:m mapping. A 1:1 mapping means a correspondence between two elements of two sets of objects (from two different models) which corresponds to the equivalence between elements from [8]. In our mapping, the integration rule for these elements is a merge into a unique element in the target metamodel, and all the attributes of the source elements are assigned to this unique element. One source element may be semantically richer/poorer than the other elements, e.g., be more general or more specific, the mapping between the two elements exists with, respectively, a generalisation/specialisation conflict (according to [9]). In this case, both concepts are associated in the integrated metamodel with a generalisation/specialisation relationship. This matches the correspondence of a type relation from [8]. The mapping of a type n:m relates to a set of elements from one metamodel to a set of elements from the other so that no 1:1 mapping between the elements of the two sets exist. This second type of mapping exists when the mapping requires the resolution of fragmentation conflicts (conflicts which arise from a

different decomposition of the real world elements being modelled [9]. No occurrence of this n:m mapping has been encountered amongst the *eSanté model* and ReMMo and, as a result, this mapping will be no further explained here. If no mapping exist between two elements from the analyzed metamodels, we are in the case of non-relation correspondence described by [8]. In this case, both elements from the analyzed metamodels need to be represented in the integrated metamodel as, e.g., a concept, an attribute, an association. In our integration of the Responsibility metamodel with *eSanté model*, when no mapping exist, the element which only exists in the Responsibility metamodel will be integrated in the *eSanté model*.

The structural heterogeneity exists when the same metamodel concepts are modelled differently by each metamodel primitives. For instance, when a concept is represented by a class in one metamodel and is represented by a relation in another metamodel, or when a concept is represented by a class in the first metamodel or by two classes in the second. This structural heterogeneity will be addressed together with the analysis of the conceptual mapping and the definition of the integration rules in Section 4.2.

This last type of heterogeneity is not relevant to us. Indeed, the syntactic heterogeneity aims at analysing the difference between the serialisation of metamodel and, as explained by [10], addresses technical heterogeneity like hardware platforms and operating systems, or access methods, or it addresses the interface heterogeneity like the one which exists if different components are accessible through different access languages. Similarly, [9] considers that the syntactic heterogeneity is the most visible type of heterogeneity and that it must be addressed by performing a syntactic rewriting during the preparation step of the integration of two databases. Regarding our mapping, this syntactic heterogeneity is not applicable since no serialisation format for

storing the Responsibility metamodel has been provided until now. Only the semantic and structural heterogeneities are therefore considered, and relevant, in our case.

4.2 Models integration

The objective of the section is to analyze the concepts from each of the models in order to define relationships, and according to the detected relation, to propose an integration following the extension rule reviewed in Section 4.1. Table I provides a summary of the mapping rules.

Table I: Mapping between concepts and integration

HL7 Luxembourg	ReMMo	Integration rule
Person IntendedRecipient Patient	Employee	Merge Specialisation Merge
ResponsibleParty EncounterParticipant AssignedEntity PatientRole Custodian Guardian Informant Author	BusinessRole	Specialisation Specialisation Specialisation Specialisation Specialisation Specialisation Specialisation
RecordTarget EncompassingEncounter Location	BusinessObject	Specialisation Specialisation Specialisation
Authorization	RightToUse	Generalization
Order ServiceEvent	Task	Specialisation Specialisation
AuthoringDevice Organization RelatedEntity	No relation	No action
No relation	Responsibility Accountability	Integration Integration

The *Employee* has been defined as a human entity which may or may not play one or more business roles. The definition of the person or the patient (HL7) corresponds to this description. Hence, we have considered a 1:1 mapping between both concepts. The integration rule that applies is the *merge* in a unique concept which keeps the name of the eSanté concept. The IntendedRecipient represents the person who is recipient of the information. This definition is richer than the one of employee. IntendedRecipient is thus a specialization of this employee.

