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Special Topic

Standards and Solutions for eHealth Interoperability

Editors

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Table 1: Age, period, cohort modelling of coronary heart mortality, men, 30-74 yrs., Czech Republic, 1980-2004.

No.	Model	D	*df*	*p*-value
0	Interception	355388.0	44	<0.001
1	Age	15148.0	36	<0.001
2	Age-Drift	3255.5	35	<0.001
3a	Age-Age*Drift	2922.5	27	<0.001
3b	Age-Period	388.2	32	<0.001
3c	Age-Cohort	1872.6	24	<0.001
4	Age-Period-Cohort	28.7	21	0.121

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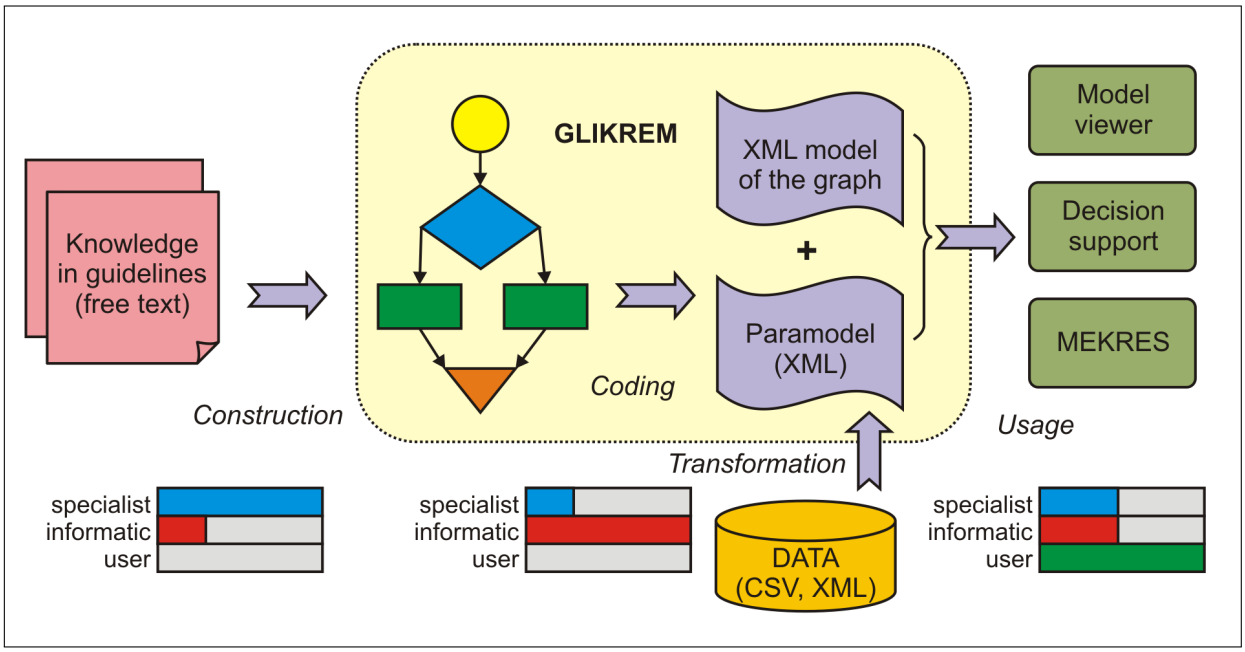

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[1] Blobel B. Architectural Approach to eHealth for Enabling Paradigm Changes in Health. Methods Inf Med. 2010; 49(2): 123–134.

[2] Kalina J. Robustní analýza obrazu obličeje pro genetické aplikace. EJBI [Internet]. 2010 [cited 2011 Jun 28]; 6(2): cs95–cs102. Available from: http://www.ejbi.eu/articles/201012/47/2.html

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Contents

Standards and Solutions for eHealth Interoperability

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There is no doubt that the way to high quality, safe and efficient health services leads to distributed cooperative care (shared care) supported by information and communication technologies [1]. Such approach requires interoperability between all principals (persons, organizations, devices, applications, components) involved [1]. Nevertheless, many papers and organizations (e.g. [2]) dedicated to health care interoperability still refer to the IEEE Dictionary definition of (semantic) interoperability as "... the ability of two or more systems or components to exchange information and to use the information that has been exchanged" [3]. However, the problem of interoperability is not limited to the early days' EDI challenge of harmonized data representation and exchange protocol. Nowadays, it is the challenge of the legally, culturally, socially, educationally and organizationally impacted aspect of commonality regarding business processes and objectives, but also interests, knowledge and skills to cooperate for jointly meeting those business objectives [1]. Those aspects go far beyond ICT ontology and communication protocols as commonly understood today. Depending on the sharing of those common aspects, comprehensive interoperability can be provided at different interoperability levels such as structural, syntactic, semantic or services, semantic, or services interoperability depending on the level of shared knowledge and skills [1].

The deployment of the interoperability paradigm is even more challenging in the case of providing health services covering diagnosis and therapy, but also independent and healthy living independent of time and location of principals and resources. Thereby, the services are not limited to caring patients (health care services), but cover also prevention, social care, life style, etc., called health services addressing citizens in general. Such health service delivery over distance is the matter of eHealth. Thereby, technology paradigms such as mobile and pervasive computing as well as adaptive systems for personalization have to be exploited [1].

eHealth interoperability requires an open systems approach, agreed methodologies and processes, the use of reference models and architectures, reference terminologies and ontologies, but also user acceptance and trustworthiness. The agreement on those requirements is established in international standards and specifications. For guaranteeing interoperability, the development process and implementation details must be harmonized. Here, the application of tools and the agreement on implementation guide comes into play.

There are many Standards Developing Organizations (SDOs) contributing to eHealth interoperability. Here, ISO and especially ISO TC 215 Health Informatics, CEN and especially CEN TC 251 Health Informatics, but also HL7 International, IHTSDO, OASIS, OMG, and many others have to be mentioned. For enabling practical interoperability, the more general and generic specifications have to be use case specifically profiled. This is managed by IHE. Many of the HL7 standards and specifications covering most of the health information interoperability challenges have been meanwhile approved at ISO.

The current Special Issue of the European Journal of Biomedical Informatics (EJBI) is mainly based on papers submitted to the International HL7 Interoperability Conference (IHIC) 2012, organized by HL7 Austria and performed from 27-28 September 2012 in Vienna, Austria. It addresses standards and specifications and their implementation in local, regional international eHealth solutions, thereby representing different institutions, countries and regions around the globe. The call of EJBI for the special topic volume "Standards and Solutions for eHealth Interoperability" attracted many authors for submissions. The quality of submissions was very high, which resulted in a big number of accepted papers beyond the usual number of pages for EJBI volumes despite the strict review process performed. Therefore, the editors have decided to publish the accepted submissions in two issues of EJBI - no. 3 and no. 4 - in 2012. The first set of papers is published in no. 3 of EJBI, and its printed version has been distributed among the participants of IHIC 2012. The second part of accepted submissions at hand will be published only electronically in no. 4 of EJBI 2012.

No. 4 of this EJBI Special Issue is first of all dedicated to EHR interoperability based on HL7 CDA. Yan Heras, Arthur R. Brothman, Marc S. Williams, Joyce A. Mitchell, Clement J. McDonald, and Stanley M. Huff address the challenge of integrating advanced translational medicine information resulting from conventional and molecular cytogenetic tests into Electronic Health Records for communication between scientists, clinicians and practioners. Analyzing de-identified test results reports from leading laboratories deploying different cyto-

genetic investigations, they developed information models and thereof a hierarchical structure of interrelated concepts and appropriate terms expressed as LOINC codes. Jong-Ho Lim, Jun-Hyun Song, Sung-Hyun Lee, Il-Kon Kim, Byoung-Kee Yi, Sun-Hee Park present a public health surveillance system in Korea, connecting different healthcare provider EHR and PHR systems on the one hand and public health centers as well as the Korean Center for Disease Control and Prevention on the other hand for near real-time reports of infectious diseases. They propose a corresponding HL7 CDA Implementation Guide implemented using the IHE XDS and XDR profiles. Harald Burgsteiner, Gabriel Kleinoscheg, Mario Hussa provide an CDA Implementation Guide for integrating cardiopulmonary exercise testing results reports into the Austrian nationwide Electronic Health Record called ELGA. In that context, the generic CDA Implementation Guide for ELGA has been profiled according to the practioners' requirements with the biggest extension in including scalable vector graphic images. They demonstrate the feasibility of implementing harmonized standard based documents based on HL7 CDA R2 and R3 as well as related IHE profiles. Contrary to the aforementioned papers, Sebastian Bojanowski and Roman Radomski present an interoperability solution for sharing diagnostic reports without requireing EHR systems. Also this solution is based on HL7 CDA, created using a report editor.

The second series of papers in this volume tackles practical tests of provided specifications as proof on concepts. For covering communication needs of the health system from primary through secondary and tertiary care, clinical studies, disease registries etc., HL7 v3 provides a very generic interoperability framework, which results in a bunch of propriatary incompatible solutions. To overcome these problems, use case and domain specific profiles have been developed. The variety of solutions creates the challenge to test compatibility and interoperability of the specifications. Alexandru Egner, Florica Moldoveanu, and Nicolae Goga present a systematically designed methodology to test interoperability of HL7v3 based applications. The test scenario deploys the TTCN-3 framework offering a test description language based on a strict type system as well as a test management and control system. Being applicable for any application domain, the test framework has been practically demonstrated for the HL7 profile Query for Existing Data to query data repositories for clinical information on vital signs, problems, medications, immunizations and diagnostic results. In integrated care settings, communication is not limited to information systems, but also includes devices. John J. Garguilo, Sandra Martinez, Julien Deshayes developed and present a tool for testing medical device interoperability, based on the ISO/IEC x73 standard set as well as HL7 v2 for message based communication between medical devices as well as between them and health information systems. According to the limitation of HL7 v2, the validation of communicated device information is performed at syntactical and (low-level) semantic levels. Using information models and nomenclatures defined in ISO/IEC x73 standards as well as HL7 Conformance Profile thereby excluding optionality, the rigor of specifications and implementations has been improved. The test tools developed have been proven and practically demonstrated in the IHE framework. Interoperability is strongly impacted by changing specifications. So, inter-versions compatibility is a huge problem. Marek Václavík compares the IHE integration profiles for patient identification management PIX (Patient Identifier Cross-Referencing) and PDQ (Patient Demographics Query) ones based on HL7 v2 and on the other hand based on HL7 v3. The paper discusses in very details the IHE Domain Infrastructure specifications, underlying data models and behavior of actors in their roles.

Seifter, Matthias Koinegg, Christian Gruber, and Philip Peinsold address the role of patients' empowerment to reduce healthcare costs and improve both quality and efficiency of the health delivery process. Engaged in the European Union PALANTE project, the authors focus on electronic Xray-Records currently implemented in a set of Styrian hospitals to cover patients' Xray exposure data from all radiological examinations. In the future, that record will be integrated in the Austrian national Electronic Health Record ELGA. Therefore, a corresponding profile of the generic Austrian ELGA HL7 CDA Implementation Guide has been defined, which also reflects the related legal framework. For patient's access to the record, a Web portal has been developed. The volume at hand concludes with a paper from Patricia A H Williams and Vincent McCauley. The authors discuss challenges, problems and solutions for the ambitious project of developing and implementing a national eHealth system in Australia. Their contribution explores the complex underpinnings of that system, exemplified at the Personally Controlled Electronic Health Record (PCEHR) project. The authors demonstrate how the use of international standards and service integration will result in a complex service oriented architecture.

As the development is under quick move, another Special Issue on Standards and Solutions for eHealth Interoperability should follow in a few years to update the community on the addressed important field of ICT support for improving safety, quality and user-friendliness of health services and the efficiency and practicality of the related processes.

The Guest-Editors are indebted to thank all authors and reviewers for their excellent work as well as the HL7 International, HL7 Europe and especially HL7 Austria for the given logistical and financial support.

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Development of LOINC for Integrating Constitutional Cytogenetic Test Result Reports into Electronic Health Records

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Abstract

Objective: To develop *Logical Observation Identifiers Names and Codes* (LOINC) codes to represent constitutional cytogenetic test results for electronically exchanging coded and structured result reports. The LOINC codes developed must be flexible and sustainable for easy maintenance. The goal is to create a standard set of codes that are flexible enough to be used for all unique conventional and molecular cytogenetic results. **Design:** Patient de-identified sample result reports were obtained from ARUP Laboratories for a variety of normal and abnormal constitutional studies using G-banding, FISH and array-CGH. Information models were created to capture the semantic relationships of the key data elements that existed in the reports. Sample reports were subsequently obtained from Emory and Mayo Clinic Cytogenetics Laboratories to verify the information models. The information models were then used to guide the systematic creation of the LOINC codes. **Results:** A post-coordinated approach was used in developing the LOINC codes for cytogenetics test results. LOINC panel codes were created to represent the hierarchical structures implied by the reports. A master panel was created to contain three LOINC subpanels; each of the three subpanels held the structure for chromosome analysis results that uses a different technique. **Conclusion:** The LOINC codes we created met our objective and will allow the use of well established health informatics standards to exchange coded and structured cytogenetic test results between testing laboratories and ordering institutions. Use of standard structures and terminologies for cytogenetic results is critical for effective communication between testing laboratories and clinicians. This minimizes misinterpretation, leads to consistency, and provides the EHR systems flexibility of customizing formatting to present more clinician-friendly reports.

