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Interoperability is more than just technology

Editors

Bernd Blobel, Mauro Giacomini

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[3] Hasman A, Blobel B, Zvárová J, editors. Data and Knowledge for Medical Decision Support. Amsterdam: IOS Press; 2013.

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Contents

Interoperability is more than just technology

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This Special Issue of the European Journal for Biomedical Informatics is dedicated to the International HL7 Interoperability Conference (IHIC 2016) "Interoperability is more than just technology", 13-15 June 2016 in Genoa, Italy [1]. It contains papers selected by an independent peer review process, strictly performed by experts from countries different from the authors' country of residence.

IHIC 2016 is the 16th event of the International HL7 Interoperability Conference series, which has been inaugurated in 2000 by the Board of HL7 Germany and its unforgettable Chair and interoperability pioneer Joachim W. Dudeck. The first event in Dresden, Germany, was entitled "Advanced Healthcare Information Standards". While the first conferences have been characterized by focusing on CDA (Clinical Document Architecture), over the time, the scope of the conferences has been extended towards all aspects of health information interoperability. The concept of interoperability has dramatically changed from standardized electronic data interchange (EDI) based on data representation at application level, the 7th level of the ISO Open Systems Interconnection stack, having been the name giver for the Health Level 7 standards framework. Meanwhile, the semantics of shared data as well as service level interoperability are considered, bringing terminology and ontology issues, but also implementation challenges such as Web services and RESTful technologies on board. As visible outcome of such development, requirements for National Interoperability Frameworks stated in the USA [2], but also hypes such as FHIR came up and are highlighted in the IHIC 2016 papers as well. So it is just consequent to address in 2016 also non-technological issues of interoperability.

The conference has been structured into four sections: a) Paradigm Changes in Healthcare and Resulting Interoperability Challenges, b) HL7 Perspectives, c) Terminology, Ontology and Classification Issues, and d) CDA-related Contributions. All sections have been introduced by related Keynotes. The papers published in this EJBI Special Issue address the different aspects of the interoperability challenge from a theoretical and methodological perspective, usability requirements, professional groups' preferences, process design, semantical ambiguity, and implementation details.

In his Keynote, Edward Hammond, Duke University (USA), discusses history as well as factors impacting the interoperability paradigm evolution, thereby especially referring to the situation in the United States. He claims use case specific interoperability definitions, and he investigates change management related obstacles in the evolution of practical interoperability. As plead over many years already, Bernd Blobel from the University of Regensburg (Germany) highlights in his Keynote that interoperability is not first at all an ICT challenge. Based on the definition of interoperability as comprehensive communication and cooperation of actors involved in health services to achieve common interests and business objectives, thereby considering their expectations and wishes in their specific environmental, social, and legal context, deploying their specific methodologies, knowledge, experiences, and skills, he introduces a Reference Architecture Model for abstracting, formalizing, and harmonizing real world business scenarios to realize advanced cross-domain, i.e. multi-disciplinary interoperability. In another Keynote, Riccardo Bellazzi, University of Pavia (Italy), approaches the advent of Big Data. Based on the outcome of EU funded projects, he explains how integration of data from heterogeneous sources can enable efficient decision support solutions.

Ken Salyards et al. present current standards and solutions for semantic interoperability of Electronic Health Record (EHR) systems. They propose a model driven approach to mapping different information representation formats, syntax and semantics. They offer Open Source solutions for components for a transformation/interface engine, thereby providing a clear separation of concerns between design and run-time throughout the development process. The ICT focused approach has been implemented at Substance Abuse and Mental Health Services Administration (SAMHSA) to manage cross-organizational behavioral and physical health care. Philip Scott, University of Portsmouth, UK, et al. present the innovative approach to EHR and EHR interoperability standards development led by end-users such as physicians with the support of patients instead of inaugurated by technicians, so extremely improving the acceptance of solutions. This process is managed by the Professional Record Standards Body (PRSB) for health and social

care. The assessment and optimization of the process is performed using the normalization Process Theory. Contrary to the Salyards' article, this approach is closer related to objectives, methodologies and principles addressed in Blobel's Keynote. Alessandro Sulis and colleagues from the Center for Advanced Studies, Research and Development in Sardinia (Italy) present traceability based definition and management of clinical processes to respond to flexible data acquisition environments. For that purpose, the IHE LBL (Laboratory Specimen Barcode Labeling) profile has been used to model and practical implement a phlebotomy process. So, the authors could extend the IHE LBL profile by new transactions for containers production and samples collection. Mark Kramer, MITRE Corporation (USA), et al. use the profiling methodology to constrain Fast Healthcare Interoperability Resources (FHIR) for practical interoperability. In that context, criteria for compatibility, containment, and interoperability of FHIR profiles have been defined. The authors propose are more stringent process of developing FHIR core resources and profiles. Frank Oemig and Bernd Blobel try to predict the future of HL7's most successful and with several IHE Technical Frameworks supported interoperability standard: HL7 v2x. They offer a transition matrix to automatically generate new representations of the standard according to updated releases. The methodology offered is not limited to HL7 v2x, but also applicable to other specifications. Roberta Gazzarata and Mauro Giacomini, University of Genoa (Italy), present a standardized solution for clinical data sharing in acute care, telemedicine and clinical trials. For that purpose, they developed several basic services to be exploited by multiple systems in different care settings based on the SOA (Service Oriented Architecture) methodology and HL7's refinement to the Healthcare Service Specification Program, such as Health Record Management Services, Health Terminology Services and Health Identity Services. Humberto FernÃˇn Mandirola Brieux and colleagues from Argentina developed a clinical laboratory risk engine for automatically providing alerts on ICU patients, using HL7 2.6 specifications. They demonstrated the feasibility of their solution for risk factors blood glucose, hematocrit, WBCs, arterial blood gases, blood urea, blood creatinine, blood sodium and blood potassium. The assessment of the solution in comparison with a traditionally managed control group significantly demonstrated that clinical laboratory risks can be better detected when using an alert system. Abderrazek Boufahja and colleagues from IHE Europe present a tooling set for checking the conformance of specifications such as CDA implementation guides and CDA documents to implement HL7 specifications in IHE projects. The design of CDA documents such as HL7 Templates, supported by the ART-DÉCOR® tool, can so be validated by formalizing the requirements with the Gazelle ObjectsChecker and transforming them correctly in IHE OCL constraints to enable practical interoperability. Stefan Sabutsch and Peter Seifter from HL7 Austria present a user centered design approach to CDA documents shared following the IHE Cross Enterprise Document Sharing specification (IHE XDS). For accommodating user preferences, they appropriately rendered HL7 CDA specs regarding structure, content, display style, etc. For that purpose, the usability of document design was assessed by analyzing the behavior of a test group. The authors recommend PDF/A-3 files including an attached CDA document as best practice for exchanging documents. Heike Dewenter and Sylvia Thun, University of Applied Sciences Niederrhein (Germany) tackle the problem of synonymous concepts for semantic interoperability in the context of the Von Willebrand disease, when using SNOMED-CT for terminology binding in HL7 V3 specifications. Elena Cardillo and coauthors from the NRC Institute of Informatics and Telematics, Cosenza (Italy), tackle the problem of semantic interoperability of EHR systems in a more general approach by presenting the Italian solution for managing and using medical terminologies and coding systems at national level. They emphasize the importance of standardized models and terminology services.

Additionally to the papers presented here, practice reports and implementation experiences have been shared at the conference. IHIC 2016 was completed by a Tutorial Day covering all topics connected to interoperability such as CDA, FHIR, SOA, but also security and privacy issues and the use of the HL7 InfoButton standard.

The Editors whish all interested parties an enjoyable reading.

The Guest-Editors are indebted to thank all authors and reviewers for their excellent work. Finally, they thank HL7 International and for sponsoring the event including the Joachim W. Dudeck Award as well as HL7 Czech Republic, HL7 Germany, HL7 Italy, and HL7 The Netherlands for financially supporting the Tutorials.

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[1] http://ihic2016.eu

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Why Do We Need an Architectural Approach to Interoperability?

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Abstract

Objectives: Health systems are on the move to increasing complexity, distribution, autonomy, number of domains or disciplines involved, thereby requesting evolution of interoperability to support required communication and cooperation among those systems for meeting intended business objectives.

Methods: Information cycle model with its phases and phase transitions as well as systems theory are used to describe structure and processes of healthcare business cases and the interoperability levels for enabling the communication and cooperation between the principals involved.

Results: When focusing on interoperability between health information systems acting as principals in an ICT business case, different levels of contribution to the common business case, i.e. phases to the completion of the information cycle, provided by the principals can be distinguished. While the first two levels, sharing data related to the business case, and sharing information derived from those data to define the required business process actions, deal with the communication challenge of interoperability, just the third level of providing the required action according to the business case concerns its operational part. Such service delivery requires appropriate system architecture for meeting the service functional cooperation challenge. When extending the consideration beyond ICT systems towards real world business systems, the architecture of non-ICT systems regarding their structure and behavior must be represented to be shared as required in the business case as well. This system extension requires domain knowledge based interoperability for covering the domain-specific concepts and relations including the constraints to be applied. When not just considering the domain-specific context, but also the context of the individual user, personalized business systems are managed.

Conclusions: Advanced healthcare systems require not just communication standards for enabling interoperability, but also multi-domain, ontology-driven interoperability standards based on a generic reference architecture, that is also shortly presented in this paper.

Keywords

Interoperability level; information cycle; systems; standards; architecture

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1 Introduction

Paradigm changes in health systems, discussed in several other papers in detail, require the advancement of the underlying interoperability paradigm [1, 2, 3]. The interoperability definition HL7 has originally referred to is the one provided at Merriam-Webster as "the ability of a system (as a weapons system) to use the parts or equipment of another system" [4]. With advancing its communication standards, HL7 has moved to the information and communication technology (ICT) related interoperability definition of IEEE: "Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged" [5]. This IEEE definition focuses on interoperability within the domain of information and communication technologies (ICT), however. Well-known is the saying that the problem in ICT solutions is the user in front of the de-

vice, and another statement tells us that the solution is excellent but doesn't fit the business domain's requirements and the user expectations. Interoperability is not just a matter of – even semantically correct – communication between ICT system, but also an issue of appropriate cooperation of all principals involved. Thereby, principals comprise persons, organizations, devices, applications, or components as defined by the Object Management Group (OMG) [6]. Therefore, the interoperability scope must be extended beyond ICT, covering all stakeholders and their ICT-independent domains contributing to the business case in question. The newest HL7 SAIF interoperability definition "interoperability is the ability of two parties, either human or machine, to exchange data or information where this deterministic exchange preserves shared meaning" goes beyond the ICT domain by involving humans, but it is still restricted to the communication paradigm [7]. The paper introduces different interoperability levels and the role of architectures for advancing interoperability beyond the aforementioned limitations.

2 Methods

2.1 Information Cycle and Related Interoperability Level

For practicing communication and cooperation, sharing of data as well as information is necessary, irrespective of whether this information sharing concerns ICT processes, existence of shared knowledge or verbal and non-verbal communication between living entities. Therefore, the information cycle model [8] is deployed in our approach (Figure 1b).

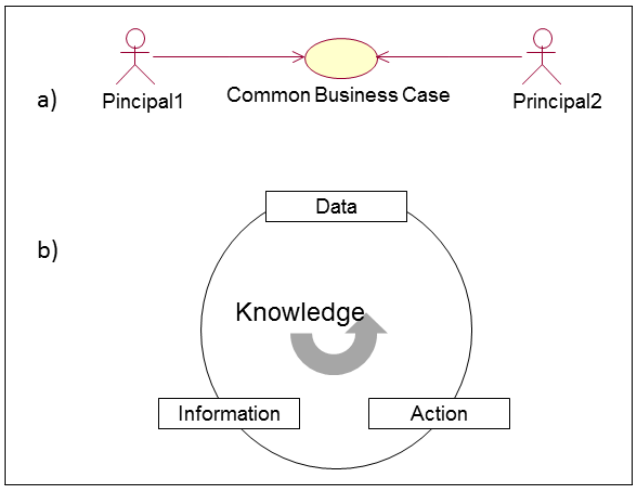

Figure 1: Information cycle (after [8], changed).

The business case serves the creation, transformation, preservation of business system components according to the business objectives. For realizing a common business case by two communicating and cooperating principals involved as described in Figure 1a, all objects and related processes including the environmental as well as contextual conditions resulting in data must be considered. Those data have to be interpreted resulting in semantically correct information. That information must guide the principals in taking appropriate action. In healthcare, those phases are called observation, diagnosis, and therapy. The phases realized in the information cycle deploy existing or emerging knowledge, skills and capabilities, which have to be shared among the principals either a priori or as part of the communication and cooperation process. In the context of health informatics interoperability challenges, ICT mediated communication and cooperation is usually considered.

2.2 Systems Approach to Interoperability

A system is an ordered composition of interrelated elements, separated from the environment it interacts with. A system's architecture describes the systems elements (components), their functions and interrelations. So, it represents the structural, functional and behavioral aspects of a system. Rules for selecting components and functions as well as constraints of the relations according to a business case are called policies. Policies define the intended behavior of a system.

A business case is a system, which provides an intended outcome according to the business objective based on given or appropriately selected inputs and eventually also specific controls, or feedbacks.

3 Results

When focusing on the information cycle, the following interoperability levels between ICT systems are realized (Table 1).

Technical interoperability deals with the connectivity of systems. Structural interoperability and syntactic interoperability address different levels of data exchange by defining either simple data units or more complex rules for structuring the data stream. Semantic interoperability concerns advanced information sharing based on common information models and common terminologies/ontologies to consistently represent the concepts relevant in the business case. Current communication standards cover this continuum by addressing first the connectivity challenge (ISO/OSI lower layers protocols), followed by the data interchange challenge (EDI, HL7 v2), and thereafter by the information exchange challenge (HL7 v3). All the aforementioned interoperability levels cannot guarantee practical interoperability in the context of the business case, as they support the communication of information as first part of the IEEE definition, but not its use. They just support principals to act properly. Communication protocols are unable to perform operations and to take any action.

Table 1: Interoperability levels between ICT systems [1].

Interoperability Level	Instances
Technical interoperability (0)	Technical plug&play, signal - & protocol compatibility
Structural interoperability (1)	Simple EDI, envelopes
Syntactic interoperability (1)	Messages, clinical documents, agreed vocabulary
Semantic interoperability (2)	Advanced information sharing, common information models and terminology/ontology
Organizations/Service interoperability (3)	Common business process

3.1 The ICT Systems Architecture Approach

The first step to overcome those limitations is the deployment of common information in an informational representation of the business process, i.e., the specification of active objects, active resources, or service-oriented architecture solutions. Such service interoperability requires common or interrelated business processes, ruling the aggregation of activities to actions and complex processes, but also architectural principles for ICT systems design and implementation. Related standards meet the service functional cooperation challenge. Examples for such solutions are the OMG's Common Object Request Broker Architecture (CORBA), HL7 FHIR resources, or The Open Group's Service Oriented Architecture with their services (CORBA services, web services, etc.). Requirements for designing such systems are formulated in functional or non-functional requirements specified, e.g., the ISO/HL7 10781 HL7 Electronic Health Records-System Functional Model and ISO/HL7 16527 PHR System Functional Model. For representing them, ICT ontologies are deployed.

For ensuring comprehensive interoperability, the functional and behavioral aspects of the real world business system must be managed in coincidence with the business objectives, and the business processes to be performed for achieving them. In consequence, the technical interoperability definition must advance to "interoperability describes ability and capability to cooperate for achieving common goals or business objectives" [1, 9]. Related standards deal with the knowledge-based interoperability challenge of interrelated business domains, represented using the domain-specific terminologies and underlying ontologies. In cases of human principals' involvement, social and psychological factors such as motivation and willingness must be considered as well. Related standards meet the skills based interoperability challenge. Summarizing the aforementioned statements, only the standards types mentioned in this section should be called interoperability standards.

3.2 Architecture Models and Frameworks

When talking about architectures, we will be confronted with a bunch of different approaches. Even within the ICT domain, many different architecture models and frameworks addressing different aspects of the ICT system have to be considered, as shown in the OPEN Process Framework Architecture (Figure 2) [10].

The process is getting even more challenging when extending the consideration to business cases (BCs) with essential non-ICT process parts. The resulting interoperability scenario is presented in Figure 3.

In the gray-shaded ICT system part, connectivity (0), interface (IF) mediated data exchange (1), sharing of semantics at data representation (DR) level (2), and services sharing at application (APP) level (3) are realized. Beyond ICT, domain-domain interoperability is managed based on sharing domain knowledge to cover domain-specific concepts and relations including constraints (4), thereby harmonizing the ontologies of the domains or disciplines involved. When not just considering the domain-specific context, but also the context of the individual user, personalized systems are managed (5).

For managing business systems according to a business case as described in Figure 3, the system must be properly represented regarding structure and behavior, also reusing and correctly representing the domains knowledge using the domain ontologies.

In [3], the authors have introduced and comparatively evaluated the following architectural models and frameworks (references to the listed architectural models and frameworks can be found in [3]):

- Zachman Framework for Enterprise Architecture;
- OMG's Model Driven Architecture;
- The Open Group Reference Architecture for SOA;
- OASIS Reference Architecture for SOA;
- ISO/IEC/IEEE 42010 Systems and software engineering – Architecture description;
- US Federal Enterprise Architecture Framework including the FEAF Consolidated Reference Model (CRM);
- ISO 10746 Information technology - Open Distributed Processing - Reference Model;
- The Open Group Architecture Framework (TOGAF) including the TOGAF 9 Architecture Development Method (ADM);

- ISO/EN 19439 Enterprise integration – Framework for enterprise modelling;
- Web Services Architecture;
- HL7 Clinical Document Architecture;
- HL7 FHIR Resources, and others.

One of the very few models going beyond a strict restriction on ICT is the Zachman Framework for Information Systems Architecture, later on generalized towards the Zachman Framework for Enterprise Architecture [12, 13]. It is a two-dimensional classification schema for descriptive representations of an enterprise, thereby using a mixture of presentation means from natural language representations through Entity-Relationship (ER) Diagrams and Chen Diagrams up to Bachman Diagrams. Also symbolic logic deploying either the predicate calculus or the conceptual graph notation has been discussed [14]. The Zachman Framework for Enterprise Architecture defines neither a development process or a development metho-dology nor specific deliverables. It doesn't help identifying and managing dependencies [15].

3.3 A Domain-Crossing Interoperability Reference Architecture

There are different types of standards and specifications harmonizing approaches to domains and their concerns: Norms, standards, or publicly available specifications (PAS). Regarding the legal force, we can distinguish de jure, de facto, ad hoc, consensus, and governmental standards. Some of the Standards Developing Organizations (SDOs) are specialized to a specific domain, while others address cross-domain or multi-disciplinary concerns. The latter are frequently governmentally accredited (e.g. CEN, NIST, DIN, NEN, or AFNOR) and

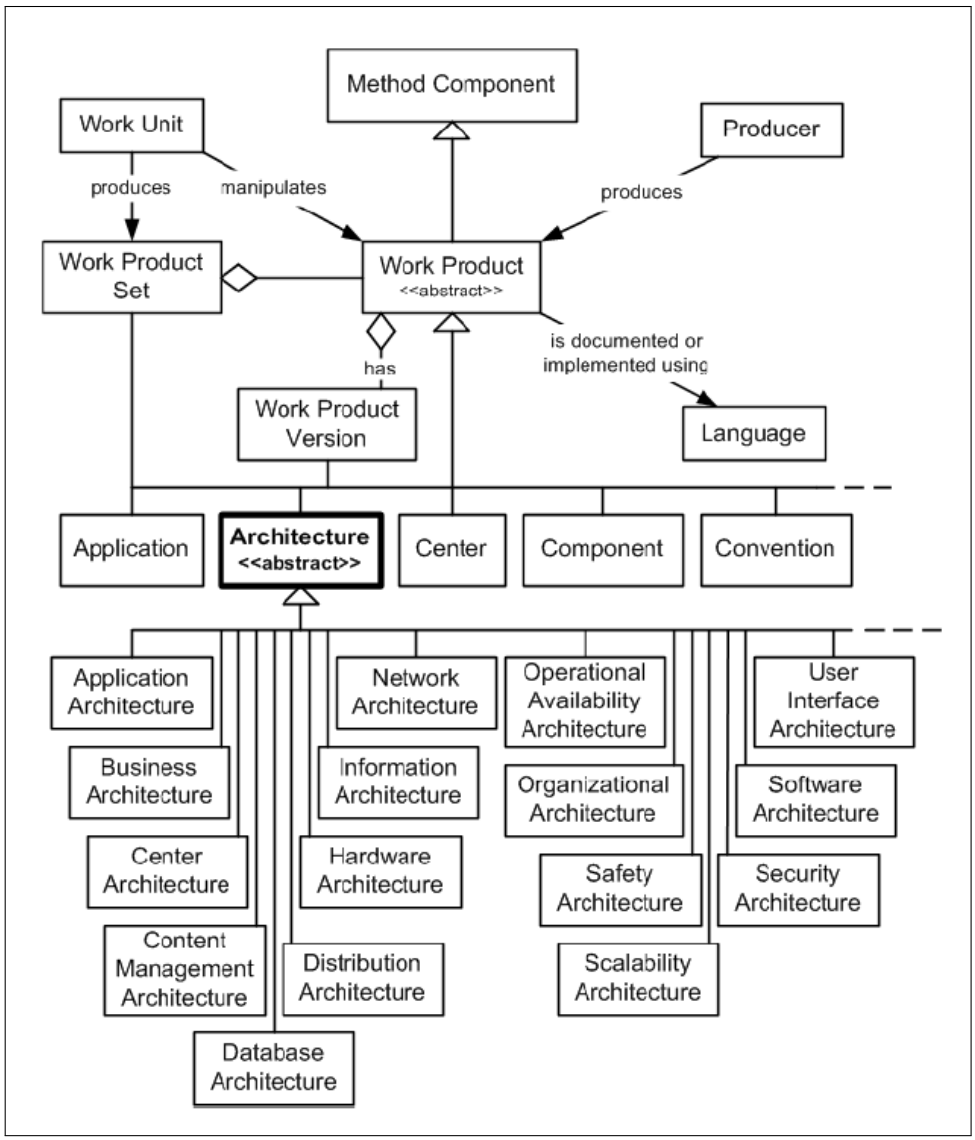

Figure 2: OPEN Process Framework Architecture [10].

domain-specifically structured in domain-specific committees and related working groups.

For modeling real world business systems, the following good modeling practice principles have been introduced [16]: a) The domains of discourse, the real world business objectives, and the domain experts must be defined, where the latter have to be dominantly involved. b)

Within this involvement, those stakeholders define the provided view of the model as well as the way of structuring and naming the concepts of the problem space.

Therefore, standards for agriculture are developed by farmers or agro-engineers, specifications for pharmacological formulas are created by pharmacists, standards in machine construction are developed by mechanical engineers, etc. Information technology specifications are usually and correctly elaborated by IT experts. However, standards for managing and optimizing business processes in health and social care including rules for practicing medicine are mistakenly mainly defined by informaticians. It is not just the lack of domain-specific knowledge and experiences what is frequently missing in SDOs acting in the health and social care informatics but also bioinformatics. Also attempts in enforcing the informatics domain specific methodologies and presentation styles cause frequently big trouble. It is impossible to represent the highly complex, highly dynamic, multidisciplinary/ multi-domain healthcare system by one domain's terminology or even by using ICT ontologies (such as archetypes, HL7 RIM, Zackman Framework, etc.) and enforcing that those styles are applied by the other domains as well.

As application-agnostic communication standards have been successfully developed to enable cross-application data and information exchange, domain-independent reference systems have to be developed to bridge between different domains and their real world business systems.

There is a long tradition in homogenously representing things across different domains practiced in philosophy, using abstract representation means of mathematics and especially logics. Another younger tradition with the same objective evolved in system theory, later on combined with cybernetics. Based on those streams, an application domain and technology agnostic approach has been developed in the early nineties at the German CORBA group the first author has been involved in. This approach of a generic composition/decomposition layer model has been further matured by the first author towards the Generic Component Model (GCM) [1, 17]. The outcome is not a layer model anymore, but a three-dimensional representation of a system, addressing the system components composition/decomposition, the representation of different domain-specific perspectives on the system represented by domain experts using domain-specific terminologies and their underlying ontologies. With that model, all use case specific different domains contributing to a real world system to realize a specific business case can be represented and interrelated. Thereby, the different domain-specific representations must be linked to

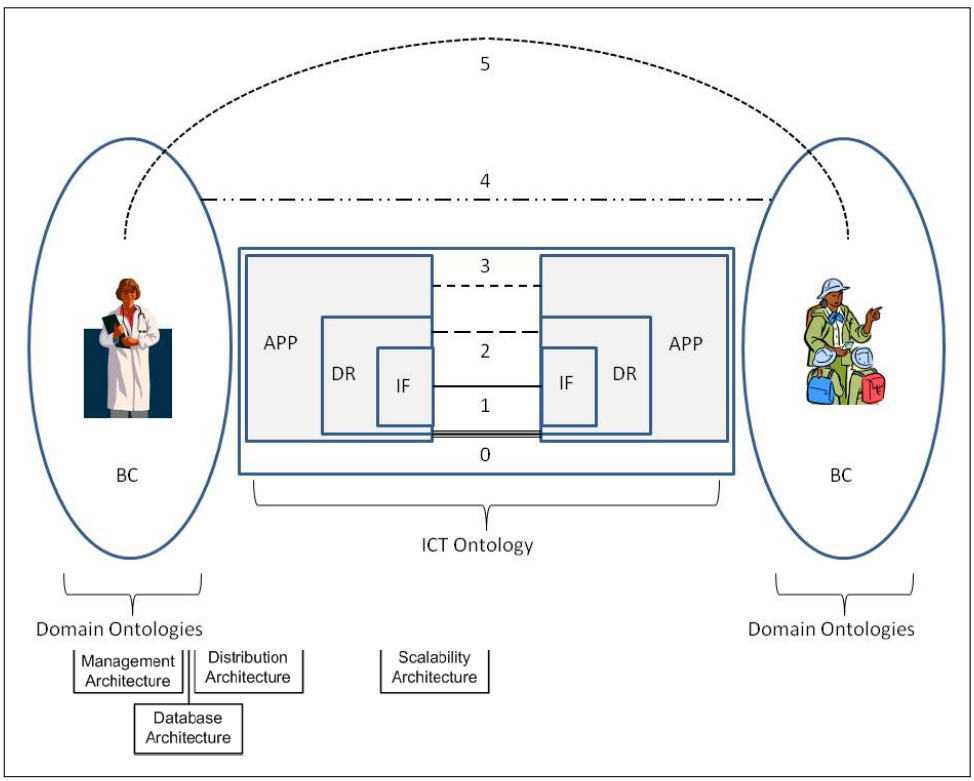

Figure 3: Comprehensive interoperability scenario [11].

the same real world component presented in the abstract reference architecture model. This process is called re-engineering the domains in a reference architecture model. The formally represented business system can be easily transformed into an ICT system supporting the real world scenario by deploying the Rational Unified Process or the related standardized representation through the ISO/IEC 10746 RM ODP [18]. This development process dimension provides the third axis to build the GCM cube.

In summary, the representation of all the domains in components of an abstract uniform component model architecture allows a formalized and harmonized re-engineering of those domains into an Interoperability Reference Architecture Model as shown in Figure 4 to describe their interoperability.

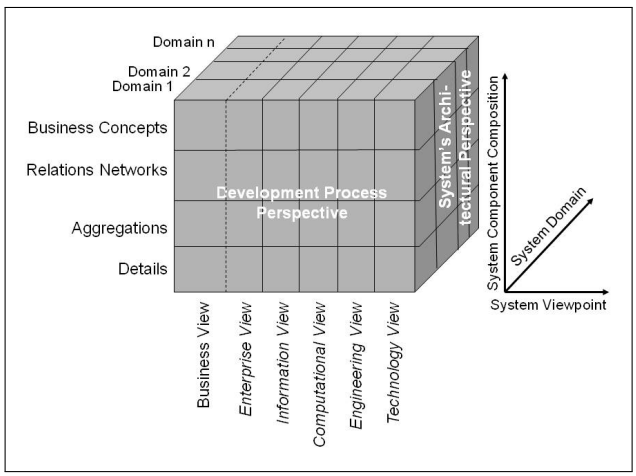

Figure 4: Interoperability Reference Architecture Model.

Not just related to the stakeholder groups involved in the system modeling process, but also related to the modeling process itself, the good modeling practice principles must be followed. Those principles require capturing key concepts and key relations at a high level of abstraction first. Different abstraction levels should be used iteratively, where the first iteration is performed in a top-down manner to guarantee the conceptual integrity of the model. Thereby, design principles such as orthogonality, generality, parsimony, and propriety must be met [16].

4 Discussion

Currently, interoperability solutions are ICT focused. Most of them are restricted to the communication paradigm, thereby supporting just one or two phases of the information cycle model.

For guaranteeing that the intended actions in a business case for meeting the business objectives are performed by all principals engaged in the business system, the operational aspect of interoperability has to be managed appropriately. Hereby, the business systems behavior is relevant, described by the business system architecture and its response to environmental and contextual conditions. Therefore, only an architectural approach can enable comprehensive interoperability. However, the consideration must go beyond the ICT domain.

The representation of health and social care systems is especially challenging due to the complexity and interdisciplinary of those systems. Multi-disciplinary systems are characterized by the huge number of different domains involved and represented by domain experts using domain-specific methodologies, terminologies, and ontologies for correctly representing domain knowledge and deriving new domain-specific insights. Those domains must be correctly interrelated, i.e., according to the real world system architecture representing all the perspectives of the domains involved, to realize comprehensive interoperability. For this purpose, the right component at the right granularity level must be interrelated according to the concepts of the different domains perspectives on that real world system component.

The very few current approaches claiming to solve that problem primarily do this either on the basis of implicit knowledge or by using one domain's specific ontologies (e.g. ICT ontologies) and/or presentation tools (e.g. UML notation) experts from other, primarily addressed domains (e.g. medicine) or involved domains (e.g. jurisprudence) cannot understand. Overcoming the problems of that approach would require universal education in all domains, training in formalizing knowledge, as well as deployment of abstraction and representation style of the minority.

The solution out of the described dilemma is an abstract, systems theory based, ontology-driven Interoperability Reference Architecture Model, preserving ontologies, methodologies and ways of thinking of all the domains involved and automating the harmonization process. It is described in very detail in [19].

5 Conclusions

Comprehensive interoperability of complex, flexible, scalable, business-controlled, adaptive, knowledge-based, multi-domain intelligent systems must follow a systems-oriented, architecture-centric, ontology-based and policy-driven approach. Interoperability is not just provided through specifications, but must be enforced at implementation level as well. This requires implementable specifications, tooling and platforms. FHIR, REST and Web Services are pushing this approach. However, one should never forget that ICT is not the matter of health and social care but a technology to support them.

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Decision Support through Data Integration: Strategies to Meet the Big Data Challenge

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Abstract

Objectives: Presentation of an overview of the reasons why data integration initiatives should be seen as enablers for effective decision support in data-intensive healthcare settings.
Methods: Typical challenges rising from the information requirements of clinical decision support systems are highlighted. We then propose a methodological solution where several heterogeneous data sources are integrated by the means of a common data model on top of which the DSS is built.
Results: We report on two successful case studies based on the DSSs developed in the context of the MobiGuide and Mosaic projects, funded by the European Union in the Seventh Framework Program. The MobiGuide patient guidance system has been successfully validated during a recent pilot study involving 30 patients (10 with atrial fibrillation and 20 with gestational diabetes), while Mosaic is currently undergoing a validation phase involving 1000 type 2 Diabetes patients.
Conclusions: In the era of big data, effective data integration strategies are an essential need for medical informatics solutions and even more for those intended to support decision processes. Building generic DSSs based on a stable (but easily extensible) data model, specifically designed to meet the information requirements of DSSs and analytics, has proven to be a successful solution in the two presented use cases.

Keywords

Decision support; data integration; big data

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1 Introduction

Almost all the stakeholders involved in healthcare processes have to face complex decisions on a regular basis. Regardless of them being patients, clinicians or health policy makers they have the common need of balancing a wide range of objectives, often competing among themselves: make difficult diagnoses, avoid errors, ensure highest quality, choose between alternative treatments, maximize efficacy and save money all at the same time. For these reasons, decision support functionalities are among the most sought after capabilities of medical informatics systems. Indeed the need for effective support to decision-making is even more urgent today than in the days of early adoption of these systems [1]. The advances of biomedical discovery including genomics (as well as other "omics" like proteomics or exposomics), the improved understanding of diseases, availability of new technologies for mobile and self-monitoring devices, the exponential increase in the use and penetration of the internet are only some of the factors contributing to the growth of the two main components needed for effective decision making: information (i.e. data) and knowledge on how to use these information. As a consequence, to thoroughly support decision processes, it is desirable for a decision support system (DSS) to consider the widest possible set of available information. In most advanced systems these might include patient history coming form EHRs [2], several clinical parameters collected by patients using self-monitoring devices [3, 4] (e.g. blood pressure or blood glucose measurements), information available from local health agencies [5] (e.g. purchases and refills of medications), genetic data [6], environmental data (e.g. pollution), patients preferences and lifestyle habits [7]. However there are at least three main challenges to face in this scenario: (i) the information that is relevant for a decision task is typically scattered across several data sources; (ii) these sources can have different data representation formats; (iii) the

Table 1: Fact sheet of the MobiGuide and Mosaic projects compared.

	MobiGuide	**Mosaic**
Project duration	4 years (Nov 2011-Nov 2015)	40 months (Jan 2013-Apr 2016)
Clinical domain	Potentially supports any domain. Pilot implementation on atrial fibrillation and gestational diabetes	Type II diabetes
Users of DSS	Clinicians and patients	Clinicians and health care managers
Type of DS	Guideline-based	Based on predictive models and visual analytics
Type of output	Clinical recommendations	Risk scores, temporal patterns and alerts
Data sources	Hospital EHR, patients' body area network, patients personal preferences	Hospital EHR, administrative data, environmental data
Data Integration main component	Data Integrator	Orchestrator
Data model	HL7 vMR + openEHR archetypes	i2b2 star schema
Data Integration technologies	BaseX noSql XML-based storage + REST web services for querying	Oracle DBMS + i2b2 hive ecosystem + REST web services for querying

volume and heterogeneity of the data may often raise "big data" challenges, which require proper technological and architectural solutions.

2 Methods

A methodology based on a data integration strategy is hereby proposed as a solution to the challenges highlighted in the previous section. The proposed methodological approach has been successfully applied in the context of two EC-funded projects, namely MobiGuide [8] and Mosaic [9], whose architecture and results will be presented in detail in the following section.

The need for a DSS to access different data, stored in different formats and originating from different sources is inevitable to achieve optimal decision support capabilities. On the other hand, tightly coupling the specific DSS implementation to each of the several data formats very likely results in increased complexity, high change requests frequency, and ultimately poor maintainability of the produced system.

An alternative approach consists in adding a data integration layer to the architecture and to represent all the needed information using a common information model that serves as a single data provider for the DSS. Several approaches to the design and implementation of such common data models have been proposed in the medical informatics literature, some of which have been specifically developed to support clinical DSS [10, 11, 12, 13]. Among these, some approaches only provide the specifications for a logical data model that defines entities and their relationships at a high level of abstraction (e.g. HL7 vMR [14]) while others also define a technological structure (e.g. i2b2 [15], which comprises a database management system, services for querying the data, etc.) able to support the implementation of the defined abstract model. In both cases one of the most important steps to perform is the reconciliation process, often referred to as mapping, of different information items to fit the entities available in the chosen target data model. This is often a resource-intensive phase of the development process both at a knowledge engineering level and in terms of required implementation efforts [16]. In fact the core of many data integration solutions consists of a set of specifically developed extraction-transformation-loading (ETL) procedures that allow collecting the information from the different sources in a single integrated repository. Given their importance, mapping and ETL processes have recently gained attention in medical informatics research literature where several advanced methodologies including semantic [17, 18, 19] and real-time approaches [20] have been described. It is also important to stress the fact that sharing a common data model also enables to create DSSs that rely on the data provided by multiple centers. This could be accomplished using two different strategies: (i) physically aggregating the data in a single corporate-level warehouse populated through periodical ETL procedures or (ii) building a federation of local repositories which share the same logical model allowing them to be collectively queried [21].

3 Results

The described methodology for building a clinical DSS on top of a data integration solution has been applied in the context of two different European research projects (Table 1) carried out between November 2011 and April 2016. The projects activities involved the University of Pavia and the IRCCS Foundation "S. Maugeri" Hospital, in collaboration with international academic and industrial partners.