Concerning the *BusinessRole*, it is defined in ReMMo as a set of employees who share common characteristics. Accordingly, the concepts of ResponsibleParty, EncounterParticipant, AssignedEntity, PatientRole, Custodian, Guardian, Informant and Author from the eSanté model correspond to specialization of the concept of *BusinessRole*.

The BusinessObject is defined as a passive element (information or document) which has relevance from a business perspective and which may be used by one or many task(s). The recordtarget, the Location, the encompassingEncounter are three concepts from HL7 which specialized the business object from ReMMo given that they provide a more accurate definition of the object. They are mapped to the business object using the specialization link. The RightToUse corresponds to a specific type of authorization. As a result, the authorization is a generalization of the right to use. Finally, the concepts of authoringDevice, Organization, and RelatedEntity only exist at the level of the HL7 model and

inversely, the Responsibility and the Accountability only exist at the level of ReMMo. As we intend to enhance HL7, both latter will be integrated in the integrated model.

5. Deployment

This section presents the enrich HL7 XML schema and parsing prototype.

5.1 Enriched HL7 XML

Based on the mapping established in section 4.2 we propose to improve the quality of the existing XML descriptions by including ReMMo concepts. In this section we focus on the fourth possible integration rules: Merge, Specialisation, Generalization and Integration described above. Figure 4 gives the enriched XML Schema for the Person concept.

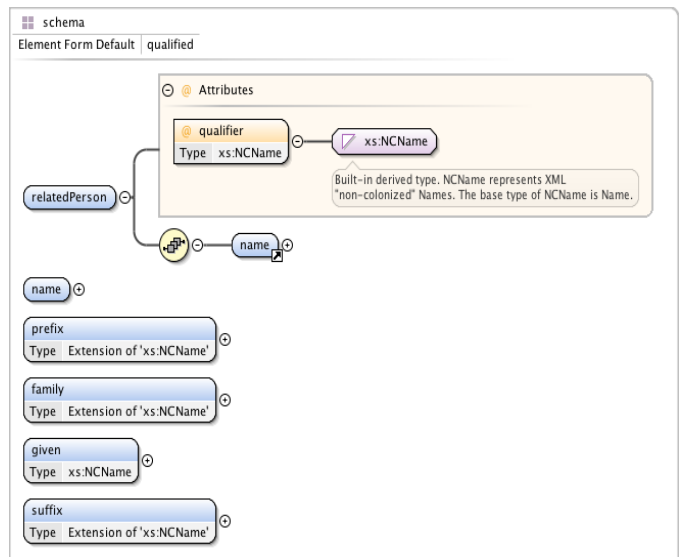


Figure 4. Enriched XML schema for the Person concept.

The Merge integration rule is realized by the adjunction of a qualifier named *Employee* to the root element *Person*, given the same semantic of the two concepts. Additional attributes related to the concept of Employee can be inserted as optional elements if needed. An example of instantiated schema is given by:

```
<?xml version="1.0" encoding="UTF-8"?>
<relatedPerson qualifier="Employee">
  <name>
    <prefix qualifier="AC">Dr.</prefix>
    <family>Jordan</family>
    <family qualifier="BR">Johnson</family>
    <given>Jeannette</given>
    <given>Maria</given>
    <suffix qualifier="AC">MBA</suffix>
  </name>
</relatedPerson>
```

The Specialization integration rule is realized by the insertion of ReMMo elements into the current *SPECIFICATION OF THE GENERAL CDA DOCUMENT HEADER* concepts description. Thereby we enrich the HL7 concepts with specific information from the ReMMo model.

To be compliant with existing HL7 description the new element is considered as optional. Figure 5 gives the XML Schema for the

RecordTarget concept enriched by the ReMMo BusinessObject concept.