Keywords

cytogenetics, LOINC, information model

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1 Introduction

Discoveries in genetics and genomics research are increasing at a rapid rate. The number of clinically available genetic tests has also increased dramatically during the past decade [1, 2]. From primary care to specialty care settings, genetic testing is changing many aspects of clinical practice and patient services. Integration of genetic and genomic data with traditional clinical data to support the diagnostic and treatment decisions at the point of care for the individual patient is touted as ushering in a new era of personalized medicine [3, 4, 5].

Realization of the promise of personalized medicine depends on effective communication between laboratories and clinical settings. The laboratory result report plays a vital role in this communication channel. However, the format of genetic test requisitions and result reports vary from laboratory to laboratory; test results lack clarity about the clinical significance of the findings and are not clinician friendly [6]. All these factors have affected efficient communication between testing laboratories and clinicians. The problem has been further compounded by clinical providers' lack of basic knowledge about genetics, and their lack of confidence in interpreting genetic results [7, 8]. This could lead to potential misinterpretation of test results and compromised patient care; genetic test result reports that use standardized terminology and improved formatting are critical to address these problems.

Realization of the benefits provided by genetic and genomic advances in clinical care depends on effective access to the right information at the right time. Electronic Health Records (EHRs) promise to improve patient care, especially by providing advanced Clinical Decision Support (CDS) at the point of care. Incorporating genetic test results into the patient's EHR is a major step forward to take full advantage of genetic/genomic advances in clinical practice. However, EHRs today require significant modifications in order to consume genetic/genomic information and to effectively utilize such information in making clinical decisions [9, 10].

Standard terminologies that are tightly coupled with standard information models are the foundations of developing CDS-enabled EHRs. However, current standard terminologies for genetic test results are not sufficient. As the movement toward predictive, personalized, preventive medicine accelerates, we must develop terminology infrastructure before clinical information systems will be able to handle the high volumes of genetic and genomic data expected in the near future.

We previously evaluated the Logical Observation Identifiers Names and Codes (LOINC) system for representing cytogenetic test names and their results [11]. LOINC is the most widely adopted standard for laboratory test result names in the United States and internationally [12]. We found that current LOINC content is not sufficient to encode cytogenetic test names and test results. In this article, we describe how new LOINC codes for constitutional cytogenetic test results were developed. As the demand for standard terminologies representing genetics and genomics data continues to increase, the approach we took and the experiences we gained through this development process may be especially useful for others to use when developing standard terminologies to support the integration of genetic and genomic data into EHRs. Others may also find our approach useful for developing standard terminologies in general.

2 Background

2.1 Cytogenetic Test

Cytogenetic tests evaluate chromosomes from the nucleus of the cell for changes in number or structure. Cytogenetic testing is used in various clinical situations. These historically included assessment of a developmentally delayed child, evaluation of a cancerous tumor, or prenatal studies to detect chromosomal anomalies in a fetus [13]. A constitutional cytogenetic abnormality is one which occurs in the germline. A cancerous cytogenetic abnormality is an acquired (somatic) genetic change associated with a neoplastic process.

The emerging field of cytogenomics includes conventional cytogenetics, which uses chromosomal banding techniques such as G-banding, in addition to molecular technologies, such as fluorescence in situ hybridization (FISH), and cytogenomic microarray (arr). FISH is often used in prenatal diagnosis when results are needed rapidly to detect chromosomal aneusomies such as Down syndrome (trisomy 21), and also to detect chromosomal deletions, duplications, or rearrangements that are not visible using microscopy.[14]. Cytogenomic microarray (arr) circumvents a limitation of FISH as it does not require foreknowledge of the chromosomal loci being evaluated.

The introduction of arr to clinical cytogenetics has facilitated the genome wide detection of DNA copy number imbalances at resolutions significantly higher than previously attainable [14]. Arr analysis allows for the simultaneous analysis of hundreds or thousands of discrete loci, not possible within a single FISH experiment and at a much higher resolution than conventional cytogenetic analysis. Although current arr technologies cannot identify balanced rearrangements, most chromosome analyses that are performed on individuals with phenotypic abnormalities, developmental delays, or intellectual disability are performed to detect unbalanced chromosomal rearrangements, (gains and losses of chromosomal segments) and have been proposed to be a first tier test [15].

Traditional cytogenetics methods can detect gross chromosomal lesions. G-banded karyotyping is generally limited to the detection of genomic imbalances in the 5-10 Mb range. Most FISH assays used in a clinical cytogenetic setting detect submicroscopic changes no smaller than 50 kb, and only in limited targeted areas. In contrast, available oligonucleotide platforms can now detect genomic imbalances as small as 500 bp [16], and the International

Standard Cytogenomic Array Consortium (ISCA) currently recommends a resolution of >=400 kb throughout the genome as a balance of analytical and clinical sensitivity to detect copy number variants [15].

The International System for Human Cytogenetic Nomenclature (ISCN) is critical in reporting cytogenetic test results. ISCN was created by the International Standing Committee on Human Cytogenetic Nomenclature to represent the outcome of cytogenetic tests [17]. The latest version of ISCN was published in 2009. ISCN has been the gold standard of describing chromosome aberrations for almost 40 years. The College of American Pathologists (CAP) checklist and the American College of Medical Genetics (ACMG) guidelines for cytogenetics indicate that current ISCN must be used in clinical reports [18, 19].

2.2 Cytogenetic Test Results from ARUP to Intermountain Healthcare

Intermountain Healthcare is a nonprofit integrated health care delivery system consisting of 22 hospitals, and more than 130 outpatient clinics. Cytogenetic tests ordered by Intermountain physicians are performed by the ARUP Laboratories. ARUP is a national clinical and anatomic pathology reference laboratory owned by the University of Utah [20].

Cytogenetic test results are transmitted electronically from ARUP Laboratories to Intermountain Healthcare through Health Level Seven (HL7) version 2.x messages. HL7 version 2.x standards are the most widely implemented standards for healthcare data exchange in the world. HL7 version 2.x defines a series of electronic messages to support administrative, logistical, financial as well as clinical processes [21]. Each HL7 version 2.x message is composed of a number of segments. Each segment begins with a three-character literal value that identifies it within a message. For example, NTE represents a Notes and Comments segment, which is used to transmit free text notes and comments; OBX represents an Observation/Result segment, which is used to transmit a single observation or observation fragment. A segment contains a group of logically combined data fields. HL7 v2.x mostly uses a textual, non-XML encoding syntax based on delimiters, such as "|" and "^".

After the cytogenetic test results are received electronically by Intermountain Healthcare, they are stored in Intermountain's Clinical Data Repository (CDR) [22]. However, the results are not sent in a coded and structured format. The report is contained in an HL7 NTE segment as a text blob, and is stored as narrative text in the CDR. The test codes that are sent in the OBX-3 segment are local codes; they are not mapped to LOINC. One reason for this is that there are very few LOINC codes available for coding cytogenetic tests and results. A second reason is that the existing LOINC codes are not consistent with how the ARUP cytogenetic tests are named or with how the results are represented in actual reports [11]. For example, no LOINC code is available for representing the cytogenetic test results that are expressed in ISCN.

2.3 HL7 Standard for Reporting Genetic Test Results

HL7 approved a new implementation guide for electronic exchange of results of genetic variation tests called the "HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-qualified Genetic Variation Model, Release 1" in 2009 [23]. This guideline was sponsored by the Clinical Genomics Work Group. The Genetic Variation Model contains a set of four nested LOINC panels; the parent panel is Genetic Analysis Master Panel, which has exactly one Genetic Analysis Summary Panel, and zero-to-one Genetic Analysis Discrete Result Panel. The Genetic Analysis Discrete Result Panel has zero-to-many DNA Analysis Discrete Sequence Variation Panel.

Intermountain Healthcare and Partners Healthcare Center for Personalized Genetic Medicine have developed a pilot implementation of the guideline. The two organizations recently announced the first transmission of a coded and structured genetic test result sent electronically through the interface established between the two institutions, with the result being stored as part of the patient's EHR [24].

However, this HL7 standard and the implementation effort are focused on reporting genetic test results performed using sequencing or genotyping technology for the identification of DNA sequence variations contained within a gene [23]. To our knowledge, no similar work has been done or is ongoing for exchange of cytogenetic test results. The development effort that we describe in this article aims to fill the gap in existing standards for cytogenetic test result reporting.

3 Formulation process

After receiving IRB approval, we obtained patient de-identified sample result reports for constitutional cytogenetics analyses from ARUP Laboratories. The sample result reports were chosen so they would cover tests that were performed using different types of cytogenetic techniques including G-banding, FISH, and arr. The sample reports also represented a variety of results, including normal, abnormal, and "findings of unknown clinical significance". We also obtained test names from the ARUP online test menu. We analyzed the sample result reports and extracted a list of key data elements that existed in the reports. Before we made any new LOINC terms, we first created information models that capture the semantic relationships of these data elements. The information models were then used to guide the systematic creation of the LOINC codes.

To ensure that the information models and the LOINC codes that would be developed could be generalized to other institutions besides ARUP, we contacted two other

large cytogenetics laboratories in the country to request the same variety of sample patient de-identified test names and result reports from them. We received sample reports from the Mayo Clinic Cytogenetics Laboratory (Mayo) as well as the Emory Cytogenetics Laboratory (Emory). The sample result reports for each laboratory were analyzed, and their key data elements were also extracted. We evaluated the new data elements and new relationships that were identified in the Mayo and Emory reports, which did not exist in the ARUP reports, and analyzed whether the information model required modification to accommodate the new data elements.

After we had established the information models for cytogenetic test results based on reports from these three cytogenetics laboratories, we compared the cytogenetics model with the HL7 V2 Genetic Variation model. The goal was to reuse the common structure and the existing LOINC codes that are defined in the Genetic Variation model as much as possible.

In the end, we created proposed LOINC codes for unique data elements that were contained in the cytogenetics models. Following the same strategy that was used to develop the HL7 V2 Genetic Variation Model, LOINC panel codes were created to represent the hierarchical structures implied by the reports. To avoid proposing creation of duplicate codes in the LOINC database, the LOINC database was searched thoroughly beforehand, and any potential matching codes were analyzed to see whether they fit our needs and should be reused. The LOINC codes have been accepted by the LOINC Committee and are included in version 2.34 of the LOINC data base that was released in December 2010.

4 Model description

We created three information models based on the sample clinical reports from ARUP, Mayo, and Emory cytogenetics laboratories. Figures 1 to 3 show the information models for conventional chromosome studies using G-banding, FISH studies, and arr studies respectively. The information models contain data elements such as chromosome analysis result and chromosome analysis overall interpretation. We did not include the specimen type as an attribute in the information models, since specimen is represented by one of the six LOINC axes and the LOINC code is carried in HL7's observation identifier. We have also excluded standard data elements, such as patient date of birth, administrative sex, and specimen collection date, which are a routine part of laboratory reporting, and are carried by dedicated fields in segments that are a routine part of an HL7 observation message, rather than as separate OBX segments identified with specialized LOINC codes. Because ISCN descriptors can change over time, accurate interpretation of cytopathology reports requires knowledge of the ISCN version number used to generate the report. We have not had to include the ISCN version number in our information model for cytogenetics reports because the version of a code system is part of the internal structure of the HL7 "coded with exception" (CWE) data type. Because of the changes in the ISCN coding system over time, the receiving EHR system will also have to keep the ISCN version number with cytogenetics test results it stores in the CDR.

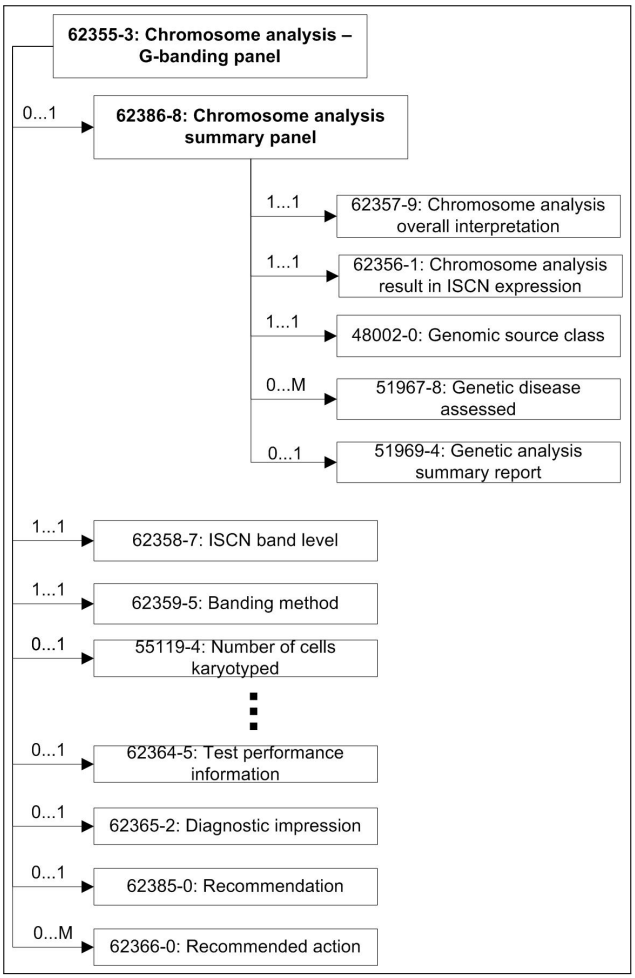


Figure 1: Chromosome analysis G-banding panel.