MobiGuide aims at developing an intelligent guideline-based decision-support system for patients with chronic illnesses [8]. The system accompanies the patients wherever they go and helps them and their care providers in managing their condition, whether they are at home, at

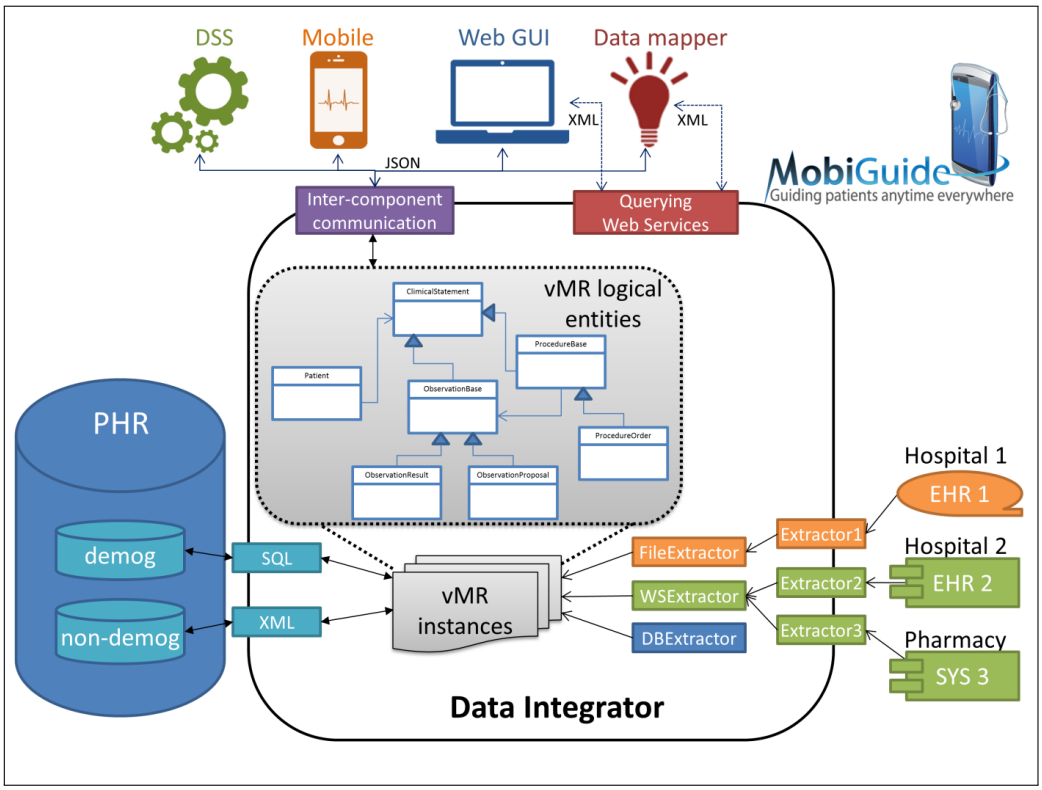

Figure 1: The MobiGuide architecture is centered around its Data Integrator component.

work, out and about or travelling abroad on holiday or for business. One peculiar characteristic of the MobiGuide DSS is that it provides guidance both to clinicians and patients directly. Patients' smartphones act as the centralized connection hub for the MobiGuide Body Area Network (BAN), which comprises a set of sensors able to provide data to the DSS while patients continue with their everyday life with the benefit of being constantly monitored by the system. Moreover, a dedicated smartphone app is used as the primary interface for the patients to interact with the system and receive feedbacks and guidance from the DSS. The DSS engine is also distributed in its nature: it features a full-fledged back-end DSS and a lightweight mobile DSS, which runs directly on the patient smartphone and is able to provide essential guidance even if the connection to the back-end system is unavailable. The MobiGuide DSS applies the knowledge contained in computer-interpretable clinical practice guidelines [22] to a continuously monitored set of patient data, and outputs personalized clinical recommendations about disease management. These recommendations include suggestions on clinical actions for the physicians to take (e.g. prescribe a certain drug or perform a specific diagnostic procedure) and advices directly delivered to patients (e.g. reminders about taking drugs on schedule or taking an additional measurement to check potentially harmful, unforeseen situations) [23]. To accomplish this, the guideline execution engine needs bio-signals originating from patient smartphones, clinical findings collected in the hospital HER and patient preferences collected with dedicated interfaces. All of these sources of information are aggregated in a centralized personal health record (PHR) [13]. A dedicated software component, namely the data integrator (DI) [24], manages all the insertions and retrievals of data from the PHR and periodically updates it through ETL procedures. The data model on which the DI and PHR are based has been derived from the HL7 vMR standard. The same logical model is also used for inter-component communications inside the MobiGuide environment [25]. The vMR standard alone does not provide a specific technical solution for its implementation. This, while complying to the same logical data model across the entire system, allowed to choose an XML representation to implement data persistence while using a lighter JSON format inter-component communication (Figure 1).

The MOSAIC project is aimed at developing novel analytics methods and tools for managing type 2 diabetes (T2DM) and its complications. Differently from MobiGuide, the type of decision support delivered by the MOSAIC system is based on a set of models, developed within the project [26], able to estimate the risk of a patient to develop T2DM or its complications, and to guide users in the management of the temporal evolution of the disease. The MOSAIC system offers two perspectives to its users: on the one hand, it allows managing patients during visits through a single-patient view. On the other hand, it allows analyzing sets of patients thanks to a population view. Being focused on these two use cases, the MOSAIC system addresses mainly physicians and health care managers, but it also proved to be a useful instrument to be shown to the patients during visits.

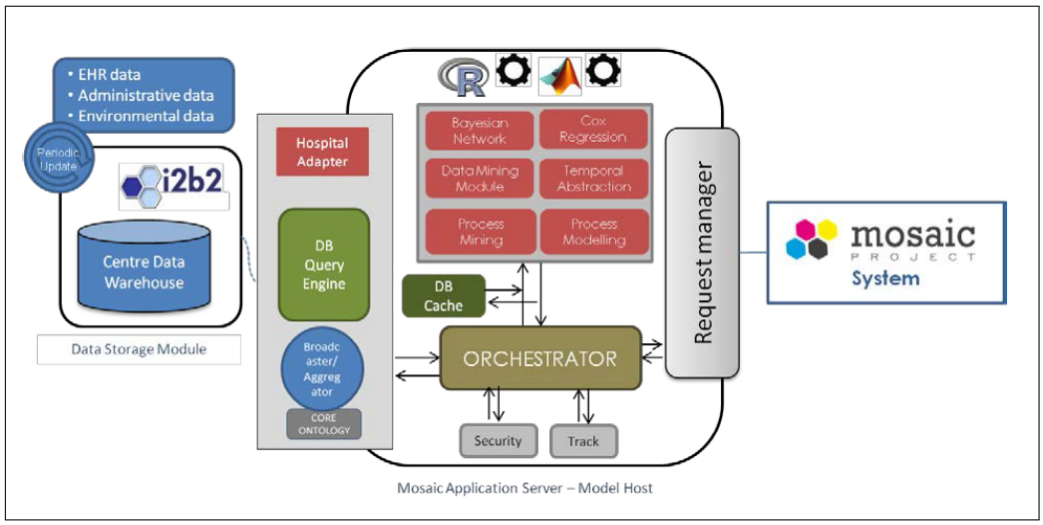

Figure 2: The MOSAIC system architecture.

The MOSAIC system has been designed to be potentially used in any context dealing with T2DM patients, including the GP practice, where diagnosis is performed and first treatments are delivered, the hospitals, where more complex cases are managed, and public health premises, where strategic and organizational decisions are taken on the basis of the analysis of patients' populations. To be able to apply the portfolio of analysis models developed in the project to the data of the different participating centers, a common data model was defined and implemented using the i2b2 technology [15]. In the MOSAIC system, the i2b2 data warehouse allows integrating clinical information coming from hospital EHRs, administrative data from the local health care agencies, and environmental data collected from satellites [27]. The data model is defined using the i2b2 core ontology, and data are loaded to the repository thanks to ETL procedures properly defined at each participating center.

The MOSAIC system has been designed as a Service Oriented Architecture (SOA), where different components from different modules access the whole functionality of the system through a set of Web Services (Figure 2). These components are linked together in an asynchronous way through a message oriented architecture and interact with each other over internet using SOAP messages, conveyed using HTTPS and other Web standards. All of them work in a collaborative way thanks to the orchestrator, a deployment engine that allows the distributed coordination among different modules and services based on choreography principles. The choreographer is a system that allows the intercommunication among services providing tools for registering, multicast and broadcast communication as well as message filtering. This approach allows an easy deployment, efficiency, and independence from the programming language thanks to the intercommunication among services developed in different platforms and technologies.

Both the MobiGuide and Mosaic systems have been validated in pilot trials involving Foundation "S. Maugeri" Hospital to prove the feasibility of the approach described in this paper. In particular the MobiGuide system has been successfully validated in a 3-months-long study involving 10 patients form the atrial fibrillation domain and 20 patients with gestational diabetes (diabetic patients were enrolled at the Parc Tauli' Hospital in Sabadell [28]). The MOSAIC system is currently being evaluated at the Endocrinology Unit of the Fondazione Salvatore Maugeri Hospital. Physicians working at the Diabetology outpatient service have started a pre-post evaluation phase, where they have been seeing patients without the system for two months and they are performing visits using the system for three months. During this period, a set of interesting variables are being monitored, and will be compared at the end of the study to evaluate the benefits of introducing the system in the clinical practice. Of the MOSAIC cohort, which consists of 1000 patients, up to now, 500 patients have been analyzed during the phase without the system and 440 patients have been visited using MOSAIC. In parallel, a set of meetings have been organized among physicians working at the hospitals and healthcare managers working at the local healthcare agency of Pavia, to evaluate the tool working on patients' populations.

4 Conclusions

Modern DSSs need to interact with multiple, distributed and heterogeneous data sources. For these reasons, effective data integration strategies are an essential need for medical informatics solutions and even more for those intended to support decision processes. Methodologies for creating and maintaining centralized data repositories allow building DSSs on top of single data providers whose data model has been specifically designed to meet the requirements of integrated decision and analytical processes. Moreover, distributing the responsibility of adapting to the repository to the ETL procedures at the single centers improves system scalability, maintainability and provides the possibility of integrating additional informa-

tion sources even at late stages of the development or after deployment. Two different implementations of the described approach have proven to be successful in the two presented research projects.

Acknowledgements

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The Elusive Search for Interoperability

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Abstract

With the arrival of the information age and transition towards Electronic Health Records (EHR) and Digital Data, the need for aggregating data across multiple sources lead to the concepts of interoperability. Initially, interoperability was defined only from the perspective of technical interoperability and semantic interoperability. Over time, what was required to make things work together expanded the concepts of the scope of this topic. Unfortunately, the momentum of what currently exists, lack of motivation to change, the cost of change, and lack of a clear Return on Investment (ROI), and unclear solutions has made interoperability seemingly an impossible goal. This paper postulates that the definition of interoperability varies based on use case. The paper discusses what adjectives the term interoperability might legitimately carry – total, partial, implied, ... The paper also discusses the problems associated with a focus on the word interoperability and attempting to create standards that enable the concept rather than a focus on what we are really trying to do and then looking at what is required to make that happen. Finally, the paper discusses the recent Request for Information (RFI) from the U.S. Office of the National Coordination (ONC) for Health Information Technology to provide suggestions about how interoperability might be measured.

Keywords

Interoperability; Health Data Standards; Electronic Health Record

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1 Introduction

As computers began to be used in the health care setting, the need to integrate data from multiple sources became desirable. At first, each system created its own interfaces among the sources and at significant cost. Further, with the implementation of new features and new sites, the interfaces had to be maintained and updated at considerable costs. Health Level 7 (HL7) came into being in an effort to create a reusable solution to this problem. HL7's initial focus was to create a standard that would support the development of a Hospital Information System (HIS) from functional components developed by multiple systems. These components were selected from a larger set and represented what different groups identified as "Best of Breed" components. The focus of the standard was to create a message that was the mechanism by which data was transferred from one functional component to another. The functions connected were largely service functions such as clinical laboratory; admission, discharge, transfer; radiology; pharmacy; scheduling; and billing. Next the standards created were designed to support both in-patient and outpatient settings; bed-side instruments; images; and some decision support applications. Even so, these standards were developed largely by technical people and did not involve the clinical community, clinical professional organizations, or government groups. The word interoperability was introduced to define what standards were supposed to do. The Institute of Electrical and Electronic Engineers (IEEE) provided a definition of interoperability that was accepted by the standards community. That definition was "the ability of two or more systems or components to exchange information (identified as functional interoperability) and to use the information that has been exchanged [1] (identified as semantic interoperability)". I would point out that the word information should be replaced by data, since that was what was exchanged. The definition seemed to be adequate as long as the purpose and use of the standard was limited in both scope and stakeholders.

1.1 Definition of Interoperability

Over time, as the use of digital data with the health care system expanded to involve more and diverse people and more and diverse purposes, we began to realize that more than just functional and semantic interoperability was required. Additional technical requirements

appeared in the form of networks, database architecture, structured and non-structured data, privacy and security, legal and propriety issues, patient consent, provenance, triggers, what to exchange, and other drivers. The targets for data exchange continued to expand. The concept of a patient-centric electronic health record in which all data created for and about a patient were aggregated into a single record has evolved. The concept of a Health Information Interchange required standards to support the aggregation of centralized or federated databases for regions of various sizes including states or even countries. The support of sharing data across multiple sites and regional groupings became desirable. The definition of interoperability now became less precise, and what was required for interoperability was less clear.

The current fuzziness of the word interoperability can be realized by simply "Googling" the word. Healthcare Information and Management Systems Society (HIMSS) defines interoperability as "the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged."[2] Data exchange schema and standards should permit data to be shared across clinicians, lab, hospital, pharmacy, and patient regardless of the application or application vendor. Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities. HIMSS defines three levels of technical interoperability: functional, structural, and semantic. The meaning of functional and semantic is consistent with IEEE. Structural interoperability defines the structure or format of the data exchange. Another, perhaps clearer term is syntactical interoperability.

A comment from the group developing these definitions best expresses the problems: "Interoperability is one of those terms everybody thinks they understand. When you press people for a definition you usually get a shuffling of the feet and a blank look. Well, it's when things talk to each other, right?"

ONC defines interoperability as: "All individuals, their families, and their health care providers have appropriate access to health information that facilitates informed decision-making, supports coordinated health management, allows patients to be active partners in their health and care, and improves the overall health of our population."[3]

Wikipedia defines interoperability as "a property of a product or system, whose interfaces are completely understood, to work with other products or systems, present or future, without any restricted access or implementation."

More generally now, interoperability must include social, political, and organizational factors.

1.2 Personal Experience with Interoperability

My group at Duke designed our first automated medical record (AMR) (what we called it then) in 1970. Initially, the sites of use were Obstetrics, Primary Care Clinic, and a Renal Dialysis Unit. Each system was independent of the others, but we created a single program, and the differences in the sites were accommodated through a data dictionary. To capture lab data for the AMR a human operator looked at the Lab system terminal and typed the data into the AMR. The error rate was high. There were many different sources of lab data at Duke, so to accommodate an interoperable interface with all, we created our first data interchange standard. The error rate was very high. The standard identified what data items were sent, the format and the syntax of the exchange. Since the terminology used to identify the data items was local, we had to map from the lab terminology to the AMR terminology. The lab names seemed to constantly change, and synchronization of the names – a condition for interoperability – seemed impossible. We participated in the creation of HL7's v2.n standard and early on transitioned from our local standard to the HL7 v2 standard. If we could not process an incoming standard, we moved the message into an error file where a human resolved the problem. In 80% of the errors we found they were due to a mismatch between what the lab sent and our ability to map it into our AMR terminology. So, even then, interoperability was an elusive goal.

We later evolved into an in-patient setting, and we added bedside monitoring into the functions supported. In this case, we had bit streams from various bedside instruments which we then had to decode, understand, map into our terminology set, and integrate into the AMR. Our first challenge was an instrument data flow that immediately turned off when activated. After lots of frustration, we finally discovered that the first byte transmitted in the data stream was the X-OFF pattern. We then had to recognize that byte and change it to activate the byte-oriented data stream. In this case, interoperability required understanding and accommodating the actual bit-stream coming into the system.

One more example occurred when we implemented the AMR (now identified as The Medical Record (TMR)) in a long term care (LTC) facility. Most patients were admitted into the nursing home from a hospital, and we wanted to transfer data from the hospital into the record of the LTC facility. In this case, we had to first identify what data elements we needed to transfer from the hospital to the LTC as well as map from the hospital local terminology into the LTC local terminology. We then discovered that frequently, patients from the LTC were readmitted back into the hospital, and the process was reversed. But the hospital wanted different data elements from the LTC so a different transfer protocol had to be established.

Two similar use cases were encountered when Family Medicine Department started seeing and taking care

of women who became pregnant. These women would deliver at Duke OB and may in fact have visits in the OB clinic if issues arose during pregnancy. The family medicine clinic and the obstetrics clinic used different data dictionaries, although the root EHR was the same. In this case, the records for the two systems had to be synchronized, with data flowing bi-directionally between the two systems. The architecture of the two EHR implementations was different, so not only mapping was required between the terminologies, but differences in format and content of the EHR had to be accommodated. Another similar example was creating the pediatric EHR automatically from the mother's OB EHR. Again two different terminologies were mapped and different data architectures were mapped.

More recently, I became involved with a collaborative research project sponsored the Patient Centered Outcomes Research Institute (PCORI) called PCORnet. In this research, queries are made across multiple datamarts aggregated through Clinical Data Research Networks (CDRN). CDRNs are made up of many different institutions and sites. For example, one CDRN, called Greater Plains Collaborative, is composed of 12 leading medical centers across 8 states and extends from Wisconsin to Texas. A Common Data Model was created and is used to define a common set of data elements for the queries. Each participant must map from local representations of data into the common model. The problem is further complicated in that sites include a mixture of claims based data and clinical data. Value sets differ for many of the data elements and what is available or not and how data are represented varies. In this case, establishing interoperability is even more challenging. Different networks, different search engines, different connections and whether CDRNS are centralized or federated may differ across the networks. How will the degree of interoperability be measured under these circumstances? Data characterization is being established by simple queries among the sites (currently 85 datamarts) represented over a million individuals.

Most recently, I have been involved in a pilot study in which data from personal sensors are moved through a series of steps to my personal care provider. Using my Apple Watch and Apple HealthKit, I use watchOS and iOS to move health and fitness data into Epic's MyChart. For my Apple Watch, I automatically capture activity data and heart rate. My scale uses a bluetooth to enter my weight. I enter blood pressure and nutritional data directly into my iPhone. Using SMART on FHIR®, the data is moved into a flowsheet in MyChart. My PCP then, at times of her choice, looks at the time-oriented data. On two occasions, she has changed my medications as a result of these data. Again, what is required for interoperability has expanded tremendously, and involves multiple stakeholders, many different technologies, networking, people issues, security and privacy, and control.

The purpose of these examples is to show that the meaning of interoperability is a function of the use case. The meaning includes understanding data representation, solving connectivity issues, mapping terminologies, defining what data is to be exchanged, dealing with an inconsistent mixture of units, dealing with a mixture of data types, and synchronization of data flows among different systems. Issues of privacy, security, unique and essentially error-free patient identification must be resolved. As data interchange broadens, provenance becomes essential. Proprietary vs open systems complicate the exchange of data. Trust and quality become big factors. The mountain of interoperability grows even higher and challenges a solution.

2 Standards That Support Interoperability

Where do standards come from? How do standards developing organizations decide what standards they will develop and with what priorities? What is the role of the various stakeholders? What is the role of the government? Do governments mandate, regulate, fund development, encourage, certify, or participate? What is the role of vendors? Do vendors participate and try to influence standards that favorite their products? Does the lack of functional and successful standards make it easier for venders to provide total solutions at a price that once committed, few can afford to change? What role should the user stakeholders play? How do they understand "the art of the possible" to encourage the creation and adoption of standards that add value to the process of healthcare? How do domain experts share their knowledge with the technical developers of standards? I suggest another important question that should be addressed is "Which comes first – standards or requirements?"

In informatics, we frequently define a word, such as interoperability, and fixate on that word rather than on what we are trying to accomplish. We pick our definition and create a standard that addresses that definition. HL7, for example, focuses on designing a standard that provides functional and syntactical interoperability. We overlook semantic interoperability because we are too late to dictate a solution, so we create a standard that accommodates the most widely used terminologies with-in the standard. Have we destroyed any chance to achieve interoperability? Furthermore, there are many other issues that must be addressed that are beyond the scope of HL7.

3 Discussion

The U.S. Office of the National Coordinator for Health Information Technology recently issued a Request for Information requesting information about how interoperability might be measured or at least evaluated. The purpose of this paper is to argue that such a task might be impossible, but importantly is really not important. We put interoperability up front and design standards that

try to accomplish this goal. We hope issues for which we have no solutions, or solutions that we are unable to enforce or get acceptance will somehow magically disappear. We spend time and resources creating work-arounds that continue to cost time and money and the problem never disappears.

Two examples illustrate this point. The first is perhaps doable, if we are willing to make it happen. The issue is unique patient identifiers. At least 80% of EHRs will contain someone else's data. We have developed a number of algorithms to create a unique identifier from a set of personal identifiers, many of which are chosen from the HIPAA Personal Health Identifiers (PHI) data elements. Validation of this method is based on the presence of the data elements used to create the identifier. The identity error rate, in the absence of a universal personal identifier, is sufficient to limit the ability to create a medication history across multiple settings. Pragmatic clinical trials are likely to be biased by duplicative patient records, some of which may be within the same institution.

The second obvious barrier to interoperability is a single common terminology, used world-wide. Existing terminologies were created for the most part for various purposes, and do not represent with sufficient granularity and precision clinical concepts. The use for financial purposes tends to dominate what is defined. New categories of data, such as biomarkers, genomics, patient-reported data, environmental data, behavioral data, and other data types are not included. Further, the full set of attributes is not specified, and even if they are specified, users ignore them. FHIR has the potential to address some of these problems by starting with fully specified data elements, fully specified resources, and profiles for stated purposes.

4 Conclusions

The potential for informatics to make a significant impact on the health of the population of the world could never be greater. Current initiatives in the U.S. include Population Health, Precision Medicine, Learning Health Systems, Big Data, Clinical and Translational Science Awards (CTSA), data sharing, PCORI, ONC, NIH initiatives, and many others. All require the ability to move, share and use data. As evidenced in this paper, the specifics of what is required and the expanse of what is required vary considerably. I suggest that we should first focus on what we want to do – truly visionary – and then create systems, standards, and tools that enable that vision. We also need to bring the community together in creating necessary standards, quick acceptance and implementation, and global use. Any barrier that needs to be overcome should become a primary concern, and energy directed toward removing the barrier – whether it is political, workflow related, people related, or technical. The world is in constant change. We must design accordingly.

References

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Interoperability in the 21st Century: Cost Effective Solutions and Guidelines for Interoperable Electronic Health Records

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Abstract

This paper describes the use of standards to enhance the capability of creating semantically interoperable documents and messages. Over the past few years, many information exchange formats have been created. While the health industry continues to develop new formats that attempt to simplify or modernize interoperability across healthcare, it is continually challenged by the difficulty of current applications to exchange documents that can be interpreted by the receiver of the document. Given the variety of standard formats, a framework should be developed that can bridge across multiple exchanged formats/syntax and semantics. It should reference the business content in a consistent way that represents clinical best practices and connects to the clinical workflow that triggers information exchange. This paper describes the use of model-driven development to bring balance to the art of data exchange by supporting semantic interoperability for design and run-time. The proposed model-based approach to mapping addresses the semantic challenges and allows sending systems to first specify the meaning of their data by relating it to a defined common data dictionary of business data elements thus making it independent of other datasets.

The resulting architecture proposes two sets of open-source components intended to provide a clear separation of concerns throughout the development process between design and run-time. SAMHSA is using this approach in its Information Exchange Hub (IExHub), the transformation/interface engine supporting both behavioral health and physical health interoperability for health information exchange network (HIEs).

Keywords

Semantic Interoperability; Electronic Health Records; Behavioral Health; Clinical Document Architecture; Consolidated CDA; Fast Healthcare Interoperability Resources; Semantic Mapping; HL7 Version 2; Model-Driven Interoperability; Model-Driven Health Tools; Information Exchange Hub; IExHub; CDA; C-CDA; MDMI; MDHT; FHIR; MDI; MDR

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1 Background

Information exchange has existed since the dawn of man. While the human mind can make inferences when information is missing or presented poorly, such inferences can be wrong due to missing, incorrect, or poorly presented information. When exchanging information human to human or augmented by minimal technology such as phone or FAX, the format and content of the information are often not very rigorous. This presents issues when exchanging information electronically.

Health information such as narrative descriptions are often exchanged between providers using a generic electronic format such as PDF and HTML. This is only marginally better than FAX and heavily reliant on human interpretation of the information received with little to no computeraided processing or analysis. A human must refer to and interpret the electronic document anytime the information can be used in the treatment of a patient. As information exchange relies on both the sending and receiving clinicians to interpret it in the same way, the semantic modifiers such as "resolved," "major," "critical,"

or "severe" that are associated with clinical information may be contextual. Thus, better interoperability requires semantic clarity that goes beyond human decoding of narrative information and requires machine processing of free-text and structured data. Similarly, it is important to convey such information as: "the patient does not report any allergies," "we have no information about allergies," or "tests reveal no allergies."

Over the past decades, many information exchange formats have been created to exchange messages and documents. While the intent of these formats and approaches is to simplify interoperability, it has presented a very complex interoperability landscape for implementers to navigate. As a Standards Development Organization (SDO), Health Level Seven International (HL7) has developed several file formats for exchanging information. These include HL7 Version 2.x, HL7 Version 3, Clinical Document Architecture (CDA), and Fast Healthcare Interoperability Resources (FHIR). All have been attempts to create machine-understandable structures with flexible semantic content, subject to implementation-specific clarifications. For standards to augment and improve interoperability, they must be associated with specific use cases. All HL7 standards have to be constrained (or extended) and combined with clinical terminology to create an implementable guide that attempts to eliminate ambiguity.

There are other content standards defined in the United States, such as the National Information Exchange Model (NIEM) and The Accredited Standards Committee X12 known as ASC X12 or simply X12. Layered below the content standards referenced above, there are transport protocols such as SOAP, REST, NwHIN DIRECT, and NwHIN CONNECT which are often tied to a particular information exchange standard and ignore semantic clarity. Figure 1 illustrates the complexity faced by EHR systems expected to convey business information using Meaningful Use standards such as C-CDA, HL7 V2, QRDA, or HQMF, or emerging standards such as FHIR.

2 Problem

Healthcare interoperability requires information to be semantically precise to ensure that its meaning is interpreted in the same way by both the sending and receiving systems. The challenge posed by semantic consistency increases exponentially when information is exchanged across multiple senders and receivers (many-to-many) across a nationwide network.

In the US, the current state of the health care delivery system is fragmented with many poorly implemented health IT systems still lagging in data (semantic) interoperability despite the billions of dollars spent to certify electronic health record (EHR) systems and launching health information exchange (HIE) solutions to integrate community-based providers.

The current standard implementations have not matured sufficiently to remove ambiguity from the exchange standards or ensure consistent semantics across communities. There are no required implementation standards for HIE organizations, the key entities that facilitate electronic health information exchange between providers. Additionally, HIEs have demonstrated poor business model sustainability. These issues directly affect the interoperability landscape, especially for specialty providers such as cardiology and behavioral health. Simply validating the structure of a document or message does not ensure the information contained will either be sufficient or be interpreted in the same way for decision support and treatment. The current state of interoperability allows different systems to process and interpret information differently even though the underlying standard structure is valid and includes all the relevant business data elements.

The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) is currently exploring ways to reduce the complexity of information sharing across the HIE without compromising patient privacy and confidentiality and supporting national regulations such as 42 CFR Part 2 [1]. SAMHSA is also creating opportunities for behavioral health clients in particular, and patients in general, to have greater control of their health information through standard-based solutions that ensure semantics interoperability across the continuum of care.

Achieving interoperability across the continuum of care requires that all systems must have a common understanding of the information shared regardless of the payload structure or transport. To bridge the differences among systems, a common, standards-based canonical definition of information meaning can help translate from one format to another while maintaining semantic precision. The goal is to allow EHRs and Health Information Exchanges (HIEs) to share information using standard structures (i.e. messages, documents, resources) and terminology as well as leverage standards-based knowledge models using standard terminology systems.

This paper describes how interoperability would be enhanced by model-driven architecture principles to add the science of semantic data definition and mapping to the art of standardsbased information exchange.

2.1 Why Mapping Fails

Throughout this paper, we emphasize the importance of semantic mapping and the use of profiles to constrain standards for precise implementation and transformation. Past attempts to map HL7 Version 2.x message elements to HL7 Version 3 classes have shown the futility of a map that relates an ambiguous concept (e.g., Observation class in V3 to an OBX segment in V2). In most cases, the structure can be constrained into a profile to exchange a certain type of information (e.g., V3 Observation to CDA Problem or V2 OBX to a device-reported bloodpressure measurement). Clearly, attempting to map an unconstrained standard structure to another unconstrained standard structure is not useful or reusable. Semantic

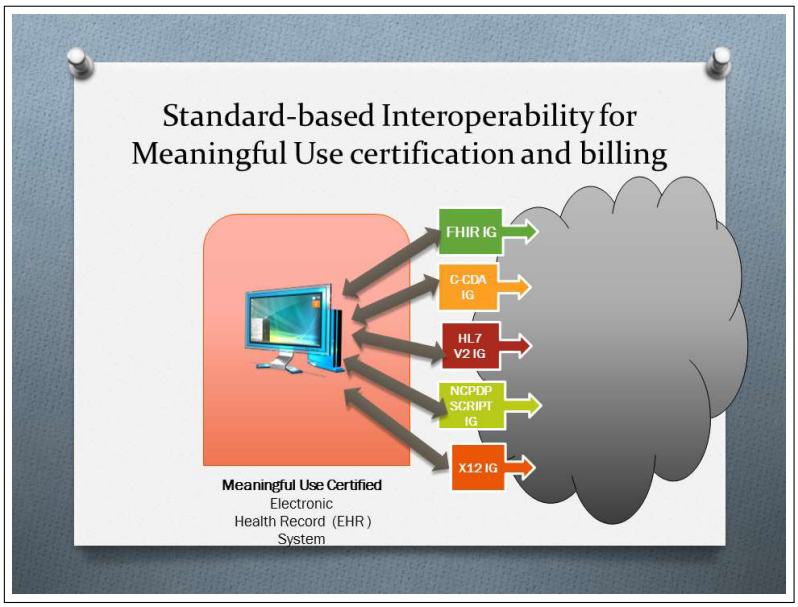

Figure 1: Standard-based Specifications required Meaningful Use certification and billing.

mappings, in contrast, are reusable. They document how business data elements are represented in a structure, for example, how a vital sign is represented in either V2 or V3—the same content but in two syntactical representations.

Semantic mapping also requires semantic clarity. Through semantic mapping we can distinguish between the dates (1) when a problem was recorded, (2) was observed, or (3) the year or age when a problem or symptom started. While dates appear trivial, certain qualifiers can clarify the meaning of a business data element and facilitate the creation of profiles and maps. Similarly semantic mapping includes mapping coded data by identifying equivalent concepts and relating local codes to standards (e.g., SNOMED CT, ICD-10, LOINC, RxNorm, etc.).

There are additional factors that affect mapping one healthcare format to another. Using the earlier example, there can be many problems observed by a healthcare professional for a patient. In each observation, data elements for the date, the type of specific problem, the severity of the problem, and who authored the observation are all recorded data elements. For this information to be used correctly later, all of the specific data elements for the observation must be bound together. Therefore, the semantics of a format are not simply represented by the semantics of a specific data element, but rather the semantic clarity of the data element is influenced by how the data elements are organized or structured (i.e., hierarchy). There are additional factors that can have an impact on semantic mapping such as relationships and values of other data elements (e.g., moodCode in CDA and the relationship between OBX-3 and OBX-5 in HL7 V2) and these must be understood to achieve a precise meaning and precise structure.

Therefore, strictly syntactic mappings fail and are generally expensive to implement for a variety of reasons:

- Lack of semantic understanding between data elements
- Lack of semantic clarity for data elements
- Complexity introduced by format structures and relationships between different data elements.

The use of a model-based mapping helps avoid the pitfalls of syntax-based mapping, driving interoperability towards semantic consistency across systems and applications.

3 Semantic Consistency across the Continuum of Care

The proposed semantic mapping approach is intended to add semantic consistency across systems using widely-adopted model-driven architecture principles, similar to the HL7 Services- Aware Enterprise Architecture Framework (SAIF). It adds the semantic versus syntax model separation introduced by the Open Management Group's Model-Driven Message Interoperability (MDMI) [2] specification as a technical approach to model-driven semantic interoperability. To address the complexity of healthcare information exchange, the canonical data elements are described using the ISO 11179 metadata registry (MDR) [6]. The canonical data are then reused to establish semantic equivalence across systems, across syntactic models (e.g. HL7 V2, CDA, FHIR, etc.), across knowledge models (e.g. Detailed Clinical Models, CIMI clinical models, OpenEHR clinical models/archetypes) and even across diverse clinical coding systems (e.g., SNOMED CT vs ICD, local system to standard systems). The maps rely on a common "model of meaning", which is a logical representation of payloads that consist of data elements organized

into a well-defined registry or "Referent Index". Similar to other standards products, the Referent Index would derive its authority from a consensus-based change management process organized by a SDO.

Using this approach, each side of the exchange must first map its own data to a common data element (i.e., vital sign result). A second map ensures that the standard syntactical structure (e.g. FHIR Observation, HL7 V2 OBX segment, CDA Observation) is used consistently to represent its data element (i.e. Vital Sign Result). This approach may map not only across standard-based syntactic models (e.g., CDA, V3, V3, and FHIR), but also across models of clinical knowledge and requirements such as Detailed Clinical Models, Open EHR Archetypes, and the Clinical Information Modeling Initiative (CIMI).

The software architecture required bringing these concepts to life, ensuring that semantic mapping provided a clear separation between data semantics and syntax/representation. This promotes the development of reusable maps for well-defined implementation specifications. The success of semantic mapping relies on a community of interest and an SDO that can maintain the data elements which make up the Referent Index.

The architecture must also provide a means of executing semantic maps at runtime and requires a sustaining effort to develop a reusable registry of data elements. SAMHSA has created the Information Exchange Hub (IExHub) project to build the transformation/interface engine supporting both behavioral health and physical health interoperability for HIEs. [3]

4 Benefits of Runtime Model-Driven Interoperability

Previous standards-based mapping projects aimed to facilitate transition from one standard sy and syntax to another (e.g., HL7 Version 2 ASCII Encoded messages mapped to HL7 Version 3 XML messages). These projects attempted to map the entire standard to its newer version without considering that both versions required additional refinements and constraints for realworld implementations.

Due to the unconstrained definitions or specified optionality of the base standards, mapping an entire standard from one format to another has proven to be unreliable. In programmatic terms, the mapping of one base class to another base class while ignoring that each class must be further specialized prior to instantiation cannot guarantee semantic interoperability. This mapping approach fails to align semantically equivalent data elements because the interoperability standards contain generic concepts and optionality intended for adaptability to a multitude of implementations. Therefore, mapping of base standards is inherently imprecise, requiring instead a semantics-driven solution.

The proposed solution includes model-driven semantic maps that are directly executable by the IExHub runtime environment which supports the bi-directional exchange of business data and information independent of format:

- CDA R2 (using C-CDA templates)
- FHIR (resources/profiles)
- HL7 Version 2 (use case specific implementation guides)
- Other formats as identified (X12, NCPDP)

Additionally, the IExHub provides a number of connectors for specific transport protocol and envelope formats to support the exchange of standard-encoded messages and documents:

- REST
- SOAP (IHE ITI Integration Profiles, NwHIN Connect/eHealth Exchange)
- S/MIME (NwHIN Direct)
- HL7 Minimal Lower Layer Protocol (MLLP)

5 Semantic Mapping Design for Model-Driven Interoperability

Semantic maps are created using an open-source Eclipse-based tool - the business analyst's "workbench" (i.e. MDI Workbench). It integrates existing open-source tools (e.g. MDHT MDMI, Art-Décor [7]) to put subject matter experts in charge of defining maps and creating model-based implementation guides for information exchange standards.

The workbench combines standards profiling and semantic mapping thus leveraging the work done by the Open Health Tools community to create the "CDA Tools" for template development and model-based validation. Consumers of CDA-based documents and implementers of CDA and C-CDA are able to generate run-time components from models of the implementation guides, thus accelerating and lowering the cost of adoption for this key standard required in Meaningful Use Stage 2 and Stage 3 (MU2/MU3) certification.

During our evaluation of standard profiling tools, the MDHT tools were used to create implementation specifications for information exchange formats beyond the CDA format such as FHIR profiles. The MDHT tool provides a model-driven framework for generating a Java runtime application program interface (API) that supports template conformance. The API enables construction of instances that conform to these templates, ensuring that documents conform to the relevant constraints. Since it is based on UML 2.0, MDHT can be used to contain any standard structure and provides built-in support for constraining a template/profile to add more specificity if required by an implementation.

For semantic data element mapping to be successful, the metadata registry [6] must be completed before a business analyst can create a semantic map. The metadata

registry should be curated by an international Standards Development Organization (SDO). This insures that the resultant Referent Index describes the canonical definition of semantic business data elements. An international SDO is best suited to curate the Referent Index so that the semantic data elements are not corrupted from adding content that is not rigorously defined.

The MDI workbench allows an analyst to create or edit maps that relate local EHR/HIE source data to information exchange formats using the Referent Index. The map editor could also be applied to creating "standard" maps that specify how a canonical data element is represented.

This frees the semantic data elements from being bound to an exchange format until an implementation guide is defined based on a well-defined use case. A **logical payload** can then be developed, not bound to a syntax or representation but derived from concrete business requirements. This leads to standards-based implementation guides which satisfy, in a verifiable way, a need for semantic information sharing. The logical payload supported by an implementation guide consists of data elements defined in the Referent Index and provides implementers with the detailed knowledge to represent that logical payload in a standard-based syntactic structure (e.g. CDA document, V2 message, FHIR transaction) and terminology (e.g. LOINC value sets).