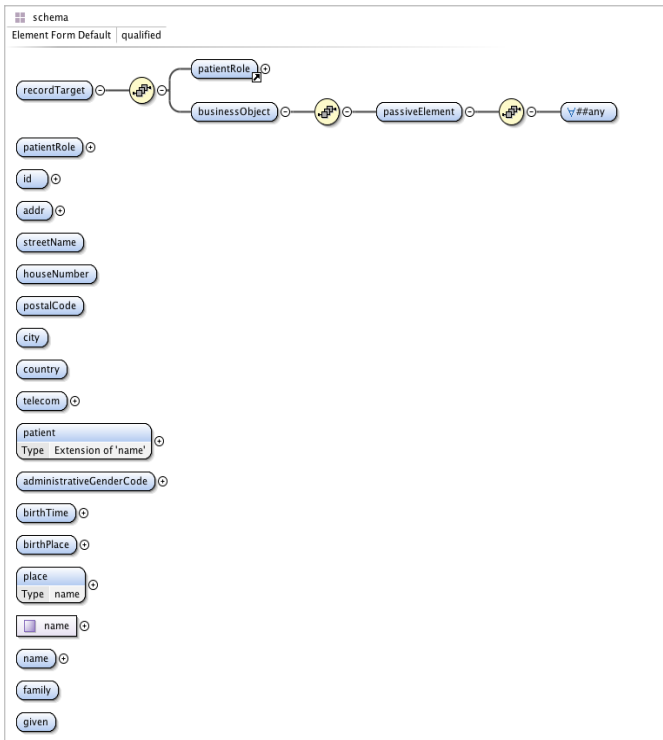


Fig 5. Example of realization of Specialization the integration rule.

An instance of such XML Schema is given below:

```
<?xml version="1.0" encoding="UTF-8"?>
<recordTarget
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:noNamespaceSchemaLocation="recordTarget.xsd">
  <patientRole>
    <id extension="extension0" root="root0"/>
    <id extension="extension1" root="root1"/>
    <addr use="use0">
      <streetName/>
      <houseNumber/>
      <postalCode/>
      <city/>
      <country/>
    </addr>
    <telecom use="use1" value="value0"/>
  </patientRole>
  <patient>
    <name>
      <family/>
      <given/>
    </name>
    <administrativeGenderCode code="code0"
codeSystem="codeSystem0"
codeSystemName="codeSystemName0"
displayName="displayName0"/>
    <birthTime value="value1"/>
    <birthPlace>
      <place>
        <name>
```

```
<family/>
<given/>
</name>
</place>
</birthPlace>
</patient>
</patientRole>
<businessObject>
  <passiveElement>
    <administrativeGenderCode code="code1"
codeSystem="codeSystem1"
codeSystemName="codeSystemName1"
displayName="displayName1"/>
  </passiveElement>
</businessObject>
</recordTarget>
```

To represent the Generalization rule we propose to use the mechanism of importing external XML Schema. This is represented by the following figure 6:

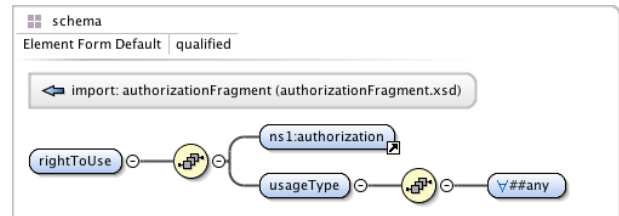


Figure 6. RightToUse XML schema fragment.

The authorization XML Schema is given in figure 7:

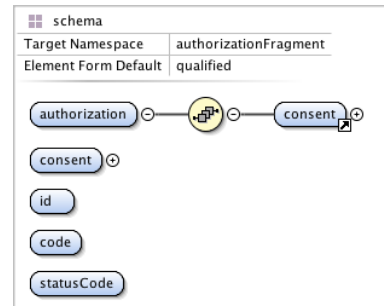


Figure 7. Authorization XML schema fragment.