We created a set of nested LOINC panel codes that define the hierarchical structure of the results. The overall parent is, "Chromosome analysis master panel in Blood or Tissue" (LOINC # 62389-2). It contains three panels which define, respectively, the results of a G-Band, FISH and arr study: "Chromosome analysis panel in Blood or Tissue by Banding" (LOINC # 62355-3), "Chromosome analysis panel in Blood or Tissue by Fluorescence in situ hybridization" (FISH) (LOINC # 62367-8) and "Chromosome analysis microarray copy number change panel in Blood or Tissue by arrCGH" (arr) (LOINC # 62343-9). The LOINC terms within the each panel carry data types, cardinalities and descriptions. For LOINC terms that have categorical values, we also created pre-defined answer lists. As shown in Figure 4, the chromosome analysis master panel contains at least one of the G-banding, FISH, or arr copy number change panel, and a required chromosome analysis summary panel. The master panel allows the laboratory to report results of individual G-

banding, FISH, or arr copy number change test results alone, or as two or more of the three tests combined.

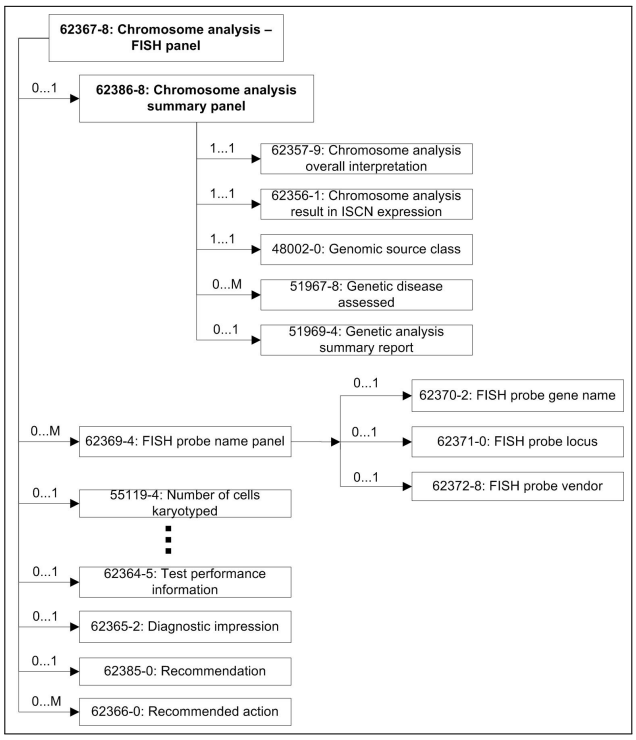


Figure 2: Chromosome analysis FISH panel.

The chromosome analysis summary panel must contain one chromosome analysis overall interpretation, which is the overall interpretation of the test. A LOINC answer list, whose values can be "normal", "abnormal", or "clinical significance unknown", is provided with this code. The master panel contains one genomic source class, whose LOINC code has an answer list with coded values such as "germline", "somatic", and "prenatal". The summary panel may have zero to many genetic disease assessed elements, and an optional genetic analysis summary report element. The summary report permits the lab to send a traditional narrative report embedded in the message. The chromosome analysis summary panel beneath the master panel will always report the overall summary of the test results. If only one method (G-banding, FISH, or arr) is used during the chromosome analysis, the optional chromosome analysis summary panel that is contained under each G-banding, FISH, or arr copy number change panel should not be used. For a given test, if multiple methods are applied, then the chromosome analysis summary panel at the higher level would allow an overall summary to be presented, and the chromosome analysis summary panel at the lower levels of each multiple method will allow summary at individual levels to be reported. The summary panel must also contain a chromosome analysis result in ISCN expression; i.e., a cytogenetics test result defined in the ISCN syntax - which provides precise, unambiguous descriptions of the cytogenetic findings. For example: "46,XX", which indicates a normal female; and "47,XY,+21", which indicates a male with trisomy 21 (an extra copy of chromosome 21, commonly known as Down syndrome). These are the two simplest examples; the ISCN notation for arr copy number change and FISH results can be quite lengthy and include precise breakpoint designations at the detailed level of individual base-pairs. For example, "arr 20q13.2q13.33(51,001,876-62,375,085)x1,22q13.33(48,533,211-49,525,263)x3" is an ISCN notation for a microarray analysis that shows a single copy loss on 20q and a single copy gain on 22q [17].

In addition to the summary panel, G-banding, FISH, and arr copy number change panels include discrete information that is specific to the technique. For example, it is important to report the human reference sequence assembly release number for an arr analysis. This indicates which version of the human assembly was used for the analysis.

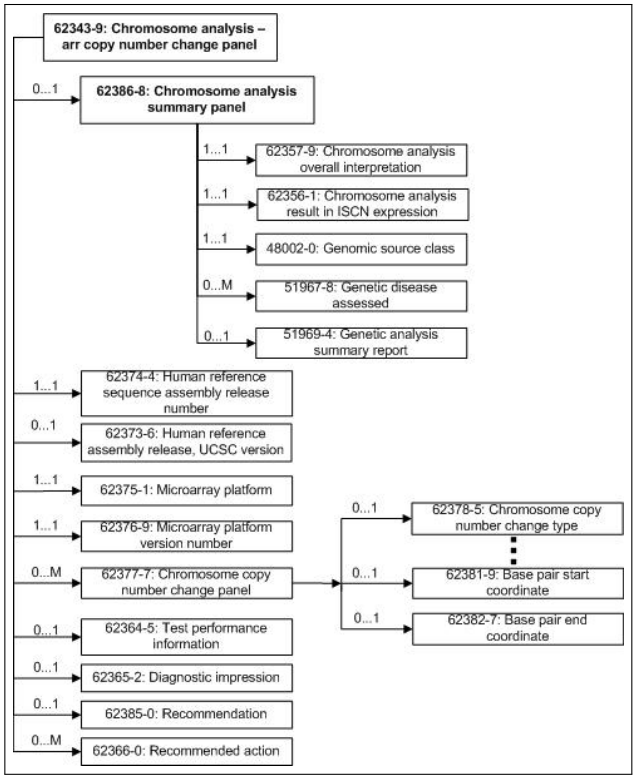


Figure 3: Chromosome analysis arr copy number change panel.

5 Validation through example

We formed HL7 version 2.5.1 standard messages based on the LOINC codes that we developed to represent the content of sample cytogenetic reports from three laboratories: ARUP, Emory, and Mayo. Figure 5 shows the HL7 version 2.5.1 representation of the G-banding chromosome analysis report presented in Figure 6. Figure 7 shows the HL7 v2.5.1 message for the arr report of copy number changes presented in Figure 8.

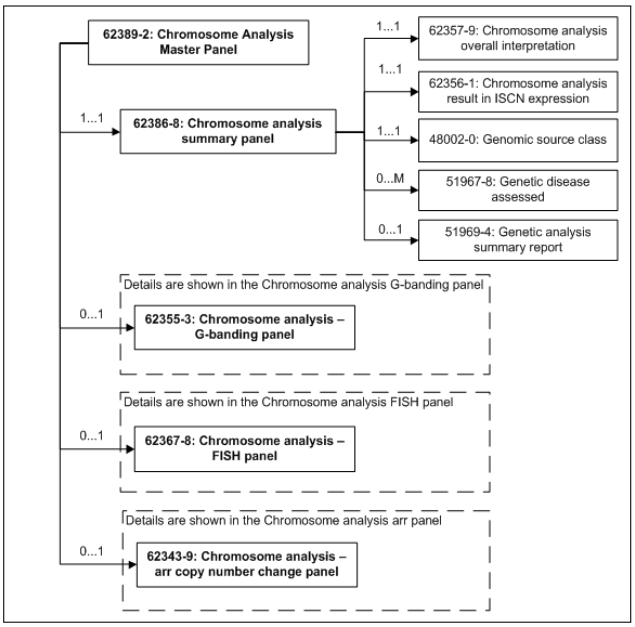


Figure 4: Chromosome analysis master panel.

OBR|1||PO-1000^ARUP|200291^Chromosome analysis chorionic villus sampling^99ARU-ORDER-TEST-ID||20100702000000|20100702100909|||||201070201410||12345^Dr.Jones||||| 20080703000000|||F|||||^Fetal demise|||||||||||||| 62389-2^Chromosome analysis master panel^LN

SPM|1|||^Placental tissue - Villi||||||||||20100702100909

OBR|2||PO-1000-1^ARUP|62355-3^Chromosome analysis G-banding^LN||20100702000000 |20100702100909|||||201070201410||12345^Dr.Jones |||||201070201410|||F||||PO-1000^ARUP

OBX|1|CWE|62358-7^ISCN band level^LN||LA14112-9^425^LN|||||F |201070201410|||||||||ARUP Laboratories

OBX|2|CWE|62359-5^Banding method^LN||LA14013-9^G-banding^LN|||||F |20080702100909|||||| ||||ARUP Laboratories

OBX|3|NM|62361-1^Numer of cells counted^LN||20|||||F|201070201410 |||||||||ARUP Laboratories

OBX|4|CWE|62366-0^Recommended action^LN||LA14020-4^Genetic counseling recommended^LN| |||||F|201070201410|||||||||ARUP Laboratories

OBX|5|FT|62385-0^Recommendation^LN||1. Genetic counseling. 2. Monitor subsequent pregnancies with prenatal diagnosis|||||F|201070201410|||||||||ARUP Laboratories

(... more OBXs could be placed here to represent other information in the G-banding panel...)

OBR|3||PO-1000-2^ARUP|62386-8^Chromosome analysis summary panel^LN||20100702000000 |20100702100909|||||201070201410||12345^Dr.Jones |||||201070201410|||F||||PO-1000^ARUP

OBX|1|CWE|62357-9^Chromosome analysis result overall interpretation^LN||LA12748-2^Abnormal^LN|||||F|201070201410|||||||ARUP Laboratories

OBX|2|CWE|62356-1^Chromosome analysis result in ISCN expression^LN||47,XY^^2.16.840.1.113883.6.299^^^^2005|||||M|201070201410|||||||ARUP Laboratories

OBX|3|CWE|48002-0^Genomic source class^LN||LA6683-3^Prenatal^LN|||||F| 201070201410 |||||||||ARUP Laboratories

(... more OBXs could be placed here to represent other information in the summary panel...)

Figure 5: Sample HL7 version 2 message for chromosome analysis G-banded test result.

In a message, nested Observation Request (OBR) segments are used to reflect the LOINC panel structures. OBRs are nested via links expressed in OBR-29-parent field, the same technique used in the HL7 implementation guide for genetic variation results [23]. The LOINC codes contained in a panel correspond to the Observation (OBX) segments. Each new panel of observations begins with an OBR segment that carries the LOINC code for that panel and is followed by a series of OBX's, each of which carries the LOINC code (OBX-3 field), and the value (OBX-5 field). For example, to represent the overall interpretation that the arr chromosome analysis test is abnormal: OBX-3 holds the LOINC code for "chromosome analysis overall interpretation"; the concept for "Abnormal" is placed in OBX-5 as the value.

We picked 20 cytogenetics reports across a wide spectrum including FISH, G-banding, and arr to verify that the proposed HL7 version 2 message had a place for expressing all of the most important information in these reports. We dissected these result reports based on the LOINC panels and codes. By dissecting these reports, we were able to represent all of the key data elements contained in the result reports in coded and structured format using the information models and the LOINC codes that we developed.

Specimen received

Specimen type: Placental Tissue- Villi
Reason for referral: Fetal Demise
Test performed: Chromosome Analysis

Laboratory analysis

Number of cells counted: 20
Number of colonies counted: N/A
Number of cells analyzed: 10
Number of cells karyotyped: 10
ISCN Band level: 425
Banding Method: G-Banding

Chromosome results: 47,XY,+21

Diagnostic Impression:
Metaphase cells analyzed revealed a male chromosome complement with an additional chromosome 21 seen in each metaphase. These results are consistent with the diagnosis of Down Syndrome.

Recommendation:
1. Genetic counseling.
2. Monitor subsequent pregnancies with prenatal diagnosis.

Figure 6: Partial sample report of chromosome analysis G-banding.