Figure 2 describes how using a model-driven semantic mapping uses two semantic mappings which allows a data element mapped to equivalent information exchange structures (syntax model) using a common semantic model. This approach can be extended and invoked to translate the EHR data to a variety of formats, for example, from C-CDA 1.1 to FHIR and HL7 Version 2.x implementation guides. To enable the adoption of standards, the Referent Index should be developed by the SDO to specify data elements semantically within an implementation guide. Interested stakeholders can reuse the maps at design-time and generate run-time specifications consistent with model-driven architecture principles.

At runtime, the map configured for specific endpoints is executed by dedicated software components.. Thus mapped, the EHR local data can then be represented correctly as an implementation guide-specific payload. A standard set of maps, which will be provided in the open source project, would describe how business data is represented in a specific CDA template, HL7 Version 2 profile, or FHIR profile (i.e., unit of exchange). As new implementation guides and profiles/templates are developed, the Business Elements could be referenced alongside each constraint applied to the standard.

A model-driven approach promotes the reuse of the Referent Index as the canonical representation of all the data exchanged through any interoperability specifications. The importance of semantic business data when creating a new profile or template is evident in the way other open-source tools such as Art Décor begin the development of a new template by first creating a data model of required data and then applying the necessary constraints to the underlying standard structure to support the data set. The model-driven approach promotes the reuse of business data elements by:

- Helping applications clarify the semantics of their local data
- Helping profile developers clarify how a message or document would represent the Business Elements in an interoperable way, using standard constructs and syntax

Figure 3 illustrates the use of metadata based on clinical terminology. This ensures that the meanings of Referent Index Business Elements are not dependent on narrative descriptions but instead on a post-coordinated expression that combines the meaning of well-defined standard concepts (e.g. Allergy + observation + date/time). These computable expressions can be used to de-duplicate and navigate the Referent Index for precise mapping and predictive reasoning.

6 MDI Runtime Transformations

Semantic maps allow information systems to specify how their local format/syntax relates to the canonical data elements in Referent Index. To transform data between two syntactic models, a second map is required to specify how the canonical data elements are represented to a target representation. To facilitate reuse each implementation guide may have an associated map that represents the community consensus on how a specific data item (e.g. vital sign result) is represented in a standard syntax (e.g. the Observation value data element of the C-CDA template). This ensures that EHR systems can exchange health information in a manner that guarantees that the content of the information is understood across disparate systems, thereby allowing for semantic interoperability.

A **transformation** consists of two mapping operations: first from a source structure to a canonical data definition and a second from the canonical data definition to the target syntax specified by an implementation guide. The IExHub automatically executes the necessary map sequence based on the source and target format and implementation guides invoked at runtime.

MDI transformations allow EHR systems to (1) migrate selected interfaces to later versions of the standards, (2) adopt new information exchange formats, and (3) maintain backward compatibility with existing interfaces inside and outside the enterprise. The transformations also allow the systems to support more than one exchange syntax/format for a logical payload.

In addition to executing semantic maps, the IExHub can also act as an application gateway linking FHIR-based applications with existing SOAP-based HIEs. The IExHub can map not only data but system capabilities and behavior (e.g., the application invokes FHIR Patient

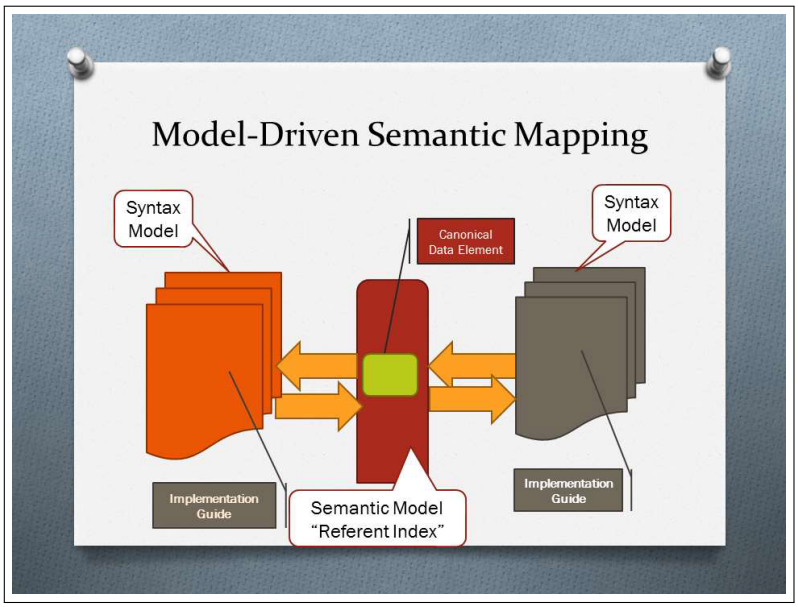

Figure 2: Model-Driven Interoperability using Semantic Mapping.

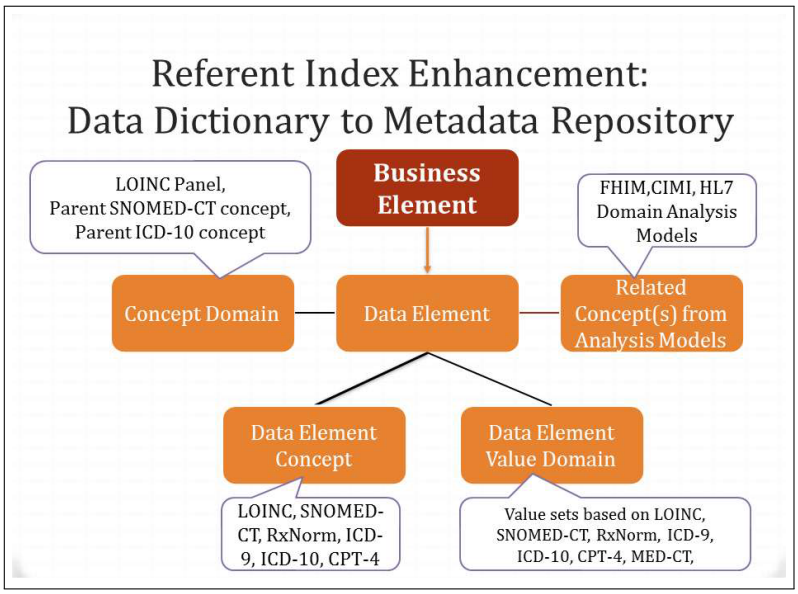

Figure 3: Data Element Metadata combined using ISO 11179.

"search" to transmit the IHE ITI-47 PDQV3 Query message supported by the HIE). The transformation includes mapping payloads and transport from FHIR over REST to HL7 V3 with ebXML over SOAP.

6.1 Transforming Atomic and Aggregate Data

Most of the transactions and message exchanges currently implemented using standards share three characteristics. They aggregate information corresponding to a specific focal structure:

- Messages (e.g. HL7 Version 2, X12, and NCPDP)
- Documents (e.g. CDA documents, FHIR resource, HQMF, and QRDA)
- Support simple interaction modes:
  - Unsolicited notifications (e.g. laboratory results reports)
  - Request/Response transaction (e.g. order request message/order response message)
  - HL7 FHIR adds support for atomic data objects

FHIR and CDA will coexist for the near future as they address complementary requirements.

- FHIR supports access to atomic elements while CDA provides access to aggregate objects containing both narrative text and structure.
- FHIR supports queries for discrete data elements while CDA supports only queries for documents or document sets.

Thus, CDA is ideal for large transactions containing a variety of sections and objects. In contrast, FHIR provide access to specific data elements (e.g. lab results, patient records, and provider records).

MDI allows the two standards (and other required interoperability standards) to co-exist and fulfill the requirements of various projects. The MDI approach supports transition from one standard or version of FHIR or CDA without affecting the business data content of resources or documents. Typically, a CDA document may be represented by two or more FHIR resources (e.g. Composition in a Bundle with dependencies).

FHIR allows systems to provide new capabilities to HIE repositories that persist aggregate messages/transaction or documents. For example, providers may create CDA documents to be sent to a data store such as an HIE, and others may make queries to the HIE and receive FHIR resources (created from data content in a CDA document) in response.

Not only is the document information mapped from one format to another, it is done with complete semantic integrity because the Referent Index data element represents the conical definition used by each template definition. Now we begin to see synergy between the different standard formats and convergence across the various areas of the health continuum for where the different formats provide the most value.

7 Model Driven Interoperability (MDI) Value Proposition

The MDI approach requires more upfront work by defining the content of semantic data elements. This approach facilitates the exchange of documents in one format or another much faster than waiting until a standard is defined to determine the semantic content required. MDI strives to ensure semantic consistency across EHR systems. Errors in data and clinical terminology transformations have caused serious safety problems by creating errors in systems attempting to decode the data. Mapping ambiguities can lead to medical treatment errors that require a systematic approach to later tackle the root cause of such errors.

Why is true interoperability so difficult to achieve? Often it's the result of focusing on strictly structural conformance to a standard syntax to the detriment of semantic validation. If the sending and receiving systems do not share a common model of meaning, then divergent semantic understandings may be derived even if they share valid structures.

MDI overcomes these data equivalence issues by promoting mappings to and from canonical business elements (e.g. LOINC encoded vital sign observation) rather than syntax node (e.g. OBX.5). A model-driven mapping approach frees implementers from the burden of dealing with syntax-based mapping and allowing for focus instead on precise semantics.

Another business benefit of MDI is managing changes in interoperability standards over time by allowing new standard maps to augment existing representations of data without requiring business analysts to redesign existing maps.

8 Model-driven Interoperability Solution for Behavioral Health Providers

Behavioral health providers are expected to adopt standard-based information exchanges without the benefit of financial incentives provided by the Centers for Medicare and Medicaid Services (CMS) to those providers who demonstrate Meaningful Use of EHR systems. Therefore, these providers require a cost-effective approach to interoperability that relies on open-source and standard-based software tools to leverage the collective investments of federal, state, and private sector stakeholders.

To reduce the cost of interoperability, the Behavioral Health Interoperability demonstration initiated by the Substance Abuse and Mental Health Services Administration (SAMHSA) implemented software components and developed methodologies to reduce the high cost of healthcare interoperability for EHR systems that are sharing healthcare information using the standards and implementation guides required by the Meaningful Use certification. The certification criteria include adoption of C-CDA for document-based exchanges, HL7 Version 2.7.1 Profiles for Laboratory Results and Orders (LRI, LOI) in addition to Health Quality Measures Format (HQMF), Quality Reporting Document Architecture (QRDA), and the emerging implementation guides for FHIR.

A model-based, semantic mapping approach separates content from syntax to allow the exchange of business data consistently. Whether using FHIR, CDA, or HL7 V2, an EHR system is able send or process laboratory results. The laboratory result data content is the same.

For an implementer, the difficulty increases each time a new implementation guide or format is proposed for adoption. Each system must map local business data to a variety of formats (e.g. HL7 Version 2, CDA R2, and FHIR) based on the constraints and criteria defined by implementation guides (e.g. C-CDA, Laboratory Results Interface, and Health Quality Measure Format). The challenge for implementers is not only to understand the information exchange format, the implementation constraints, and implementation guidance, but also to create semantic relationships between local data elements and the stan-

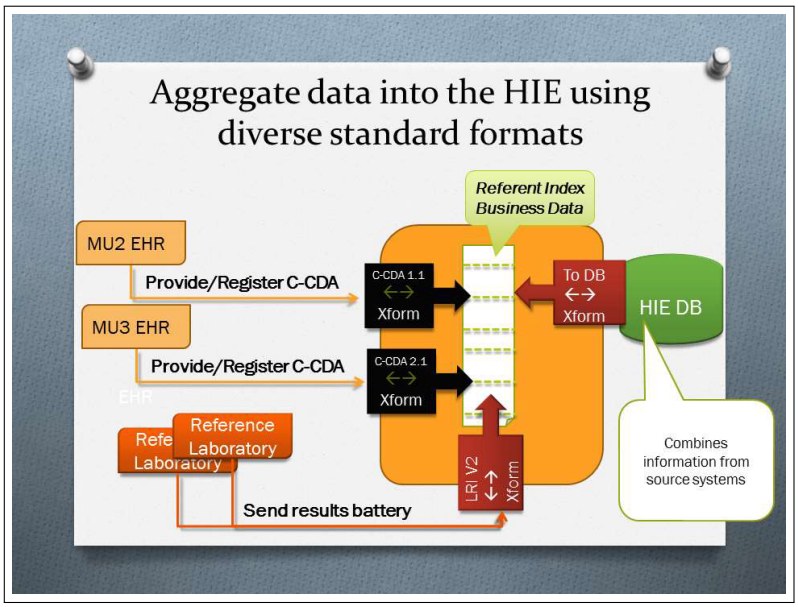

Figure 4: Aggregate Transactions and Domains Persisted by HIEs.

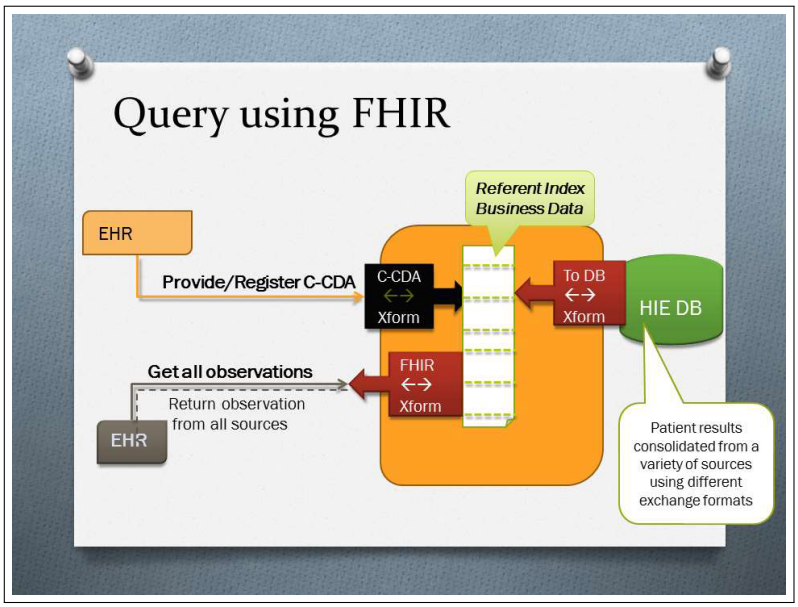

Figure 5: Retrieving Atomic Data from Aggregate HIE Database.

dard data element identified in the target implementation guide. If these semantic relationships are incorrect, the resulting CDA document or HL7 Version 2 message may pass validation and even certification but may carry the incorrect business data. These semantic errors may amplify when an HIE or another data aggregation system combines information received from multiple senders. Each semantic error further limits the ability of such systems to process the data pertaining to a patient of population.

The Behavioral Health Interoperability project used the model-based approach outlined in this paper to show that it can address the semantic challenge and financial limitations facing this domain. Our team showed that semantic mapping can be applied directly to application semantics to map local data to/from canonical data elements and then use a set of standard maps to represent the application data using the standard implementation guides mandated by national regulation.

9 Conclusions

The inherent complexities in adopting multiple information exchange syntax models and terminologies in interoperability scenarios are mitigated using a MDI approach. The principles and architecture outlined in this paper require a community of interest to maintain a clinically relevant Referent Index and contribute standard-

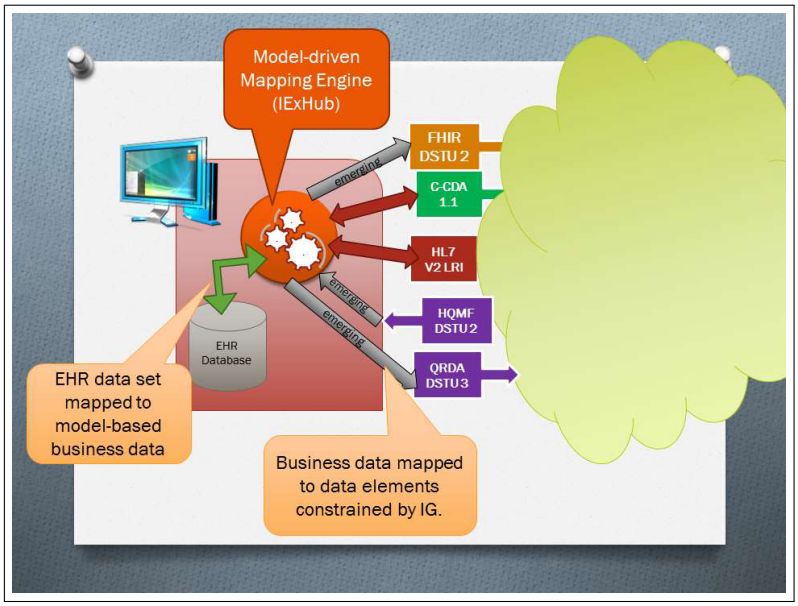

Figure 6: Semantic Mapping enables Meaningful Use standards adoption.

based maps for implementation guides rather than base standards. MDI also recognizes the need to support a variety of interoperability specifications and leverage clinician-designed knowledge and create a framework to support these standards without many-to-many syntax maps and relying instead of one-to-many semantic maps.

Key benefits of MDI include:

- Simplifying the process of mapping local EHR or other local data to standard semantic definitions using a canonical information representation, ensuring that information semantics rather than format drive any decision related to mapping data across systems and organizations.
- Create reusable open-source mapping definitions that enable diverse EHR or other systems to conform to common information exchange formats. A library of mapping/transformation models specific to an information exchange standard implementation guide (e.g. HL7 C-CDA 1.1, HL7 LRI, etc.) would ensure that meaning of business information is mapped identically across information exchanges.
- Promote mapping to implementation guides, not to a base information exchange Standard/format. This is an important principle that acknowledges that health information technology standards require explanation using additional constraints before a real-life implementation is possible. Therefore, by mapping to an implementation guide or a profile of a standard, we ensure that the business semantics are clearly addressed and have unambiguous or unique representations in the payload for each business data element. This principle also guarantees that the complexity of the "on the wire" representation of business data is isolated to a specific map and does not permeate into an application's own representation, thus separating concerns of application optimization from information exchange optimization.
- Promote model-based development of specifications for new profiles and templates traceable to the well-defined, consensus based business data dictionary leading to an implementation ready specification.

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A New Approach to Interoperable Information Standards for Health and Social Care: Normalizing Culture, Contracts and Co-design

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Abstract

Background: In recognition of the limitations of technology-led standards for practitioner implementation of electronic care records, the Professional Record Standards Body for health and social care (PRSB) was established in the UK in 2013. The remit of PRSB is to develop and assure standards for the content and structure of records across all care sectors, based upon professionally-led and patient-guided requirements as endorsed by the professional bodies of the constituent health and social care disciplines. This new initiative is a very different approach from previous national information projects and faces challenges including organizational culture, operational procurement requirements and the logistics of collaborative design.
Objective: This paper describes the progress of PRSB and the practical issues it faces to achieve deep stakeholder engagement and widespread adoption of its standards and guidance. The goal is to offer a sustainable approach that builds on the strengths of work to date, learns from past experience of what works and what fails, and draws upon theoretical models of transformational change.
Methods: We conceptualize the PRSB strategy in terms of organizational change frameworks, evaluate it against models of success factors in health information technology and employ Normalization Process Theory (NPT) to articulate the activity stages required for realization of its goals.
Results: We present an NPT model of how PRSB standards can become embedded in routine practice for care practitioners, patients/citizens, government agencies and information technology providers. We suggest some critical success factors for cultural change, moving the supplier market and sustaining a genuine co-design approach.
Conclusions: It is abundantly clear that interoperability involves far more than just technology. Improving information sharing between care practitioners and with patients and citizens requires the innovative professionally-led and patient-guided approach that PRSB has pioneered. It is necessary to formally evaluate the impacts of implementation, both to build a compelling evidence base and to generate a virtuous cycle of iterative maintenance and general adoption.

Keywords

Electronic health records; Organizational change; Culture; Contracts; Collaboration;

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1 Introduction

Based upon earlier work by the Health Informatics Unit of the Royal College of Physicians [1, 2], a Joint Working Group set up by the Department of Health Informatics Directorate recommended that an institution should be established, provisionally called the "Professional Records Standards Development Body" (PRSDB), to take forward the work of developing and assuring professional guidance for patient record content and structure across all care disciplines in the UK.

The Professional Record Standards Body for health and social care (PRSB) was formed in 2013 as a Community Interest Company. Its stated objects in its Articles

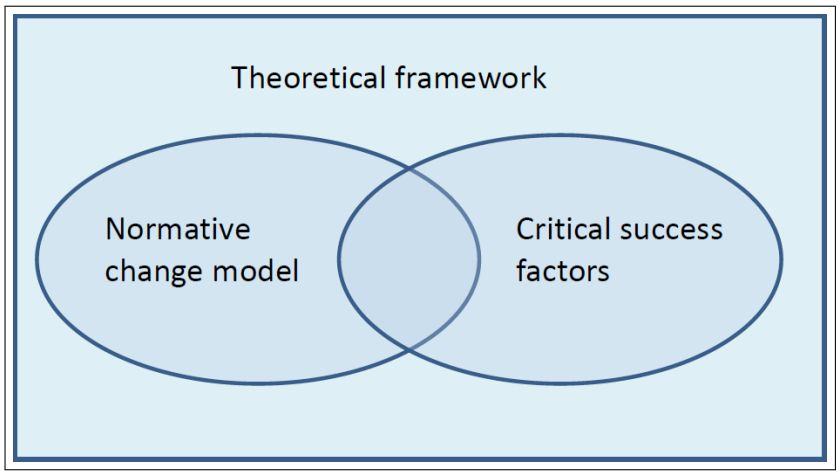

Figure 1: Relationship between conceptual perspectives.

of Association were: "to ensure that the requirements of those who provide and receive care can be fully expressed in the structure and content of health and social care records." PRSB's founding members were a core group of Royal Colleges and other professional bodies. Importantly, PRSB also includes patient representative groups so that the needs of citizens and family carers are taken into account alongside the views of clinicians and other care providers.

During 2015, PRSB was commissioned by the Health and Social Care Information Centre (HSCIC) to undertake five projects:

- Produce information models for a defined subset of the discharge summary from hospital to general practitioner.
- Advise on a forthcoming national programme on diagnostics.
- Provide guidance on secure use of email for healthcare communications.
- Produce a roadmap for development of standards for communicating medication information.
- Create a methodology for clinical user testing of professional record standards.

We have previously reported the initial progress made with a proof-of-concept project to derive formal information models and conformant technical artefacts from the professionally defined record standards [3]. In this paper we address the questions of stakeholder engagement and practitioner adoption of PRSB standards and guidance, reflecting on experience gained in the five projects listed above and from wider consultation across the four nations of the United Kingdom.

The objective of this report is to describe the progress of PRSB and the practical issues it faces to achieve deep stakeholder engagement and widespread adoption of its standards and guidance. The goal is to offer a sustainable approach that builds on the strengths of work to date, learns from past experience of what works and what fails, and draws upon relevant theoretical models of transformational change.

We strongly endorse the view that interoperability is far more than just technology. In a forthcoming paper [4], we propose a systemic model that aims to capture the complexity of devising, deploying and maintaining record systems dependent on people for the provision of information. This is based on the argument that consideration needs simultaneously to be given to the political and economic context, the service ecologies, and to professionals and service users as active processors of information, not simply passive consumers. Information about care is created to be understood and utilized by others. In the record, it is a form of indirect or mediated communication affected by multiple factors – psychological and social – as well as technology and the other influences that contribute to the fidelity and utility of the record. We argue for creating and sustaining information-centered service cultures in which records and information quality are integral to practice and not just another burden on the practitioner.

2 Methods

2.1 Approach

There are numerous conceptual models that could be applied to the PRSB scenario, depending on the objectives and desired output of the modelling exercise. In this case, the goal is to embed a new way of working as routine practice for care professionals and the health information technology (HIT) supplier market, so some form of transformation framework is needed to describe and explain. Such frameworks seem to operate at two distinct levels. Firstly, there are normative models of the necessary steps to manage change. This kind of model is typically an eponymous distillation of 'management wisdom'; a "how-to" guide, or catalogue of critical success

factors. At the second level are theoretical models of how and why a change is succeeding or failing. This order of conceptualization is, by its nature, more usually derived from philosophical, sociological or psychological theory. Figure 1 attempts to illustrate the relationship between these conceptual levels.

2.2 Normative Models of Organizational Change

In this section, we briefly outline some common features from three well-known normative models of organizational change: those of Kanter [5], Kotter [6, 7, 8] and Fernandez & Rainey [9]. Table 1 (extending Table 4 in [10]) summarizes the key steps in each of these frameworks.

The basic ideas of each of these models are clearly very similar. Obvious common factors are: establishing the need, building a shared vision, assembling a coalition of support, planning, resourcing, communication, institutionalization and continuous development. We use these common principles to consider the progress made by PRSB and its future strategy.

Parallels can be inferred from general information technology acceptance models such as TAM [11] and UTAUT [12]. Similar themes can be found in specific recommendations for successful information technology adoption in healthcare [13, 14, 15] and in a recent 'blueprint' for acceptance of healthcare information sharing [16].

2.3 Theoretical Frameworks for Effecting Change

Several theoretical frameworks have been proposed to inform the design, development and evaluation of transformational change [17]. One way to differentiate between these frameworks is their level of abstraction: there are micro-, meso- and macro-system perspectives to consider [18]. Some focus on individual psychology, while others are primarily sociological. A common thread across such frameworks is the recognition that changing individual and organizational behaviour is complex, with diverse interacting contextual factors, so the actual mechanisms to effect change are not necessarily obvious or straightforward. Here we consider two widely used frameworks: Theory of Change and normalization process theory (NPT). They operate at different levels, but the contrast is instructive.

Theory of Change emerged from the field of international development projects [19, 20]. It is a way of conceptualizing change to deconstruct, describe and justify the theory behind the supposed working of a specific initiative. A Theory of Change approach expects extensive discussion with stakeholders to absorb multiple viewpoints. It begins from the long-term goals and maps back to the necessary pre-conditions, causal pathways, interventions, assumptions, rationale and measurable indicators. Theory of Change will analyse the context (political, organizational, social and environmental), the actors (both implementers and 'subjects' of the change), the assumptions (about the participants or the mechanism or effectiveness of the proposed interventions and indicators) and the justification (reason to believe that the intervention will work as expected). It uses a graphical model with explanatory narrative to visualize how the various elements of the situation will interact, where intervention can be made and what indicators can be measured. This is "a working model against which to test hypotheses and assumptions about what actions will best bring about the intended outcomes" [21]. In summary, Theory of Change is an abstract methodology to arrive at a concrete explanation rather than a pre-defined explanation in itself.

By contrast, NPT does seek to provide a substantive explanation of how practices become part of everyday life. The purpose of NPT is to help explain the "dynamic processes" involved in the implementation of "complex interventions and technological or organizational innovations" [22]. It recognizes that collective behaviour is not simply the sum of individual choices, but is constrained or promoted by social factors. NPT is formally defined in three propositions [23]. Firstly, that practices become routinely embedded through the implementation work done individually and collectively. Secondly, that implementation work involves four mechanisms: coherence, cognitive participation, collective action and reflexive monitoring. Thirdly, that the sustainability of the practice needs continuing action from its participants. While the first and third propositions may – at least, once they are articulated – seem like stating the obvious, the four constructs in the second proposition offer meaningful empirically-derived insights into the mechanism of adoption of new practices [24]. NPT has been used in several health-related studies [22, 25].

For the kind of change that PRSB is working to bring about, NPT fits well. We are not yet modelling specific interventions and indicators, as in Theory of Change, but are looking at the general stages of the approach becoming routine practice (which is in itself one of the common normative principles of organizational change noted above).

3 Results

3.1 Organizational Change Principles

In Table 2, we summarize how PRSB has implemented the common principles of organizational change identified in 2.2 and highlight where further work is needed.

3.2 Normalization Process Theory

In this section we consider how PRSB work done so far fits with the four constructs of NPT. There are some overlaps between the four NPT constructs and the com-

Table 1: Comparison of normative change models (adapted from [10]).

Kanter	Kotter	Fernandez & Rainey
Analyse the organisation and its need to change.		Ensure the need.
Create a vision and common direction.		
Separate from the past.		
Create a sense of urgency.	Establish a sense of urgency.	
Support a strong leader role.		
Line up political sponsorship.	Create a guiding coalition.	Build internal support for change and overcome resistance.
		Ensure top-management support and commitment.
		Build external support.
Craft an implementation plan.		Provide a plan.
Develop enabling structures.	Empower broad-based action.	Provide resources.
Communicate, involve people and be honest.	Communicate the change vision.	
Reinforce and institutionalize change.	Anchor new approaches in the culture.	Institutionalize change.
	Institutionalize success through formal policies, systems, and structures.	
	Consolidate gains and produce more change.	Pursue comprehensive change.
	Generate short-term wins.	

mon normative principles outlined above. The difference in perspective is between normative (*what* should happen – the principles) and normalization (*how* it works – the theory). This is necessarily a subjective assessment. It is mostly retrospective but does offer some prospective hypotheses about next steps. The definitions of the four constructs are given in [23].

Coherence in NPT means the "sense-making" work that is done. Formally it is "work that defines and organizes a practice as a cognitive ensemble", held together by a set of meanings and competencies. This involves differentiation from other activities and a shared sense of purpose [24]. The work of PRSB has involved helping stakeholders to understand the distinction between its work and national IT programmes in each of the four UK nations and how it relates to existing standards bodies, both international (for example, IHTSDO and HL7) and national (such as the NHS Standardisation Committee for Care Information [26]). This has been a gradual and continuing process going back over a decade. The demise of the National Programme for IT in the NHS in England led to a general realization that a more consensus-based approach and practitioner leadership were needed. In particular, the work of formally establishing PRSB as a legal entity required numerous discussions and compelled stakeholders to become sufficiently clear about what this new "thing" meant and what value it added. The regular participants in the PRSB Advisory Board who represent the constituent professional bodies do seem to have attained this coherence. However, there remains variation and further sense-making work to do to reach a point where every individual volunteer and professional member body understands what contribution they are invited and expected to make as distinct from their 'day job' role. For example, some of the royal colleges have specialist health informatics groups with considerable expertise and a recognized structure. However, other professional bodies simply happen to have volunteer members with an interest in informatics, with little real organizational support for their activities.

The formal NPT definition of **cognitive participation** is work that "defines and organizes the actors" and is "shaped by factors that promote or inhibit" participation. This mechanism entails activity to develop engagement and ownership, resulting in a community of practice. Again, the formal constitution of PRSB required tasks of initiation and enrolment that delineated the founder member bodies and their individual representatives. This was shaped by aspects such as the relative enthusiasm of each member body, the personal background and seniority of the nominated representatives. The depth of informed debate at PRSB Advisory Board meetings certainly demonstrates cognitive participation, which was very evident in the initial surveys of the medical profession and has been demonstrated by continuing engagement of practitioners and patient groups in substantive project work.

Collective action is about enacting or operationalizing a practice. It includes the facilitation of participant interactions, their trust in the new practice and how the distribution of specialist skill-sets is affected. Crucially, it also involves "contextual integration" – the "fit" with existing structures, processes and social context. The standards development work of PRSB has highlighted the need for new and expanded skill sets: there are clear differences in informatics maturity and capacity level between member bodies. Interaction within multi-disciplinary project groups has demonstrated the need for a 'common language' and glossary of concepts and processes to support

Table 2: PRSB application of common normative change principles.

Principle	Actions taken
Establish the need for change.	First iteration of medical record headings began with a series of three on-line polls (1,000, 1,500 and 3,000 responders to a single question) found overwhelming support for the concept. A longer questionnaire to doctors and patients explored detailed response to draft 36 medical record headings: overwhelming interest (>3,000 responders in 2 weeks). Consultation by Joint Working Group of Department of Health.
Build a shared vision.	The message accompanying the questionnaire was that (1) professional definition of requirements was needed so that they could be fit for purpose and (2) wide participation and consensus is better than clinical representatives on standards committees. Wrote to the president of every medical royal college and major specialist society to nominate a representative to lead specialty contribution and actively engaged patient groups. Series of well-attended workshops and online questionnaire consultations on draft record headings. Direct contact with every specialty representative who had concerns to explore the concerns and to ensure they were addressed.
Assemble a coalition of support	First iteration of medical record headings endorsed by the Academy of Medical Royal Colleges meeting and welcomed by a very wide range of organisations including medical defence organizations, the NHS Litigation authority and the NHS Ombudsman. PRSB establishment phase built support from member bodies and government agencies. Initial explanatory email followed up with telephone calls to President or Chief Executive, and several face to face meetings. Supporting coalition grown over time with high level meetings with Department of Health, HSCIC and NHS England, resulting in recognition in IT strategy. Regular and growing involvement of Scotland, Wales and Northern Ireland, including four nation reports at every advisory board meeting. Active engagement of patient advocacy organizations.
Plan and resource.	Negotiations and project commissions from national agencies. Growing capacity in executive leadership, clinical assurance, technical oversight and project management.
Communicate.	Communications advisor appointed, with emphasis on Plain English and jargon-free content. Informal communication via member bodies and more formally through website, events, webinars, Chief Clinical Information Officer network. Recognized as immediate high priority, with new website in development.
Embed as routine practice.	The current challenges addressed in this paper using NPT.
Sustain continuous development.	

effective co-operation. There is still work to do to influence the culture of national agencies to integrate fully with the PRSB approach. Historically, especially in England, there has been a highly top-down style of managing information systems and standards [27], which is at odds with the essentially collective ethos of PRSB. A related example is the PRSB wish to base conformance validation on a 'comply or explain' basis, not simply mechanical compliance as currently practiced. Implementation of PRSB standards is at an early stage: one dependency is changing the commercial environment from supply-led to demand-led. There are already requirements in English NHS standard contracts to deploy PRSB standards but these are so far only weakly enforceable. As trust develops – 'relational integration' in NPT terms – we aspire to generate demand from frontline practitioners and patients to influence local procurement decisions and therefore move the supplier market. PRSB has formed an open vendor forum and recent discussions have demonstrated a realization among certain suppliers that having PRSB as a clinical design authority for interoperability standards would be commercially valuable.

Reflexive monitoring is the work of formal and informal evaluation that reflects the depth of cognitive participation and collective actions. NPT describes both individual and communal appraisal. A semi-formal lessons learned review was performed at the conclusion of the 2015 work programme. PRSB has recently undertaken a corporate strategy development as part of its 'gearing up' to meet demand from service commissioners. These exercises offered helpful critical reflection by stakeholders about the exact nature of PRSB's contribution and ways of working. The very articulation and iterative clarification of organizational practices serves to embed them (at least internally). However, a particular gap is formalized evaluation of implementing PRSB standards to create a dynamic feedback loop of user experience.

In summary, Figure 2 outlines a retrospective view of how the NPT constructs have been applied and Figure 3 shows a prospective view of further work anticipated.

4 Discussion

4.1 Building practitioner and patient demand

The case for nationally defined and agreed standards is now accepted as overwhelmingly obvious, but there is a danger of over-claiming and appearing either not credible or not relevant to real people on the ground trying to change systems and processes. PRSB therefore has to work at two levels to make change happen. National influence must continue so that the central strategy, di-

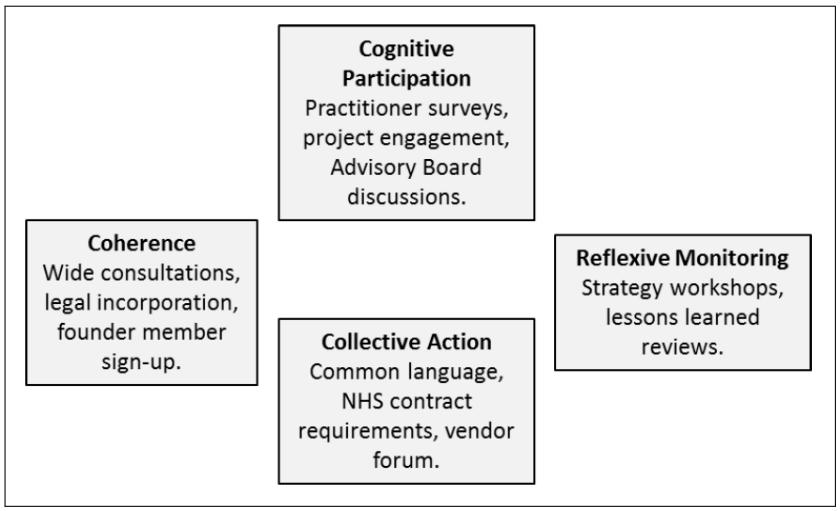

Figure 2: Current progress shown as NPT constructs.

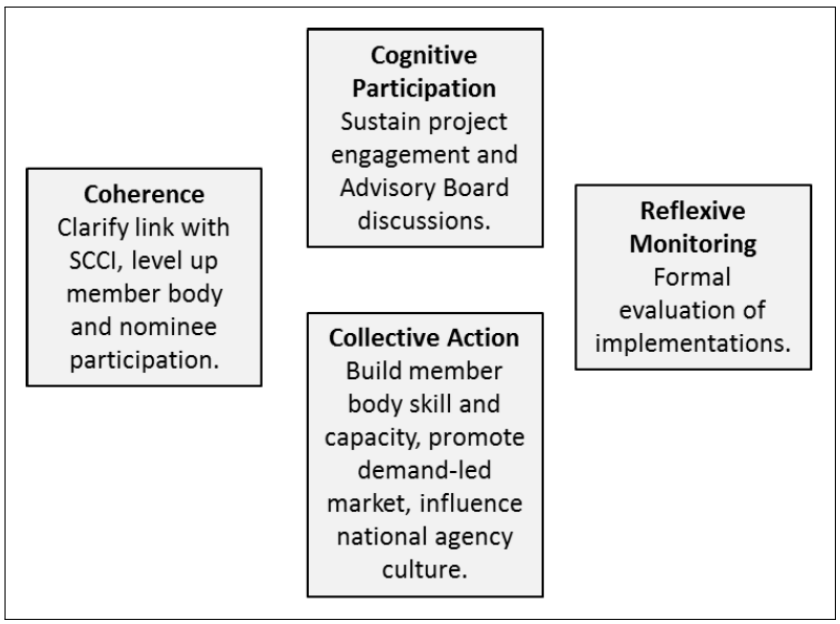

Figure 3: Further work to normalise the work of PRSB.

rection and incentives are established and reinforced by those with the power – in policy, service commissioning and regulation. Local engagement and persuasion is also needed, so that practitioners, executives, local commissioners, Chief Clinical Information Officers (CCIOs) and Chief Information Officers (CIOs) feel not only instructed to make the change to comply with national policy but empowered and enthused and accountable for making the change because they understand the benefits and importance to their patients and the whole care system.