This mechanism permits to define a new high-level concept, while keeping the link to another concept without interfering with existing one. The XML fragment shown below is an example of such implementation:

```
<?xml version="1.0" encoding="UTF-8"?>
<rightToUse xmlns="authorizationFragment"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:noNamespaceSchemaLocation="rightToUse.xsd">
  <authorization xmlns="authorizationFragment">
    <consent>
      <id/>
      <code/>
      <statusCode/>
    </consent>
  </authorization>
  <usageType/>
</rightToUse>
```

The last integration rule is the simpler rule in the way that the ReMMo concepts are not present or related to the HL7 Luxembourg model. Then these concepts are just represented as new XML Schema fragment that will be added into the integrated metamodel as new concepts. To illustrate that the Responsibility and Accountability XML Schema are given in figures 8 and 9:

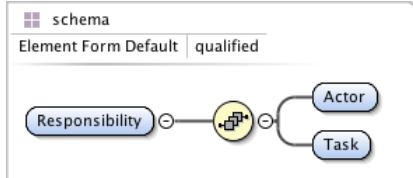


Figure 8. Responsibility XML schema fragment.

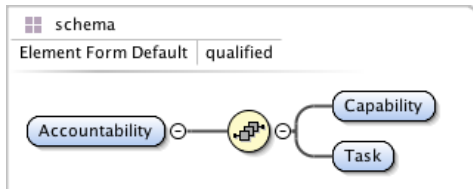


Figure 9. Accountability XML Schema Fragment.

5.2 Parsing schema

Based on the proposed integrated metamodel that overcomes the *Specification Of the General CDA Document Header* and ReMMo models and provides implementation of their related concepts into XML Schema files it will become possible to simulate and generate, at least in an (semi-)automatic way, the rights, including the top levels concepts of responsibility and accountability, for controlling the access of healthcare business applications and services.

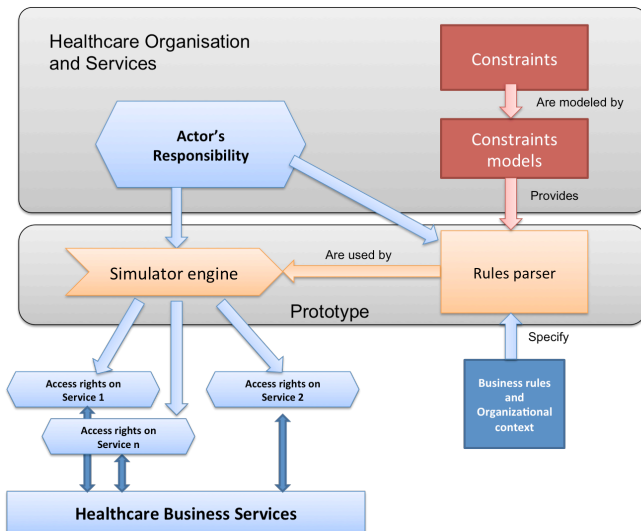


Figure 10. Access rights simulator platform architecture overview.

By adding an intelligent engine parsing integrated metamodel XML Schema instances and taking into account business and organizational context rules, the simulation of modification into the access rights (authorization, access, etc.), and their impact on the information system, can be established and analyzed. Figure 10 gives an overview of such system.

The main blocks of the platform are: integrated metamodel (actor's Responsibility, Constraints models and Business and Organizational context Rules) as provider of knowledge and data, then the simulator engine and rules parser as processing platform and finally the access rights as output for visualization, analyze, and treatment by the healthcare applications and services.

6. Illustration

The context of the illustration is the following: Bob is treated in Institution A by Alice which is surgeon in pulmonology. Bob also agree to be treated by Sam who is his attending physician in institution B. Because Alice is going to order a specific treatment for Bob's lung, she needs to have access to Bob's medical history handled by Sam. The latter wish that only Alice gets access to the record and wants the information to be disclosed to the other doctors from institution B. This context has been analyzed in the following considering without and with the Responsibility extension.