6 Discussion

The Secretary of the Department of Health and Human Services stated at the American Health Information Community (AHIC) meeting on September 12, 2006, "...genomics will play an increasingly larger role in medicine, and now is the time to figure out how best to incorporate genetic information into e-health records, before multiple nonstandard approaches take hold" [25]. A survey published in 2009 has identified lack of standards for data elements, terminology, structure, interoperability, and clinical decision support rules as some of the major barriers and challenges to the integration of genetic/genomic information with clinical data [9]. As information and knowledge of genetics/genomics continue to rapidly expand, providers will require point of care education and

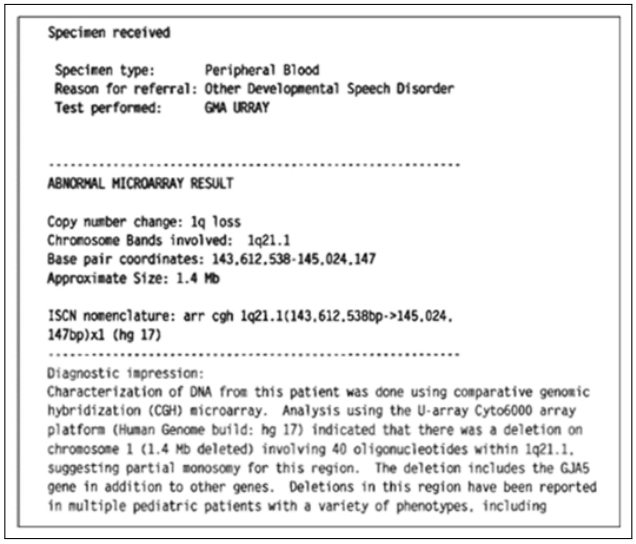
CDS system integrated into EHRs to remain current with the best practice guidelines and to take full advantage of genetic/genomic advances in medical practice. Our development effort has extended LOINC coverage for genetic sequencing test results to cytogenetics. The information models we created enable the transmission of structured constitutional cytogenetic test results electronically from the testing facilities to the ordering institution, for incorporation into the EHRs. Such integration could minimize the opportunity for misinterpretation of the results. And this can be done with existing HL7 messages and infrastructure.

```
OBR|1||PO-1001^ARUP|0040201^Genomic Microarray, U-Array Chip^99ARU-
ORDER-TEST-ID||20100702000000|20100702100909||||||201070201410
||12345^Dr.Jones|||||20080703000000|||F|||||^Other developmental speech||||||||||||||
62389-2^Chromosome analysis master panel^LN|
SPM|1|||^Peripheral blood||||||||||20100702100909
OBR|2||PO-1001-1^ARUP|62377-7^Chromosome analysis arr copy number
change panel^LN||20100702000000|20100702100909|||||201070201410|
|12345^Dr.Jones|||||201070201410|||F|||PO-1001^ARUP
OBX|1|CWE|62374-4^Human reference sequence NCBI build
id^LN||LA_X5^NCBI35^LN|||||F|201070201410|||||||||ARUP Laboratories
OBX|2|CWE|62375-1^Arr platform^LN||^U-Array
Cyto6000|||||F|201070201410|||||||||ARUP Laboratories
(... more OBXs could be placed here to represent other information in the arr
panel...)
OBR|3||PO-1001-2^ARUP|62386-8^Chromosome analysis summary
panel^LN||20100702000000|20100702100909|||||201070201410||12345^Dr.Jones|||||
201070201410|||F|||PO-1001^ARUP
OBX|1|CWE|62357-9^^Chromosome analysis result overall interpretation^LN
||LA12748-2^Abnormal^LN|||||F|201070201410|||||||||ARUP Laboratories
OBX|2|CWE|62356-1^Chromosome analysis result in ISCN expression^LN||arr
cgh 1q21.1(143,612,538bp->145,024,147bp)x1^^2.16.840.1.113883.6.299^^^^2005|
|||||F|201070201410 |||||||||ARUP Laboratories
OBX|3|CWE|48002-0^Genomic source class^LN||LA6683-2^Germline^LN|||||
F|201070201410|||||||||ARUP Laboratories
OBR|4||PO-1001-3^ARUP|62377-7^Chromosome copy number change
panel^LN||20100702000000|20100702100909|||||201070201410||12345^Dr.Jones|
|||||201070201410|||F|||PO-1001-2^ARUP
OBX|1|CWE|62378-5^Chromosome analysis copy number change type^LN||
LA14034-5^Deletion^LN|||||F|201070201410|||||||||ARUP Laboratories
(... more OBXs could be placed here to represent other information in the copy number
change panel...)
```

Figure 7: Sample HL7 version 2 message for chromosome analysis arr copy number change test result.

The standardization of genomic data representation is a vital component of a national CDS infrastructure to enable the widespread and consistent usage of genomic data and the practice of personalized medicine [10]. The information models and the set of associated LOINC codes that we created are an essential step toward the efficient use of molecular cytogenetics data in health care, decision support and research. By integrating structured test results and coded answers into a patient's EHR, best practice guidelines can be triggered for specific syndromes. Through research that tracks patient outcomes which have been correlated with genetic test results, we will be able to learn the significance of many kinds of findings. Uniformly structured genetic test results that use standard codes will enable the development and deployment of well-structured, informed, patient-specific, and genetic test specific education materials. The proper representation of genetic results will also allow development of professional publications and other online resources that can be delivered by the EHR to clinicians within the patient care work flow through integration with the infobutton standard [21, 26]. Secondary use of the combination of genetic, genomic, and clinical data as exemplified by the eMERGE project are also made possible by such integration [27].

Easy to read (clinician friendly) reports may improve patient care [28]. With structured and coded results, the receiving systems can customize the content and format of reports according to local preferences and the needs of different target audiences. For example, information that is most important to patient care such as results, clinical relevance of the tests, and recommendations can be placed at a prominent location in the report. Some laboratory technical information that is of less interest to the clinicians, such as number of cells analyzed, may be placed at a less prominent location in the report. In our LOINC panels, we created a LOINC code "recommended action", and the LOINC answer list for this code includes three values: genetic counseling recommended, confirmatory testing recommended, additional testing recommended. This structured and coded list is not part of the reports currently reported by the laboratories; we introduced this code to the cytogenetics LOINC panels with the hope that it would help promote clinician friendly reports.



```
Specimen received

Specimen type:       Peripheral Blood
Reason for referral: Other Developmental Speech Disorder
Test performed:      GMA URRAY


------------------------------------------------------------
ABNORMAL MICROARRAY RESULT

Copy number change: 1q loss
Chromosome Bands involved:  1q21.1
Base pair coordinates: 143,612,538-145,024,147
Approximate Size: 1.4 Mb

ISCN nomenclature: arr cgh 1q21.1(143,612,538bp->145,024,
147bp)x1 (hg 17)
------------------------------------------------------------
Diagnostic impression:
Characterization of DNA from this patient was done using comparative genomic
hybridization (CGH) microarray.  Analysis using the U-array Cyto6000 array
platform (Human Genome build: hg 17) indicated that there was a deletion on
chromosome 1 (1.4 Mb deleted) involving 40 oligonucleotides within 1q21.1,
suggesting partial monosomy for this region.  The deletion includes the GJA5
gene in addition to other genes.  Deletions in this region have been reported
in multiple pediatric patients with a variety of phenotypes, including
```

Figure 8: Partial sample report of chromosome analysis arr copy number change.

6.1 Challenges in Naming Genetics Test Orderable

Test order names are a special problem in genetics testing in general and molecular cytogenetics in particular because different laboratories use different naming styles and different names for the same meaning. For example, they variously use the syndrome name of interest, the test methods, the target specimen, and/or the targeted genome in their names. This situation creates a problem for ordering clinicians because the actual testing varies from laboratory to laboratory and within a single laboratory over time. NCBI is working to develop a database that intends to capture the fine details of genetic test procedures by laboratory to ameliorate this problem. We do not propose a set of standard names for genetic tests or-

ders in this proposal; rather, we propose a way to convey all of the relevant information about the test that was done and its results within the test report.

The severity of the problem with test order names varies with the method type. The test order names for a conventional banding technique are relatively consistent across laboratories. For example, conventional karyotyping order names are usually based on specimen type, e.g., blood or amniotic fluid. Order names for FISH tests vary the most. Some laboratories ask the ordering providers to first choose Chromosome Analysis FISH-Metaphase test on the test requisition form, and then provide a separate menu for choosing syndromes and or probes of interest (e.g., Williams syndrome, Cri-du-chat syndrome), but do not ask the user to identify the particular genomic sequences of interest. Other laboratories use the syndrome name, the method, and the genetic variation of interest, to name their tests (e.g., "Williams syndrome, 7q11.23 deletion, FISH" and "Cri-du-chat syndrome, 5p15.2 deletion, FISH" are shown as two different test names) [29]. The first approach, which names a test by independently combining the important semantic parts at the time of test order, could be described as a post-coordinated approach, and the second strategy of combining the various parts into a single test name prior to ordering could be described as a pre-coordinated approach. For the reporting of FISH test results, we chose the post-coordinated approach, because it is simple and flexible and requires the fewest number of codes to express the essential nature of the test. A zero-to-many FISH Probe Panel reports all the FISH probes used in a FISH test.

Because arr testing targets the entire genome, the naming of arr test orders is less complicated than for FISH testing, and typically needs only the type of specimen precoordinated with the arr platform (usually commercially purchased). The arr platforms do vary considerably by laboratory so our proposed reporting specification requires both the commercially obtained microarray platform and its version number to be recorded.

One of the efforts of International Standard Cytogenomic Array Consortium (ISCA) is to develop recommendations for standards for the design, resolution and content of the cytogenomic arrays, and the design is intended to be platform and vendor neutral [30]. And while the three laboratories we worked with happened to use the same arr platform, they have named their arr tests differently, e.g., "Genomic Microarray, U-Array Chip", "Chromosomal Microarray, EmArray 60 K", and "Array Comparative Genomic Hybridization (aCGH), Whole Genome, Constitutional" [31, 32, 33]. Without communication with the cytogenetics laboratories, clinicians and patients will not be able to determine whether these tests produce comparable results based on the test names alone. We created a platform and vendor neutral LOINC code to represent the arr test, chromosome analysis microarray copy number change panel, and allow for the differences in platforms to be described within the result message.

We encourage laboratories to employ the panel names we have proposed for organizing reports as order names where they apply, but they can also continue to use their local order names which will be included in OBR-4, Universal Service Identifier, for linking the report to the originating order, but continuing effort in the cytogenetics industry to standardize cytogenomic array design and their naming will be critical in improving interoperability in ordering.

6.2 Limitations

Our analysis of cytogenetic test names and results was not exhaustive. We requested sample reports and imports from additional cytogenetics laboratories, and received them from ARUP Laboratories, Emory Cytogenetics Laboratory, and Mayo Clinic Cytogenetics Laboratory. These are large and representative cytogenetics laboratories, which are active members of ISCA. We believe the information models and LOINC codes that we developed based on the sample result reports from these three laboratories are applicable to cytogenetic result reports from all other cytogenetic laboratories; evaluations including more institutions will be needed to substantiate this assertion.

7 Conclusions

We have described how the LOINC codes for representing cytogenetics result reports were developed. The sample result reports can be dissected based on the LOINC panel structures, and can then be transmitted through HL7 v2.x messages in a coded and structured way using these LOINC codes.

The proposed LOINC codes met our objective and will allow the use of well established health informatics standards to exchange coded and structured cytogenetic test results between testing laboratories and ordering institutions. Use of standard structures and terminologies for cytogenetic results is critical for effective communication between testing laboratories and clinicians. This minimizes misinterpretation, leads to consistency, and provides the EHR systems flexibility in customizing report formats to present more clinician-friendly reports.

8 Acnowledgements

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Surveillance system using HL7 CDA in Korea

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Abstract

Objective: The current process for reporting infectious disease in Korea is a complex workflow based on manual entry and verification of data and requires transmission of report via obsolete technologies such as FAX. As such, it incurs unnecessary time and effort that hinder real time monitoring of epidemic outbreak. Further, the lack of standardized coding of data in the report makes it difficult to manage and analyze the data from different sources. We propose an interoperable infectious disease reporting system based on HL7 standards that simplifies the reporting workflow and enables near real time reporting in Korea. **Method:** We first analyze the current process of infectious disease reporting in Korea and identify its shortcomings in detail. Next we analyze KRFID (Korea Report Form of Infectious Disease) and related regulations to draw a data architecture design. Finally we take existing HL7 CDA implementation guides such as PHIN and Healthcare Associated Infection (HAI) Reports Template and conduct a comparative analysis to derive our design of CDA. **Result:** The final design of CDA consists of Patient and Infection sections. The Patient section includes 4 entries and the Patient section has 6 entries. KRFID is composed of 24 data items, of which 14 are included in the CDA header and the other in the body. The value of each entry is encoded using either SNOMED-CT or LOINC. **Conclusion:** The system we developed enables fast reporting by eliminating unnecessary workload and delays. In the reporting process, the steps for manual entry, printing a form, and sending it via FAX at healthcare providers can be omitted and the procedure in which employees at Regional Health Centers manually enter data through KCDC web portal can also be removed. The system also offers interoperability by using international standards. Specifically, we adopted HL7 CDA for the report form and LOINC and SNOMED-CT for encoding data. Finally, due to the regulatory requirement that all infectious disease reports should be documented and archived, the adoption of CDA as the electronic format of KRFID satisfies the regulation as well as the need for real time monitoring of infectious diseases in Korea.