4.2 Political and practitioner diversity

Due to the devolution of health policy, varied approaches are needed for the four UK nations. For example, whereas England has an extensive national infrastructure to manage information policy and programme execution, the other UK nations (who have similar ambitions around health and social care integration and patient access to records) typically lack such levels of resource and recognition by central government. There are also striking divergences in the political complexion of the current administrations that manifest in the financial models of funding and managing health services.

The kind of practitioners who are drawn to participation in information standards development are often at the 'geeky' end of the spectrum [28]. While such expertise is necessary and valuable, this creates a risk of over-engineering proposed solutions (as was found with HL7 version 3, for instance) and alienating the more 'average' care provider. The PRSB methodology of wide-ranging stakeholder consultation should mitigate this risk.

4.3 Role of professionals and professional bodies

The role of the professional bodies is key in setting the expectation of the respective groups in adhering to commonly agreed standards. There is concern from the regulatory authorities that the professional bodies and indeed the professionals themselves have on occasion been remarkably silent about recent scandals in care provision. A similar lack of leadership or complete engagement is also observable in respect of information standards. There is a need for narratives and case studies from respected peers to persuade the professionals and their societies to become the leaders and owners of this agenda. Practitioners are very interested in the concept of bringing their combined might together to influence IT vendors and tell them what is required. This is the kind of pressure that has real potential to change the market.

4.4 Limitations

As noted above, this is necessarily a subjective assessment and is inevitably biased by personal participation in the formation and execution of the work of PRSB.

5 Conclusion

PRSB offers a unique opportunity to demonstrate that interoperability a field that is led by practitioners and citizens rather than technologists. Substantial progress has been made but significant challenges remain. NPT offers a helpful theoretical lens to analyze the situation and focus attention on how to continue influencing institutional culture and contracting processes and sustain deep engagement from professional bodies in co-design practices. It is necessary to formally evaluate the impacts of implementation, both to build a compelling evidence base and to generate a virtuous cycle of iterative maintenance and general adoption.

Acknowledgements

PRSB wishes to acknowledge the support of its member bodies, its volunteers and the resources provided by HSCIC and NHS Scotland.

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Traceability Based Description of Clinical Processes: Extension of IHE Guidelines for Phlebotomy Workflows

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Abstract

The increasing diffusion of data acquisition systems paves the way to traceability based process management and definition. In the clinical context, IHE formalizes the reference guidelines, periodically enhanced to reflect processes evolution.
In this work we describe how we have modeled the phlebotomy process following the IHE references and best-practices to obtain a fully traceable workflow. The work has resulted in two new transactions for the IHE LBL profile, describing samples containers production and samples collection. The complete workflow has been implemented and successfully tested in real clinical environments. The traceability data acquired have then been studied using Process Mining techniques to compare the production model with idealized workflow and guide further developments.

Keywords

Traceability; IHE; HL7; Interoperability; Process Mining

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1 Introduction

The management of a healthcare process depends on many factors, coming from the clinical domain, the nature of the process, the fundamental actions and their collateral effects, the main stakeholders and their respective interactions, the relationships between patients, operators and devices supporting the considered clinical pathway. The ever-increasing penetration of digital acquisition systems brings the promise of a more systematic clinical processes management approach based on process traceability and quantitative description.

In this paper we report on how we modeled – within the context of international guidelines and best-practices, in particular IHE (Integrating Healthcare Enterprise) [1] – a clinical process with the goal of a fully traceable and quantitative description of its running. Specifically, we considered the phlebotomy process in clinical laboratories. From the analysis of the traceability requirements, we developed two new IHE transactions which have been actualized in a commercial product [2] thus demonstrating the feasibility of this approach in a production context.

Traceability data provide useful information about what activities were performed, by whom, and when. Together, they allow reconstructing the actions that brought about a specific result. With this information the process can be analyzed and improved, with potential benefits to safety and quality of care.

The IHE is the reference institution for the interoperability of systems in the healthcare environment; the consortium is divided into clinical domains and, for each one of them, it periodically publishes a specific Technical Framework. Technical Frameworks describe the domains processes in the form of use cases, workflows and transactions that can be mapped to significant events. They form an ideal basis for a traceability system to monitor the process. There are at least two reasons to follow the IHE's guidelines when modeling a clinical process: they are defined, starting from a process-oriented point of view, by a wide number of experts in the field and they can provide useful information about correctness and completeness of

the process chain. Furthermore, an IHE-based process solution ensures a high level of reliability and repeatability. However, not all clinical processes are completely covered by IHE guidelines; the initiative iteratively improves them with the collaboration of clinical experts and software vendors. It is possible to submit Supplements and Change Proposals to the Technical Committees should uncovered aspects of a clinical process be found; after a period of evaluation and testing, the extensions can be included into the official guidelines. Our work shows that traceability can be a powerful tool to extend IHE coverage.

The remainder of the paper is structured as follows. Section 2, provides a brief overview of the clinical context (laboratory medicine) and its IHE profile coverage, followed by the definition of the process from a traceability perspective. Section 3 describes the transactions we proposed as an extension to the IHE Laboratory guidelines, their implementation in a commercial device and how they fit in a specific process mining use case. Section 4 analyzes the effect of the work. Finally, Section 5 draws conclusions and describes future work.

2 Methods

In this section, after a general description of laboratory medicine workflow, we will target the phlebotomy process and we will contrast its steps with the existing IHE profiles and transactions. We will then analyze the issues of the IHE guidelines for this sector and introduce our contribution to fill the missing segments.

2.1 Laboratory Workflow and Errors

Laboratory is a crucial part of the clinical practice and an error in its process can bring serious consequences in the rest of the patient care [3].

As shown in Figure 1, traditionally the laboratory workflow is divided into three main subprocesses:

- **pre-analytical**: it consists of tests ordering, patient identification, sample collection and transportation to the laboratory and sample preparation for analysis (i.e., sorting and routing, aliquoting, centrifugation, etc.);
- **analytical**: it includes all the steps to perform the requested analysis on the samples;
- **post-analytical**: it consists in reporting and distribution of test results.

In the past decades the most error affected phase was the analytical one, but "automation, improved laboratory technology, assay standardization, well-defined rules for internal quality control, effective quality assurance schemes and better trained staff" [4] have made it the most affordable part of the overall process [5]. The improvement is highlighted in many studies showing how after this evolution the majority of errors have moved to the pre-analytical and post-analytical phases [4] [5] [6]: in particular the first one [7] [8] can be considered the most error-prone segment of the whole Laboratory process.

In this paper we focus on the part of the pre-analytical phase that concern phlebotomy, whose central aspects are patient identification and sample collection. The most common errors in this subprocess are patient misidentification, use of inappropriate containers for specimen collection and wrong tube filling [7]. Automated systems and devices, combined with the adherence to best-practices and guidelines, can help in avoiding a wide number of these errors, guiding the operators in the correct execution of secure phlebotomy and automatically tracing the main events that enable the analysis of the process, in order to iteratively improve it.

2.2 IHE Coverage for Phlebotomy

Phlebotomy main steps are identification and sample collection, which can be respectively mapped to IHE PDQ (Patient Demographics Query) [9] and LBL (Laboratory Specimen Barcode Labeling) [10] profiles. All transactions for both profiles are based on HL7 messages.

PDQ profile describes two transactions, ITI-21 and ITI-22 [11], which are two of the most supported by vendors. They allow a Patient Demographics Consumer (PDC) to query a Patient Demographic Supplier (PDS) for patients information. They match the patient identification step of the process, as they cover the information exchange needed to retrieve and check patient identity.

Sample collection, in a venipuncture process supported by automation, can be associated to the LBL integration profile, whose use cases cover the robotized labeling of specimen containers and involve two actors:

- **LIP (Label Information Provider)**: it is the actor that provides the information about the labels;
- **LB (Label Broker)**: it is the actor responsible for the labeling of the containers according to the information provided by the LIP.

The main information needed for the labeling are embedded in the HL7 messages exchanged between the actors and they are: patient data, drawn specimens with their unique id, tests to be performed on every specimen and type of container to use. This information is very useful for traceability purpose.

The profile provides two different use cases according to the actor that initiates the transaction: in case of LAB-61 (Request Mode) the LIP sends a labeling request to the LB; on the other hand, in LAB-62 (Query Mode) the LB queries the LIP to retrieve the information needed [12].

2.3 Phlebotomy Process in a Traceability Perspective

In order to create a traceable system in the field of laboratory pre-analytical phase based on IHE transactions,

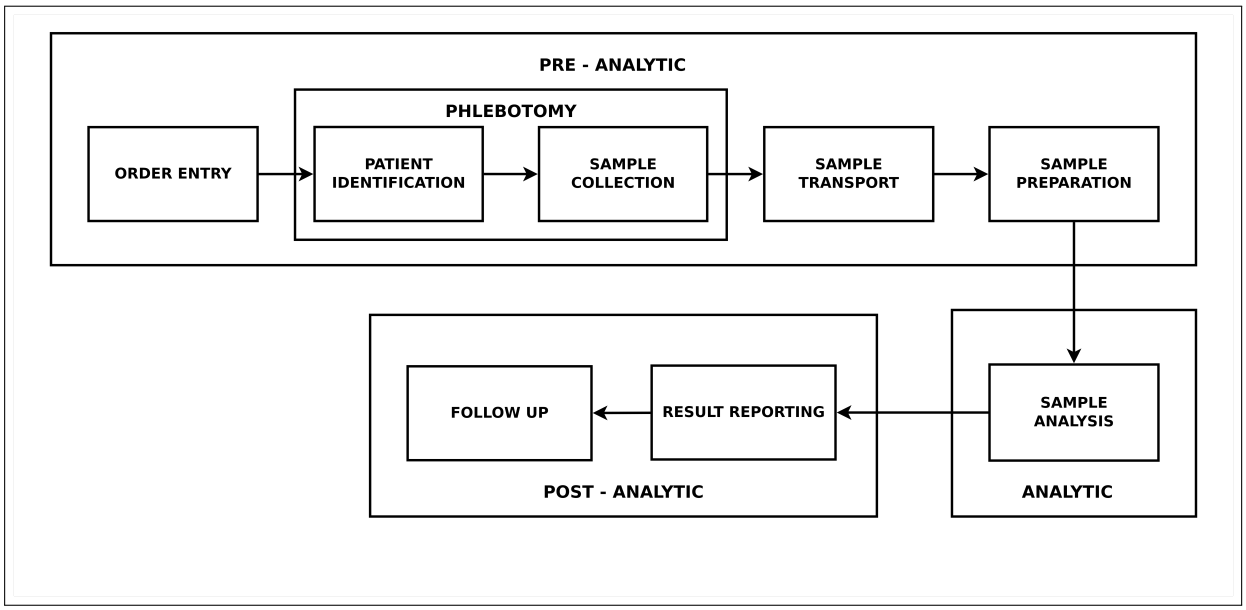

Figure 1: The laboratory workflow.

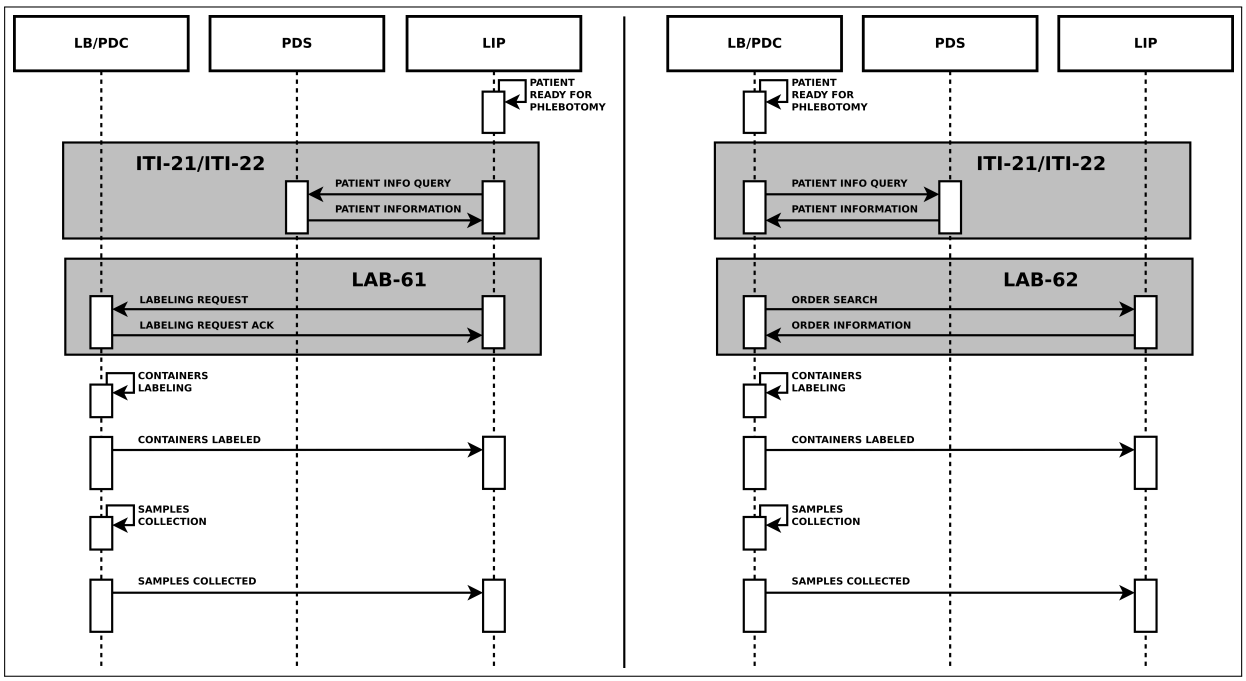

Figure 2: The sample collection process and its IHE coverage in case of Request Mode and Query Mode

we formalized the phlebotomy process supported by automation as illustrated in Figure 2. The figure delineates two possible scenarios, one for each LBL's use case, and highlights how the IHE transactions maps the steps of the process.

In case of Request Mode the main steps are:

1. **Patient ready for phlebotomy**: the patient needs to perform some tests that have been requested before;
2. **Patient Identification**: the LIP queries the PDS for patient data using a unique id. In this way the phlebotomist is sure of the patient identity;
3. **Labeling requests from the LIP**: the LIP sends the labeling request to the LB/PDC with all the necessary information; the LB/PDC responds with an ack message;
4. **Containers Labeling**: the LB/PDC prints the labels and attaches them to the correct containers;

5. **Containers Labeled**: the LB/PDC sends a message to the LIP to acknowledge the containers production;
6. **Sample Collection**: the phlebotomist draws the specimens;
7. **Sample Collected**: the LB/PDC sends a message to the LIP to acknowledge the collection has ended.

In case of Query Mode the main steps are:

1. **Patient ready for phlebotomy**: the patient needs to perform some tests that have been requested before;
2. **Patient Identification**: the LB/PDC queries the PDS for the patient information using a unique id. In this way the phlebotomist is sure of the patient identity;
3. **Order Search**: the LB/PDC queries the LIP for orders related to the patient. The LIP responds with information about the tests to be performed, the labels and the containers to use;
4. **Containers Labeling**: the LB/PDC prints the labels and attaches them to the correct containers;
5. **Containers Labeled**: LB/PDC sends a message to the LIP to acknowledge the containers production;
6. **Sample Collection**: the phlebotomist draws the specimens;
7. **Sample Collected**: the LB/PDC sends a message to the LIP to acknowledge the collection has ended.

As we said, it is important to trace these main steps in order to reconstruct the actions that brought to a specific result. We can map the actions to the following sets of traceability events.

In the case of Request Mode the events are:

- **RE1**: the LIP queried the PDS for patient information;
- **RE2**: the PDS responded with the patient information;
- **RE3**: the LIP sent a labeling request to the LB/PDC;
- **RE4**: the LB/PDC labeled the containers with the correct information and notifies the LIP that the containers have been labeled;
- **RE5**: the phlebotomist performed the samples collection and notified the LIP of the completion.

In the case of Query Mode the events are:

- **QE1**: the LB/PDC queried the PDS for patient information;
- **QE2**: the PDS responded with the patient information;
- **QE3**: the LB/PDC queried the LIP for order information (tests and containers);
- **QE4**: the LIP responded with the orders information;
- **QE5**: the LB/PDC labeled the containers with the correct information and notifies the LIP that the containers have been labeled;
- **QE6**: the phlebotomist performed the samples collection and notified the LIP of the completion.

Building the traceability environment, emerged that two issues prevent from reconstructing, from a traceability point of view, the complete process with IHE transactions:

- once the LB has finished to produce the labeled containers, no message is sent to the LIP to notify it about the success or failure of this operation;
- when the phlebotomist has completed the samples collection, no notification is sent to the LIP about the effective production of the specimens and their delivering to the laboratory.

This motivated our proposal of two new transactions that complete the process which are LAB-63 and LAB-64. Figure 3 shows how the two new transactions fill the missing steps of the whole Phlebotomy. In section 3 we describe the two new transactions in detail.

3 Results

The extension for the IHE LBL profile we proposed consists of two new transactions:

- **LAB-63 (Labeled Containers Production Confirmation)**: this transaction is sent by the LB immediately after that the robotic device has finished to produce the labeled containers, to notify the LIP about the effective completion of this operation;
- **LAB-64 (Specimens Collection Confirmation)**, sent by the LB immediately after that the phlebotomist has performed the specimens collection.

Figure 4 shows the interaction diagrams for the actors in the two transactions. Basically, they provide HL7 message exchanges between LB and LIP: the LB sends a message with the information about the completed actions and the LIP responds with an acknowledgment to confirm the reception of the message. The actions that trigger them are *CONTAINERS LABELED* for LAB-63 and *SAMPLE COLLECTED* for LAB-64. For the LAB-63 the message carries the data about the labeled containers which are, for every labeled container, patient identifier,

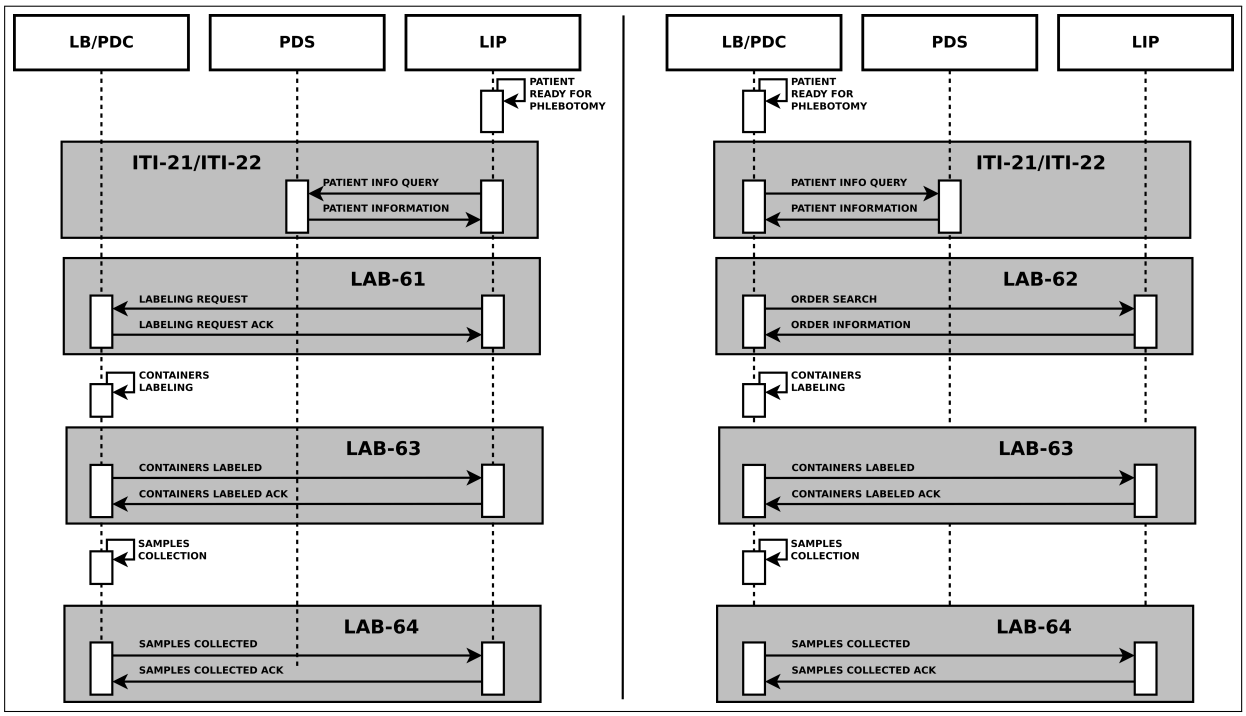

Figure 3: The mapping of the IHE new transactions to the specimens collection process

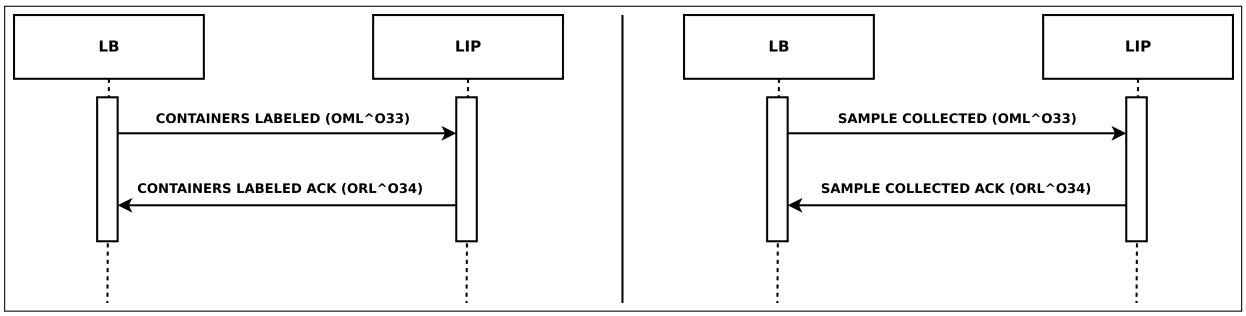

Figure 4: The integration diagrams of the LAB-63 and LAB-64 transactions

type of the container to use, barcode identifier and related tests. For LAB-64 the message carries the same information but in this case they refer to the specimens that have been collected. It is important to note that in both cases the data are a subset of the specimens issued by the previous transactions of the workflow (LAB-61 or LAB-62) and they can coincide with the whole required batch or not. Indeed it can happen that not all the containers had been actually prepared (LAB-63) or filled (LAB-64).

The choice of the proper HL7 message is very important, as its structure must carry all the needed traceability information. According to the prerequisites specified before, the most suitable message for both transactions has been identified in the OMLˆO33 (Laboratory Order Message), since its specimen-centric structure perfectly fits with our needs: as a matter of fact, it provides for each specimen a list of containers and a list of order batteries. Notice that this message is also the reference one for the LAB-61 transaction.

Table 1 reports the segments and blocks structure of OMLˆO33 message. Concerning the segment blocks carrying the information about specimens and orders, OMLˆO33 message is very similar to the homologous message used for the LAB-62 RSPˆK11. The OMLˆO33 message is structured as follows:

- PID and PV1 segments contain patient and visit information;
- every SPM segment carries the related specimen information. An OMLˆO33 message must have at least one SPM segment. This segment begins a block structure; it means that until another SPM segment is found in the message, all segments following refer to the same SPM block;
- ORC, OBR, TQ1, OBX can appear more than once for the same SPM segment. They carry all details about tests that will be executed on the specimen they refer to. Every SPM segment must be followed

by at least one block of these segments (notice that only ORC and OBR segments are always mandatory).

Table 1: OMLˆO33 message structure

Segment	Description	Card.
MSH	Message Header	R, [1..1]
[	— PATIENT begin	R, [1..1]
PID	Patient Identification	R,[1..1]
[PV1]	Patient Visit	RE, [0..1]
]	— PATIENT end	
{	— SPECIMEN begin	R, [1..*]
SPM	Specimen	R, [1..1]
[SAC]	Specimen Container	O, 0..*]
{	— ORDER begin	R, [1..*]
ORC	Common Order	R, [1..1]
[{TQ1}]	Timing Quantity	RE, [0..1]
[	— OBS. REQ. begin	O, [O..1]
OBR	Observation Request	R, [1..1]
[TCD]	Test Code Details	O, [0..1]
[{OBX}]	Obs. Result	O, [0..*]
]	— OBS. REQ. end	
}	— ORDER end	
}	— SPECIMEN end	

The most important traceability fields of the message are:

- PID-3 (Patient Identifier): it is the patient identifier;
- SPM-2 (Specimen ID): it contains the barcode identifier of the label applied to containers in LAB-63 and of the filled specimen in LAB-64;
- SPM-4 (Specimen Type): it is the specimen's type that the printed tube will contain (LAB-63) and of the specimens to draw (LAB-64). For example, B for Blood, U for Urin;
- SPM-27 (Container Type): it provides, for both transactions, a code referred to the specific container that will be printed or filled. Internally, the LB can associate this code to the specific tube model and manufacturer used;
- OBR-4 (Universal service ID): it reports, in both cases, the code of the test that will be performed on the referred specimen (e.g., LDL Cholesterol).

According to HL7 standard, the acknowledge message is the ORLˆO34. Its structure, shown in Table 2, is similar to the OMLˆO33 one, except for the MSA acknowledge segment and for the fact that patient, specimens and orders segments are optional.

As we can infer from the transactions details above, our extensions for the LBL profile completely address the issues discussed in the previous section.

According to IHE roadmap for new proposals, we submitted a Supplement to the Committee for public discussion in July, 2011. The first version has been debated during the IHE Laboratory Technical Committee face-to-face meeting held in Tokyo in September 2011. The LAB-63 transaction has been reviewed and accepted, with the name *Labels and Containers Delivered*. The work on the LAB-64 has been postponed because the confirmation of specimens collection goes beyond the scope of the LBL profile, involving various actors of other profiles.

Table 2: ORLˆO34 message structure

Segment	Description	Card.
MSH	Message header	R, [1..1]
MSA	Message Ack	R,[1..1]
[{ERR}]	Error	C, [0..*]
[	— RESPONSE begin	O, [0..1]
[PID]	Patient Identification	O, [0..1]
{	— SPECIMEN begin	O, [0..*]
SPM	Specimen	R,[1..1]
[{SAC}]	Specimen Container	O, [0..*]
[{	— ORDER begin	O, [0..*]
ORC	Common Order	R, [1..1]
[{TQ1}]	Timing/Quantity	RE, [0..1]
[OBR]	Observation Request	R, [1..1]
}]	— ORDER end	
}	— SPECIMEN end	
]	— RESPONSE end	

Since 2012, the Supplement is available at the IHE website [13], and the LAB-63 transaction has been featured in the set of Connectathon tests for the Laboratory LBL profile.

3.1 Application of LAB-63 in a commercial device: Inpeco ProTube System

The LAB-63 implementation has been included in the prototype of an IHE compliant device supporting fully traceable sample collection. The prototype is one of the outcomes of the collaboration between our center and the Inpeco [14], a company specialized in laboratory automation, in the context of a project focused on traceable laboratory solutions following international standards and best-practices for clinical guidelines and health informatics. The prototype has been developed by following the philosophy that error rates in the sample collection process could be decreased by supporting operators through the use of automated systems.

The main components of the system are two:

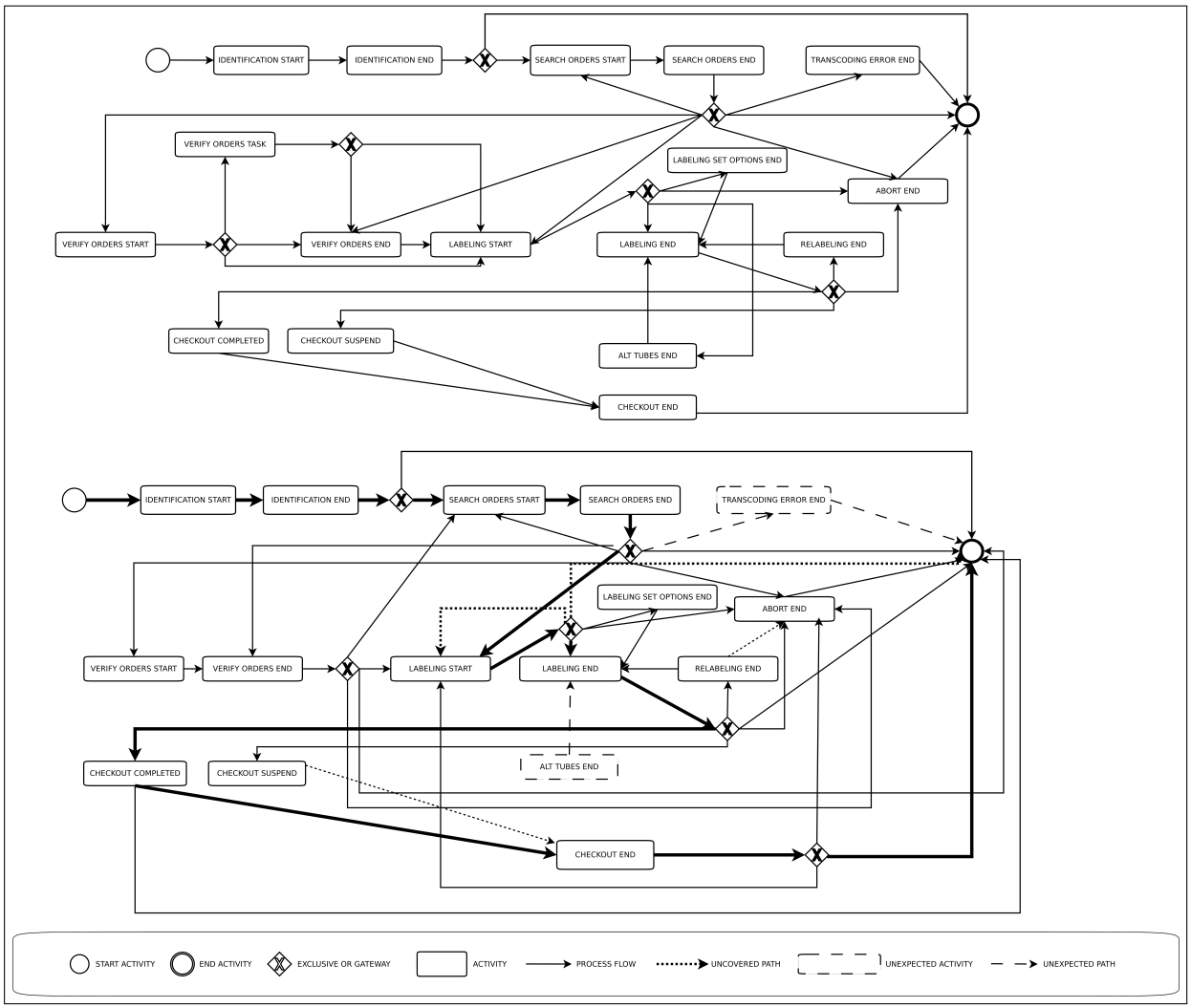

Figure 5: Comparison between the BPMN sample collection process theoretical model and the one inferred through Process Mining. Most covered paths are depicted in bold.

- **Labeling Device**: it is a machine, produced by Inpeco, able to print label and attach them to the tubes. The tube is inserted into the labeler which can recognize its cap color and length, ensuring that the correct container is used;
- **HUB**: it is a server that communicates with clinical Information Systems to retrieve information about patients and their related laboratory requests. It also collects the traceability events of the entire process.

The workflow of the system follows the query mode steps described in 2.3. From an IHE transactions perspective, the Labeling Device is the LB/PDC actor, while the HUB represents the LIP/PDS. The system ensures that all main operations performed along the process are traced by generating the related event logs, with the aim to optimize performance and reduce error rates. The prototype has been industrialized and commercialized by Inpeco, with the name of ProTube, and successively tested in some real clinical environments. Piva et al. in 2015 observed the benefits of the system in the University Hospital of Padua [15]

3.2 Application of LAB-63 for process analysis: traceability data and Process Mining

Traceability data play an essential role for the logging, monitoring, control and improvement of a clinical process: at every point of a process chain, events must be collected and recorded, and they should carry all relevant information about the performed actions: when it happened; who was the operator; and the systems involved.

Process Mining is a young discipline, placed in the middle between Business Intelligence and Business Process Management, and useful to bridge the gap between them: classical data mining concepts are enriched with a process driven approach.

Different types of Process Mining [16] can be used to analyse a workflow:

- **discovery** aims to infer a process model from traceability data, without a-priori information;
- **conformance** compares an existing model (inferred or theoretical) with actual traceability data, checking the conformance between reality and the model itself;
- **enhancement** improves, extends or repairs the a-priori model, using traceability data to infer a model better conform to reality, taking into consideration some new aspects and points of view.

Figure 5 shows the result of Process Mining algorithms applied to traceability data coming from a real clinical site, using a ProTube prototype for the phlebotomy process [17]. It shows a comparison between the theoretical model and the one inferred from traceability data through the use of Discovery Process Mining techniques. Both models have been depicted adopting the Business Process Model and Notation (BPMN) specifications. [18]. Concerning the theoretical model, the following macro activities have been identified:

- **IDENTIFICATION**: query and retrieve of patients information;
- **SEARCH ORDERS**: query and retrieve of patient orders;
- **TRANSCODING ERROR**: atomic activity indicating that an error occurred while computing the required tubes for the retrieved orders;
- **VERIFY ORDERS**: this activity is performed if some orders have to be filtered (according to the site configuration) or have some peculiarities (i.e., timed repetitions)
- **LABELING**: production of the labels;
- **LABELING SET OPTIONS**: configurations for the labeling;
- **RELABELING**: sample relabeling;
- **ALT TUBE**: choice of different tube types;
- **CHECKOUT**: confirmation that all tubes or part of them are filled and ready for transport;
- **ABORT**: interruption of the process caused by the operator

Notice that not all these activities strictly refer to the IHE transactions for the phlebotomy process; some of them are strictly related to specific features of the prototype (e.g., labeling abort, transcoding errors). The CHECKOUT activity in the model is related to the new LAB-63 transaction.

4 Discussion

The new two transactions that we proposed, LAB-63 and LAB-64, complete the description of the phlebotomy process. The first describes the preparation of the specimen container, while the latter covers specimen collection. From an IHE point of view, LAB-63 is completely within the LBL profile scope, while LAB-64 involves other IHE Laboratory domain profiles.

The availability of traceability data enables the application of Process Mining techniques to analyze, reconstruct, monitor or discover a process, enabling the comparison of the real behaviour of a system with its theoretical model. Figure 5 compares theoretical and mined BPMN models obtained applying Discovery [16] algorithms to ProTube prototype traceability data collected in a clinical experimentation site. The figure highlights that there are some activities and paths belonging to the theoretical model that are not covered by the mined one; on the other hand, the inferred model also shows some activities and paths that are not present in the theoretical one. These results can be used to improve the theoretical model, by adding the missing activities and paths, and also to detect errors and exceptions which have to be handled by directly acting on the process components – e.g., actors and procedures. Process Mining analysis also measures the overall process performance through a study of the most covered paths and relevant key performance indicators, such as turnaround time and lead time [19].

In [20] and [21] there are two examples of the use of Process Mining for the analysis of IHE workflows, based on the implementation of the *Audit Trail and Node Authentication* (ATNA) profile and the *Audit Record Repository* actor (ARR). The ATNA profile controls the access to protected health information – for instance, demographic data and clinical documents – logging every access into the ARR. The authors use log information as an input for the Process Mining algorithm to discover patient pathways. This approach, however, presents some difficulties to identify the traces (intended as the set of event logs belonging to the same process instance) and thus perform process reconstruction.

5 Conclusions

Our work demonstrates the benefits that the application of IHE workflow formalizations, traceability-oriented analysis and process mining techniques can bring to health process management. The two new transactions (LAB-63 and LAB-64) we presented to the IHE Laboratory Committee fully covered the traceability of two events critical for the phlebotomy process – i.e., specimen container preparation and sample collection.

LAB-63 was accepted by the IHE and, after a brief revision work, allowed for Trial Implementation. It was successfully tested at the 2013 European Connectathon by two vendors and, according to IHE roadmap, only another

Connectathon testing session is needed before the transaction can be definitively included in the Technical Framework [22]. In 2015, the LAB-63 was further improved to handle additional specimen descriptions and usage specification [23].

LAB-64 instead needs additional discussion, as its scope involves not only the LBL profile, but also external profiles. This transaction has been the starting point for the development of a new IHE Laboratory Profile, called SET (Specimen Event Tracking), whose first version is in the agenda of the Technical Committee for the 2016-2017 period.

The extended IHE workflow also served as the basis to formalize the phlebotomy processes from a process mining perspective: starting from the main IHE transactions, we identified a set of events to trace the process' behaviour and to compare it to the real one.

In the future, the most important priorities are the definitive inclusion of LAB-63 in the Technical Framework and the development of the SET profile. Moreover, the methodology described in this paper, for creating an IHE-compliant traceability system, will be extended to different clinical processes related to other IHE domains and profiles.