Case of HL7 without Responsibility extension: To access Bob medical history, Alice only has to introduce her business role of pulmonologist in institution A and she automatically gets the rights to access Bob's medical records. This is very simple and very fast but it lacks of accuracy given that she doesn't have to motivate the reason underlying its request. Hence, by extension, everyone from the institution B may access patient's record without necessary firm reasons.

Case of HL7 with the Responsibility extension: To access Bob's record, Alice is again required to introduce her business role (to know pulmonologist) but she must additionally motivate the reason of her request by justifying her responsibility, accountability, and intended medical act. In parallel, given the Luxembourgish context, a condition (see Fig. 3) expresses that the responsibility exists if Bob agrees to be treated by Sam. Acknowledging the request, Sam will be able to introduce in the XML document of the patient file that this file is available for the pulmonologist that are responsible to provide a treatment to the patient Bob. As result, all other doctors/ pulmonologists from institution A will not be able to consult Bob's record anymore.

7. Related works

This section summarizes the related works related to the use of the concept of responsibility in the IT and security domain. To date, this concept has been poorly addressed by the research concerned in the management of IT and authors having published on those topics are limited. Storer and Lock [13] define the responsibility as duties which are to be discharged by agents. Sommerville [14] completes this definition and precise that the duties exist in order to achieve, maintain or avoid some given state, subject to conformance with organizational, social and cultural norms and Stahl [15] introduces the notion of answerability: The responsibility is the ascription of an object to a subject rendering the subject answerable for the object. Martin [16] presents an interesting work to introduce the multi-facet of the responsibility in IT. Strens and Dobson [17] address the responsibility concept to consider the security of the information system and they advocate that the security must be perceived through a sociotechnical approach rather than only through a technical point of view. Without defining a formal model of responsibility, they explain that the responsibility is built around three types of needs: the need to know, the need to do, and the need to show how the responsibilities are fulfilled. Cholvy [18] is interested in formally modelling the concept of responsibility in the field of IT. For the authors, this formalization is complex due to the different

meanings of the responsibility. In [19], Sommerville proposes a model of the causal responsibility. As introduction, he depicts the advantages of modelling the responsibility without considering the agent that will be assigned to this responsibility. The four advantages are: (i) it focusses on the responsibility itself and on the intention of the organization, (ii) it permits to analyze the relationship between responsibilities, (iii) it provides a basis for the assignment of responsibilities and (iv) it provides a basis for vulnerability analysis (i.e., do the agents have the requested capabilities, competencies, resources, and so forth). As a summary, this review shows that the concept of responsibility has only been tackled by a restricted number of authors and that it has mainly concerned the definition and the requirement engineering for information system. Although the many potential opportunity highlighted by the existing research, none of them has addressed the responsibility with the aim at enhancing the access rights management in the healthcare domain.

8. Conclusions and future works

This paper presents an integration of ReMMo with the *Specification Of the General CDA Document Header* metamodel and an innovative HL7 XML standard supported by a dedicated prototype for the access rights management. The integrated metamodel aims at significantly enhancing the semantic associated to the management and the implementation of the access rights into healthcare related applications and systems considering the healthcare staff business roles, responsibilities and accountabilities on the first hand, and business rules and processes on the second hand.

Adding the possibility with the prototype to simulate and visualize the changes into the organization offers the advantages to accurately enhance the access rights provided into a healthcare information system. Thereby, it proves that the management and the security of such system are strongly enhanced. Concretely, this mapping has been illustrated in a concrete case of access rights management for patient medical records sharing between surgeons from two healthcare institutions.

As future works, the next step of the research consists in pursuit the development of ReMMo, and of the integration between the later and the HL7 Luxembourg metamodel. Among the foreseen extensions, a first work consist in the elaboration and integration of business and security constraints (e.g. separation of duty, two-men-rules, and so forth). A second objective is the business extension of the prototype to other healthcare partners which need to exchange patient's records in a secure way. To that end, a special attention will be put on the openness of the future developments (using open standards), on the interoperability among platforms and on the compatibility with all the worldwide HL7 extension versions.

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