Keywords

HL7, Surveillance, CDA, XDR, Interoperability

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1 Introduction

Due to advanced means of transportation and urbanization of societies, the spread of infectious diseases gets faster and faster nowadays and the importance of real time monitoring of such diseases becomes even bigger to prevent disastrous pandemic. At present, the regulatory process for reporting diagnosed infectious diseases in Korea [1] involves manual entry of data, paper-based reporting formats, obsolete delivery methods such as FAX, and a redundant two stage reporting (from healthcare providers to Regional Health Centers and back to KCDC (Korea Centers for Disease Control & Prevention)).

Although a recent effort to modernize the process includes a web portal at KCDC allows that the reporting from Health Centers to KCDC can be done via internet, yet it requires manual entry of data, failing to use available electronic health records (EHRs). All these factors contribute to delayed reports and prevention of effective and real time monitoring of infectious diseases.

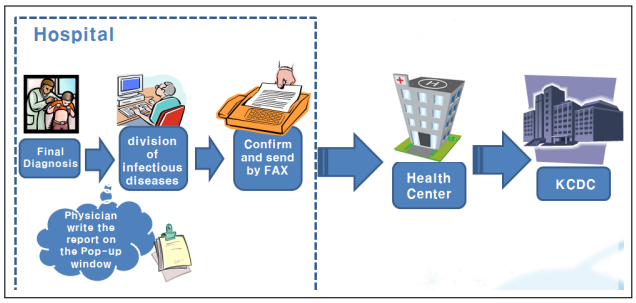

Figure 1: Workflow of infectious diseases report

Another problem with the current reporting process is that there is no regulatory requirement about the terminology and coding system for data included in the reports and it makes hard to process and analyze the data. The regulation also requires that all reports must be archived in the paper form at Regional Health Centers which should be taken into consideration in the design of new system.

In this paper, we design a new electronic infectious disease reporting system that addresses all the above issues with the current reporting process. The system offers a high level of interoperability by adopting international standards including HL7 CDA [2], SNOMED-CT (Systematized Nomenclature of Medicine – Clinical Terms) [3], and LOINC (Logical Observation Identifiers Names and Codes) [4]. It is anticipated that the new system can help establishing a new regulatory process for infectious disease reporting and reduces the cost and time for end-to-end reporting, leading to effective and near real time monitoring and surveillance of infectious diseases.

Korea Report Form of Infectious Diseases						
Personal data	Name	Kil-dong Hong	Social Security number	890101-123456DB		
	Phone Number	0531111234	Occupation	Student	Gender	Male
	Address	Deagu Korea				
	Unknown address	X	Unidentified	X		
Name of disease	Cholera					
Onset date	20111201		Diagnosis date	20120101		
Test result	test not done					
Patient Type	Confirmed		Inpatient or out patient	inpatient		
Contact with	Infected group		Infection location	Internal	X	
				Abroad	Country	China
					Period	2month
Death or not	Alive	Y	Death reason			
Optional record	Remarks					
	Facility code	123456				
	Doctor name	Henry	License numbers	123456		
Facility name	Kyoung-pook hospital		Facility director	Jhon		

Figure 2: CDA KRFID

2 Methods

We first analyze the current process of infectious disease reporting in Korea and identify its shortcomings in detail. The regulatory procedure for reporting in Korea is as follows. First, a physician upon detecting of an infectious disease reports to the QI (quality improvement) department. Second, the staff of the QI department reviews and confirms the report. Third, the QI department reports it to a Regional Health Center, using a fax, an e-mail or a paper format. Next, the Regional Health Center sends the report to the KCDC. The whole process is illustrated in Figure 1.

Next we analyze KRFID (Korea Report Form of Infectious Disease) [5] and related regulations to draw a data architecture design. There are 2 types of public health reporting (immediately and within 7days). And each type has a report form. In this paper, we are handle the immediately reporting type that requires near real time reporting.

Finally we take existing HL7 CDA implementation guides such as Healthcare Associated Infection (HAI) Reports Template [6] and Consolidated CDA Templates [7] and conduct a comparative analysis to derive our design of CDA. Table 1 lists the data items of KRFID and CDA location. The data items are coded using either LOINC that is a database and universal standard for identifying medical laboratory observations; or SNOMED-CT that is a systematically organized computer processable collection of medical terminology covering most areas of clinical information such as diseases, findings, procedures, microorganisms, pharmaceuticals etc.

Table 1: Lists the data items of KRFID and CDA location

Data items	CDA location
Name Parent name Social security number Phone number Gender Address Zip code Facility code Doctor name Facility name Director of Facility	CDA head
Patient occupation Name of disease Onset date Diagnosis date Test result Patient type Contact with Infection location Reason of death Remarks	CDA body

3 Results

We started with the list of data items defined by the PHIN messaging guideline, which is compared with that of KRFID. We first noted that insurance-related data are

not required by KRFID, which are, therefore, removed from out list.

Table 2: Data items coded using LOINC

Data items	LOINC codes
Name of disease	29308-4 / Diagnosis
Problem location	56824-6 / Problem location
Remarks	51855-5 / NOTE

We next applied LOINC to code the newly added data items. Codes for only three data items (name of disease, problem location, and remarks) were found in LOINC, which and their corresponding LOINC codes are listed in Table 2. For those data items that could not be LOINC-coded, we applied SNOMED-CT. These data items include patient status, patient care status, test result and contact with. Table 3 lists the data items and their corresponding SNOMED-CT codes.

```
<title>Korea CDC report</title>
<effectiveTime value="20000407130000+0500"/>
<confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N"/>
<languageCode code="en-US"/>
<recordTarget>
    <patientRole>
        <id extension="710101-1111111" root="2.16.840.1.113883.19.5"/>
        <patient>
            <name>
                <given>Kil-dong Hong</given>
                <family></family>
                <suffix/>
            </name>
            <administrativeGenderCode codeSystem="2.16.840.1.113883.5.1" code="M"/>
            <birthTime value="19320924"/>
        </patient>
        <providerOrganization>
            <id root="2.16.840.1.113883.19.5"/>
            <name>Kyoung-pook hospital</name>
        </providerOrganization>
    </patientRole>
        <assignedPerson>
</recordTarget>
<author>
    <time value="20000407130000+0500"/>
    <assignedAuthor>
        <id root="20cf14fb-b65c-4c8c-a54d-b0cca834c18c"/>
            <name>
                <prefix>Dr.</prefix>
                <given>Robert</given>
                <family>Dolin</family>
            </name>
        </assignedPerson>
        <representedOrganization>
            <id root="2.16.840.1.113883.19.5"/>
            <name>Kyoung-pook hospital</name>
        </representedOrganization>
    </assignedAuthor>
</author>
<informant>
    <assignedEntity>
        <id nullFlavor="NI"/>
        <representedOrganization>
            <id root="2.16.840.1.113883.19.5"/>
            <name>Kyoung-pook hospital</name>
        </representedOrganization>
    </assignedEntity>
</informant>
```

Figure 3: CDA Header

The HL7 CDA developed in this study contains two sections: infection and patient. The infection section consists of four entries and the patient section has six entries. KRFID has 24 data items, 14 of them are included in the CDA header and 10 of them included in the CDA body. Table 4 presents the sections and entries of the CDA we developed. The name of disease, test result and infection location commonly include onset date, diagnosis date and travel period as effectiveTime. Since the reporting system only considers information on patients and their diseases, the CDA entry type is fixed to be "observation". We applied SNOMED-CT to encode values.

Fig 2 illustrates a CDA example to report a case of a patient named Hong Kil-doing, a student at age 23, living in the city of Daegu, Korea, who visited Kyung-puk hospital on January 1st, 2012 and was diagnosed a cholera. Figure 3 is the CDA header and Figure 4 is the CDA body showing entries of diagnosis and laboratory test result only, omitting the rest for presentation purpose.

Table 3: Data items coded using SNOMED-CT

Data items	SNOMED-CT codes
Patient occupation	184104002 / Patient occupation
Status	391741014 / Status
Patient care status	447503010 / Patient care status
Test result	2550471015 / Laboratory test result
Contact with	20251010 / Contact with

```
<section>
  <templateId root="2.16.840.1.11111.2.2"/>
  <!--  **  Infection section   ** -->
  <code code="67942010" codeSystem='2.16.840.1.113883.6.96'
    displayName="Infection"/>
  <title>Infection</title>
  <text>
    ...
  </text>
  <entry typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.11111.2.2.1"/>
      <code code="29308-4" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"  displayName="Diagnosis" />
      <statusCode code="completed"/>
      <effectiveTime value="20120101"/>
      <value xsi:type="CD" code="67942010"
      codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED CT"
      displayName="cholera"/>
      ...
    </observation>
  </entry>
  <entry typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.11111.2.2.2"/>
      <code code="2550471515" codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED CT"
        displayName="Laboratory test result" />
      <statusCode code="completed"/>
      <effectiveTime value="20120101"/>
      <value xsi:type="CD" code="1211635010"
      codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED CT"
      displayName="test not done"/>
      ...
    </observation>
</section>
```

Figure 4: CDA Body

4 Discussion

The system we developed enables fast reporting by eliminating unnecessary workload and delays. In the reporting process, the steps for manual entry, printing a form, and sending it via FAX at healthcare providers can be omitted and the procedure in which employees at Regional Health Centers manually enter data through KCDC web portal can also be removed. Figure 5 presents the new workflow of infectious disease reporting based on CDA.

The system also offers interoperability by using international standards. Specifically, we adopted HL7 CDA for the report form and LOINC and SNOMED-CT for encoding data. Finally, due to the regulatory requirement that

Table 4: CDA section and entry

Section	Entry	Remarks
Patient	Patient occupation Patient status Death observation Reason of death	
Infection	Name of disease Test result Patient type Contact with Infection location Remarks	Includes Onset date as effectiveTime Includes Diagnosis date as effectiveTime Includes Travel priod as effectiveTime

all infectious disease reports should be documented and archived, the adoption of HL7 CDA as the electronic format of KRFID satisfies the regulation as well as the need for real time monitoring of infectious diseases in Korea. [8]

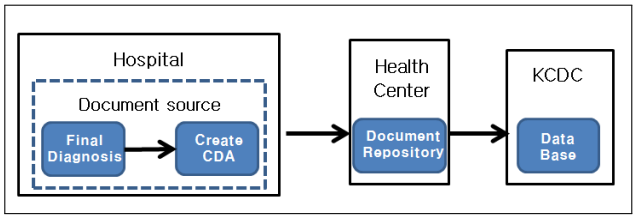

Figure 5: New workflow of infectious diseases report based on CDA

At present the application of the system is limited to the class of infectious diseases that are required to be reported immediately, but will cover the rest of diseases in the future. The current status of the project is final development stage and a pilot program to collect feedbacks and various usage statistics is being planned.

5 Acknowledgements

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An implementation guide for a CDA report about cardiopulmonary exercise testing (CPET) results in the Austrian health record

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Abstract

In this article we present an answer to the question how difficult might it be, to define a working CDA report that fulfills the requirements of the Austrian specifications of the nationwide electronic health record called ELGA. We chose the results of standardized cardiopulmonary exercise testing (CPET) results as an example document. We therefore analyzed existing documentation and interviewed sport scientists and medical doctors to find out how this type of medical documentation is best structured and what data must be and can optionally be included. We then worked out the appropriate elements of a CDA report for levels 2 and 3. Only one adaptation had to be made to the official Austrian health records stylesheet, which was necessary to be able to integrate scalable vector graphic (SVG) images. After this project we can conclude, that the time and technical effort to construct documents for the nationwide Austrian electronic health record is quite little. The biggest problem still might be to obtain a consensus of all involved parties when trying to define an official report, which was not necessary in our case

Keywords

Electronic Health Record, CDA level 2, CDA level 3, CDA report, implementation guide

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1 Introduction

Beginning with mid 2013 the Austrian minister of health will introduce a nation wide electronic health record (in German called "Elektronische Gesundheitsakte" or short ELGA). This is one of the cornerstones of the Austrian eHealth strategy [1]. It will start with only a few core applications like medication, and will be expanded during the following years with more aspects like laboratory results, radiology records, vaccination record, etc.

The ELGA will be based on international standards like HL7/CDA, LOINC and IHE profiles like XDS. Documents in these health records will be formatted according to CDA release 2. All documents in the ELGA must have a maximum level of compatibility. Therefore the agency in Austria to coordinate and facilitate the implementation – former ARGE ELGA, meanwhile called ELGA GmbH [3] – releases central implementation guidelines and stylesheets. This is valid for at least the header section of the documents. The bodies of the employed documents, the medical contents themselves, must be consistent with nationally harmonized implementation guidelines, which are to be derived from international guidelines.

This model enables interested parties, to develop nationwide harmonized report and document definitions for

each and every necessary or interesting medical case. The current ELGA model in Austria can also be seen and used as a toolbox, where you can get reference standards, implementation guides, etc., pick the appropriate header parts, define body elements according to the data to be stored and develop stylesheets to display the data correctly.