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HL7 v2+: The Future of HL7 Version 2?

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Abstract

Background: HL7 version 2.x is the most popular and most propagated data exchange standard in the world. It is mature and adopted by several IHE Technical Frameworks. Nevertheless it has some weaknesses especially in the way it is documented. Several conformance constructs (optionality/usage and repetitions) are still under discussion although the meaning is unambiguous and clear. The deadline for HL7 v2.9 proposals is over and the next ballot is in preparation for May 2016.
Objectives: Therefore the question arises what will come next? HL7 v2.10? HL7 International is in favor of distributing new releases every year, so that this is a good opportunity to update the representation and documentation of HL7 v2.x while maintaining backward compatibility for running interfaces.
Methods: A semantic analysis of the conformance constructs being used by HL7 v2.x allows for developing transition matrices so that the new representation can be automatically generated in large parts. Of course, a new separation into domains require manual support.
Results: This paper demonstrates the new representation form rendered out of the HL7 Comprehensive Database.
Conclusions: Harmonizing HL7 v2.x with other standards in the way it is represented simplifies implementation and therefore supports interoperability among applications.

Keywords

Communication standards; HL7 version 2; interoperability, versioning; compatibility

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1 Introduction

HL7 version 2.x is in use since its inception at the end of the 1980s. It has been adopted by global interoperability initiatives like IHE [1] and is therefore part of several Technical Frameworks. The most prominent versions used by IHE are v2.3.1 and v2.5. Obama's Meaningful Use initiative executed by ONC is based on v2.5.1 with enhancements (pre adoption) stemming from v2.8.1 and v2.8.2. Other countries, e.g., UK, are facilitating v2.4. Worldwide, each vendor is implementing its own mixture of versions.

The community is currently working on HL7 v2.9 combined with a discussion about what will come after v2.9. A lot of efforts have been placed on the maintenance and further development of the different versions for HL7 v2.x during the past two decades leaving a large burden on the individual editors who tried to keep the different MS Word documents in sync. As we know today, we have not been successful in that regard all the time, an improvement appears to be necessary.

Observing the way other standards (e.g. HL7 V3®and FHIR®[2]) are written, the time has come to take the opportunity for a major step forward and getting rid of old-fashioned conformance constructs. The first step will be done with HL7 v2.9 where chapter 2C (Vocabulary) will not be maintained by hand any more, but generated from a database (Figure 1). An HL7 project [3] (running for four years now) has examined all tables across all v2.x versions and provided detailed feedback about the consistency, asked for clarification and suggested necessary technical corrections. The ultimate target of this project is a common vocabulary model and future maintenance across all HL7 standards in an equal way. The result of this project is worth another paper and would lead to far here. For Hl7 v2+ only the major achievements in consolidating the tables into a solid vocabulary model consisting

of vocabulary domains, value sets and codesystems as input into HL7 v2+ are taken.

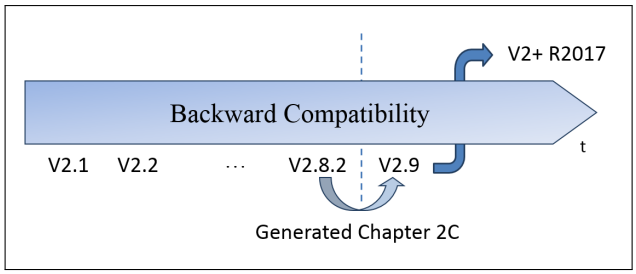

Figure 1: Transition to HL7 v2+.

The next step is the complete generation of the standard from a database. The best input is the HL7 Comprehensive Database that contains the whole documentation already [4].

2 Methods

A thorough analysis [5] of the conformance constructs used by HL7 v2.x supports the conclusion that a migration to a better and common representation is possible. A first step is to isolate implementation aspects from runtime information. As such, the "R" (required) and "RE" (required but may be empty) indicators as the cause for long-lasting discussions are to be replaced by "Must Support". Table 1 demonstrates how this conversion is done.

The second conversion concerns the transition of "repetitions" into cardinality. Table 2 demonstrates how.

Using this machinery, a transition can be done automatically. Another algorithm can be used to convert the Abstract Message Syntax into a hierarchical folder structure (Figure 3).

3 Results

Following, the current status is presented. Details can be found at [6]. The most prominent visualization of the current enhancements may be seen by the HTML rendering using the newest style that is borrowed from FHIR® (Figure 2).

The topmost navigation bar allows for accessing the different areas of the specification. Each starting page is new and allows an easy entry into the requested topic. These pages must be created manually because a semantically correct association to a new structure cannot be computed.

3.1 Overall Representation

Another improvement is the overall representation form that does not use the Abstract Message Syntax (AMS) any more. As can be seen by Figure 3, instead of different kind of parentheses a hierarchy is introduced that can directly be generated from the "old" specification (AMS) using a 4 phase algorithm. In addition, use of "Must Support" and "Cardinality" flags unifies the appearance.

Segment	Cardinality	Must Support	Status
ORU^R01^ORU_R01			
MSH	1..1	Yes	
SFT			
UAC	0..1		
PATIENT_RESULT	1..*	Yes	
PATIENT	0..1		
PID	1..1	Yes	
PD1	0..1		
PRT			
NTE			
NK1			
ARV			
PATIENT_OBSERVATION			
OBX	1..1	Yes	
PRT			
VISIT	0..1		
PV1	1..1	Yes	

Figure 3: Message Structure Representation.

The segments are directly hyperlinked to a complete segment documentation which will be provided on a separate page. The segment groups are indicated with a folder icon and an associated segment group name so that all related segments will become a sub-element thereof.

The "Cardinality" and "Must Support" column only indicate a value, if a constraint is placed onto this segment or group. This way the provided information to read the specification is reduced.

3.2 Segment Representation

The segments are provided in an enhanced way as well. Again, the usage/optionality information in combination with the repetition indication is replaced by "Must Support" and "Cardinality" and therefore unifies with other standards.

3.3 Vocabulary Model

As mentioned in the introduction, a major step forward that is partially provided with v2.9 is the migration to a common vocabulary model. This is accompanied by an enhanced set of meta-data including a movement away from a simple numbering of tables. The common four digit notation will go away in subsequent steps.

This step is visualized by a vocabulary domain name (short name) used in the vocabulary column of the data types and segment definitions (Figure 4). Figure 5 demonstrates the metadata for vocabulary that is still ready for improvements.

Table 1: Value Set for "Must Support".

Value	Description	V2.x compliance	Specialization in profiles
Y	Must support this element, i.e. a development must handle this element	"R", "RE"	Y
N	Element is forbidden	"W", "B", "X"	N
(empty)	Optional	"O"	O, Y, N

Table 2: Value Set for "Cardinality".

Value	Description	V2.x Compliance	Rep./#
0..0	Forbidden	"W", "B"	
0..1	Optional	"RE", "O"	
0..n	Optional, repeating n-times	"RE", "O"	"Y"/n
0..*	Optional, repeating	"O"	"Y"
1..1	Required	"R"	
1..n	Required, repeating n-times	"R"	"Y"/n
1..*	Required, repeating	"R"	"Y"
n..m	*Does not occur yet*		

3.4 Next Steps

The whole transition process requires a lot of effort until its establishment and acceptance. This paper presents the current status in this long-lasting process realizing that some more steps are necessary:

- Rearranging the presentation into different domains (ADT, billing, orders&observations, pharmacy, etc.),
- Integration of the two possible encodings (ER7, v2.xml),
- Harmonizing the data types for vocabulary,
- Separating data types, vocabulary and segments into different pages,
- Removing duplicate message definitions by introducing interaction diagrams,

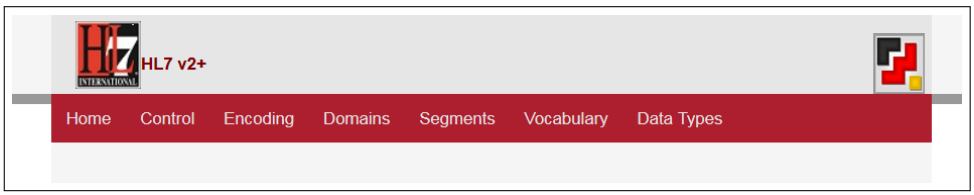

Figure 2: Modern Representation of HL7 v2+.

Seq#	Data Element	Description	Must Support	Cardinality	Length	C.LEN	Vocabulary	Data Type
1	00104	Set ID - PID		0..1	1..4			SI
2	00105	Patient ID	No (withdrawn)					
3	00106	Patient Identifier List	Yes	1..1				CX
4	00107	Alternate Patient ID - PID	No (withdrawn)					
5	00108	Patient Name	Yes	1..1			nameType2	XPN
6	00109	Mother's Maiden Name		0..1				XPN
7	00110	Date/Time of Birth		0..1				DTM
8	00111	Administrative Sex		0..1			administrativeSex	CWE
9	00112	Patient Alias	No (withdrawn)					
10	00113	Race		0..1			race	CWE
11	00114	Patient Address		0..1				XAD
12	00115	County Code	No (withdrawn)					
13	00116	Phone Number - Home	No (backward)					XTN

Figure 4: PID segment with new Representation.

- Including other artifacts like XML schemas for conformance profiles, and
- Perhaps allowing for a dynamic behavior, e.g., when working with message structures.

4 Discussion

Advancing standards for error correction, scope extension, adoption of new use case, introduction of new components or parameters, etc., results in versioning specifications which contradicts to harmonization and therefore interoperability. Additionally, the presentation style has been changing, and finally each version might be implemented differently, leading to chaotic conditions. To overcome the problems, among others a) a solid vocabulary model representing vocabulary domains, value sets and codesystems must be established, b) the variety of semantics for the value sets must be reduced and simplified, c) the concept representation for the different specifications must be formalized towards a specific ICT ontology, d) automation of specification development process to avoid individual interpretations and inconsistencies is inevitable.

Although this change in representing and providing the standard does not impact any running interface, some kind of retention and therefore rejection is anticipated. Of course, a change in writing the standard is always accompanied with further education requiring time.

5 Conclusions

The discussion performed in the paper deals with the improvement of standard specification and implementation processes for enabling interoperability, focused on the ICT domain. The authors presented ongoing developments for HL7 v2+ towards specification harmonization which will pay off in the near future leading to better implementations and more interoperability. When not limiting interoperability to that domain, but integrating also the supported, ICT independent business domains and their stakeholders, alternatives have been developed, which are even more generic than the presented approach and cover this as well. For more information, see, e.g., [7].

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Concept Domain Information

Display Name:	Description:	Interpretation:
Administrative Sex	Administrative Sex	Geschlecht

Code System Identification Information

CS-OID:	CS Symbolic Name:
2.16.840.1.113883.18.2	administrativeSex

Code System Version Information

OID Version:
1

Value Set Information

OID:	Symbolic Name:
2.16.840.1.113883.21.2	hl7VS-administrativeSex

Binding Information

Binding:
representative

Table Metadata

Table:	Steward:
1	

Value	Display Name	Interpretation	Comment	Usage Note	Modification Date	Active
F	Female	weiblich			Jul 13 2015	X
M	Male	männlich			Jul 13 2015	X
O	Other	andere			Jul 13 2015	X
U	Unknown	unbekannt			Jul 13 2015	X
A	Ambiguous	mehrdeutig			Jul 13 2015	X
N	Not applicable	nicht zutreffend			Jul 13 2015	X

Figure 5: Meta-Data for Vocabulary.

A Standardized SOA for Clinical Data Sharing to Support Acute Care, Telemedicine and Clinical Trials

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Abstract

Background: Developed countries are planning the creation of national EHR (Electronic Health Record) systems to modernize the healthcare field and improve its quality, security and efficiency.
Objectives: To support clinical data sharing, it is important that an EHR is designed to be integrated within an appropriate architectural context aimed to satisfy the needs of all actors involved in this information management by adding and integrating new functionalities to existing solutions.
Methods: SOA (Service Oriented Architecture) provides a good approach to promote the easy integration and alignment of a new and existing solution into a cohesive architecture. The HSSP (Healthcare Service Specification Program) was formed to adopt the SOA approach to guarantee interoperability between applications and distributed and heterogeneous devices, by providing a set of standards to design and develop specific services.
Results: The authors present a landscape architecture to support the collaboration between actors involved in the treatment of chronic diseases. The core of this architecture consists of services compliant to HSSP standards. Among these, the authors developed: Health Record Management Services, Health Terminology Services and Health Identity Services. The proposed architecture and these services have already been adopted in different systems: a telemonitoring system to support the continuity of care of CHF (Congestive Heart Failure) patients, two systems to share clinical data to manage clinical trials in both infectivology and ophthalmology.
Conclusions: The main advantage of the proposed architecture is its flexibility that allows it to be adapted over time and to be adopted in all health care scenarios.

Keywords

Electronic Health Record; Service Oriented Architecture; Clinical Data Sharing; Healthcare Specification Project

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1 Introduction

Technological-scientific progress in the medical field is extending the population's life expectancy with the consequence that a person can undergo many healthcare encounters in her/his lifetime. In order to correctly and efficiently treat a patient, it is essential that all medical staff collaborate and have a complete knowledge of his/her past experience and clinical history, particularly in the case of chronic diseases or acute events where the patient may be aided by a large number of clinicians and specialists.

In this complex scenario, the Electronic Health Record (EHR) represents the most suitable solution designed exactly to support these needs. The EHR is a digital repository for healthcare information related to a person's lifetime with the goal of supporting treatment continuity, education and research, whilst always guaranteeing privacy protection [1]. In many developed countries such as Italy [2], Austria [3], Luxembourg [4], Denmark [5], Norway [6], and the United Kingdom [7], the Healthcare Ministries are increasingly interested in the potential benefits provided by the EHR to modernize the healthcare field and improve its quality, security and efficiency, so consequently, they are planning the creation of national EHR systems [8, 9, 10].

Different steps of clinical data integration within the EHR are described in literature. Waegemann indicated the Automated Medical Record (AMR), the Computerized Medical Record (CMR) and the Electronic Medical Record (EMR) as different stages of automation within

one health institution. The Electronic Patient Record (EPR) was also mentioned, whose purpose is to extend record integration across the borders of institutions. The successive step is the EHR which allows each responsible citizen to manage and have control over his/her own medical data [11, 12].

Even though Wargemann pointed out these phases of patient clinical data integration in 1999, at present there is not a common and effective automatic communication between all these entities. The implemented EHR solutions provide the citizen with a tool to insert and save his/her own clinical data in a manual way; in fact, the possibility to automatically feed information into the EHR is often missing, even in the easiest of cases, where automated instruments produce the information directly.

These solutions show other critical problems. Firstly, the formats typically used for information filing are not structured documents and simply represent digital copies of paper documents, such as pdfs, jpegs etc. [1]. This lack of semantic management and organization of the information content does not allow the EHR to be automatically and easily accessible and interpretable when required. This is exactly the case of patients suffering from chronic and/or infectious diseases. For correct and efficient treatment, it is extremely useful to know the complete patient clinical history contained in the EHR, particularly when the health state of the patient becomes critical, in order to accelerate the emergency procedures, raising the chances of saving lives. In addition, all the data, collected during a patient's lifetime, would be highly useful, if made available to advanced research centers. In fact, the medical field is undergoing a significant change in the way healthcare professionals interact with patients' data. Clinical data is more and more often defined as valuable in helping to make decisions about patients' treatment [13, 14].

In order to support clinical data sharing, it is important that an EHR system is designed to be integrated within an appropriate architectural context aimed to satisfy the needs of all actors involved in this information management. In the UK, the National Health Service (NHS) invested in the largest civil IT project in the world, the National Programme for IT (NPfIT), with the aim of seeking to revolutionize the way care is delivered, improve quality and use NHS resources more effectively. Despite these high expectations, the NHS has historically experienced some high profile IT failures and the sponsors of the programme admitted that there remains a number of critical barriers to the implementation of the project [15]. Clinicians' reluctance to accept new IT systems at a local level is seen to be a major factor in this respect. In particular, findings show that clinicians often perceived that the IT systems, proposed by the NPfIT, would have little positive impact on making their job easier or improving patient care; although it was mentioned that there was no resistance to new technology as many new medical technologies had already been embraced [15]. Therefore the clinician's approval is fundamental for the effective success of every e-health application, which occurs when new technologies are designed with an effective collaboration between the physician and IT staff.

Another important aspect to be considered is that IT efforts to evolve are hampered by the extensive existing investments in hardware, software, and medical devices, which must continue to be supported by healthcare organizations, while being under increasing pressure to modernize systems. The Service Oriented Architecture (SOA) provides a highly feasible approach to promote the easy integration and alignment of a new and existing solution into a cohesive architecture [16].

Firstly, this paper describes the landscape architecture that the authors designed and proposed to allow the complete and effective collaboration between all the actors which can be involved in an overall care cycle, in order to manage both acute events and chronic illness. Then it presents the state of the implementation of this architectural solution which is being developed and employed in different systems to support the treatment of different diseases and the continuity of care. In particular, this architecture is applied to the management of certain chronic illnesses such as in the treatment of cardiovascular diseases, infectious diseases and eye infections and also to the surveillance of multi-resistant microorganisms.

2 Methods

The clinical data that is managed within the proposed solution depends on the particular class of patients considered by each implemented solution. For patients suffering from cardiovascular diseases the data is related to the complete clinical history and also to vital signs, if continuous monitoring is necessary after hospitalization, during the rehabilitation.

If the patients are affected by infectious diseases, for example, related to Human Immunodeficiency Virus (HIV) and to Hepatitis B/C Virus (HBV/HCV) the clinical data refers to specific blood tests indicated to monitor their health status.

If the patients are affected by degenerative eye diseases, the managed data is related to information collected during specific encounters (like the status of the vision and the objective description of the retina situation).

In the case of surveillance of multi-resistance to antibiotics the exchanged data are more varied, and consist of anamnestic information on the patient, location of where the infection was acquired, identification of the microorganism and its antibiogram spectra.

The actors who are involved in the treatment of these patients and diseases are:

- Departments and care units of Ligurian hospitals: Infectious Diseases Departments, Departments of Neurosciences, Ophthalmology and Genetics, Coronary Care Units
- General practitioners

- Specialists
- Internal and external hospital laboratories
- The Ligurian regional EHR, also called "Conto Corrente Salute" ("Health Checking Account")
- Clinics for rehabilitation or the patient's home
- Advanced Ligurian and Italian research centers
- External Clinical Decision Support (CDS) systems (e.g. openCDS community [17])

In order to share the clinical data mentioned, two HL7 products, derived from the HL7 version 3 (v3) Reference Information Model (RIM) were used: the HL7 v3 Clinical Document Architecture Release 2 (CDA R2) and the HL7 v3 Virtual Medical Record (vMR). In particular, on one hand the authors adopted the CDA R2 [18] for the information transmission between hospitals, general practitioners, specialists, laboratories, the regional EHR, clinics or the patient's home and advanced research centers; on the other hand, the vMR data model was chosen to provide clinical information to external CDS systems [19].

The structure of CDA R2 is extremely generic and flexible, and is therefore adaptable to satisfy the requirements of different interoperability scenarios. For this reason, an Implementation Guide (IG), which constrains the CDA R2 specification, must be provided for each use case. The IG is usually produced by HL7 International, then each country-specific HL7 Affiliate organization is authorized to edit a national version appropriate for the local healthcare context. The choice of IG is related to the clinical and administrative data that are managed, which in turn depends on the particular class of patients considered by each implemented solution. At present, the HL7 Italian affiliate has not yet produced an Italian CDA R2 IG which can be adopted for the management of patients suffering from cardiovascular diseases, but it developed the Italian localization of the "Implementation Guide: CDA Release 2 – Care Record Summary Release 2 Discharge Summary" [20]. The authors decided to take into account this IG and if necessary a few CDS R2 sections from the "Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD)" [21]. For the management of patients who are affected by infectious diseases the authors considered the HL7 Italy IG for Laboratory Reports [22], which represents the Italian localization of the IHE (Integrating the Healthcare Enterprise) Laboratory Technical Framework [23]. Finally, for the management of patients affected by degenerative eye diseases, the Italian localization of the "Implementation Guide: CDA Release 2 – Care Record Summary Release 2 Discharge Summary" [20].

The SOA approach was utilized as a vehicle to transmit the clinical information across these health organizations. One of the SOA key principles lies in the ability to adapt the architecture over time, adding new services, replacing existing services and reconfiguring, all with minimal impacts to service consumers. The SOA reduces the amount of client point to point interfaces needed within a given environment [24].

To design the reference architecture the authors took into account the specifications provided by the Healthcare Services Specification Project (HSSP). The HSSP is a program jointly promoted by the HL7 International and the Object Management Group (OMG) and is regulated by the Statement of Understanding (SOU) between HL7 International and the OMG. The HSSP was formed in 2005 in order to define health industry SOA standards that promote interoperability. In particular, the main HSSP objective is to use the SOA approach to provide and guarantee an effective interoperability between applications, and distributed and heterogeneous devices, which belong to independent socio-health system organizations. The aim of every HSSP project is the standardization of a specific service, which is related to a functional socio-health domain, as a generic service. The intention is to standardize generic functions and protocols, which allow application and technical communication, in order to invoke, accept or reject and report the performance of these functions. The HSSP characterized the SOA services into three clear categories which are:

- Healthcare-Unique Services. This category calls-out service capabilities that are either unique to healthcare, or for which healthcare has unique requirements. For instance, both record management, clinical decision support and order management appear here.
- Business Services. Business-services describe those capabilities that support business competences or processes. Some examples are terminology, payroll, accounting, human resource management and demographics.
- Technical/Infrastructure Services. These services involve capabilities like service instance location, protocol/message routing, etc. [25].

This work focuses on the first two service categories mentioned above, which are the most interesting ones from a research point of view, as Technical/Infrastructure Services are mature components of the SOA, widely used in well-assessed distributed environments such as banking and assurance systems. The following objects from Healthcare-Unique Services and Business Services were selected in the present architecture:

- Health Record Management Services (HRMS) and Health Decision Support Services (HDSS) from the Healthcare-Unique Services category
- Health Terminology Services (HTS) and Health Identity Services (HIS) from the Business Services category.

HRMS are standardized services to manage patients' profiles and clinical history and the interfaces are defined by the Retrieve, Locate and Update Services (RLUS) Release 1 standard [26]. The RLUS standard provides a set

of interfaces through which information systems can access and manage information within and between healthcare organizations. RLUS allows health data to be located, accessed and updated regardless of underlying data structures, security concerns or delivery mechanisms. It is independent of but compatible with underlying structures, including local security implementations, data models, or delivery mechanisms. By separating and exposing those aspects of resources that facilitate inter-organization workflows in a service layer, this specification abstracts the problem of interoperability away from underlying systems. It is not intended to replace existing systems or implementations, but to create an interface standard for a service-oriented layer to expose those healthcare assets and resources within an organization that are needed to meet business or medical needs.

The RLUS standard, as all HSSP products, is distributed through the HL7 Service Functional Model (SFM) which provides a service interface specification at a functional level (SFM for RLUS is available at [27]). An interface specification is defined by the Software Engineering

Institute (SEI) Software Architecture Glossary as a statement of what an architect chooses to make known about an element in order for other entities to interact or communicate with it [28]. Starting from the HL7 SFM, the OMG develops the "Requests for Proposal" (RFP) which are the basis of the OMG standardization process. In this phase vendors and other submitters propose solutions which satisfy the requirements indicated in the RFP while leaving design flexibility to the submitters and implementation flexibility to the users of the standard. The result of this process is the OMG Service Technical Model (STM) which specifies the technical requirements of the service [29] (STM for RLUS is available at [30]).

HDSS are standardized services to research, query and execute modules to help in decision making and their interfaces are defined by Clinical Decision Support Services (CDSS) Release 1 standard [31]. The CDSS standard provides interface specifications and technical requirements which are needed for a standardized approach for leveraging machine-executable medical knowledge in an application-independent manner. A Decision Support Services (DSS) receives patient data as the input and returns patient-specific conclusions as the output. In this way, it can significantly facilitate the implementation of systems that require patient-specific inference such as Clinical Decision Support (CDS) systems and quality reporting systems. CDS systems are solutions which provide physicians and other healthcare stakeholders with patient-specific assessments or recommendations in order to assist in clinical decision making. Examples of CDS systems include outpatient systems that attach care reminders to the charts of patients who need specific preventive care services, Computerized Provider Order Entry (CPOE) systems which provide patient-specific recommendations as part of the order entry process, and laboratory alerting systems which warn physicians when critical laboratory values are detected [31].

HTS are standardized services to manage clinical and health codifications and terminologies and their interfaces are defined by Common Terminology Services Release 2 (CTS2) standard [29]. The CTS2 standard provides a consistent specification to develop service interfaces to manage, search and access terminology content, either locally, or across a federation of terminology service nodes, independent of the terminology content and underlying technological stack. Structured terminologies supply the basis for information interoperability by improving the effectiveness of information exchange within a specific domain. Specifically, the structured terminologies provide a tool to organize information and to define the information semantics using consistent and computable mechanisms. In a shared semantics environment, the CTS2 provides a modular and common set of behaviors which can be used to deal with a set of terminologies chosen by the clients. The service contributes to interoperability by supporting an easy access to the foundational elements of shared semantics [29, 32]. The HL7 SFM for CTS2 is available at [29] while the OMG STM is available at [32].

HIS are standardized services to define, update and generally manage identities and their interfaces are defined by Identification and Cross-Reference Service (IXS) Release 1 standard [33]. The IXS standard provides a set of service interfaces to uniquely identify and index various kinds of entities (patients, providers, organizations, systems and devises) both within and across health organizations. The IXS allows any system which uses the service to maintain a common description for each entity and to manage the entities. The unique identifier and standard way to search, retrieve and manage entity data allows healthcare applications and healthcare enterprises to find, exchange and reference entity data while maintaining the data context and associations [33, 34]. HL7 SFM for IXS is available at [33] while OMG STM is available at [34].

3 Results

3.1 Proposed Architecture

The landscape architecture, which the authors proposed to support the collaboration between actors involved in the treatment of chronic and/or infectious diseases and in the surveillance of antibiotic multi-resistant microorganisms, is represented in Figure 1. The core of this architecture consists of two Healthcare-Unique Services, the HRMS and the HDSS, and two Business Services, the HTS and the HIS.

The Health Record Management Service, whose interface is compliant to RLUS standards, permits the standardized transmission of clinical data within a clinical document between hospitals, general practitioners, specialists, laboratories, the regional EHR, clinics or a pa-

tient's home and advanced research centers. The HRMS provides operations to allow an authorized client to get and put resources mapped using the HL7 v3 CDA R2. In particular, the put resource operations are used to share clinical data with other specific clients of the HRMS; typical examples are the cases in which:

- A department/care unit of a hospital or clinic/patient's home, a laboratory or a specialist wants to update the regional EHR
- A department/care unit of a hospital wants to contribute to medical trials by sending information to research centers.

When the HRMS receives a CDA R2 as a parameter of a put resource operation, it processes the header content to extract the author in order to know who is authorized, so as to re-address the document. Before sending this resource, the service has to modify some of the elements in its content. Indeed, in this CDA R2 it is possible that the code attribute used for the clinical statement (e.g. observation) belongs to a code system defined within the specific system (e.g. department/care unit or laboratory). This occurs in Italy, as the national effort to provide a standardized nomenclature was motivated by exclusively economic purposes, which are related to the refunds of outpatient specialist health services and to the definition of the essential level of assistance founded by the Italian national healthcare system. In addition, this nomenclature was produced in 1999 [35] and it was excluded from the rapid evolution of the clinical care world. These limits led to the creation of many different local terminologies which represent an obstacle to achieving information interoperability.

For these reasons, a HTS, whose interface is compliant to the CTS2 standard, was also included in the architecture design in order to permit the sharing of information semantics. The Health Terminology Service provides functionalities to search and query structured terminological content pertaining to code systems and therefore allows the mapping of a code of a specific code system in the corresponding code of the reference code system. In this work, the adopted reference code system is the standardized vocabulary LOINC (Logical Observation Identifiers Names and Codes) [36]. Thanks to this service, the HRMS is able to modify all the codes of a specific code system in the corresponding LOINC code to allow the transmitted CDA R2 to be correctly interpreted by both external clinician/research and computer processes.

The other class of CDA R2 elements, which the HRMS must manage, is related to the patient identifiers (ID). In fact, a person in his/her lifetime may have episodes of care provided by several healthcare organizations, many of whom assign and maintain the patient's identifier autonomously. In this context, each organization or even department often assigns its own ID, which uniquely iden-

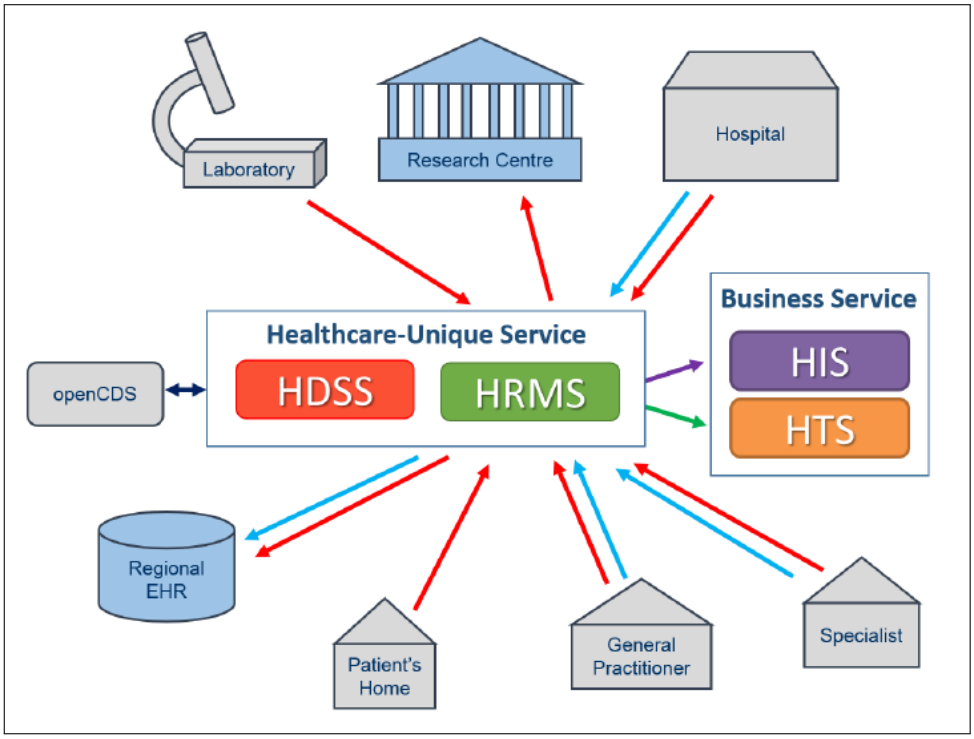

Figure 1: The proposed Service Oriented Architecture compliant to HSSP specifications. Grey actors represents systems that interacts with the central services through client applications, while light blue ones represents actors with provide access to the content of their system with RLUS web service interfaces. Red arrows represent calls to RLUS Put operation, light blue arrows reppresents calls to RLUS Get operations, purple and green arrows respectly represents call to IXS and CTS2 query operations and blue arrows represents interactions with external decision support systems..

tifies the patient for its own purposes, with the result that these ID values are meaningless outside that system or organization. In order to manage all the identifiers, the authors also introduced a HIS, whose interface is compliant to the IXS standard. The Health Identity Service provides query operations, given an identifier, to retrieve the list of all other IDs, which are linked to it. In this solution, as a reference identifier the Italian fiscal code provided by the Italian Economy and Finances Ministry was adopted. The reason for this choice is that the same code is used by the Italian Health Ministry to identify patients within the Italian National Health System. By calling these functionalities, the HRMS can modify all identifiers assigned by a specific system (root) in the corresponding ID by referring to the root of the address system. The use of the Italian fiscal code is limited to the cases in which the identity of the patient is indispensable; in all other cases, the privacy of the patients is maintained by the automatic work of the HIS. After these changes, the CDA R2 is ready to be addressed to the specific actor, typically the regional EHR or the center responsible for research activity in which the patient is involved.

The other class of functionality provided by the HRMS is the get operations, which are used to access a patient's information; a classic case is when a general practitioner, a specialist, or a department/care unit wish to be informed about the patient's clinical history stored within the EHR. When the HRMS receives a request to get a resource related to a specific patient, it first queries the HIS to obtain the corresponding patient's identifier within the regional EHR, where the information is stored. If the applicant is authorized to have access to the clinical data, then the Health Record Management Service interacts with the EHR to obtain the resource. Before sending the CDA R2 request, the HRMS queries the HTS to verify if for each code referring to LOINC, there is a corresponding mapped code in the local code system defined for the specific system which is requesting the information. In the case in which a corresponding mapped code is found, the HMRS integrates the LOINC code with the local code obtained and then addresses the standardized document to the applicant.

The last service, which the authors included in the described architecture, is the HDSS, whose interface is compliant to the CDSS standard. This service allows the EHR to interact with the international medical community, in order to improve the relevant shared data, which can be processed to provide patient-specific assessments or recommendations. In this case, the information is mapped using vMR, as indicated by CDSS standard. Finally, to set up this architecture, dedicated interfaces and clients were also designed in addition to the standardized services mentioned in order to allow each actor to communicate with the services in a standardized manner.

3.2 Status of the implementation

The first service that the authors designed and developed was the HRMS. A Windows Communication Foundation (WCF) Service [37], whose interface is compliant with RLUS standards and are described through Web Service Description Language (WSDL) files, was implemented. One of the advantages of the RLUS is its flexibility and adaptability to different semantic content. These concepts are realized by the separation of functionality and semantic content in the interfaces. Relevant semantic content is designated by a Semantic Signifier that is defined for client use through XSD (XML Schema Definition) files. The principal Semantic Signifier used to allow the communication between actors involved in this architecture was the CDA R2.

Then the authors considered HTS. For the design, they started to implement a terminology repository in order to store all the information needed to manage clinical and health codifications and terminologies. In this phase, the specifications provided by OMG in the CTS2 STM were adopted. In detail, CodeSystem, CodeSystemVersion, EntityDescription, MapCatalog, MapVersion, MapEntry resources of CTS2 STM were considered. In the same time, the authors started the implementation of the interfaces of the HTS. For each CTS2 resource, the authors planed the development of WCF services to support read, query, maintenance and history functionality categories. At the present, the terminology repository is ready to manage all these capabilities for each CTS2 resource type, while services to provide read and query functionalities for CodeSystem are available.

Lastly, the HIS was designed. The authors implemented a repository to manage entities and implemented WCF services to manage patient's identifiers. Therefore, Patient class of CDA R2 was chosen as semantic signifier.

The proposed architecture and these implemented WCF service have already been adopted in different systems. The first one was used within the Artemis funded Project CHIRON [38]. CHIRON is an acronym for "Cyclic and person-centric Health management: Integrated appRoach for hOme, mobile and clinical eNvironments". It intends to propose an integrated framework designed to allow a person-centric health management throughout the complete care cycle, focused on patients affected by Congestive Heart Failure (CHF). Within the CHIRON telemonitoring system, the described Health Record Management Service was used to allow the standardized communication between the monitoring platform [39] located in the patient's home and the institutional openEHR based EHR, used as the core of the internal CDS system [40]. The authors collaborated on the development of the client hosted in a patient's home which provides clinical data to the HMRS through CDA R2 and implemented the EHR interface, which receives the tele-monitored data and converts the information mapped in CDA R2 in information mapped using the openEHR approach [41].

A second system which the authors implemented was a solution to realize the "Interoperable" tier indicated the EHRCR (Electronic Health Records for Clinical Research) Functional Profile Working Group [42] in order to manage clinical trials on HIV patients. The core of this solution was formed by the HRMS and the HIS that automatically orchestrated the bi-directional communication between the hospitals and research centers. The HRMS was responsible for managing clinical data, while the HIS, had the same purpose for administrative data. At present, this system involves two hospitals and four regional and national research centers [43].

Some client and web servers implemented in this solution were also adopted in another solution to connect a tool to manage both clinical data and clinical trials in ophthalmology and the one of the involved hospitals [44].

Another solution in which the authors are applying this architecture is for the surveillance of antibiotic multiresistant microorganisms; the implementation of all clients and interfaces is being coordinated. These solutions will support the communication between Infectious Diseases Departments, Departments of Neurosciences, Ophthalmology and Genetics, advanced Ligurian and Italian research centers and external CDS systems.

Finally, the HTS will be the focus of a project with the Veneto region. The HTS will be adopted to manage semantics between the ACG (Adjusted Clinical Groups) and the regional EHR.

4 Conclusions

In this paper a landscape architecture, supporting the reuse of clinical data and enhancing collaboration between the actors involved in the treatment of illness throughout the complete care cycle, has been described and discussed. The core of this architecture consists of four standardized services, based on the HSSP specifications, which allow the transmission and interpretation of clinical data enclosed within HL7 v3 CDA R2 between hospitals, general practitioners, specialists, laboratories, the regional EHR, clinics or patient's home and advanced research centers. In the present state of implementation, this architecture is realized through:

- A Health Record Management Service compliant to RLUS standards
- A Health Identity Service compliant to IXS standard
- A Heath Terminology Service which provides a subset of functionalities indicated by CTS2 standard
- A set of specific clients that permit the existing software to interface with these services. This implementation was successfully employed within three systems:
- A tele-monitoring system to support the continuity of care of chronic patients affected by CHF
- An architecture to manage clinical trials on HIV patients
- An solution to manage clinical trials in ophthalmology

One of the positive aspects of this proposed landscape architecture is certainly its flexibility which allows the system to be future proof, adding and integrating new functionalities to an existing solution. This feature permits the reuse of software, which was financed by previous investments; a fundamental element to be approved by healthcare organizations. In fact, while services were developed ex novo by the authors, the client applications were developed as an additional tool that interacts with the existing system, adding functionalities. In addition, the applicative solutions were designed in close collaboration with the medical staff in order to satisfy all requirements; a crucial point in order to be accepted by the final users. In fact, S. Fernando et al. declared that the major reason which caused the failure of NPfIT was directly linked to the clinicians' reluctance to accept new IT systems because it was affirmed that the proposed solution provided little positive impact on making their job easier or improving patient care [15].

The authors' experience, received through the collaboration with clinicians, technicians and patients, teaches that one of the most required features is the transparency to the final user. All actors would only approve a solution if it did not necessitate a serious change in their treatment of illness and would consequently produce an important improvement in patient care or a consistent decrease of human errors or time consumption. For example, the insertion of the Health Decision Support Services within the architecture was prompted by clinicians' request to provide data to external CDS systems.

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HL7 Clinical Laboratory Risk Engine Alerts in Hospitalized Patients

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Abstract

The objective of the study is to assess a HL7 clinical laboratory risk alert System in hospitalized patients versus the conventional methodology.

Method: We studied laboratory tests administered to 300 medical patients in the Belgrano Hospital intensive care unit. We considered two groups of 150 patient tests. In the first the group (control group), clinical laboratory risk was diagnosed in a traditional way. In the second group (alarm group), clinical laboratory risk was diagnosed with an alert system. The alert was triggered when a patient showed low or high levels of any of the following variables: blood glucose, hematocrit, WBCs, arterial blood gases, blood urea, blood creatinine, blood sodium and blood potassium.

Results: Clinical laboratory risk was detected in 20.3% of the control group patients of tests while, in the alert group, clinical laboratory risk was detected in 34.3% of the patients tests; the difference between the two groups was significant ($p<0.001$), with a sensitivity rate of 99% and a specificity rate of 98%.

Conclusion: Clinical Laboratory risk is more easily detected when using an alert system.

Keywords

Clinical laboratory risk alert; HL7; informatics system; critical values; alert values; critical values reporting

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1 Introduction

In the intensive care unit (ICU) it is important to monitor certain laboratory variables, often several times a day.

In previous studies we have found that alerts are useful in the ICU.[1]

The importance of the data obtained is such that significant changes or unusual values should be communicated immediately to the health personnel in charge. All staff must know how to recognize and interpret these critical values [2, 3]

Physicians are faced with the task of comprehending and acting on a rising flood tide of information. It is therefore important that systems be in place to help them monitor laboratory results.[4]

Several studies show the importance of controlling the exchange of information to the delivery of care on all levels of the health care delivery system — the patient, the care team, the health care organization, and the encompassing political-economic environment.[5]

Effective clinical alarm management relies on designs that promote appropriate use, clinicians who take an active role in learning how to use equipment safely over its full range of capabilities, and hospitals that recognize the complexities of managing clinical alarms and devote the necessary resources to develop effective management schemes.[6]

There is no particular alarm message standard to HL7 version 2.5; however, there is one in HL7 version 2.6. There is an IHE profile that defines the entire infrastructure (actors, responsibilities) to manage alarms. Specifically used as an alarm message: the ORU ^ R40 form HL7 v2.6 (7.3.12 ORU – Unsolicited Alert Observation Message) (Event R40) [7, 8, 9]

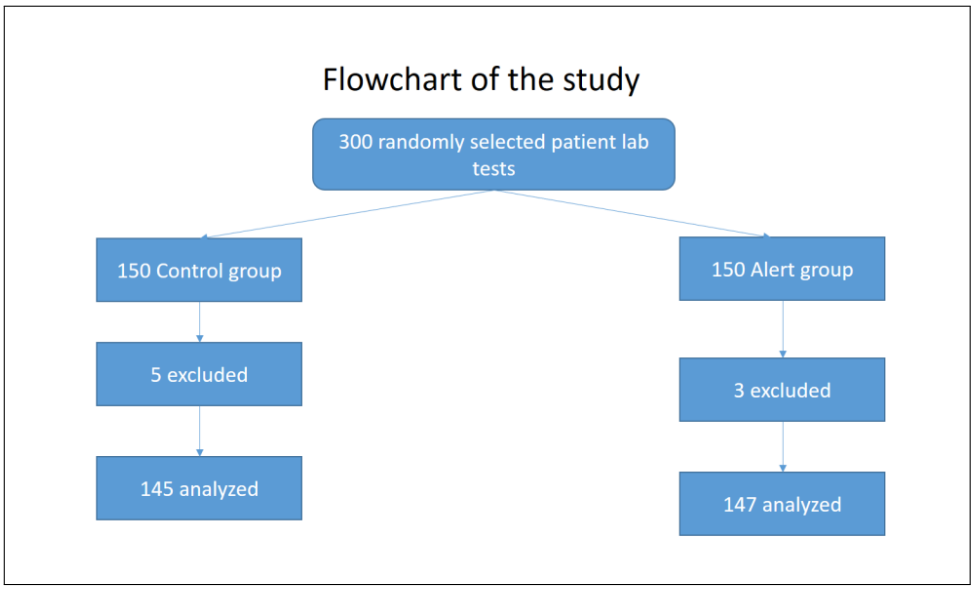

Figure 1: Flowchart of the study.

Several tools have been developed in the field of health care using data and information systems systematically; making decisions on the basis of the best available peer-reviewed evidence; applying program-planning frameworks (often based in health-behavior theory).[10]

Occasionally, the importance of the data obtained requires immediate communication with the health personnel in charge. All laboratory staff must know how to recognize and act on these critical values.[11, 12]

We think a clinical laboratory risk alert on laboratory values outside particular ranges is better than sending the data via an HL7 interface from the LIS system to the EHR, so we did a study to measure the efficacy.

Objective: The objective of this study is to prove that an alert is a helpful tool for doctors to better detect clinical laboratory risk in hospitals. This was a randomized experiment study with a control group. This research was carried out in the Belgrano Hospital ICU, where patient data were gathered in a sequential manner. We worked with two groups of patients: the control group and the group in which an alert was utilized .Although all the doctors were informed about the study beforehand, both groups of doctors who attended these patients carried out their tasks in the usual way during the study, and only the doctors who attended patients in the alert group were informed if patients had values above or below normal in the following variables: blood glucose, hematocrit, WBCs, arterial blood gases, blood urea, blood creatinine, blood sodium and blood potassium over or under normal values. The 8-bed unit is staffed by 10 physicians and 20 nurses and discharges an average of 32 patients per month. The total starting sample consisted of 300 patient laboratory tests.

We selected 300 laboratory tests performed on patients treated at the Belgrano Hospital intensive care unit who were hospitalized between November 1, 2015, and December 20, 2015. These patient tests were divided into two groups through routine random number generation. In the control group, clinical laboratory risk was detected in the traditional way, while in the alert group, clinical laboratory risk was detected with the help of an automatic alert system. (Figure 1)

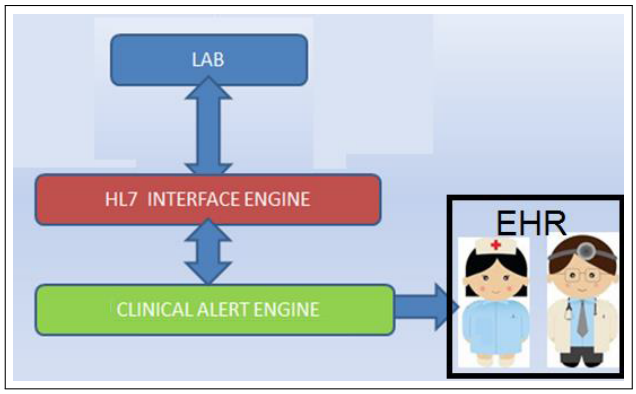

Figure 2: How the alert engine works.

The criterion standard was created by a committee of experts who retrospectively analyzed all the information available in the medical records in order to determine which patients in both groups were at clinical risk.

Inclusion criteria: Patients who underwent blood glucose, hematocrit, WBCs, arterial blood gases, blood urea, blood creatinine, blood sodium and blood potassium tests. Deceased patients were also included.

Exclusion criteria: Patients who did not undergo lab tests were excluded from this study.

The Alert engine use the standard Health Level Seven International (HL7). The alert is triggered when a patient shows low or high levels of the following variables: blood glucose, hematocrit, WBCs, arterial blood gases, blood

LOINC code	Sex	variables	Over	Under	Unit	Alert Message
5792-7	B	blood glucose	0	70	mg/dL	Low blood sugar
5792-7	B	blood glucose	100	1000	mg/dL	High blood sugar
4544-3	M	hematocrit men	0	38	%	Low hematocrit
4544-3	M	hematocrit men	50	100	%	High hematocrit
4544-3	F	hematocrit woman	0	34	%	Low hematocrit
4544-3	F	hematocrit woman	44	100	%	High hematocrit
57021-8	B	WBCs (white blood cells)	0	4500	per mcL	Low WBC
57021-8	B	WBCs (white blood cells)	10000	1E+05	per mcL	High WBC
3094-0	B	blood urea	0	7	mg/dL	Low blood urea
3094-0	B	blood urea	20	100	mg/dL	High blood urea
2160-0	B	blood creatinine	0	0.6	mg/dL	Low blood creatinine
2160-0	B	blood creatinine	1.2	10	mg/dL	High blood creatinine
1959-6	B	blood sodium	0	135	mEq/L	Low blood sodium
1959-6	B	blood sodium	145	200	mEq/L	High blood sodium
2823-3	B	blood potassium	0	3,5	mEq/L	Low blood potassium
2823-3	B	blood potassium	5	10	mEq/L	High blood potassium
		Arterial blood gases				
2703-7	B	Partial pressure of oxygen (PaO2)	0	75	mmHg	Low Partial pressure of oxygen
2703-7	B	Partial pressure of oxygen (PaO2)	100	1000	mmHg	High Partial pressure of oxygen
19884-6	B	Partial pressure of carbon dioxide (PaCO2)	38	42	mmHg	Low Partial pressure of carbon dioxide
19884-6	B	Partial pressure of carbon dioxide (PaCO2)	38	42	mmHg	High Partial pressure of carbon dioxide
2744-1	B	Arterial blood pH	0	7,38		Low Arterial blood pH
2744-1	B	Arterial blood pH	7,42	10		High Arterial blood pH
59415-0	B	Oxygen saturation (SaO2)	94	100	%	Low Oxygen saturation
59415-0	B	Oxygen saturation (SaO2)	94	100	%	High Oxygen saturation
1959-6	B	Bicarbonate - (HCO3)	22	28	mEq/L	Low Bicarbonate
1959-6	B	Bicarbonate - (HCO3)	22	28	mEq/L	High Bicarbonate

Figure 3: List of variables.

urea, blood creatinine, blood sodium and blood potassium.

How the alert engine works: The Alert engine receives and processes data from the Laboratory Information System (LIS) and the Health Information

System (HIS). Low or high levels of the above mentioned variables trigger an alert, and a warning message displays on the HIS system screen. (Figure 2).

The alert engine is a program created in C♯ that contains the rules for triggering alerts. The alert engine receives patients' laboratory results from the Laboratory Information System (LIS) via HL7 v2.4 messages and then processes this information. If the engine detects a critical value in a patient's laboratory results, such as low or high levels of blood glucose, hematocrit, white blood cells, arterial blood gases, blood urea, blood creatinine, arterial sodium or arterial potassium, the alarm is triggered.

The algorithm works as follows: The system has a configuration table with the variable that we want to control, its maximum and minimum reference values and with messages to send in each case (see Figure 3)

The system has a SQL query routine whose parameters receives the LOINC code, sex and the laboratory value. This routine returns all alerts that must be displayed and send them to a function programmed in C♯, with which the system builds the message alert in HL7 to be sent to the EHR.

The alarm sends a message that is displayed on the electronic health record (EHR) and is the first thing a physician or nurse sees when the patient's record is opened (Figure 2).

2 Results

The average age of the study population in both groups was 67.05 years, with the oldest patient 96 and the youngest 22 (Table 1).

Table 1: Age of sample population.

	Alert	Control	Both
Total	150	150	300
Age max	93.00	90.00	93.00
Age min	34.50	22.00	22.00
Average age	67.34	66.76	67.05

Clinical laboratory risk was detected in 34.3% of the alert group patients, while in the control group, clinical laboratory risk was detected in 33.8% of the patients, a non-significant difference between the two groups, as shown in Table 2. The sensitivity was 0.99 and the specificity was 0.98.

Table 2: Results alert group.

Total	147	145
Undetected clinical laboratory risk	130	131
Detected clinical laboratory risk	68	67

Clinical laboratory risk was detected in 20.3 % of the control group patients, while in the criterion standard, clinical laboratory risk was detected in 32 % of the patients; the difference between the two groups was significant ($p<0.001$).

3 Discussion

The results demonstrate that the clinical laboratory risk alert we built was of significant help. The rate of clinical laboratory risk detection was lower in the group with no alert system than in the group with an alert system (20.3% versus 34.3%). The alert had a high sensitivity and specificity and this fact helped doctors to diagnose clinical laboratory risk. However, there was a bias in our method: Control group doctors knew that we were carrying out a research on the clinical laboratory status of patients in the unit and that they were being monitored. This might have affected their behavior and, consequently, the outcome of this research. Clinical laboratory risk in hospitalized patients is often undiagnosed. After thorough research, we have not found precedents of this tool being used in the healthcare industry. In the intensive care unit of our hospital, we observed that clinical laboratory risk was higher than we thought, so we considered some strategies to find a method to avoid this problem. Many times doctors worry about certain pathology a hospitalized patient may have and they underestimate complementary diagnostic aspects.[13] We think clinical laboratory alerts are useful to solve specific problems in a certain area, for a specific group of professionals or in a certain point in time. We think they cannot be used without any control. For example, in our hospital, intensive care physicians did not pay a great deal of attention to patients' clinical laboratory results and the alert was useful for this.

We designed a study on clinical laboratory alerts using interfaces with electronic and laboratory reports to collect information allowing alerts to be generated on possible clinical laboratory risks. In our study we observed that this kind of clinical laboratory alert makes the physician aware of possible clinical laboratory risk and decreases the patient's clinical laboratory risk. We think it is very important to use alerts, and in our study we managed to show their usefulness: Physicians using alerts could diagnose more problems than those who did not receive alerts. We highly recommend paying attention to the design of the system: It is important to avoid an excessive number of alerts on electronic clinical laboratory reports because the excess of information generates frustration in doctors, who may skip reading some useful information.

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Model-based Validation of HL7 CDA R2 Documents and Implementation Guides Using Gazelle ObjectsChecker and ART-DECOR®

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Abstract

Numerous tools define metamodels to describe the requirements included in CDA specifications, the most recent and standardized one is the HL7 Templates Standard. The Templates Design resulting of this standard allow distributing the CDA specification in a formal way. One application of this normalization is the validation of CDA documents. IHE-Europe/Gazelle team developed already a methodology named Gazelle ObjectsChecker in order to generate model-based validation of XML requirements, including HL7 CDA standard.

The aim of this paper is to describe the way the requirements from HL7 Templates Standard are imported on Gazelle ObjectsChecker, and the benefit of such methodology for CDA implementation guides and for CDA documents validation.

Keywords

ART-DECOR®; Gazelle ObjectsChecker; HL7 CDA R2; HL7 Templates Standard

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1 Introduction

The specification of formal description for HL7 templates was a subject of discussion for several years in HL7 circles. HL7 Templates Standard DSTU R1 [1] was published in October 2014, and was the output of several years of work and discussions. ART-DECOR® consulting group supported this standard by participating in discussions and by development of a templates editor tool based on the HL7 Templates Standard. In recent years, IHE-Europe and Gazelle team developed a methodology to validate XML documents and especially HL7 CDA documents, named Gazelle ObjectsChecker. The aim of this methodology is to describe the requirements using formal language in order to generate validation tools.

The purpose of this paper is to explain how Gazelle ObjectsChecker succeeded to import requirements from Customer Templates Design into its models, and how this process was beneficial for all the intervenants, including the HL7 CDA implementation guides.

In the first section, we expose the state of the art: ART-DECOR®, HL7 Templates standard, and Gazelle ObjectsChecker. In the second part, we explain how Gazelle ObjectsChecker was coupled with ART-DECOR®, and how the coupling allows to validate HL7 CDA documents and to improve the quality of CDA implementation guides. And finally, we expose an application of this work: first, a comparison between the validation tools coming from the coupling of Gazelle ObjectsChecker and ART-DECOR®, with other validation tools, then we describe the result of validation of several HL7 Templates exchange documents coming from multiple domains.

2 State Of The Art

2.1 Introduction

CDA validation tools are generally based on a known process of validation [3] [4]:

- XML validation: check the validity of the CDA document regarding the XML standard [17]
- CDA schema validation [18]: check if the CDA document has a valid structure regarding the CDA schema
- Validation the CDA document regarding the Basic requirements of CDA Standard [3]
- Validation based on requirements coming from CDA implementation guides.

This paper is related to this last step of the CDA validation process. This last step could be performed by multiple validation tools like Gazelle ObjectsChecker, ART-DECOR® schematrons, MDHT, Trifolia schematrons, and MARC-HI Everest tool. Many technologies are used to modelise the requirements coming from CDA implementation guides, in order to use this modeling in the validation process.

2.2 ART-DECOR® and HL7 Templates Standard

ART-DECOR® is an open-source tool suite that supports the creation and maintenance of HL7 Templates, Value Sets as well as Data Sets and features cloud-based federated Building Block Repositories (BBR) for Templates and Value Sets. It supports comprehensive collaboration of team members within and between governance groups. The tool offers a Data Set and a Scenario editor, two Template editors, a Value Set editor and includes browsers for various international terminologies such as LOINC and Snomed CT. The tool covers all important phases of the creation artefacts for healthcare information exchange:

- capture of the clinical requirements in so called data sets and scenarios
- terminology mapping and associations
- template specifications with rules and value sets; it fully supports HL7's Templates Exchange Standard (see below)
- publication of all specifications, both online and offline available
- validation (schematron generation)
- support of the maintenance process (issue and ticketing system)

Since 2014 HL7 has an exchange standard (HL7 Templates Standard: Specification and Use of Reusable Information Constraint Templates, Release 1) that represents a big step forward in the process of use and re-use of templates. The standard's formal language enables governance groups busy with creation and maintenance of templates and associated artefacts to better express the constraints and vocabulary bindings. Template metadata captures the context in which this template has been created/updated and what relationships to other templates exist or are stated. This allows optimal support for template lifecycles and fosters the use of template registries and repositories (Building Block Repositories).

ART-DECOR® is used in over 30 projects throughout Europe and other parts of the world, e.g. the national infrastructure ELGA in Austria, the Dutch Nictiz (National Healthcare Standards Institute), the RIVM (National Institute of Public Health and the Environment in the Netherlands), HL7 and IHE Germany. The main ART-DECOR® servers host thousands of template definitions within the European Realm in HL7 Templates Standard format and an increasing number of re-used templates.

ART-DECOR® has a tight connection to IHE's Gazelle ObjectsChecker: the template definitions (in HL7 Templates Standard) along with the value sets captured in the tool and the generated schematron-based validation environment can be transferred and used in the IHE testing suite in a very straight-forward manner.

2.3 Other meta-models for CDA requirements description

Other meta-models exist to describe the CDA requirements, the best known are Trifolia XML description[9] and the description model of MDHT[7].

Trifolia Workbench model

Trifolia workbench is a web based application [9] that allows to edit CDA requirements and export the templates definitions in a proprietary XML format [5] [6], which can be interpreted as the metamodel description of the CDA requirements used by Trifolia.

MDHT

Model-Driven Health Tools (MDHT) [7] is a UML based tool allowing to formalize the representation of HL7 CDA requirements and implementation guides. The description of these requirements is based on the UML class diagram model, and a set of CDA profile stereotypes to provide information related to the CDA requirements and templates [8].

2.4 IHE Gazelle ObjectsChecker (GOC)

Introduction

Gazelle ObjectsChecker [2] [3] is a tool for the validation of XML clinical documents, and it is part of IHE-Europe Gazelle platform [10]. This methodology simplifies the treatment of XML requirements, like CDA specifications, and allows moving forward from using schema-

trons [19]. The tool provides a model-based validation using UML class diagram description [11] and OCL formal description of requirements (Object Constraint Language) [12]. The content of the UML models is filled based on the CDA implementation guides requirements.

Process of validation tools generation

Gazelle ObjectsChecker processes the UML models following this schema:

- Process the OCL constraints using an OCL processor
- Generate java code for validating CDA documents using the CDA model of requirements description
- Generate unit tests based on OCL constraints
- Generate documentation for each constraint

The generation of code is based on M2T technology, which allows the extraction of UML data and the creation of structured text files based on templates of generation [2].

All these steps are automatic steps, the only manual part is filling the UML models with OCL constraints, which is significant, because it takes time and is error-prone (we need a complete testing process to make sure there are no misunderstanding and bad interpretations of CDA requirements).

Advantages of Gazelle ObjectsChecker

The use of UML models allows benefiting from the strength of UML modeling tools, like searching for requirements, packaging of specifications constraints, friendly UML GUI editors, and constraints auto completion capability; such tools allow improving the maintainability of the validation tools based on Gazelle ObjectsChecker.

This tool has also large requirements coverage; it supports complex requirements like complex algorithms of validation, conditional and iterations checks, and allows datatypes [16] verification, which is a considerable advantage comparing to schematrons validation technology. Another advantage of this technology regarding the schematrons validation process is the time of processing [2]. This tool allows also runtime access to value sets repositories, and provides direct link to the original specifications, by coupling between constraints and requirements from specifications.

Usability

Gazelle ObjectsChecker is largely used by IHE-Europe for the validation of IHE CDA documents and many other XML based standards. Multiple CDA validators were developed based on this technology (over 40 validators between IHE, epSOS [13] and many national projects from Europe). These validation tools are heavily used during the connectathons [14] and European projectathons like epSOS [13] and EXPANDathon [15]. Some of the validation tools were also integrated in third party tools as a front-end validation. Developers' feedback regarding the process of managing models and generation of validators was positive [2], however the heaviest part in this process is the writing of OCL constraints into the UML models.

The aim of this paper is to describe the methodology used to extract automatically the CDA requirements from Templates Design. This methodology allows also improving the quality of the CDA implementation guides.

3 Coupling ART-DECOR® and Gazelle ObjectsChecker (GOC)

3.1 CDA documents validation based on ART-DECOR® Rules

Handwritten edition of OCL constraints in the UML models has always been the most complex task in Gazelle ObjectsChecker during the creation of CDA validators. This task is time consuming as it takes sometimes many days to manually formalize the requirements from CDA implementation guides into OCL constraints. Also, it can be a source of errors and false positive or false negative checks, due to human interpretation of the requirements. To deal with this problem, Gazelle ObjectsChecker generates an exhaustive list of unit tests for each handwritten constraint. Such testing is also time consuming.

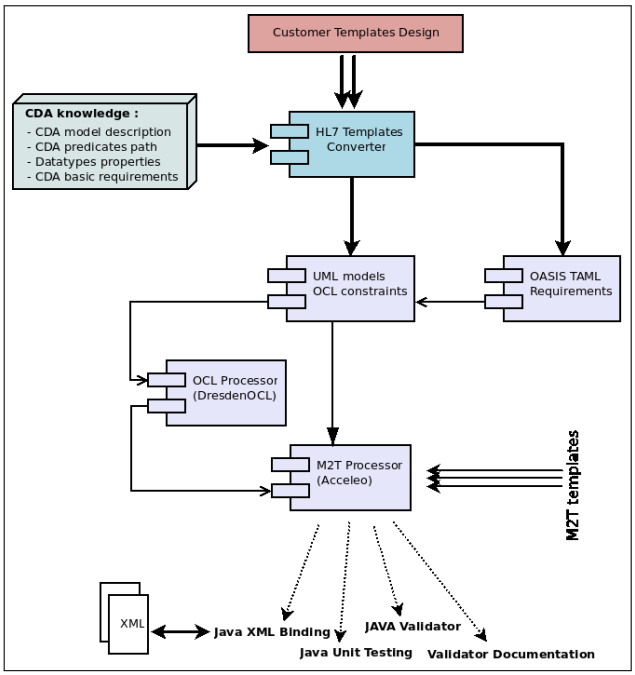

Figure 1: Principle of coupling ART-DECOR® and Gazelle ObjectsChecker.

The aim from coupling Gazelle ObjectsChecker with ART-DECOR® and HL7 Templates Standard is to deal with these problems by importing requirements from Cus-

tomer Templates Design based on HL7 Templates standard, and generating OCL constraints automatically.

The principle of coupling Gazelle ObjectsChecker and ART-DECOR® is described by figure 1; from the Customer Templates Design we generate TAML description of requirements [22], and we generate OCL constraints which are included into a UML class diagram using the stereotypes of Gazelle ObjectsChecker. The new module that allows such conversion is HL7 Templates Converter, which is developed by IHE-Europe/Gazelle team.

HL7 Templates Converter module allows to transform the requirements described in the Templates Design, including: checking of the cardinality of elements and attributes, fixed values and value sets attributed to coded elements, datatypes specialization, choices specification between CDA elements, templates inclusion, templates closing feature, and every kind of specification based on the structure of HL7 Templates description. The generation of OCL constraints based on the requirements in the HL7 Templates description is exposed in reference [26]: this document specifies when and which situations need a constraint to be generated by HL7 Templates Converter module. This document can also be used by other validation tools which take Templates Design as input for their validation tool, like the DECOR's schematrons generator.

This generation module takes advantages from knowing the model and the structure of CDA documents, the generation of OCL constraints is based on this knowledge:

- CDA model: knowing the CDA model allows to predict the elements used in the Templates Design, and inform the user if there is a misuse or an element which should not be used. Also, a good number of problems in the Templates Design are a bad specification of attributes values, especially when it comes from a CNE CDA vocabulary.

- CDA predicates paths: this knowledge allows better distinguishing between the CDA elements (like the templateId/@root, the observation/@code and the entryRelationship/@typeCode).

- Datatypes properties: such knowledge allows catching the extension between datatypes and allows preventing a misuse.

- CDA basic requirements: such requirements define how to use and to extend the CDA standard for implementation guides. These requirements are verified during the generation of OCL constraints in order to prevent a misuse of the CDA standard [21].

Using of Gazelle ObjectsChecker with ART-DECOR® simplifies the work of the HL7 Templates editors, as there is no need to specify an XPath distinguisher between the CDA elements described; this distinguisher is detected automatically based on the knowledge of CDA model.

Open and closed templates management

Open and closed templates can be defined as follows (see HL7 Templates Standard):

- **Open templates** permit anything to be done in the underlying standard that is not explicitly prohibited. This allows templates to be built up over time that extend and go beyond the original use cases for which they were originally designed.

- **Closed templates** only permit what has been defined in the template, and do not permit anything beyond that. There are good reasons to use closed templates, sometimes having to do with local policy. For example, in communicating information from a healthcare provider to an insurance company, some information may need to be omitted to ensure patient privacy laws are followed.

In most CDA-template libraries templates are defined as open.

Another typical situation is that templates in a repository for re-use are defined as open as when they are used within a document definition (document level template) a governance group may decide to use all templates as closed, i.e. no other content then specified is allowed. The same may temporarily apply during conformance testing, for example a connect-a-thon where it may be required to detect undefined content.

The following figure 2 shows a CDA template definition, CDA instance and the corresponding expected errors: Section B is defined as required (1..1) and therefore must be present in an instance. This gives errors in both open and closed template environments. If an "alien" section X is interspersed in the instance that is not in the definition this will be accepted with no errors in an open environment but will be rejected in with a closed template.

Sometimes one expects error message even with open templates that cannot be detected. A typical example is a typo in a template id in the instance. This will not be detected in open environments but only in closed ones.

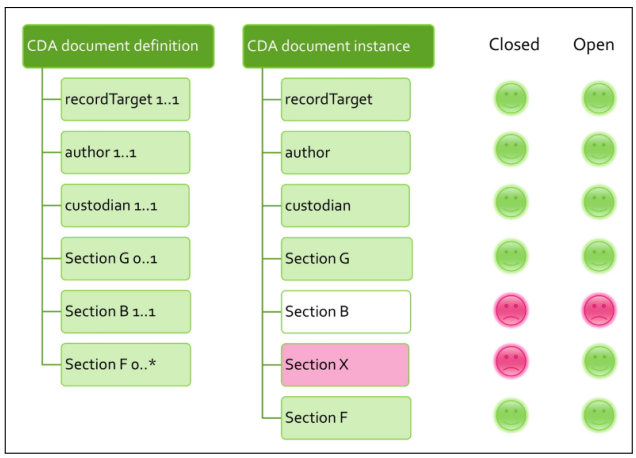

Figure 2: CDA template definition, CDA instance and the corresponding expected errors in open and closed environments.

ART-DECOR is the only known template tool that generates schematron for open and closed environments and Gazelle ObjectsChecker can validate open and closed environments.

3.2 Customer Templates Design validation

HL7 Templates Converter module allows verifying the information in the Customer Templates Design, before using them to create the Gazelle ObjectsChecker model with the OCL constraints. The requirements verified by this module are described in an independent document: HL7 CDA Requirements for HL7 Templates Standard [20], which contains the general CDA requirements which should be respected by CDA implementation guides. These requirements are divided into two kinds of requirements:

- CDA Model requirements: these requirements are directly related to the CDA schema, i.e. the XML structure.
- CDA Standard requirements: these requirements are related to the basic requirements which are described in the normative description, but not described in the CDA schema [21]

The HL7 Templates Standard allows the description of any kind of HL7 implementation guide, including non CDA guides. ART-DECOR® provides a schema for the exchange documents validation, which includes schematrons assertions in order to verify the conformity of the Templates Design, but this validation is not enough to verify if there are nonconformity between the written Templates Design and the CDA standard itself. The validation performed by HL7 Templates Converter module allows dealing with this lack. This module of validation can be seen as a validation of the specification itself, regarding the general rules of the CDA standard.

3.3 Benefits

Coupling advantages for Gazelle ObjectsChecker

This module allows eliminating the manual part of requirements formalization into OCL constraints, and allows going directly from Templates Design to the generation of Java validation code. This process was packaged into one executable that takes as input the URL to the Building Block Repository, and generates a ZIP file containing an executable, which takes as input a CDA documents, and generates as output an XML documents containing checks results. There is no more manual intervention for the creation of new validators using Gazelle ObjectsChecker, only a Template Design is sufficient to generate the validation tool. The gain on time in validation tools creation was huge; we go from some weeks to a few minutes.

Another advantage is the robustness of the tool. All the OCL constraints are generated automatically based on the requirements included in the Templates Design. The misunderstanding of specifications requirements is not possible any more. There is no need to heavily test the behavior of each OCL constraint, only acceptance tests are needed in order to verify that the HL7 templates were well written into the ART-DECOR® tool, and the exported Templates Design is in concordance with the original CDA specification.

Coupling advantages for ART-DECOR®

This coupling allows ART-DECOR® to move rigor at point of content profiles and implementation guides documentation and avoid discovery of issues/gaps at the time ObjectsChecker input is created. Also, it allows to reduce gaps and misunderstanding of CDA specifications, first because the use of the generated validation tool with acceptance tests will provide a feedback about the conformity of the HL7 Templates Design with the original specification, and second because the HL7 Templates Converter provides a report about the conformance of the Templates Design with the CDA standard, and such information is valuable for writers of implementation guides.

Coupling advantages for Implementation Guides Authorities

The import of requirements from Templates Design to Gazelle ObjectsChecker provides a way to validate the implementation guide itself. First, by having a validation tool we have a way to test CDA samples and to check if the output is conform to the implementation guide, that there are no conflicts with the specification. Second, Gazelle ObjectsChecker provides during the processing of the requirement a validation of the Templates Design regarding the CDA standard, which raises the reliability on implementation guides.

4 Applications and Illustration

4.1 Customer Templates Design validation

Using samples from diverse projects

Based on the CDA requirements in [20], and based on the HL7 Templates Converter module, a model of validation of Templates Design was created, and OCL constraints were included based on these requirements. Gazelle ObjectsChecker was used to validate the Customer Templates Design. Reference [20] can be interpreted as a restriction of the HL7 Templates Standard when used to describe CDA implementation guides.

From the online ART-DECOR® instance and Gazelle instance, we chose a number of projects, and we executed the validation of their Templates Design. Figure 3 de-

scribes the number of errors found during this manipulation.

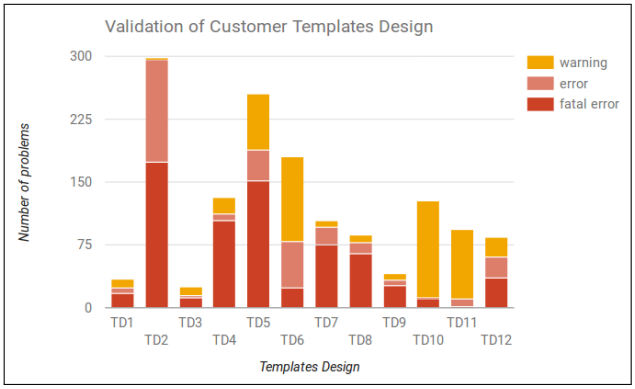

Figure 3: Validation of Customer Templates Design.

The analysis of figure 3 proves that there is a lack of validation regarding the CDA standard in the implementation guides. This validation is helpful to improve the quality of these specifications.

The percentage of the errors found is between 0.01% and 0.1% regarding the complete number of checks performed, which proves the strength of ART-DECOR in the detection of requirements errors in an early stage.

Errors found, lesson learned

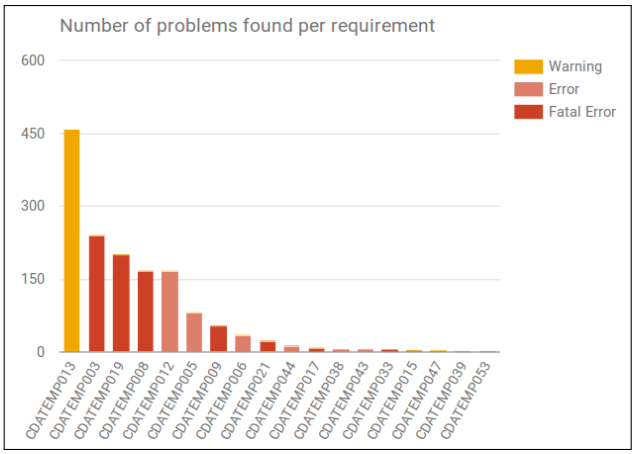

Figure 4: Number of problems found per requirement.

Figure 4 describes the list of most frequently found errors, based on the validation of a set of Customer Templates Design. The list of the complete requirements checked are in reference [20], where each requirement is identified by a unique identifier taking the form of CDATEMP-YYY. The most found errors are related to requirements:

- CDATEMP-013: a warning about the use of an attribute having default value. It is not mandatory to specify it in CDA documents as specified by the CDA standard; however a good number of templates force to provide attributes with a default value as a mandatory element. Example: AssignedAuthor/@classCode has the value 'ASSIGNED' by default, CDA templates does not need to make it mandatory.
- CDATEMP-003: fatal error: an element SHALL be from CDA model. This error occurs for example when the author specifies elements in a component that do not belong to it. Example: to specify ¡addr¿ element as a child element of ¡author¿.
- CDATEMP-019: fatal error: related to a misuse of a code or a valueSet. This error occurs when Templates Design allows having a value for an attribute; however this value is not permitted in CDA standard. Example: Participant/@type SHALL not be described by a valueSet containing codes out of the valueSet ParticipationType.
- CDATEMP-012: error: If isOptional attribute is specified with the value 'true', the original CDA attribute SHALL not be mandatory. This error occurs when the author is relaxing the CDA requirement, making an attribute optional when CDA requires it. Example: specify Act/@classCode as isOptional='true'; this is not permitted because this attribute is mandatory in CDA.

These requirements are not easily checked manually, the automation of these checks allows the consultants and implementation guides writer to move forward from fixing technical minor errors to the core of CDA elements specification.

4.2 Validation of CDA documents

IHE CDA pharmacy samples validation

In order to test the import module from ART-DECOR® to Gazelle ObjectsChecker, we created three BBR (Building Block Repositories):

- IHE-PRE: Templates related to IHE Prescription from pharmacy domain [23]
- IHE-DIS: Templates related to IHE Dispensation from pharmacy domain [24]
- IHE-PADV: Templates related to IHE Pharmaceutical Advice [25]

From these HL7 templates, we created schematrons validators using DECOR module, and model-based validator using Gazelle ObjectsChecker. The aim of this application is to compare the generated schematrons and Gazelle ObjectsChecker validators to the existing validation tools for IHE pharmacy: handwritten schematrons and handwritten model-based validators based on Gazelle ObjectsChecker. The indicators of comparison are:

- The number of checks tested

- The average of the number of errors found for a set of CDA samples

The most checks done are by the schematrons generated from DECOR tool, then the OCL constraints generated by Gazelle ObjectsChecker. The difference between the number of DECOR schematrons checks and Gazelle ObjectsChecker constraints is due to the fact that Gazelle ObjectsChecker filters out the requirements already tested by the schema, as it is redundant to test them again. This filtering is based on the knowledge of the CDA model. Such filtering allows improving validation time.