In this project we also enforced this strategy. We set our goal to find out, how easy or tricky it would be to generate a new sort of document that would be suitable to be integrated into the Austrian nationwide health record. We looked to choose a domain where there was no active development or already published standard available to date.

1.1 Cardiopulmonary Exercise Testing (CPET)

One domain that might be of interest – but is definitely not a typical core application of health records – are cardiopulmonary exercise tests, that give answers to questions about how capable a patient is to perform sportive activity that might require endurance.

During medical or sport scientific performance analysis tests on healthy subjects, athletes or patients, several physiological parameters are collected with different measurement instruments to be able to judge the performance and/or training state of the specific subject. Relevant physiological performance parameters are amongst others e.g. the heart rate (HR), blood lactate concentration (LaC) and spirometric data like O_2 intake (VO_2), CO_2 output (VCO_2) and total ventilation (VE), to name only a few.

Based on these parameters algorithms should be able to calculate so called individual aerobic and anaerobic thresholds. Since these thresholds are the results of a highly dynamical system – the human body during exercise – there are several algorithms available that might also yield different results.

The results of the analysis of these parameters and thresholds are the foundation for a decision about therapies in case of health problems (like intensity and amount of movement therapy) or about training suggestions for an aimed increase of physical performance ability for athletes or more generally, active persons.

2 Methods

This document contains a draft specification of the contents of the diagnostic findings for a cardiopulmonary exercise test. The draft focuses on possibly becoming a part of the Austrian health record currently in development.

There a two official main foundations for this document. First, the central document "Implementation Guideline for CDA documents of the Austrian health care system" [2]. And second, we chose to use the "CDA laboratory report for the Austrian health care system – addendum to the implementation guideline" [4] for the structuring of the diagnostic findings according to CDA level 2 and 3.

2.1 Human readable vs. machine readable: CDA Level 2 or Level 3

CDA documents must be readable for human readers as a matter of principle. This is basically valid for all contents that have been signed and authorized by the creator. Technically, this has been implemented via the so called CDA text level ("Level 1") and section level ("Level 2").

Additionally, CDA documents can also contain coded parts that are meant for further automated machine processing, e.g. for the automatic generation of diagrams from data coming from findings that had been created at different points in time, like trends. These machine readable parts are technically placed in the so called CDA entry level ("Level 3") as a part of the documented findings.

The header on the one hand contains administrative data, like common information about the document, personal data of the patient, etc. and on the second hand is used partly also as a source for meta data, that are necessary for the registration of the document in the ELGA. The header of our document has already been designed to be compatible with the to date published documents of the ELGA. The relevant parts for the findings of the cardiopulmonary exercise tests are contained in the so called body of the document.

The specification at hand for these findings has been developed in cooperation with the sport scientific laboratory of the Graz University of Applied Sciences. Additionally medical doctors for sports medicine have been interviewed, to validate the documentation contents. The whole project was carried out at our department in collaboration with students. The project was basically divided into two phases: first, the determination of relevant data and second, the development of the guideline itself.

In the first phase, we interviewed several sport scientists and analyzed current documentation of cardiopulmonary exercise tests. Since not every sport scientific laboratory uses the same equipment, the data being collected is quite different, in terms of which data is being collected at all. Some are measuring only the heart rate, others additionally blood lactate, more rarely spirometric data is collected too. Starting with these raw values, the questioned individual aerobic and anaerobic thresholds can be calculated. All these data had to be coded according to the requirements of HL7. The results and details of this work will be reported in section 3.

In the second phase of the project, the coded elements were structured and combined in our implementation guideline. In the end, we had to adapt the more general XSL- and XSD-documents a little to be able to present our specific CDA-reports properly.

For our cardiopulmonary exercise test reports the following documents are of primary interest as a foundation:

- CDA documents for the Austrian health care system – implementation guideline: basic guideline about the structure of CDA documents in Austria (in the following briefly called "CDA-guideline") [2]
- CDA laboratory report for the Austrian health care system – addendum to the implementation guideline: extends the CDA-guideline with those specifications that are necessary for the creation of a laboratory report as a CDA document ("laboratory-guideline") [4]
- ELGA reference stylesheet 1.01.009 RC: basic stylesheet for the human readable presentation of CDA documents in a browser ("CDA-style") [5]

3 Results

In this section we present and discuss the possible contents of a CDA document for cardiopulmonary exercise test results. For every single test result section we identified and documented the following information:

- definition of the data to be stored
- design of a possible later presentation in the browser
- possible coding of the data in the CDA document (example of structure) – for CDA level 2 and level 3 respectively
- possibly a necessary adaptation of the existing XSL document (for the human readable presentation in the browser)

To be able to report about our CDA implementation on only a few pages, a lot of information had to be omitted in this report. A more detailed version is available from the corresponding author. In the following subsections and paragraphs we will basically only describe the kind and amount of data that has to be stored to represent a complete cardiopulmonary exercise test result. We at least describe how we would suggest to code the data respectively, but have to omit every detail about the browser presentation or the actual coding in CDA level 2 or level 3.

3.1 CDA Header

Many elements in the header section of a valid CDA document are already predefined in the official Austrian CDA-guideline mentioned earlier in this report. All of these elements are also marked as required in the header and will not be further described. These elements are:

- the root element
- the realm of the document („realmCode")
- document format („typeId")
- document-ID („id")
- code for the confidentiality of this document („confidentialityCode")
- code for language in which the document had been written („languageCode")

The following paragraphs describe the header elements that we had to define ourselves. All of the elements following in this section are also part of the document header:

Template („ClinicalDocument/templateId") The template defines the sum of limitations of this specification in relation to the CDA R2 standard. Because findings of cardiopulmonary exercise tests are currently not seen as a part of the ELGA, we are not able to give a specific definition of the "templateId". Probably, the "templateId" of CDA documents coming from cardiopulmonary exercise tests will also be included in the structure of ELGA core application Ids, like it is stated in the CDA-guideline, section 6.2.5.
Optionality: [R] [1..1]

Document class („ClinicalDocument/code") The document class we use for our reports is the one of the „PERSONAL HEALTH MONITORING REPORT".
Optionality: [R] [1..1]

Document title („ClinicalDocument/title") The title of the document can be freely chosen by the document creator and describes the kind of document in more details. The meaning of the title has to be chosen according to the document classes. In most cases the title will be e.g. "Cardiopulmonary Exercise Test".
Optionality: [R] [1..1]

Document date („ClinicalDocument/effectiveTime") The date of the creation of the document. The moment in time, when the document had been edited the last time.
Optionality: [R] [1..1]

Versioning of the document („setId" und „versionNumber") According to the specifications in the CDA-guideline a versioning is required for all documents.
Optionality: [RO]

Patient („ClinicalDocument/recordTarget") To represent the patient, we adapt the specifications and structures from the laboratory-guideline (section 5.3.1 - patient). To be able to specify a possible sport club where a patient could be a member of, the element "patientRole" can be extended by an element "providerOrganization". This element is subject to the specifications of the CDA-guideline (5.11.1 – POCD_MT000040.Organization).
Optionality: [R] [1..1]

Creator of the document („ClinicalDocument/author“) Here again, we take the specification and structure from the CDA-guideline (6.3.2 – creator of the document). The author is the very person, who has authored the content of the document, not necessarily its writer (i.e. the author is the person who dictates a document, whereas the writer would be the person who types it).
Optionality: [R] [1..*]

Custodian of the document („ClinicalDocument/-custodian“) In each document it has also to be stated which organization is responsible for the custody and storage, including the archiving, etc. of the document. Also here, we take the specification and structure from the CDA-guideline (6.3.4 – custodian of the document).
Optionality: [R] [1..1]

Legal Authenticator („ClinicalDocument/legalAuthenticator“) The legal authenticator is the person who takes over the legal responsibility of the contents of the document. This is also not necessarily the author. Again we borrow the specification and structure from the CDA-guideline (6.3.6 - legal authenticator).
Optionality: [R] [1..1]

Service Events („ClinicalDocument/documentationOf/serviceEvent“) The element "documentationOf", represents the actual health care service, that is being represented in the document. This element is in a close relationship with the document type: with this element the health care service can be specified, but it must not lead to a contradiction with the document type. Here we borrow the specification and structure from the CDA-guideline (6.5.1 - service events).
Optionality: [O] [0..*]

3.2 CDA Body

In the body we place all the elements that contain the real data from the cardiopulmonary exercise tests and its results, whereas the header mainly comprises meta data for the document itself. The contents of these elements now, are the results from our investigation of documentation coming from cardiopulmonary exercise testings for performance analysis. We discussed these findings with several sport scientific laboratories and medical staff, to gain a more common view on the necessities of the documentation.

3.2.1 General data of the examination

Opt	Element	Description
[R]	date	date of the examination
[R]	protocol	how has the examination taken place, which performance protocol had been used
[R]	parameter	which examinations had been done

3.2.2 Personal data

Opt	Element	Description
[R]	height	physical height
[R]	weight	physical weight
[RO]	BMI	body mass index
[O]	bodyfat	the total bodyfat of the patient

The body mass index can be calculated from the physical height in centimeters and weight of a body in kilograms and is defined as

$$BMI = \frac{weight}{height^2} \quad (1)$$

The problem with the element bodyfat is that the value can vary extremely, depending on which measurement method had been used.

3.2.3 Calculated Values

Opt	Element	Description
[R]	heartrate	heartrate 3 minutes after stop
[R]	relative performance	fraction of heartrate after stop to maximum heartrate
[R]	relative maximum performance	relative maximum performance in relation to the body weight
[R]	blood lactate	resting blood lactate level
[RO]	maximum oxygen intake	maximum oxygen intake in liter/minute
[RO]	maximum relative oxygen intake	relative maximum oxygen intake in ml/kg/min

In this section one can find rather self explanatory elements, that are either direct results of measurements, like the heartrate three minutes after stopping and the resting blood lactate level, or that had to be calculated or set in relation to other values, like the relative maximum oxygen intake, that depends on the bodyweight.

3.2.4 Thresholds and maximum values

Opt	Element	Description
[R]	maximum performance	maximum performance, maximum heartrate and maximum lactate
[R]	aerobic threshold	performance, heartrate and blood lactate at the aerobic threshold
[R]	anaerobic threshold	performance, heartrate and blood lactate at the anaerobic threshold

There are very many possibilities to calculate or estimate both, the aerobic and the anaerobic threshold. For this guideline we have only defined a few codes to specify the methods of computation and protocols. See subsection 3.2.7 for a coarse overview of our defined codes. For further methods of calculation or performance test protocols, additional codes must be specified. An expression of this element with sample values can be seen in Figure 1. Since our stylesheet has been developed for the Austrian health record and there is currently no automated multi-language support, the output is available in German language only, but a coarse description in English is given in the caption of the figure.

Schwellen- und Maximalwerte

	Leistung (Watt)	Herzfrequenz (1/min)	Laktat (mmol/l)
Maximalleistung	360	184	12.8
Aerobe Schwelle			
Laktat (2 mmol/l)	209	150	2
Laktat (LTP1)	188	142	1.7
Anaerobe Schwelle			
Laktat (4 mmol/l)	266	168	4
Laktat (LTP2)	268	168	3.9
Herzfrequenz (HRT)	267	168	3.9

Figure 1: An example of the output of our stylesheet (available in German only) for the CDA body element "thresholds and maximum values". The three columns with numbers display values for the actual performance power, the heartrate and the blood lactate level calculated at different performance levels (rows), like maximum level, at a blood lactate of 2 mmol/l, at the individual aerobic threshold (LTP1), at a blood lacate level of 4 mmol/l, at the individual anaerobic threshold (LPT2) and via the heartrate deflection.

3.2.5 Training intervals

Opt	Element	Description
[R]	interval training	development of competition specific endurance
[R]	endurance method intensive	mixture of aerobic and anaerobic energy supply
[R]	endurance method medium	development of the anaerobic threshold (endurance performance level)
[R]	endurance method extensive	development and stabilization of fundamental endurance
[R]	endurance method regenerative	support of recovery process

Based on the results of the cardiopulmonary exercise test, sport scientists or doctors are able to suggest training intervals for the patients or athletes. In CDA level 3 we represent these suggested training intervals with the element "referenceRange". The suggested training duration is represented via the element "effectiveTime" with separate values for "high" and "low". In case a training duration is or should not be given for a certain training interval the "effectiveTime" element remains empty. Figure 2 shows some sample values for this CDA body element. Note that the stylesheet also produces some explanations for the values, including literature references for better human readability. These explanations can be seen just beneath the table. Again, this figure is available in German only, but an English description is given its caption.

3.2.6 Raw data

The raw data values section comprises all measured values during the whole cardiopulmonary exercise test. That can well be several hundred values, since e.g. the heartrate is typically measured every 5 seconds, and such tests take about 10 to 20 minutes. Most often, several physical parameters are collected in parallel, also at different intervals. These data are stored differently in CDA level 2 and level 3: we refrain from storing individual values in level 2 – only a single image containing the plots of all parameters is stored, while in level 3 the values of all parameters are coded machine readable.