For each kind of validator, we selected a set of CDA documents coming from multiple vendors using Gazelle platform, and we executed the validation tool on it. Gazelle ObjectsChecker coupled with ART-DECOR® and the schematrons generated from ART-DECOR® generate nearly the same number of errors, far from handwritten schematrons. But, even if the number of the errors is not the same we suppose that the output of the validation is the same, and all the requirements are tested by all the tools. We are not proving that the validator with the most number of errors is the better one, and the others are missing some rules; but it is only a comparison between the granularity of the requirements. Validation tools generated from ART-DECOR® contains a greater granularity than the other tools; hand written requirements may combine some requirements in the same check, which explain why they have less number of errors found. Gazelle ObjectsChecker coupled with ART-DECOR® has in one hand the advantage over the generated schematrons regarding the filtering and the optimization of the requirements executed, and in the other hand Gazelle ObjectsChecker offers the possibility to validate the model coming from HL7 Templates Standard before generating the OCL constraints.

Comparison to schematron validation

Based on the study of the last paragraph, we noted that the negative constraints are better supported by handwritten rules, even if HL7 templates standard support it using XPath rules. The granularity is better in validation tools based on ART-DECOR® export. The use of ART-DECOR® as a modeling tool of constraints simplifies the creation and the deployment of validation tools, even consultant that does not know schematrons and OCL language can create and generate their own validation tools. Gazelle ObjectsChecker allows optimizing the checks based on the knowledge of the CDA standard, and allows providing a pre-validation and testing before the generation of validation tools; from the testing in the last paragraph, for a less number of checks Gazelle ObjectsChecker has the same granularity of errors as the schematrons generated by DECOR. However, the generated schematrons are easier to deploy, even if Gazelle ObjectsChecker provides standalone validation tools using jars of validation. Finally, another advantage of Gazelle ObjectsChecker is the strength of the tool in the validation of basic requirements of the CDA standard [2].

5 Conclusion

HL7 Templates Standard provides the possibility to exchange templates description for reusability and exchange purpose. The designing of thousands of HL7 templates using ART-DECOR proved the strength of HL7 Templates Standard as a templates exchange format. The HL7 templates available from the ART-DECOR® site are valuable resources for templates editors.

HL7 Templates standard allows also normalizing the input for validation tools by improving the interoperability between HL7 CDA templates editor tools and HL7 CDA validation tools. Combining Gazelle ObjectsChecker and ART-DECOR® improves the validation process, and also brings added value to templates definitions by identifying requirements issues. This coupling improves the quality of validation tools based on Gazelle ObjectsChecker, reducing the time of validation tools creation, adding robustness to the constraints because they are generated and not handwritten. Finally this process improves the quality of the CDA specifications by bringing further checks regarding the CDA requirements, which reduce the gaps and misunderstanding of CDA specifications.

We applied this process for the definition of IHE pharmacy profile templates edition using ART-DECOR®, for the generation of validation tools using Gazelle ObjectsChecker and ART-DECOR® schematrons and proved the strength of HL7 Templates Standard and its ability to describe all needed requirements. The validation output proved that the results of validation have a better level of granularity and specialization than handwritten validation tools, the number of checks is bigger than other tools, leading to better identification of the errors.

Many perspectives can follow this paper, a complete testing process for generators of validation tools can be developed, and a harmonization between outputs of templates editor tools can improve the validation process of existing validation tools consequently.

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Best practice of Rendering CDA in a Cross Enterprise Document Sharing Environment

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Abstract

While much has been written about the clinical document architecture and the challenges on semantic interoperability, the modelling of content and the implementation, little attention has been paid to the representation of the medical payload in CDA documents and its implications on usability and accessibility.
The authors compare different methods to display CDA documents in a cross enterprise environment on the example of the Austrian national patient health record system. Strategies and decisions as well as technological approach and security implications are presented.

Finally, a combination of PDF/A-3 and attached CDA document is proposed as a best practice method for future implementations.

Keywords

Clinical Document Architecture; Rendering; XSLT Stylesheet; User-centric design; Eye tracking; Formatting Objects Processor; PDF/A-3 formatter

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1 Introduction

One of the most important requirements of the CDA standard is that a CDA document has to be human-readable via any common standard web browser. The clinical content of a CDA document is encoded via XML, formatting is possible with a reduced set of a HTML-like markup language [6]. A web browser will show the human readable part of CDA (the so called narrative block) without any formatting and line breaks. The CDA document can be displayed as formatted HTML document if a "stylesheet" is used which enables an XSL Transformation (XSLT). XSLT stands for XSL Transformations, which converts the XML input in HTML output while the original input file remains unchanged. A standard web browser may act as an XSLT processor and as a renderer for the result HTML output, if the document is associated with an XML stylesheet. The name and path to the stylesheet may be indicated in the XML-header of the CDA file, so that the web browser can render the document automatically.

```
<?xml version="1.0"
      encoding="utf-8"
      standalone="yes"?>

<?xml-stylesheet
      type="text/xsl"
      href="../stylesheet/CDA.xsl"?>
   ...
```

Health Level Seven International issued CDA Rel. 2 with a basic XSLT stylesheet (named CDA.xsl). Every standard conformant CDA document shall be displayed in a technically correct way with this instruction set, but only part of the administrative data in the CDA header is rendered. One of the main characteristics of CDA is, that it does not mandate a specific stylesheet to be used. Therefore, many different views on one document are possible and all CDA documents may be viewed with one stylesheet. A stylesheet must not add relevant information not present in the CDA document. If an additional different stylesheet were used, this information would be

lost. A stylesheet must not be based on the machine readable content of the CDA document either as using the entries as a source for the stylesheet may lead to misinterpretation of the content [10].

However, the creator of a CDA document cannot be certain on how the document will be rendered by other recipients. An electronic signature of a CDA document is also possible and limited to the XML content unless no additional mechanisms are used [1]. It is interesting to note that there exist only a handful of publications dealing in detail with the presentation of CDA documents [2, 11, 3].

The same is true for C-CDA that is used in the USA. As "many clinicians are frustrated with the usability of C-CDA", HL7 International and the Office of the National Coordinator for Health Information Technology (ONC) launched a "rendering tool challenge" for C-CDA in 2016 [4].

1.1 ELGA – National health record system

ELGA, the Austrian national patient health record [1], was put in operation in December 2015. ELGA allows a cross domain exchange of health data between all authorized Austrian health care providers via IHE XDS/XCA profiles. In the first phase, four distinct document classes – physician and nurse discharge letters, laboratory and radiology reports – can be shared. The format for the documents is restricted to CDA Rel. 2. All files are required by law to conform to the nationally harmonized HL7 CDA implementation guidelines for proper use in ELGA. ELGA provides secure and reliable access to health data for any patient visiting a Health Care Provider (HCP). The data may be imported into the local electronic health record system (EHRS, e.g. general health practitioner or hospital clinical information system) where documents must be rendered. This implies that every EHRS has to deal with displaying ELGA documents, thus entailing the opportunity to adjust the appearance to the local graphical user interface and corporate design.

To facilitate the use of CDA documents for health IT system vendors, it was decided to provide stylesheets by ELGA. It quickly became apparent that the expectations of clinicians could not be met with the original stylesheet issued with the standard CDA Rel. 2. Consequently the stylesheet for the four document classes should be tailored to the specific requirements of the Austrian clinicians and should meet their demands for usability and accessibility. On the other hand it is allowed to implement any other type of displaying CDA documents in specific information systems.

At the beginning of the project methods to display CDA documents in a distributed multi-stakeholder environment on different IT systems were evaluated.

[1] http://www.elga.gv.at

2 User-centered design approach

The deliverables of the different ELGA working groups from the years 2008-2015 have been adopted for the design of the stylesheet. The working groups consist of public, relevant stakeholders who were invited by the ELGA GmbH to send delegates. For the four different document classes "Physician Discharge Letter", "Nurse "Discharge Letter", "Laboratory Report" and "Radiology Report" separate working groups were appointed to guarantee transparent and consensus-based decisions. Experts of the working groups were interviewed to determine which administrative data is important in their daily work routine and must be visible "at first sight" and what information can be made visible by scrolling down and up and clicking onto the document. The individual experts generated a recommendation about the relevance, sequence and positioning of the administrative data.

On the basis of this recommendation a team of usability experts was able to draw up a vertical design prototype which was submitted to the Expert Group for approval. The usability of the draft was tested with test persons in a usability laboratory. Video-based eye trackers were used to get a better understanding of detecting the most relevant information, to increase operability and to avoid high complexity or distraction. Additionally, it was verified whether specific content could be realized correctly and interpreted by individual subjects. With the findings from the usability testing, the draft design prototype was revised and was used as a template for the implementation of the stylesheet. The ELGA reference stylesheet itself was implemented in software by external software companies.

3 Transformation of CDA documents in a multi- stakeholder environment

First, methods to display CDA documents in a distributed multi-stakeholder environment with different IT-systems were evaluated as to their feasibility and security. The development of a proprietary CDA viewer application for a rendering documents without the use of a web browser was not considered. Through literature search and analysis of state-of-the-art procedures we figured out five approaches to transform CDA documents:

1. Global stylesheet (available at a central location)

   Every CDA document defines an absolute path to the corresponding stylesheet with public access via internet. The advantage of this method is that only a web browser with internet connection is necessary to represent a CDA document. At the same time this method includes a significant security risk because it enables the execution of codes. Unfortu-

nately, this method violates the same-origin policy in the web application security model, and thus ultimately represents a cross-site scripting, which is blocked in standard web browsers by default for security reasons. A reconfiguration of all browsers in the environment of ELGA is hardly feasible. Standard web browsers are blocking cross site scripting for security reasons. This option would require changing all security levels of all browsers involved which would be a task for service desks.

2. Local stylesheet (and providing a generic stylesheet)

   The transformation process is provided via a local stylesheet. Every CDA document includes a relative path to a reference stylesheet. If the file is defined without a path, then the stylesheet has to be in the same folder as the CDA document. A generic stylesheet could be available for download and the user has to make sure that this (or another) stylesheet matches the local path relative to the CDA document.

   As long as the reference stylesheet can be downloaded from a trusted source in a secure manner, this method has the disadvantage that the distribution of new versions of the stylesheet can only be carried out by implementing organizational measures. The source of the stylesheet cannot be sure how the document is presented at the recipient.

3. Packaging CDA documents with a stylesheet

   Another method is that a CDA document and the stylesheet will be delivered as one bundled package. As long as that CDA document is displayed with the attached stylesheet, the document is rendered as intended by the sender. The advantage of this method would be that for every document a customized style sheet can be provided. A disadvantage, however, is that the recipient eventually has to deal with a variety of stylesheets.

4. Self Displaying CDA

   A (CSS) stylesheet can be embedded in the CDA document in a way that the file can be rendered without an external stylesheet [5]. This solution could solve all problems as the rendering would happen automatically. HL7 International launched a project in 2010 to create a CSS stylesheet that would enable CDA documents to be displayed in a web browser without transformation. The main idea was to include a CSS stylesheet within a CDA document to enable the displaying of the content without the use of additional resources. It did not interfere with the ability to preferably display a CDA document with a locally defined stylesheet. However, the task could not be solved due to some technical problems, for instance embedded content could not be displayed with CSS. Thus, the project was withdrawn in 2012 without relevant results [8].

5. PDF/A-3 with embedded CDA

   This method delivers the document as a PDF file and embeds the CDA file into the PDF file. The adopted standard PDF/A-3 (ISO 19005-3) which is based on PDF 1.7 (ISO 32000-1: 2008) has supported this variant since 2012 [9]. PDF is widely accepted as a standard document in the world of web. PDF documents can be displayed reliably, archived and viewed, printed and electronically signed in an easy way. Viewers are available free of charge. Therefore PDF is widely accepted as a standard document in the world of web. Major browsers (e.g. Firefox, Chrome) can show PDF files directly, and for other browsers (e.g. Safari) plugins usually exist. Semantic interoperability can be supplemented by embedding CDA documents in PDF files. This method has already been proposed on the website of HL7 Germany [7].

4 Implementation of a CDA reference style sheet for ELGA

The decision in favor of the preferred solution "PDF/A-3 with embedded CDA" was taken in 2011. At that time, PDF/A-3 was not yet available, and the "Self displaying CDA" was still far away from a sufficiently stable and functional implementation. The idea of a central stylesheet was dropped because of the security problems. Packaging of CDA documents with stylesheets appeared to be too complex and did not fit into the strict XDS-based architecture of ELGA. Therefore it was decided to publish an ELGA stylesheet as a template for further development.

At the beginning it was discussed whether the definition of a customized stylesheet for each document class in order to present the specific content is the best approach. For example, laboratory findings heavily differ in their tabular structure from other text-based documents such as discharge letters. However, it was decided that for all the documents a generic stylesheet should be used to ensure a uniform appearance of all CDA documents. Additionally with a distinctive design (recognition factor) a fast orientation within the structured document can be ensured.

Built on the results of the working groups the following design decisions were taken:

- Only the narrative block of a CDA document is rendered (no level 2 and 3 content)
- A table of contents of the most important metadata and sections will be prefixed
- Important meta data precede the clinical content, less important information can be folded or be placed at the end of the document
  - Title, date, version

  - Patient name, date of birth, social security number, procurator/trustee/legal guardian
  - Encounter
  - Author, receiver (if indicated)
  - Other metadata is put at the end or can be unfolded
- No sorting, ordering or filter functionality in the clinical content to avoid the risk to misinterpret the information of the document by any sequence of sections In practice there is no guarantee that the section texts are filled in correctly and associated (e.g. allergies or diagnoses are in the "wrong" sections)
- Embedded multimedia files are allowed (ELGA accepts only a few multimedia formats: PDF, JPG, PNG, GIF, MPEG, MP3)
- Simple print function (similar to the on-screen display)
- Specific markups - in everyday clinical practice, it is helpful to highlight texts with colors. Pathological laboratory values, for example, are not typed in bold only, but also use red color to distinguish them from normal values. Color highlighting may be made only in blue (red is not perceived by many people) exclusively. Blue can be seen by color-blind people as grey.
- Typography: Usage of a legible on-screen sans serif font (Arial, sans-serif) that is supported by all major browsers and font size of text body with 100% – so the text is displayed in the size defined by the user.
- Limited line width – on modern monitors the browser window can be very broad, the eye finds it harder to jump back to the next line in wide rows harder. Therefore, the line width was fixed to 900 pixels.
- Ragged alignment, bigger line spacing (compared to printed documents)
- Section text is indented after the heading. Jumping between paragraphs is easier for the eye.
- Tables are always represented in the same width as the body text.
- Column width of tables: CDA documents allow the use of tables, but do not allow the user to define the column width. Therefore the project-specific markups, which have been developed for ELGA, can be used in reference stylesheet.
- Table rows with alternating background color
- Interactive elements (e.g. to fold out) always have a hover function (i.e. change the appearance when the mouse is being passed over it)
- Exclusive use of a small set of colors according to accessibility criteria. Colors have to be clearly visible and distinguishable in printed form: black, grey, blue, yellow, bright yellow
- Display embedded images and other multimedia files automatically
- Translation of coded values and "NullFlavors" in the metadata through translation tables inside the stylesheet regardless of the display name (e.g. translate LOINC code to text, translate "NullFlavors" for birth date UNK to "unknown date of birth")
- Usage of HTML 4.0 for strictly conforming XHTML 1.0 documents and UTF-8
- Stability against non-conforming content in the narrative block
- Robustness against maliciously composed documents

Of course some limitations have to be accepted:

- While the default browser is capable of directly displaying Base64 embedded JPG and GIF images, other media types can only be displayed if they have been previously decoded. This functionality cannot be implemented by an XSLT stylesheet. A Base64 decoder servlet must be available in the local working environment. ELGA provides a base servlet available for download. If the decoder is missing, an appropriate error message is displayed in the output document.
- CDA with "unstructured body" can only show the information of the header. The PDF file has to be opened by the user with one mouse click.

Figure 1 shows an example CDA document using the reference stylesheet.

4.1 Transformation process for printing and long-term archiving

Due to the different possibilities of monitor screens and paper the requirements to print CDA documents differ from the screen-oriented representation:

- Printable representation similar to the HTML output (as much as possible)
- Headers and footers with serial numbering
- Printing document and PDF Attachments
- Scaling the graphics and page limitation
- Placeholder for multimedia files (audio, video) with a notice
- File format supporting long-term archiving (PDF/A)

- Tagged PDF (requirement by accessibility)
- Option to show the interactive HTML "folded" information
- Embedding of the original CDA document (PDF/A-3)
- Hyphenation, paragraph settings to automatically prevent widows and orphans

These requirements are made possible by the use of XSL-FO (Extensible Stylesheet Language – Formatting Objects) and a corresponding FOP (Formatting Objects Processor) from the Apache project. XSL-FO was designed for paged media and the concept of pages is an integral part of XSL-FO structure. It is capable of a great deal of expressiveness. Tables, lists, side floats, and a variety of other features are available. [12]

The software executable, called CDA2PDF converter, cannot be directly executed in the browser, therefore a servlet container is required.

The conversion of a "ELGA" CDA document to PDF format looks similar to the HTML browser-based document (see figure 2). Noteworthy is the page footer with the additional file name and the information about the creation of the PDF file placed on the left side. Not visible are the folded information blocks, which are placed on the last page, because they are hidden behind interactive HTML elements.

5 Conclusion and Discussion

5.1 Security Considerations

Although the injection of malicious code (e.g. Javascript) can be inhibited in the stylesheet, the multimedia content is also a potential security risk. This cannot be blocked by the stylesheet itself. If the media type (PDF, MPEG) is approved in principle the content cannot be checked by the stylesheet. In the ELGA environment firewalls were built that block both malicious code in multimedia attachments as well as in not well-formed or non-conforming XML data. In addition a schema validation and validation of correct PDF/A file format in the attachments will be carried out in the near future.

5.2 Electronic Signature

In a PDF/A file content and presentation are not separated, so a PDF/A document can easily be signed electronically. In comparison, the electronic signature of a CDA document is fundamentally flawed and is not provided in the CDA standard. This kind of signature would also include the representation (i.e. the stylesheet). If only the CDA document is signed, and not the XSLT stylesheet, an inconsistent presentation of CDA document may occur. The principle of implementing the electronic

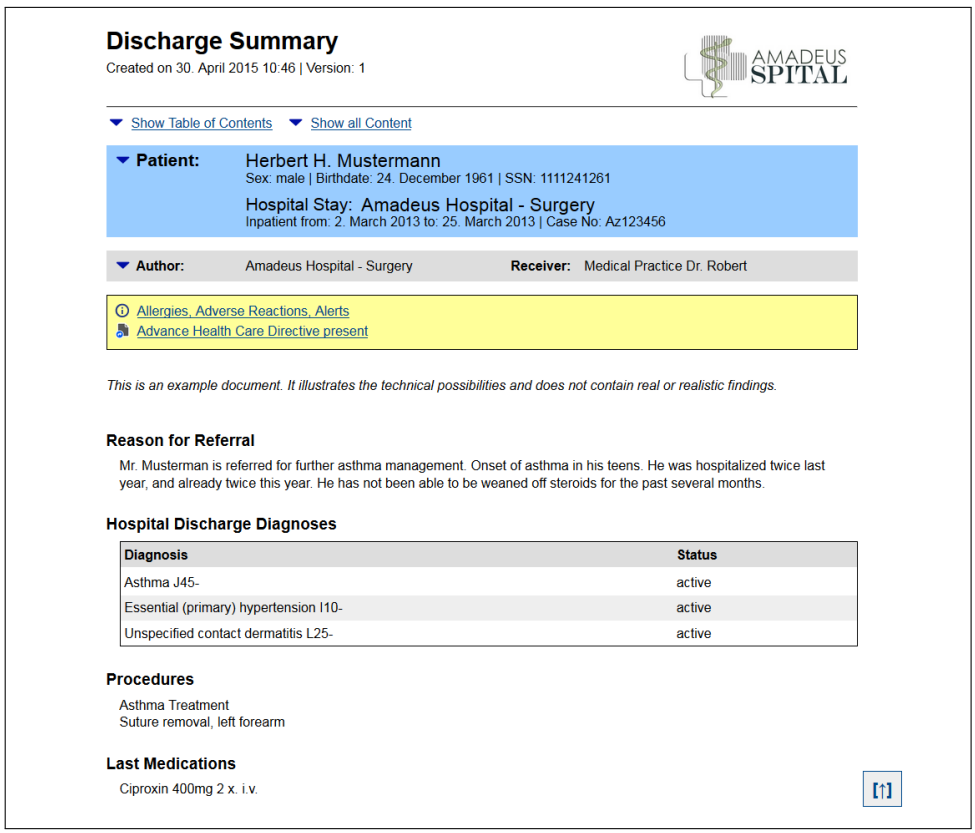

Figure 1: Reference stylesheet

signature for CDA documents should include the clinical data and also the representation part.

In the "ELGA ecosystem" an electronic signature for CDA documents is not intended and is not necessary. Although an electronic signature can be applied to the original documents in the individual EHRS, the exchange format CDA only contains an indication that the original document has been signed. However, the ELGA infrastructure ensures that only identified and authorized HCP can register documents. At the same time the immutability ("file fixity") is ensured by hash values (document and registry entry) in the document registry.

5.3 Best practice solution

From these considerations and the experience gained from the ELGA project we propose a best practice solution for future similar projects.

PDF/A-3 files including an attached CDA document should be used for the exchange of documents. The PDF/A-3 files shall be generated via a common XSL-FO converter from a CDA document as input file. The resulting PDF file may easily be electronically signed, exchanged, displayed and archived. By attaching the origi-

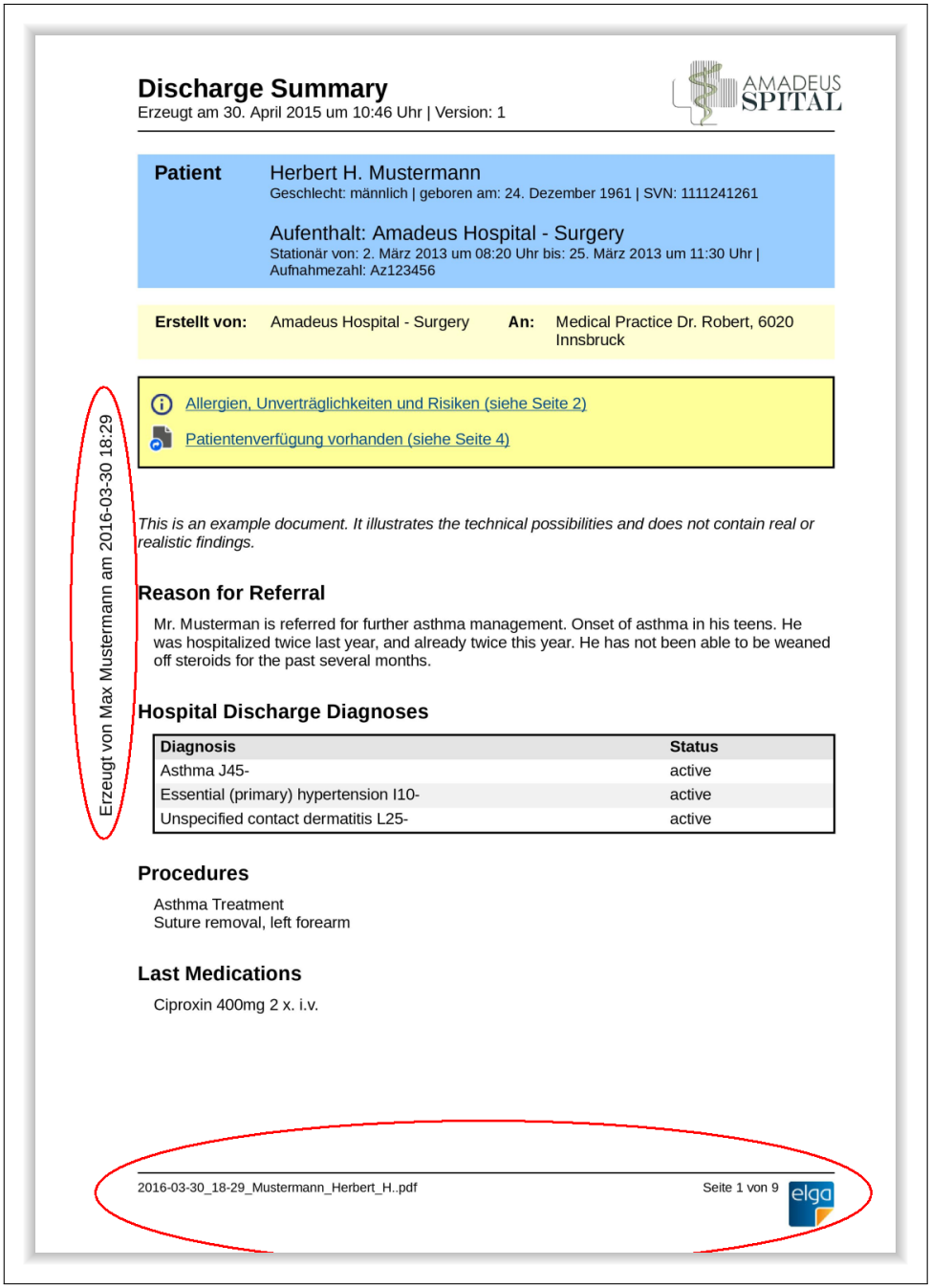

Figure 2: CDA document in PDF format

nal CDA document all features of the CDA standard, in particular semantic interoperability, will be preserved.

CDA is essential from the point of view of semantic interoperability. CDA documents contain the relevant information for the document management and potentially machine-readable clinical content. PDF/A offers clear advantages in terms of immutability of the representation and long-term archiving, widespread tools for the representation and an electronic signature. PDF/A-3 files including a CDA document as an attachment combines the best of both worlds.

To ensure that PDF/A-3 files are generated correctly with a uniform appearance, an appropriate converter CDA2PDF can be provided which generates a corresponding pdf output file from a CDA document. The feasibility of the converter has been proven in ELGA and the converter uses the ELGA web portal to produce clinical documents for all Austrian citizens.

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The authors are indebted to their colleagues from SDOs such as HL7 for open minded and kind cooperation and valuable support.

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Improved Handling of Synonymous SNOMED CT Concepts used in HL7 Version 3 by the Example of the Von Willebrand Disease

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Abstract

Background: In the context of synonymous concepts, errors and term duplications in SNOMED CT are likely. This affects in particular clinical ideas with multiple types of display, like the example of the Von Willebrand disease.
Objectives: It is required to ensure a common and correct interpretation of medical terms. Thus, it is necessary to distinguish between the clinical ideas of disease, disorder and syndrome in the Von Willebrand context. To perform a critical examination of the associated hierarchical order in SNOMED CT and above that, to follow the given rules of correct terminology binding.
Methods: The synonymous concepts problem is analyzed in reference to the Von Willebrand context in the SNOMED CT International Version 31012015. Improvements of handling are formulated based on the valid SNOMED CT compositional grammar and the SNOMED CT Editorial Guidelines. Terminology binding is examined regarding the prerequisites given in the "Using SNOMED CT in HL7 Version 3 Implementation Guide, Release 1.5
Results: Many Von Willebrand concepts in SNOMED CT are not fully defined but primitive, which means that their defining characteristics are not sufficient to distiguish synonymous meanings. Improved handling of synonymous concepts is proposed by the installation of a broader grouper concept and an adaption of the SNOMED CT hierarchical structure to avoid misinterpretations and duplications.
Conclusions: The terminology binding between the SNOMED CT semantics in the Von Willebrand context and HL7 V3 seems technically well described. It has been shown, that the problematic handling of synonymous terms is assigned to hierarchical structure problems out of SNOMED CT.

Keywords

SNOMED CT; HL7 Version 3; synonym; Von Willebrand disease

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1 Introduction

SNOMED CT is a terminology with approximately 350.000 concepts and over 800.000 synonyms [1]. The function of a synonym is the representation of a term that can be used to select a concept with most similar meaning. A concept may have plenty of synonyms. This allows the end-users to choose preferred terms that refer to special clinical ideas.

In the context of synonymous concepts, errors and term duplications in SNOMED CT are likely. Problems were described at an early stage by the merging of SNOMED RT and United Kingdom's National Health Service's Clinical Terms Version 3 into SNOMED CT. During the creation of the terminology individual modelers were allowed to merge several concepts from the source terminologies into one concept. A single concept then became the name of the SNOMED CT concept and the other(s) became a synonym. Significant errors that result from this process were due to wrong modeler assigning, e.g. a more general concept as a synonym of a more specific concept [2].

Given the problems of synonymous concepts, other relating errors like inconsistent hierarchical connections and term duplications occur. This affects in particular clinical ideas with multiple types of display, like the example of the Von Willebrand disease. As this disease has focus on the blood system, it touches a very broad range of medical disciplines and a great variety of stakeholders.

Terminology users continue to encounter confusion about which concepts and codes to select when using Von Willebrand disease, Von Willebrand disorder or Von Willebrand syndrome because of unclear distinctions. Above that, end users describe problems and uncertainties to undertake correct classifications of several synonymous Von Willebrand 2 subtypes. Related duplications and overlaps can be found in the current SNOMED CT concept model. An unclear term interpretation and a lack of semantic interoperablity may imply negative consequences on clinical safety that should be avoided.

An uninterrupted electronic communication of medical content is made possible by the interaction of semantic and syntactic standards. The semantic standard SNOMED CT, which describes medical content, needs a "syntactic partner" capable of receiving such content and ensuring the exchange of data. Matching syntactic standards are in this context HL7 Version 2, HL7 Version 3 and HL7 CDA [3]. Markwell et al. (2008) refers to this specification as terminology binding. Terminology binding describes the preparation of a compound between terminology elements and an information model [4]. Above that, it is important to mention that HL7 V2 and V3 both provide syntax and semantics. This means on the one hand, that HL7 standards contribute to the definition of the meaning of the information exchanged, but on the other, there may insecurities what kind of semantic expression has to be chosen.

A key factor of SNOMED CT is its big expressivity. This may lead to cases where overlaps occur with semantics that may also be represented by an information model such as the HL7 Reference Information Model (RIM). For example, a single SNOMED CT coded expression can represent a meaning that the HL7 RIM could also represent using a combination of several coded attributes or classes. Clear rules and guidance on these overlaps are needed to minimize ambiguity and erroneous interpretation.

This paper describes an approach for improved handling of complex synonymous terms in SNOMED CT taking over the Von Willebrand example and to provide solutions for correct terminology binding that the semantic meaning inside of the information model may be unambigous.

1.1 Disease, disorder and syndrome

Clinical findings represent observation results. The use of the terms disease, disorder and syndrome are connected to the description of abnormal clinical states but differ in their definitions:
A disease is a definite pathological process having a characteristic set of signs and symptoms. It may affect the whole body or any of its parts, and its etiology, pathology, and prognosis may be known or unknown [5]. A disorder is defined as a derangement or abnormality of function; a morbid physical or mental state [6]. A syndrome is a group of signs and symptoms that occur together and characterize a particular abnormality or condition [7].

Whether or not this designation is accurate, distinctions are definitely made in certain contexts. It is Parkinson disease, not Parkinson disorder; sleep disorder, not sleep disease. Specialist literature shows that disease is mostly connected to the influence of extrinsic factors. Disorder itself has a focus on condition of the individuals.

1.2 The Von Willebrand disease

The von Willebrand disease is defined as a bleeding disorder caused by a deficiency of the large and complex glycoprotein "Von Willebrand factor (VWF)". VWF itself is an essential factor in blood clotting. The Von Willebrand disease is an inherited bleeding disorder characterized by incomplete penetrance and variable expressivity.

There are 3 different types of von Willebrand disease:

Type 1: The predominant defect is a partial quantitative deficiency. There are two subtypes of Type 1, Type 1a and Type 1b. Most patients with type 1 Von Willebrand are able to live normal lives with only mild bleeding issues. The predominant effect is a quantitative deficiency of VWF.

Type 2: The predominant defect is a partial qualitative deficiency. Patients with type 2 are at greater risk for complications and experience mild to moderate bleeding. These individuals may suffer worse bleeding in the case of infection, surgery or pregnancy.

Type 3: The predominant defect is a complete deficiency (quantitative and qualitative). Patients with type 3 are at risk for severe bleeding as well as internal and gastrointestinal bleeding.

The Type 2 Von Willebrand, which represents 20-25% of all cases, has four different subtypes:

- Type 2A is the most common subtype. In Type 2A the blood platelets do not bind together well
- Type 2B is the next most common. In Type 2B, the VWF binds to platelets in the bloodstream, instead of binding at the site of the injury to the blood vessel
- Type 2N is much rarer. VWF also helps to carry around factor VIII in the blood and stabilize it so it can take part in the formation of a solid clot. In Type 2N the VWF does not transport factor VIII.
- Type 2M is an extremely rare sub-type. In Type 2M, binding of the VWF to platelets is impaired.

The etiology of the Von Willebrand disease is, that it can be acquired or hereditary. The acquired form is also called Pseudo-Von Willebrand's disease or platelet-type. It differs from the three hereditary forms (Type 1-3), that have already been described. In this context, the term hereditary is often used synonymously with congenital. Acquired Von Willebrand's is preferentially called "acquired Von Willebrand's syndrome" in medical specialist literature. The term von Willebrand's disease is often reserved for the congenital/ inherited form [8, 9].

2 Methods

We analyze the synonymous concepts problem referring to the Von Willebrand context in the SNOMED CT International Version 31012015. The CliniClue-XPlore-Browser Version 2012.8.0270 and the IHTSDO SNOMED CT Browser Version 1.0 are used for content display.

Potential improvements in the handling of synonymous concepts are to be formulated according to the SNOMED CT compositional grammar. The terminology binding is checked regarding the prerequisites given in the "Using SNOMED CT in HL7 Version 3 Implementation Guide, Release 1.5" [10].

3 Results

3.1 Positioning of Von Willebrand related concepts in SNOMED CT

The SNOMED CT International Edition 20150131 uses | 128105004 | von Willebrand disorder | as a grouper concept for Von Willebrand related concepts. | 128105004 | von Willebrand disorder | is defined as:

|128105004 |von Willebrand disorder| **is a**
|64779008|blood coagulation disorder| **is a**
|362970003|disorder of haemostatic system| **is a**
|64572001|disease| **is a**
|404684003|clinical finding|

All of the von Willebrand disorder related concepts are child concepts of | 128105004 | von Willebrand disorder | ; with the Fully Specified Name (FSN) | 128105004 | von Willebrand disorder (disorder) |.

Furthermore, | 128105004 | von Willebrand disorder | contains 10 different synonyms.

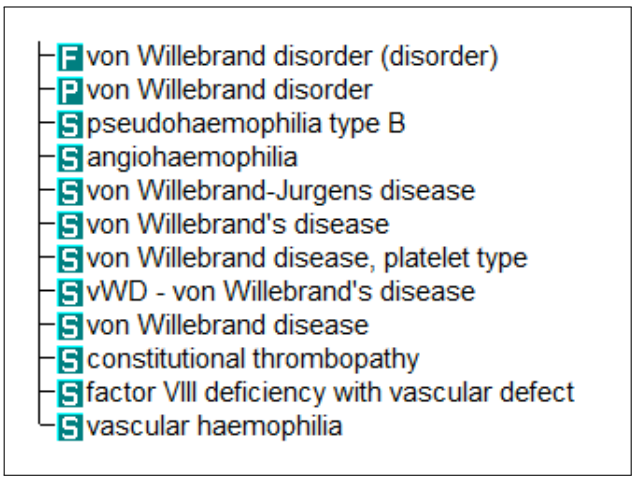

Figure 1: FSN and synonyms of | 128105004 | von Willebrand disorder | .

It is noted that there are incompatible synonyms attached to 128105004 | von Willebrand disorder (disorder) | such as | von Willebrand disease, platelet type | . The latter provides an inappropriate specification on the given hierarchical level.

| 128105004 | von Willebrand disorder | has 29 child concepts.

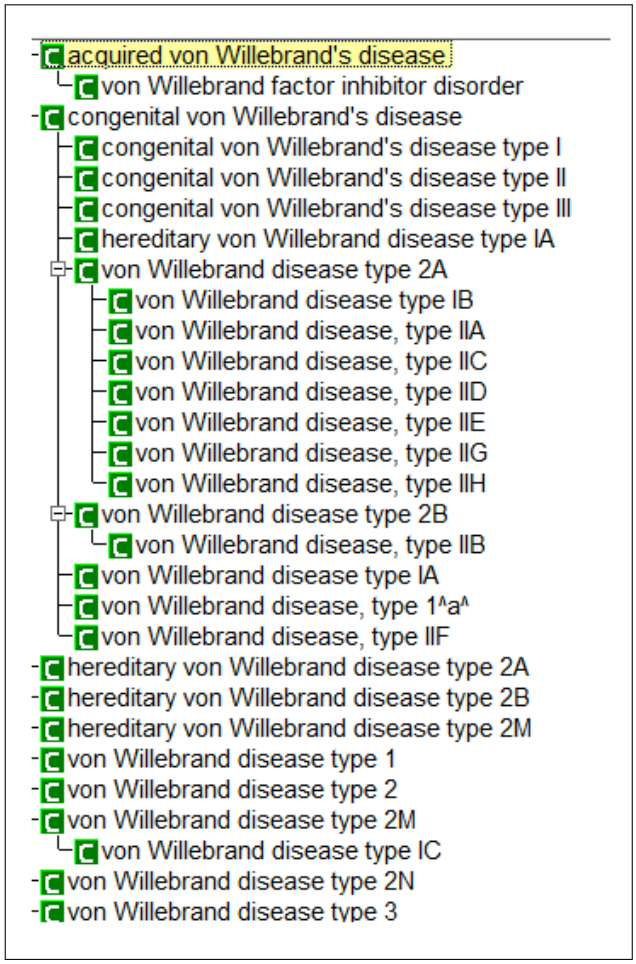

Figure 2: Child concepts of | 128105004 | von Willebrand disorder | .