Trainingsbereiche

Traningsmethode	Herzfrequenz	Dauer
Intervalltraining (GB)	>168	
Dauermethode intensiv (EB2)	155 - 168	10 - 45 min
Dauermethode mittel (EB1)	143 - 154	30 - 90 min
Dauermethode extensiv (GLB)	132 - 142	bis über 90 min
Dauermethode regenerativ	<132	bis 30 min

Grundlagenbereich (GLB) - Entwicklung und Stabilisierung der Grundlagenausdauer; aerobes Ausdauertraining
Entwicklungsbereich (EB) - Entwicklung der anaeroben Schwelle (Ausdauerleistungsgrenze); gemischt aerobe und anaerobe Energiebereitstellung
Grenzbereich (GB) - Entwicklung der wettkampfspezifischen Ausdauer; überwiegend anaerobe Energiebereitstellung

Das Grundlagenausdauertraining[2)] ist in den Ausdauersportarten die vorherrschende Trainingsart. Die ideale Zusammensetzung der verschiedenen Trainingsarten für den Freizeitsport (nicht für Anfänger) ist folgende: GLB : EB1 : EB2 = 50 : 35 : 15

[2)] *Zintl, F. & Eisenhut, A. (2001). Ausdauertraining. Grundlagen, Methoden und Trainingssteuerung. München: BLV.*

Figure 2: The element "training intervals" filled with sample values and illustrated via our stylesheet. It gives recommendations in the form of heart rate ranges and training durations for different types of training. The German text beneath the table gives the human reader some explanations of the data above, including e.g. a literature reference. The second and third column shows the suggested heartrate and the duration of the specific training method, respectively. The five rows correspond with the five elements of the table at beginning of section 3.2.5.

According to the general Austrian stylesheet it is possible to include such images in a CDA document. In this case it seems to us, that an adaptation of this general stylesheet would be advisable, since it is not able to display SVG-images (scalable vector graphics). SVGs enable users to zoom in at all levels of highly detailed data without getting a blurred image. Example adaptations that would at least be necessary are given in Listing 1. An example of an included image can be seen in Figure 3.

Opt	Element	Description
[O]	image	a plot of all values is optional, since all individual values are coded in CDA level 3
[R]	heartrate	individual values of the heartrate must be coded in CDA level 3
[RO]	spirometric data	individual values of the spirometry must be coded in CDA level 3, when a spirometry had been done
[RO]	blood lactate	individual values of the blood lactate must be coded in CDA level 3, when blood lacate had been measured

3.2.7 PerformanceCDA codes (LCDAC)

Due to the fact that not all relevant examinations can be covered by an existing LOINC code, we had to make up our own codes for certain areas. When performance tests and their results should be comparable, one has to specify exactly what so called "protocol" had been used during the test (e.g. in which step sizes after which duration had the performance been increased?) and which algorithm had been used to calculate the individual thresholds. Since the number of algorithms and protocols is very exhausting, we can only give a coarse categorization of our defined codes here. We divided the codes into the following groups:

Group	Description
10.xx	Heart
20.xx	Oxygen intake
30.xx	Performance
40.1x	Threshold, aerobic
40.2x	Threshold, anaerobic
60.xx	Training recommendations
100.xx	Performance test protocol

To our best knowledge, also other established coding systems like the ICD CPT 94620/94621 code sets only give a coarse picture of which parameters had been obtained but can not included details about the specific realization of the test itself that is necessary to interpret the results correctly. Anyway, these codes could be specified additionally in future versions of this CDA.

4 Discussion

In this article we present the results of a project. The aim of the project was to give an answer to the question how difficult might it be, to define a working CDA report that fulfills the requirements of the Austrian specifications of the nationwide electronic health record called ELGA.

Given the frameworks and existing guidelines from the ELGA GmbH it turned out to be quite simple, as long as you work out a detailed enough specification the data of concern. Experts in this working area turned out to be invaluable helpers, when it comes to define the data needed and also the need of structure within these data. We began by taking e.g. some old – sometimes even handwritten – documents and analyzed them, including hints of sport scientists and doctors while reading the documentation (i.e. to get an explanation of which part of the data is really important).

Once the data and structure is worked out, the single elements can be quite easily defined. Most of the elements we needed to display in a browser later to more or less exactly represent the old documentation, were already contained in the public available CDA-stylesheet. Only one adaptation had to be done from our side, which was necessary to be able to integrate scalable vector graphic (SVG) images in the CDA.

Listing 1: In order to be able to insert SVG images (scalable vector graphics) into the document the stylesheet had to be extended with this little XML segment

```
<xsl:if test="//n1:observationMedia[@ID=\$imageRef]/n1:value[@mediaType='image/svg+xml']">
    <br clear="all"/>
    <xsl:element name="embed">
        <xsl:attribute name="src">data:
            <xsl:value-of select="//n1:observationMedia[@ID=\$imageRef]/n1:value/@mediaType"/>;base64,
            <xsl:value-of select="//n1:observationMedia[@ID=\$imageRef]/n1:value"/>
        </xsl:attribute>
    </xsl:element>
</xsl:if>
```

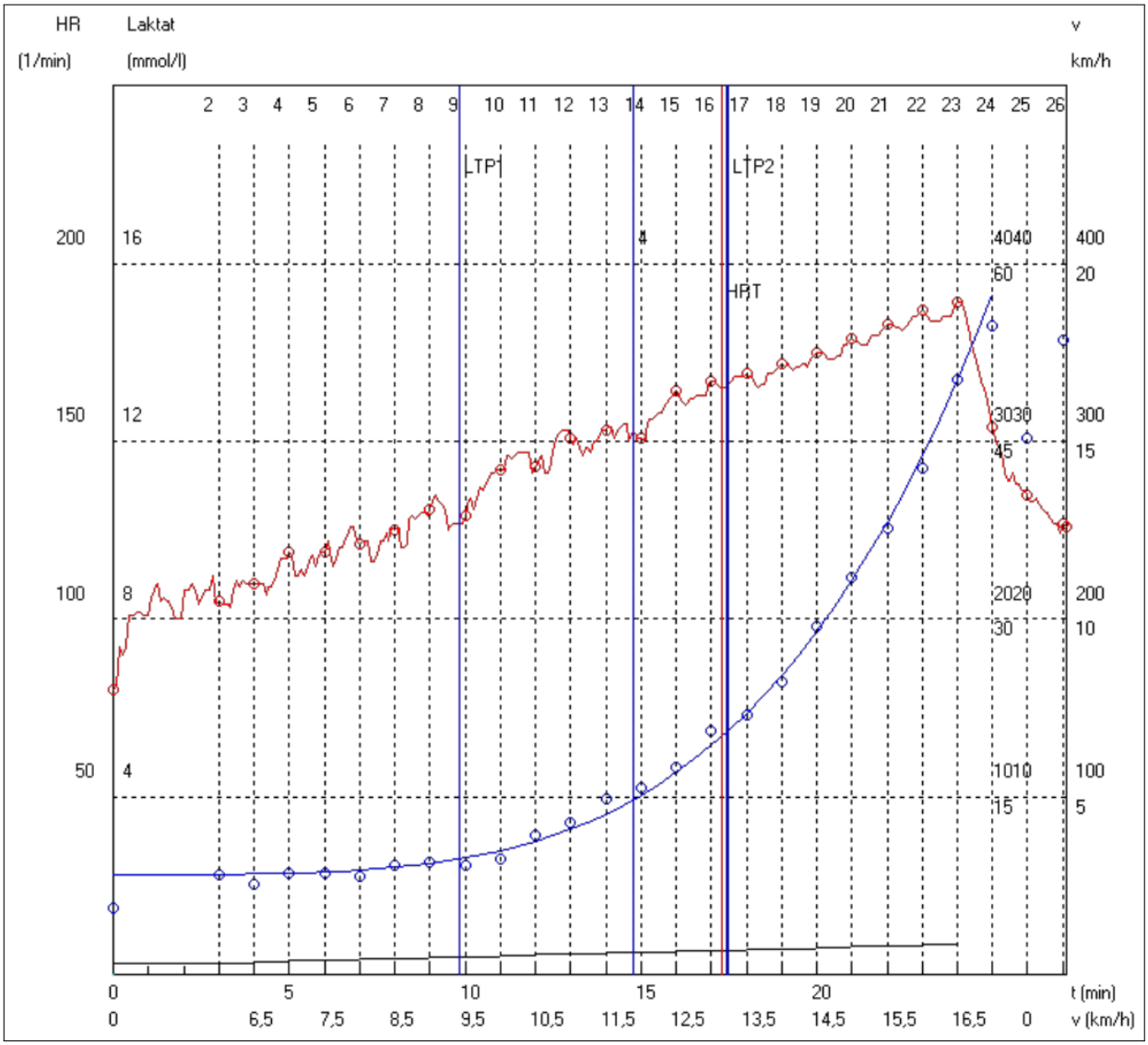

Figure 3: Example of an image included in the CDA document. Here, e.g. blood lactate (blue) and the heart rate (red) is plotted against the time. One can see the typical increase in both parameters – linear with a little knee for the heart rate and exponential for blood lactate – while increasing performance.

The next steps might be to try to really integrate this report type in the Austrian electronic health record, which would require a real need for this kind of documentation, successful balloting in HL7 work groups, and so on. But this was not the primary goal of this project, as we already stated at the beginning of this discussion.

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The Prototype of Standalone Diagnostic Report Editor as a Proof-of-Concept for an Interoperable Implementation of Health Level Seven Clinical Document Architecture Standard (HL7 CDA) not Integrated with Electronic Health Record (EHR) System

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Abstract

Objectives: The concept of the study was to investigate the possibility of HL7 CDA implementation in the environment with no EHR system. The potential business and operational limitations were taken into account. **Methods:** The standalone diagnostic report editor has been chosen as a proof-of-concept prototype for such implementation. The detailed functional requirements have been defined. **Results:** The prototype has been developed as a single HTML file, containing Javascript code and embedding CDA XML template, CDA XML schema definition and XSL transformation. **Conclusions:** The HL7 CDA based solution can be implemented in the environment with no EHR system. The concept of the standalone report editor has been proven as possible and reasonable.

Keywords

HL7 CDA, EHR system, Interoperability of EHR

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1 Introduction

The Health Level Seven Clinical Document Architecture (HL7 CDA) [1,2] is commonly accepted as the standard of electronic clinical document, but its use is rather limited to the well-developed countries. One of the obvious limitations to its widespread global use is relatively low number of EHR systems implemented in some countries or regions. EHR systems are often perceived as too expensive for small medical service providers, which results in paper based cooperation between health care providers possessing EHR systems and their smaller partners, like subcontractors of specialized medical services. The usual process is that the health care provider issues an order, including the referral document in paper form, to be realized by the subcontractor and then the service report document is delivered, again in paper form, to the referring organization. Both documents have to be delivered by patient. Additionally, the business requires that the subcontractor reports the service performance to the ordering organization in parallel process, often not supported by any system. The common worldwide practice of HL7 CDA implementation for referral documents [3, 4] assumes that both, the health care provider and its subcontractor, use the EHR system.

2 Objectives

Our concept was to investigate the possibility of fully interoperable implementation of HL7 CDA at small medical service provider organization, which has no EHR system implemented, to allow operational exchange of electronic medical documents with bigger partner with implemented EHR system. The investigation should take into account potential business or organizational limitations, which such implementation might face.

To prove the reason and possibility of the concept, we defined the objective of our work as to design the CDA document structure and to develop the prototype of standalone CDA document editor as a proof-of-concept. The proposed solution should meet the following criteria:

- minimum cost of software purchase and external services,
- no database system,
- no online connection during patient visit and document issue,
- no need of integration with any other systems,
- full compliance with the CDA standard and best practice of CDA implementation,
- interoperability based on CDA only, with no extensions, no templates or profiles agreed with the referring health care provider (intended recipient of the report),
- maximum use of data from available sources to minimalize the amount of data being entered by the user.

3 Methods

Diagnostic ultrasound has been chosen as an example of medical service, which may be ordered by health care provider using the EHR system, but performed by subcontractor possessing no EHR system of its own.

To support the electronic exchange of medical and business information between two partners, we have specified the following functional requirements for standalone editor of diagnostic ultrasound service report:

- Any CDA-conformant referral document can be opened from the local file system and visualized.
- The header data from the referral document are used to create (part of) the header data for the report document.
- The configurable template of report document determines the XML structure of CDA document and is a source of the header data related to the diagnostic service performer.
- The report document, prefilled with (some) header data, is edited by the service performer, but the amount of data required to be entered by the user, is minimal.
- After completion of the report, the final document is visualized in read-only mode for authentication.
- The generated report document is CDA-conformant.
- Both documents, the referral and the report, can be validated against CDA schema definition.
- The report document can be printed.
- The report document is stored in the local file system.
- The new version of the report document can be generated based on the report document opened from the local file system.

We assumed that both CDA documents, the referral and the report, will be delivered electronically by free to choose method, not supported by our prototype. The documents will be conformant to the HL7 CDA Release 2.