In SNOMED CT, the parent concept of all kinds of Von Willebrand disorder,- disease or syndrome concepts is | 128105004 | Von Willebrand disorder | . | 128105004 | Von Willebrand disease is a synonym of | 128105004 | Von Willebrand disorder | and it has no parent or grouper concept function.

All of the child concepts of | von Willebrand disorder | , except | congenital von Willebrand´s disease | , are not fully defined but primitive which means that their defining characteristics are not sufficient to uniquely distiguish its meaning from other similar concepts.

Figure 3 shows the concept model of | 128107007 | von Willebrand disease type 2 | in a detailed view.

The concept is primitive, with the FSN at | 128107007 | von Willebrand disease type 2 (disorder) | , the synonym | 128107007 | hereditary von Willebrand disease type 2 | and has no child concepts.

Figure 3: Summary of | 128107007 | von Willebrand disease type 2 (disorder) | .

In the 201501131 Version of SNOMED CT

- | 359729006 | von Willebrand disease type 2M (disorder) |
- | 359732009 | von Willebrand disease type 2N (disorder) |
- | 359711001 | hereditary von Willebrand disease type 2A (disorder) |
- | 359717002 | hereditary von Willebrand disease type 2B (disorder) |
- | 359725000 | hereditary von Willebrand disease type 2M (disorder) |

are child concepts of | 128105004 | von Willebrand disorder | . Above that, the upper five concepts are originally kinds of | von Willebrand disease type 2 | , which hasn´t been modelled in SNOMED CT so far.

3.2 Improvement approach on Von Willebrand related concept structuring

The proposed design tries to improve the structure of the Von Willebrand type disorders and to simplify navigation, especially for the stakeholders. We take a four step,top-down approach with regard to the hierarchical structure of SNOMED CT.

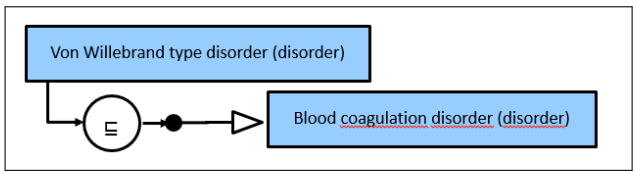

Figure 4: Concept model design for | von Willebrand type disorder (disorder) | .

Step 1: A new and broader grouper concept named | von Willebrand type disorder (disorder) | shall be created. The first draft of a concept model for | von Willebrand type disorder (disorder) | is shown in Figure 4

| Von Willebrand type disorder (disorder) | is displayed as a child concept of | 64779008 | Blood coagulation disorder (disorder) | via an "is_a" relationship.

Step 2: Switch the hierarchy from | 128105004 | von Willebrand disorder (disorder) | to | von Willebrand type disorder (disorder) | . This will be a primitive grouper concept and all existing children will need to be given a stated "is a "relationship to this new grouper concept.

The SNOMED CT Editorial Guide January 2015, Section 7.6 Naming Convention for the disorder hierarchy states that "*In the disorder hierarchy, the word 'disorder' in singular should be used. When the concept is a general grouper of disorders of a body system, body site, or other broad general category, the word 'disorder' should be used in preference to 'disease' for the FSN. This rule in favour of 'disorder' over 'disease' applies only to broad groupers, and is not applied at 'leaf' level*"[11].

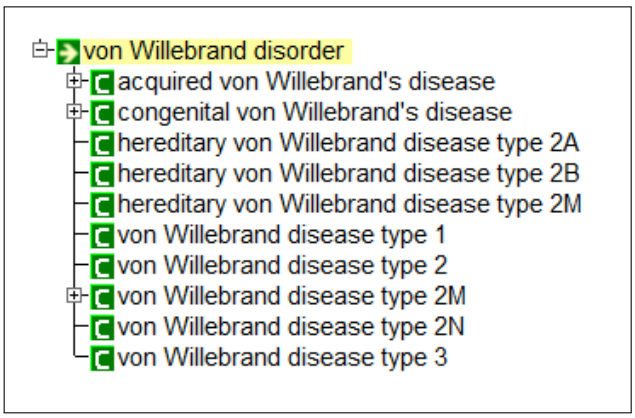

Figure 5: 128105004 | von Willebrand disorder (disorder) | as a grouper concept.

Figure 5 shows the original hierarchy design with | 128105004 | von Willebrand disorder | , with the FSN | 128105004 | von Willebrand disorder (disorder) | , as a grouper concept:

Figure 6 shows the new concept von Willebrand type disorder (disorder) with the switched hierarchy from | 128105004 | von Willebrand disorder (disorder) | :

As von Willebrand type disorder is expected to be a primitive concept, it shall be pointed out that normally the use of intermediate primitives is prohibited [11]. There are few exemptions when the use of intermediate primitives may be allowed, as

- There is no other option and the concept is clinically necessary
- The impact of adding the concept in question has been fully explored and understood
- The impact is deemed manageable and a plan for management has been determined

In this special case, the use of an intermediate primitive seems to be acceptable, as the specific child concepts are known or searchable, and that the switch of the hierarchy to Von Willebrand type disorder has additionally been proposed by IHTSDO terminology experts.

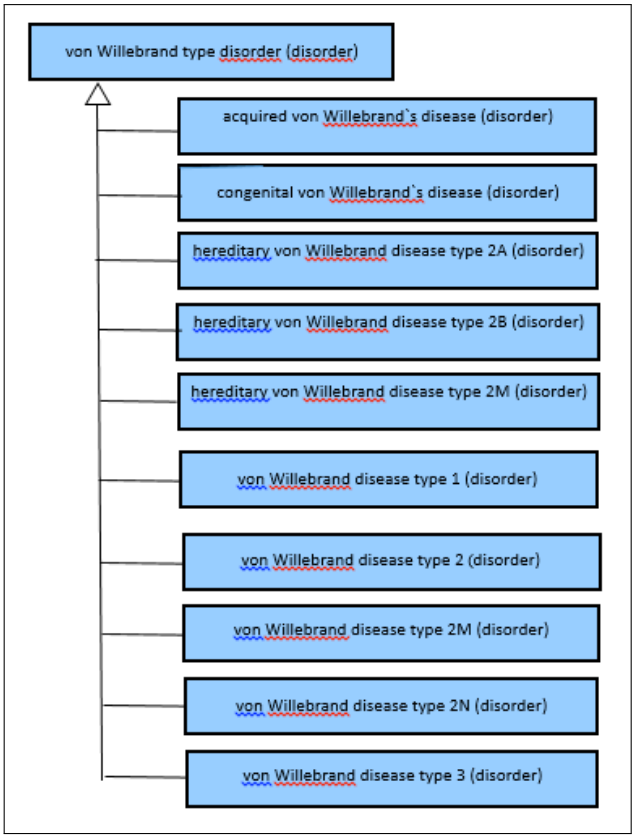

Figure 6: Von Willebrand type disorder (disorder) with subhierarchy in diagramming style.

Step 3: Retire | 128105004 | von Willebrand disorder (disorder) | as a grouper concept

Step 4: Re-organization of subtypes of | 128107007 | von Willebrand disease type 2 (disorder) | We provide a preliminary design of six new concept models for "is_a" relationships in Figure 7

In this context and to avoid duplications in future SNOMED CT editions, it is also possible to retire:

- | 359729006 | von Willebrand disease type 2M (disorder) |
- | 359732009 | von Willebrand disease type 2N (disorder) |
- | 359711001 | Hereditary von Willebrand disease type 2A (disorder) |
- | 359717002 | Hereditary von Willebrand disease type 2B (disorder) |
- | 359725000 | Hereditary von Willebrand disease type 2M (disorder) |

from the current position (see Figure 2), as they are now defined as child concepts of | 128107007 | von Willebrand disease type 2 | .

The described design tries to improve the structure of the von Willebrand type disorders and to simplify navigation, especially for the stakeholders.

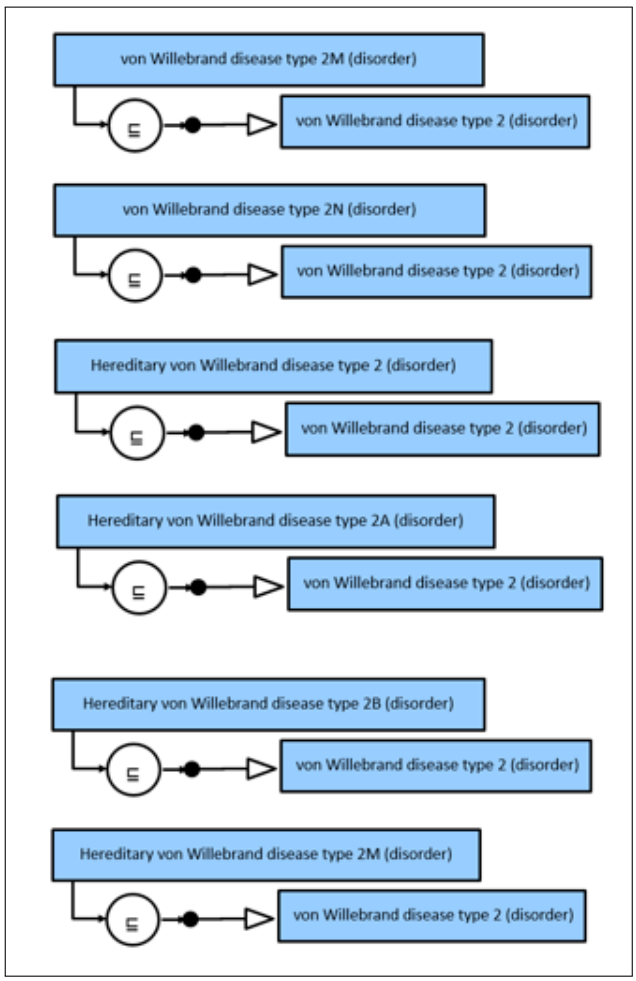

Figure 7: Possible "is_a" relationships of von Willebrand disease type 2 (disorder).

3.3 Terminology binding in the Von Willebrand context

The HL7 implementation guide "Using SNOMED CT in HL7 Version 3" offers recommendations how to provide semantic interoperability through the harmonized interaction of terminology and information model.

In HL7 V3, observation is displayed as an isolated event, whereas an HL7 V3 condition is an ongoing event. Symptoms and findings, e.g. the Von Willebrand disease, are observations. There is a distinction in SNOMED CT between "clinical findings" and "diseases" where the latter is necessarily a pathological condition. The SNOMED CT clinical finding/disease distinction is orhtogonal to the HL7 observation/condition distinction. This means that

```
<observation classCode="OBS" moodCode="EVN">
   <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
     <text> von Willebrand disease type 2 </text>
       <value xsi:type="CD" code=" 128107007 | von Willebrand disease type
         2 |" codeSystem="2.16.840.1.113883.6.96">
          <displayName value=" von Willebrand disease type 2 "/>
       </value>
</observation>
```

Figure 8: Assertion of the clinical finding "Von Willebrand disease type 2".

```
<act classCode="DOCSECT" moodCode="EVN">
  <code code="8646-2" codeSystem="2.16.840.1.113883.6.1" codeSys
     temName="LOINC"/>
     <title>Hospital Admission Diagnosis</title>
        <text>Hospital admission diagnosis </text>
           <actRelationship typeCode="COMP">
             <observation classCode="OBS" moodCode="EVN">
                <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
      <value xsi:type="CD" code="128107007|von Willebrand disease type 2 |"
         codeSystem="2.16.840.1.113883.6.96">
        <displayName=" von Willebrand disease type 2"/>
      </value>
    </observation>
  </actRelationship>
</act>
```

Figure 9: Context dependent assertion of the diagnosis "Von Willebrand disease type 2".

a SNOMED CT finding or disease can be an HL7 observation or condition.

The distinction between an HL7 observation and HL7 condition is made by setting the Act.classCode to "OBS" or "COND". The distinction between a SNOMED finding and SNOMED disease is based on the location of the concept in the SNOMED CT hierarchy [12].

Figure 8 shows the assertion of the clinical finding "Von Willebrand disease type 2":

A diagnosis like Von Willebrand disease has clinical meanings as it is the result of a process whereby for example symptoms are determined to describe the condition afflicting a patient.

Figure 9 shows the context dependent (hospital admission related) assertion of the diagnosis "Von Willebrand disease type 2":

A concern is something that a clinician is particularly interested in and wants to track.in terms of patient history. As a defeciency of the blood clotting system and possible bleeding issues, all information on Von Willbrand disease presence are important in this case.

The HL7 Patient Care Technical Committee is developing a formal model for the tracking of conditions. In that model, a problem is wrapped in an act with a new Act.classCode "CONCERN". The focus is on the use of SNOMED CT, where the Patient Care condition tracking model is the definitive source for the structure of a problem list [10].

4 Conclusions

As there is a great variety of SNOMED CT concepts connected to the Von Willebrand disease context, meaningful concept structuring inside of the terminology is one of the major goals. We tried to construct an appropriate hierarchical order concerning the concept | 128105004 | von Willebrand disorder | . In this context and according to stakeholder needs, a revised and functional organization of subtypes of | 128107007 | von Willebrand disease type 2 (disorder) | has been provided as well.

Some irregularities have to be taken into account, like f. e. incompatible synonyms or duplications. The risk of addressing this problem is that | 128105004 | von Willebrand disorder (disorder) | has currently the function of a grouper concept. If the descriptions are changed to a new grouper concept like | 128105004 | von Willebrand type disorder (disorder) | this may cause miscoding. Above that, it is possible that the end users may choose this grouper concept rather than a more granular child concept.

Other relating problems and exemptions, that have to be taken into account in the future, raise from the terms "congenital" and "hereditary" in connection to von Willebrand diseases. As specialist literature states that the von Willebrand disorders or – diseases type 1 up to 3 are all hereditary it may be irritating why it is necessary to have a concept | 359729006 | von Willebrand disease type 2M (disorder) | on the one hand and | 359725000 | hereditary von Willebrand disease type 2M (disorder) | on the other. There is a need for further refinement of the hierarchy respective these attributes [9]. Regarding these

problems, it seems to be appropriate to check the current hierarchy first in terms of duplication. It needs to be clarified, whether there is a need to keep | 359725000 | hereditary von Willebrand disease type 2M (disorder) | if | 359729006 | von Willebrand disease type 2M (disorder) | may mean exactly the same. Additionally, it should be addressed whether "congenital" and "hereditary" may have a synonymous meaning together with the Von Willebrand disease, and if they do, duplicate concepts may be retired. The idea is to keep the more common and frequently used term "congenital Von Willebrand disease" or "hereditary Von Willebrand disease".

The terminology binding between the SNOMED CT semantics in the Von Willebrand context and HL7 V3 seems to be well described. It has been shown, that the problematic handling of synonymous terms is assigned to hierarchical structure problems out of SNOMED CT. HL7 standards rely on the "model of meaning" that states a common understanding of a certain context. It is crucial to provide fully defined SNOMED CT concepts in the Von Willebrand context whenever possible and to structure the assigned hierarchical order.

The Von Willebrand example seems to be suitable to show how small semantic differences lead to big effects. It is a demanding task to identify and to work on comparable synonymous issues in SNOMED CT for effecient content improvement, with the overall objective to facilitate terminology usage and – in the end – patient safety.

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Healthcare Terminology Management and Integration in Italy: Where we are and What we need for Semantic Interoperability

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Abstract

Objectives: The purpose of this paper is to present and discuss the adoption and use of medical terminologies and coding systems in Italy, focusing on their management and integration for guaranteeing semantic interoperability among Electronic Health Records (EHRs). Semantic interoperability guarantees meaningful exchange of data between two or more healthcare information systems, ensuring that data content is not only understandable within its original context, but also in the destination one, and is capable of supporting health service management, clinical decision-making care collaboration, as well as public health reporting, and improving clinical research.
Methods: The approach used for the coding systems management and integration in the Italian Fascicolo Sanitario Elettronico (FSE)[a] use case is presented according to the current Italian regulations on federated EHRs.
Results: Results show the need to promote an advanced approach, in conformance to the literature best cases, which takes care about a better integration and maintenance of medical terminologies and coding systems through the use of standardized models of terminology services.
Conclusion: The paper presents terminology interoperability issues arisen from the described approach and related requirements to propose a solution that could allow, through sophisticated terminology services framework, to achieve also in Italy semantic interoperability.

Keywords

Health Information Management; Clinical Coding; Health Information Exchange; Terminology as Topic; Semantics

[a]This is the italian equivalent for Electronic Health Records.

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1 Introduction and Objectives

The importance of knowledge management in the healthcare domain is well recognized and widely treated in the literature. This is strictly related to the use of vocabularies, terminologies or classification and coding systems to better organize and define clinical concepts and to identify access keys to codified data that can be thus combined, manipulated and shared among healthcare professionals (physicians, data analysists, and all the healthcare operators) during the entire process of care. Those systems, generally referred as Knowledge Organization Systems (KOS), in fact, allow to structure and represent complex information fostering their correct interpretation and sharing.

More specifically, coding and classification systems are essential instrument for the unambiguous coding of clinical concepts during the process of care and during the delivery of health services (e.g. diagnostic process, statistical analysis for epidemiological studies, etc.) and for improving access to and elaboration of data in healthcare information systems. They are used particularly to overcome problems related to the lexical complexity of the domain, that is characterized by a high level of specificity. Content and structure of classification systems vary according to their granularity, scope and to the cultural and social context they are built for. A detailed overview of the differences and scopes of these types of resources in the healthcare domain is presented in [1].

In the last decade, the problem related to management, integration and correct use of terminologies and coding systems in healthcare has become a non-trivial resolution issue. Standards, at a national and local level, are often adapted to different purposes, other than those for which they were originally built. On one hand, this entails that it is not possible to use them in their completeness,

and, on the other hand, those standards will inevitably undergo a misuse of their original structure. The use of the International Classification of Diseases (ICD) in the Italian primary care setting is an example of this issue, as the classification system, originally built for classifying morbidity and mortality information for statistical purposes, is used by General Practitioners (GPs) for coding diagnoses and comorbidities and also for a plethora of other applications (e.g. in research, health care policy, and health care finance), generating ambiguities in the registered information, coding errors, concept generalization, dissatisfaction about the coding practice, etc. [2].

Issues related to terminology management and integration have been treated by many researchers in the last 20 years. Initial studies and applications were focused on the use of the Unified Medical Language System (UMLS) Metathesaurus, known as the first medical terminology integration service, a largest repository of biomedical vocabularies (more than 100), developed by the US National Library of Medicine [3]. Researchers used the UMLS Metathesaurus to create knowledge-based representation for controlled terminologies of clinical information and to extract and validate semantic relationships. It is the case for example of the Medical Entities Dictionary (MED) [4] that provides domain coverage, synonymy, consistency of views, explicit relationships, and multiple classification while preventing redundancy, ambiguity (homonymy) and misclassification. More recently researchers and stakeholders, especially in some European (EU) countries and in the United States, are promoting the use of terminology server's services which permit access, query and search for the different semantic resources (terminologies, coding systems, ontologies). These tools are specifically designed to work with controlled vocabularies as they provide, among others, vocabulary management, distribution or update functionalities [5].

As many other European countries, after the publication of the European Directives on Integrated EHRs, Cross-boarding care, Semantic Interoperability of healthcare data [6] also Italy carried out an Institutional Programme for the digital healthcare in order to adapt the EU legislation to the national context. This programme was in particular targeted to the construction of a national federated and interoperable infrastructure for the management and sharing of patient's healthcare data, namely "Fascicolo Sanitario Elettronico" (FSE), which is the Italian equivalent acronym for EHR [7, 8, 9]. This infrastructure aims to promote the decentralization of patient care, facilitate access to healthcare data for both healthcare providers and patients, and improve diagnostic and therapeutic care pathways. In order to allow an efficient healthcare data management in the context of the FSE, regulatory actions, finalized to uniform and standardize the use of coding systems for coding consumers' healthcare data and their transmission in an interoperable perspective, have been recently launched. This would allow the exchange of patient's data and documents between different healthcare information systems through a codified and shared language. In particular the Legislative Decree No.179/2012[1] urges Italian Regions and Autonomous Provinces to establish and implement regional FSE systems, highlighting the need to ensure interregional interoperability services.

Giving the context and issues described above, the aim of this paper is to show i) where Italy is positioned with respect to other countries regarding the topic of healthcare terminology/coding systems management and integration, ii) what effort has been made after the legislation on FSE to implement terminology management within the context of FSE itself, and iii) what stakeholders and researchers still need to do in order to guarantee Semantic Interoperability[2] and adopt standardized and updated medical terminologies to facilitate data access, registration, integration, and sharing within the national context so to be aligned to EU countries for promoting cross-border care.

2 Terminologies and Coding Systems Management in the FSE

Approaching the world of medical terminologies is quite confusing at first glance, despite the aim of those systems is to organize the domain knowledge in a structured and clear way. Due to the standardization effort, a huge number of medical terminologies and classification systems have been developed, but although they are called "standards", they are quite far from being unique for each medical semantic area. Because of this, in the last two decades significant effort has been spent by researchers to create conversion mappings among them, often enriched with a semantic network.

The management of medical terminologies in Italy is even further complex, mainly because the legislator has never addressed the theme from a general and integrated point of view, but often according to the needs of the moment, especially the economic ones. The most significant legislative interventions are the Ministerial Decree 26/07/1993, which makes mandatory diagnoses encoding in the hospital discharge letters by using the 9th revision of the International Classification of Diseases – Clinical Modifications (ICD-9-CM) and the recent Prime Minister Decree No. 178/2015[3], which is more specifically focused on the FSE, widely addressing medical terminologies use in a specific section. Over the years between 1993

[1] Decreto Legislativo N. 179 del 18/10/2012 Ulteriori misure urgenti per la crescita del Paese. Available from: `http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legge:2012-10-18;179`

[2] With Semantic interoperability is meant the ability of a healthcare system to share information and have that information properly interpreted by the receiving system in the same sense as intended by the transmitting system.

[3] Decreto del Presidente del Consiglio dei Ministri N. 178 del 29/09/2015, Regolamento in materia di fascicolo sanitario elettronico, Gazzetta Ufficiale n.263 11/11/2015. Available from: `http://www.gazzettaufficiale.it/eli/id/2015/11/11/15G00192/sg`

and 2015 a lot of recommendations about the use of standard terminologies in different types of clinical documents [10, 11], such as prescriptions and Patient Summary (PS), were issued by technical working groups, but none of them had the power to encourage the effective creation of a national task force for coordinating the numerous efforts related to the use and management of medical standardized terminologies. Beside the national vacatio legis, different regional and local initiatives led to the creation of systems tailored for specific contexts of use, thus losing semantic interoperability, which is the fundamental feature of standardized terminologies.

The following sections will describe, on one hand, the governmental effort, supported by the National Research Council of Italy (CNR), for the regulation of the use of coding systems in FSE and, on the other hand, the work done for the implementation of the Logical Observation Identifiers Names and Codes (LOINC) in Italy.

2.1 Italian Regulations for the Use of Coding Systems in the FSE

Since 2009 CNR is cooperating with governmental bodies, respectively the Department of Digitalization of Public Administration and Technological Innovation of Public Administration and the Agency of Digital Italy (AgID), to define the national technological infrastructure of the FSE[4], also supporting the regulatory action and participating to national Technical Boards with all the different stakeholders involved into the matter. This activity led to i) the definition of the FSE infrastructure [9], whose aim is to allow the full interoperability among the different regional EHR systems; ii) the publication of national guidelines for the implementation of regional EHRs[5], which guided Regions in presenting their EHR projects compliant to the national infrastructure; and iii) the definition of Specifications related to different interoperability aspects.

The cited Prime Minister Decree on the FSE states that the content of the clinical documents produced and to be stored in the FSE have to be represented through classification and coding systems able to ensure, eventually recurring to transcoding, semantic interoperability at regional, national and international level (art.25) and refers to its Technical Annex for all the relative details. The Technical Annex specifies the use of the following standard terminologies:

- ICD-9-CM for diagnoses encoding;
- LOINC for laboratory tests encoding;
- ATC (Anatomical Therapeutic Chemical Classification System), developed by the World Health Organization (WHO), for medications' active ingredient encoding;
- AIC (Autorizzazione all'Immissione in Commercio), developed by the Italian Medicines Agency (AIFA), for medications encoding.

Furthermore, their use in the PS and in the Laboratory Report (the two kinds of document to be firstly implemented, according to the law) is described in detailed tables.

Those standard terminologies are not new into the national context but their systematic use is not always consistent and needs to be adapted in order to be coherent with the new requirements. At the state of the art when the Prime Minister Decree entered into force, standard terminologies were often known by name, but barely used or properly used, thus causing a general underestimation of all the possible benefits deriving from them.

In recent years, different studies [2, 12] try to get an outline of the Italian situation related to the effective use of standardized terminologies among physicians, especially focusing on GPs, or to evaluate how different classification systems would adapt to the use in GPs' daily practice and how to support them in the coding process. They generally agree in depicting either an inappropriate use or a not sufficiently deep knowledge of the recommended classification system, i.e. ICD-9-CM, that brings GPs to use only high level codes (e.g. for ICD the three digit codes) instead of selecting the adequate code respecting granularity and precision. The wrong use of coding systems is often related to the lack of an adequate training of the professionals involved in the process of care.

About laboratory observations, the state of the art is slightly different because existing regional and local coding systems are like service catalogs more oriented to reimbursement purposes than to detail clinical information. Moreover, they differ in each Region and increase the existing idiosyncrasy when they are mapped to internal laboratories catalogs. The following paragraph presents the process of adapting and introducing LOINC into the Italian context.

2.2 LOINC Implementation in Italy

In 2009, when the first CNR project related to the FSE infrastructure started, LOINC was just mentioned as recommended standard by the Tavolo di Sanità Elettronica, a temporary technical board in charge of releasing technical specifications for e-health documents. A detailed analysis of the laboratory records workflow and data description revealed a strong use of idiosyncratic conventions to represent the same clinical concepts in different local electronic

[4] Projects realized between 2009 and 2016 are: InFSE, OpenInFSE, Interventi a supporto della realizzazione del Fascicolo Sanitario Elettronico, Realizzazione di servizi della infrastruttura nazionale per l'interoperabilità per il Fascicolo Sanitario Elettronico, Realizzazione di servizi e strumenti a favore delle Pubbliche Amministrazioni per l'attuazione del Fascicolo Sanitario Elettronico.

[5] Linee Guida per la presentazione dei piani di progetto regionali per la realizzazione del Fascicolo Sanitario Elettronico. Available from: http://www.agid.gov.it/sites/default/files/linee_guida/fse_linee_guida_31032014_dpcm_dt.pdf.

systems. LOINC, internationally renowned standard for clinical and laboratory tests encoding, appeared as the right solution to overcome this issue. The Institute of Informatics and Telematics (IIT) of the CNR in agreement with Regenstrief Institute (RI), which is the LOINC creator and manager, started the translation process of the standard into Italian, refining it from release to release by establishing translation rules, thanks to the continuous collaboration with different domain experts. The first LOINC Italian translation was realized according to the part based translational approach (as described in [13]) and published in 2010, containing 43,152 codes. Further refinements based on the analysis of the automatic process outcomes were conducted at each biannual release, the last of which in December 2015, containing 61,424 codes. Thanks to the creation of the LOINC Italia workgroup, the adaptation and the introduction of the standard in Italy has been continuously managed and supported also cooperating with the LOINC master creators. This is often a weak point of the national version of international standardized terminologies as they lack of planned maintenance and references. LOINC Italia working group has over time produced support materials for the use of the standard, provides educational activities and assists all the processes that require relations with the LOINC mother company, such as new codes submission requests.

Mentioned FSE projects offered also the chance to test the introduction of the LOINC Italian version into some laboratories. It was a time of major confrontation with the actual daily practices of laboratories and an occasion for assessing the usefulness and usability of the translation results. Mapping local terms to a standardized vocabulary is not only a matter of interoperable informative systems, but it requires a deep knowledge of both the destination terminology structure, i.e. LOINC, and the way in which the tests are actually realized. It was possible to find solutions to the multiple issues encountered during this phase thanks to a continuous collaboration with RI experts and the keen interest of the laboratorians involved in the mapping process. The high percentage of correct mappings and the low percentage of not identified matches demonstrate that the first impression of the system is not as difficult as one might expect for people unaccustomed to the use of standard terminology, and secondly, that the training phase is effective making the system well understandable.

All the actions taken for introducing and adapting LOINC in Italy revealed that a central coordination center is essential for having a common reference point to address questions, support users, maintain relationships with governmental bodies and third parties, keep updated the standard and consider international updates and challenges in the domain. An integrated management of a medical terminology cannot be able to leave all those aspects out of consideration, as they all contribute to make effective and efficient the use of a standardized system.

3 Preliminary Results

According to the Prime Minister Decree No 178/2015 and to the agreement between CNR and AgID, the interoperability platform of the FSE was firstly released in the last month of December 2015. It offers a series of services for allowing a "dialog" between two regional EHR systems and the consequent exchange of clinical documents. Regions are progressively starting to test their interoperability services in order to accomplish step by step to their regional EHR projects drawn up according to the cited Decree. The management of standard terminologies to be used in PS and laboratory reports is being centralized and offered through the FSE platform[6] to serve as a common point of reference for Regions and end users. Services that have been firstly released include, among others, the download of the official versions of the recommended standard terminologies and additional support (e.g. guidelines, manuals); the possibility to have information about the version to be used and how to use it in the specified documents; to perform queries, by keywords or codes, to find data in one or all the medical terminologies available in the platform; helpdesk services to contact national qualified support centers; and finally, the possibility to require, through the platform, specific training activities.

This is only a first step performed to reach the general objective of centralizing the management of medical terminologies through an integrated system based on internationally recognized standards. Toward this aim, there are many international initiatives in the literature that could be considered. Some of them offer mapping and multilingual functionalities (e.g. the HETOP terminology service, that offers cross lingual multi-terminological mappings on a semantic basis [14]), some others integrate semantic resources represented as ontologies and allow users to continuously update their mappings (e.g. the Bioportal repository)[7]. Furthermore, some international initiative promoted the use of common terminology models to accommodate multiple vocabulary and ontology distribution formats and support of multiple data stores for federated vocabulary distribution. It is the case of LexGrid, a community-driven initiative coordinated by the Mayo Clinic Division of Biomedical Statistics and Informatics [15], and of the HL7 CTS2 (Common Terminology Services 2)[8] specifications for the development of standardized terminology services. Regarding this last standard, its most relevant international implementation is by Mayo Clinic Informatics, but similar experiences are known also in France (by PHAST, a non-profit development stan-

[6] www.fascicolosanitario.gov.it

[7] http://bioportal.bioontology.org/

[8] http://wiki.hl7.org/index.php?title=Common_Terminology_Services_-_Release_2_%28Normative%29

[9] http://wiki.phast.fr/index.php?title=Common_Terminology_Services_2_(CTS_2)

[10] http://www.wiki.mi.fh-dortmund.de/cts2/index.php?title=Hauptseite

dards and services organization, that used CTS2 to build the Standard Terminology Services - STS[9]), Germany (by the University of Applied Science, Dortmund[10]), Austria (by the Ministry of Health, that used a modified version of the cited Dortmund Terminology Server as central eHealth terminology source in Austria, Austrian Terminology Server[11], especially for the national federated patient health record "ELGA") and Italy (by the University of Genova [16], and by the Codices company that use it to develop the Distributed Terminology Assets Management system13). In particular in Italy, the raising awareness of the fundamental importance of having an integrated and centralized system for terminologies management is driving the first initiatives related to HL7 CTS2, such as the cited ones, and also the first requirements of some Regions about it.

4 Discussion

This paper shows the Italian status regarding semantic interoperability in health domain, presenting what has been done starting from the national state-of-art and from some issues related to the different local realities. In fact, the autonomy in healthcare management given to Italian Regions and the lack of a centralized management of a terminology service generated, over the years, a proliferation of different regional solutions/implementations, causing thus many issues from different perspectives.

As already mentioned, the activity carried out by the Italian Government, with the continuous support of the CNR, has been first of all aimed at ensuring the cooperation among all the different actors involved into the subject so to realize a service for centralized management of healthcare services according to the current Italian regulations and compliant to the stakeholders' needs. Within this activity the need for an integrated and centralized medical terminology service, ensuring semantic interoperability of information exchanged, is motivated, as stated above, by several critical factors: i) the widespread misuse of medical coding systems in most national health facilities; ii) the large use of local coding systems instead of the recommended standards; iii) the adoption of obsolete coding systems. The semantic interoperability among health information systems is a longstanding aspiration of the healthcare community, but the way to reach it can lead to many non-trivial issues, particularly for the application domain. In Italy the problem is not only related to a technical matter, but there are also other open issues, most of which would be solved through the creation of a national authority for medical terminologies management, such as in some EU and non EU countries (e.g. Belgium, with the Terminology Center belonging to the Federal Public Service of Health, Food Chain Safety and Environment; Sweden, with the National Board of Health and Welfare that provides nationally agreed upon concepts and terms within health and social care services in the terminology database; United kingdom, with the UK Terminology Centre - UKTC; etc.).

The national interoperability is only the first step on a long pathway to have an efficient and effective EHR. The international level, only addressed in some research projects (e.g. EpSOS[12]; SemanticHealthNet[13]; Antilope[14]; Trillium Bridge[15]), could turn out as a further issue for Italy in the next future. Furthermore, the adoption of unappropriated (or not updated) standards could leave Italy out from "international" semantic interoperability. It might be necessary then an additional step oriented to transcoding the national recommended systems to up-to-date versions or other standard classification systems or nomenclatures in use in EU and non EU countries (such as SNOMED CT that is already adopted in many Countries). As discussed in this paper, the activity carried out with LOINC is a valuable example of the importance of a constant work on the codes translation and more generally of the efficient management of the standard itself (e.g. the importance of developing tools for promoting its distribution and supporting its implementation and mapping).

5 Conclusions

The paper presented the initiative undertaken in Italy to provide regulations to the use of medical terminologies and coding systems within the context of FSE, the national federated EHR, and what has been done to reach national semantic interoperability. Preliminary results show that, despite the recent advancements promoted by the law and supported by the AgID and CNR projects, a lot of work still needs to be done to be aligned with international initiatives that promote the use of integrated management services of medical coding systems as well as dedicated Authorities to coordinate the entire process. To accomplish this task, it is strongly required a synergy and cooperation among national Standard Development Organizations (SDOs), which are responsible for each system maintenance and distribution. It is to be considered that the implementation of integrated terminology services is just the beginning of a process. In fact, the most important aspect in managing medical terminologies is the constant maintenance over time to update resources and the coordination of processes such as transcoding, translation, and licensing that need to be accomplished by a dedicated governmental authority. To this end, the creation of a national body strictly focused on these themes appears urgent to not let the national FSE infrastructure be merely a matter of technologies, forgetting its most important aim: the clinical information management and sharing to improve patient quality of care. In this perspective, the

[11] https://termpub.gesundheit.gv.at/TermBrowser/gui/main/main.zul
[12] http://www.epsos.eu/
[13] http://www.semantichealthnet.eu/
[14] https://www.antilope-project.eu/front/index.html
[15] http://www.trilliumbridge.eu/

creation of a central terminology management service is not only a way to reach semantic interoperability, but it is also a way to better support healthcare professionals in improving the quality of their data ensuring maximum benefits along the healthcare process and the cooperation among different healthcare providers.

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International Conference Electronic Healthcare Documentation

Prague, Czech Republic, February 11, 2016

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The International Conference Electronic Healthcare Documentation was held on 11 February 2016 in the House of Physicians in Prague, Czech Republic. Jointly organized by the EuroMISE Mentor Association and Czech Society of Biomedical Engineering and Medical Informatics, the conference was performed under the auspices of Charles University in Prague, First Faculty of Medicine. The event was opened by short speeches of Štěpán Svačina, President of the Czech Medical Association J.E. Purkyně, Bernd Blobel, Chair of the Scientific Program Committee, and Jana Zvárová, Chair of the Conference Organizing Committee. The morning program was divided into two sections. The first section was opened by the Keynote Lecture "Developments in Medical Informatics: Can the Future be Predicted from the Past?", provided by Jan H. van Bemmel (The Netherlands), former President of the International Medical Informatics Association, from 2000-2003 acting as Rector Magnificus of Erasmus University Rotterdam, The Netherlands. The second morning session was introduced by Bernd Blobel (Germany), former Chair of HL7 Germany, Chairman of the CEN / ISSS eHealth Standardization Focus Group as well as Founder and long term Chair of the EFMI Working Group "Electronic Health Records", with his Keynote Lecture "EHR / PHR Systems Today and in the Future". Beyond the Keynotes, five lectures on the topics of the conference have been presented in the morning sessions. The afternoon session was introduced by a lecture of Anna Adelöf (Sweden) titled "The Emerge of Clinical Terminology - SNOMED CT", followed by another six speeches. The last session of the conference was devoted to a panel discussion on the topic "Electronic Health Care Documentation - What Should be Integrated and How Can this be Done?", which was opened by a lecture of Pirkko Nykänen (Finland). The discussion clearly demonstrated that different professional groups in healthcare require different representations of information. However, this problem has not yet been satisfactorily solved. All conference papers have been published in the first issue of the International Journal on Biomedicine and Healthcare in 2016 (available at www.ijbh.org). The conference, attended by 36 delegates from six countries, was concluded with a dinner at Profesní dům of the Faculty of Mathematics and Physics, Charles University in Prague. The sightseeing tour for conference participants through the historic part of the building was guided by Antonin Kučera, former Associate Dean of the faculty, with the organizational help of his colleague Jaroslav Pokorný. The conference was accompanied by the mentoring course "Health Information Management", provided by the EuroMISE Mentor Association on 10 and 12 February 2016.