4 Results

The functional architecture of the prototype of Diagnostic Report Editor is shown as Figure 1. The diagram also documents the implemented data flow between the Referral document, the Report Text Editor and the resulting Report document. The Referral document is a source of data related to patient, to referring health care provider and to ordered medical service. The Report Template is a source of data related to service performer and represented organization.

The CDA design of the Report document has been shown in Table 1. All CDA header values originate from the Referral document or from the Report Template, except the current date and extensions for document identifiers, which are generated by the script. Some of the prefilled values can be edited in the Report Editor. The only value in whole document, which cannot be prefilled by the system, is the actual text of the report, expected to be entered by the Report document author.

The Report document will be conformant to the HL7 CDA standard on level 2, because we assume that all system interpretable data will be contained in the CDA Header of the document. The structured body section will consist of the title and text elements, both filled in with human readable content only. However, there is no concept-related limitation to the potential use of the content based on clinical statements and upgrade to the level 3 of the CDA. It would just require more complex functionality of the Report Text Editor.

Our prototype will process the Referral document on any level of the CDA. If the Referral document is on level

3, the prototype is able to interpret the ordered procedure data and to include it to the service event element of the Report document. If there is no such data, the diagnostic service performer will be expected to fill in the appropriate fields using the Report Text Editor.

The Report document content will be constrained by the Report Template, except the constraints for the PatientRole and InFulfillmentOf.Order elements which derive from the Referral document and should be defined by its originator.

All defined functional requirements for the Diagnostic Report Editor have been implemented. Its user interface consists of two screens: the Referral Viewer (see Figure 2) and the Report Text Editor (see Figure 3). Both components use the same XSL transformation, formatting the XML CDA-conformant documents for presentation [5, 6]. To avoid the need of exchange of CDA document together with XSL file, we have decided to use our own XSL formatting of the CDA document, ignoring the xml-stylesheet processing instruction, if used in the Referral document. However, the original style sheet definition appearing in the Referral document will be copied into the Report document, assuming that the system of the referring health care provider will use the same XSL transformation for both documents. The finalized Report document is visualized for authentication (see Figure 4).

The prototype has been developed using open source components only, and does not require any commercial software to run, except Microsoft Windows operating system. The solution consists of single HTML file containing Javascript code [7]. The script uses jQuery library for all operations on XML structures and HTML elements. The jQueryUI library is used to generate and manage the user interface elements, and moment.js for date format conversion. The HTML file embeds XSL transformation, CDA XML template and CDA XML schema definition, all of them in the form of base64-encoded strings. Operational parameters related to the context of document issue are registered using Internet Explorer User Data persistence mechanism. The CSS style sheets containing user interface display elements and layouts are embedded in the same single HTML file. The prototype has been tested in Microsoft Windows environment using Internet Explorer version 7, 8 and 9.

4.1 Object identifiers

The assumed lack of EHR system and lack of any other database, results in some difficulties with proper assignment of global object identifiers (OID), which is important element of best practice of HL7 CDA implementation [8]. There are three groups of the OID processed by our prototype:

First, the OIDs being assigned by the referring organization, like PatientRole identifier. It is required by the standard and should be understood as the patient identifier assigned by the health care provider organization, but not necessarily the organization providing the particular service being documented by the CDA document. In our case we used the PatientRole.id assigned by the referring health care provider organization and taken from the Referral document together with other patient data.

The second group are the OIDs related to the diagnostic service performer. To secure global uniqueness of those identifiers, we need an external service provided by the third party, for assigning the OIDs to objects contained in the Report Template. Thus, our solution requires the registration procedure for new and modified Report Templates. Every potential user of our Report Editor will be required to fill in the registration form with his or her personal data and data of the represented organization, if applicable. The third party system assigns the relevant object identifiers at its own OID node.

The third group are the identifiers of the generated Report documents. Due to assumed lack of online connection during patient encounter, the identifiers have to be generated locally, by the script embedded in the Report Editor. The global uniqueness of the Report document identifier is secured by local uniqueness of the extension attribute and the global uniqueness of the root attribute, which is assigned by the third party responsible for Report Template generation. To restrict the possibility of generation more than one document instance with the same document identifier, we register and update after each new document issue, the next available documentId, using the Internet Explorer User Data persistence mechanism. When issuing new version of already existing document, the new version is registered as the new document instance, but using the same setId as the previous version. To restrict the possibility of generation more than one document instance with the same version number and the same setId, we need to register in the Internet Explorer User Data all documents which have more than one version, using their setId and versionNumber.

5 Discussion

Our goal was not to propose the solution to be implemented operationally, but just to explore the minimum requirements for proper implementation of HL7 CDA standard. The biggest challenge was to design the proof-of-concept prototype with no integration with EHR system, Additionally, our intention was to base the interoperability of our solution on the power of the standard itself, with no need to agree on a common implementation of data exchange with partner owning an EHR system. It should not be treated as an reasonable alternative for bigger, fully functional, shared EHR system, but the substitute for paper-based document exchange.

The reason for development and implementation of simple applications similar to our prototype is limited to specialized medical providers, which do not need the EHR system, because their responsibilities regarding medical documentation is limited to its archiving. They do not need the typical EHR system functionalities, like com-

plex searching, sharing, analysis and processing of data extracted from medical documentation. According to the current Polish regulations, there are two possible cases for such implementation:

- When the potential system owner uses electronic form of documents for their exchange with its partner, but documents are printed for the purpose of archiving.
- The partner takes over the responsibility for the whole document management process.

All the assumptions made when designing the requirements for the proof-of-concept prototype have been fulfilled. A few minor drawbacks have been identified:

- It was impossible to resign completely from external services needed to run the prototype. At the initial use of the Report Editor, its user must be registered by an external third party to generate personalized Report Template, containing newly registered individual ISO OID node, being the globally unique identifier of the service provider organization, and its sub node for the document identifiers. It is not the major problem because the external service is needed just at an initial usage of the Report Editor, but not during the operational work.
- Ignoring the style sheet instruction contained in the Referral and Report documents and using the build-in standard transformation for presentation results in different appearance of the document for its authenticator and for the recipient. The Report document is rather simple and most of its content is directly copied from the Referral document, so the recipient of the Report document will see the header of the document in the same layout as seen at the Referral document authentication.
- Document validation against the standard HL7 CDA xml schema (cda.xsd) only, with no semantic validation [9]. According to the aim of this work, the functional requirements for the prototype were minimized. It seems however, that more complex validation, against other xml schema or the rules defined in the schematron notation [10], would be reasonable. It is possible to embed the schematron, implemented as an XSLT, in the main HTML file. The schematron will use the rules contained in the separate .sch file named the same as the relevant template id used in the CDA document.

6 Conclusions

The HL7 CDA based solution can be implemented in the environment with no EHR system. The requirement of no integration with other systems, except an interoperable exchange of CDA-conformant document, has been proven as possible and reasonable to implement. A standalone CDA document editor for small, specialized medical service providers might be designed and developed with minimal cost of software purchase and maintenance. All header data for the report document may be copied from the referral document and from the report template. To allow the proper use of global object identifiers, the report template has to be generated by the external party and report document identifiers has to be generated locally by the report editor.

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Using TTCN-3 for testing the interoperability of HL7v3 based applications

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Abstract

HL7v3 standard was designed to facilitate communication between all types of eHealth applications, regardless of the domain of activity. The flexibility of the HL7v3 messages led, however, to proprietary definitions of HL7v3 messages and structures. In order to unify the communication in different domains, profiles have been developed and standardized. In this context, testing plays an important role in assuring interoperability, as well. This paper presents a method to test the interoperability of HL7v3 applications, using the standardized TTCN-3 test scripting language and its corresponding TTCN-3 test system. The full testing process is described, highlighting all the components involved and providing guidelines for implementing them. This approach requires testers to be familiar to the TTCN-3 environment.

Keywords

HL7v3, TTCN-3, testing, QED, eHealth

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1 Introduction

Testing the interoperability of HL7v3 based applications plays an important role in the growth of the eHealth community. HL7v3 is a very complex standard and its characteristics make testing a difficult task. This paper proposes a new approach to the interoperability testing of HL7v3 applications. The solution was validated in the context of a HL7v3 profile, Query for Existing Data (QED). However, it is adaptable to other profiles, as well.

The solution is based on the TTCN-3([1]) test scripting language and TTCN-3 test system. The most important advantage of this approach is that TTCN-3 is a standardized testing technology, which is reliable, very flexible and independent of the platform and the technology of the system under test. In addition, the TTCN-3 test system is portable and modularized. This paper presents the implementation details of the testing procedure, with highlight on adapting HL7v3 applications to the TTCN-3 test system.

2 Testing HL7v3 applications

HL7v3 was designed to facilitate communication between virtually any type of eHealth application, regardless of its corresponding healthcare domain. However, the way HL7v3 was designed caused sometimes interoperability issues. HL7v3 allows implementers to define custom message structures. This led to the development of many applications that communicate medical data in proprietary formatted messages. To overcome this, HL7v3 profiles have been developed and standardized for different healthcare domains. These profiles are the first step towards HL7v3 interoperable systems.

In this context, interoperability testing plays an important role in the growth of the HL7v3 community. However, testing the interoperability of HL7v3 based applications is especially difficult, because of the differences between message structures. Testing usually focuses on a specific HL7v3 message structure, which limits the applicability of the testing solution. This paper proposes, however, a generic approach to test the interoperability between

HL7v3 applications.

The solution is a testing framework based on the standardized TTCN-3 testing language and a TTCN-3 test system. The approach is validated on a specific HL7v3 profile, i.e. Query for Existing Data (QED). QED is an IHE profile [2] which allows systems to query data repositories for clinical information on vital signs, problems, medications, immunizations and diagnostic results.

2.1 TTCN-3 architecture

Testing and Test Control Notation version 3 (TTCN-3) is a strongly-typed scripting language, used for defining complex test specifications. TTCN-3 provides mechanisms to describe test behaviors by unambiguously defining the meaning of a test case pass or fail. TTCN-3 is a standardized testing language that has been used for more than 15 years in standardization and industry. It is very flexible, portable and well suited for conformance and interoperability testing. TTCN-3 test case specifications do not depend on the platform, architecture or technologies used by the System Under Test (SUT). It provides a built-in verdict mechanism that allows easy evaluation of the testing results. Moreover, TTCN-3 has a refined template matching mechanism that is very flexible and easy to manage.

With TTCN-3 testing language testers can define test cases and the order in which they are executed. However, to execute test cases, a TTCN-3 test system is needed. The TTCN-3 test system can be thought of as a set of interacting entities that implement specific test system functionalities. Figure 1 depicts the general architecture of a TTCN-3 test system, highlighting the main components and the relationship between them.

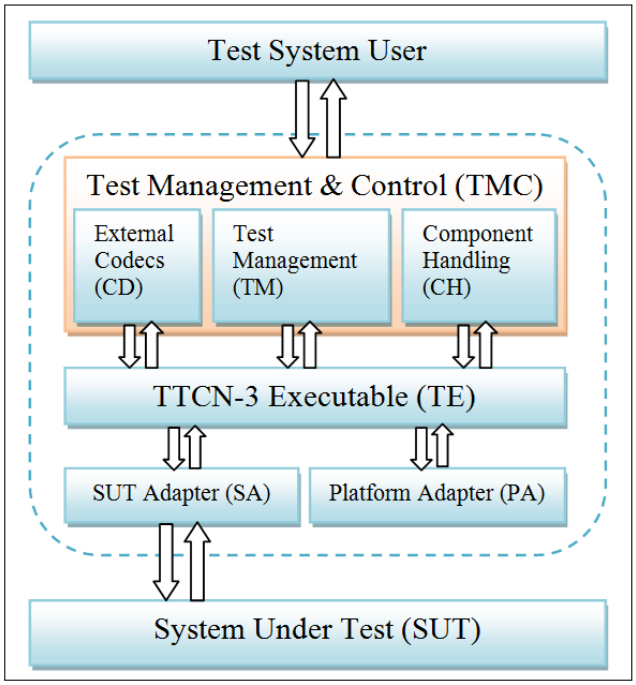

Figure 1: General architecture of a TTCN-3 test system

The central layer, TTCN-3 Executable (TE) handles the execution of TTCN-3 statements. TE depends on the services provided by the other two layers. Test Management Control (TMC) includes three entities: External Codecs (CD), Test Management (TM) and Component Handling (CH). CD is responsible for encoding and decoding data, TM represents the interface with the Test System User, and the CH is used for distributed execution of the test cases. Platform Adapter (PA) implements TTCN-3 external functions and provides timing mechanisms. SUT Adapter (SA) adapts the message/procedure based communication between the TTCN-3 test system and the SUT to the particular execution platform of the test system. CD and SA will be subsequently referred to as the Codec and the Adapter, respectively.

The majority of the TTCN-3 tools provide default implementation for the TM and CH. This is not the case of CD, SA or PA, since they cover aspects of the test system, which are either test suite or SUT specific.

2.2 The TTCN-3 type system

The TTCN-3 type system extends the basic constructs that usually have correspondents in programming languages with additional testing specific concepts, such as built-in data matching, distributed test system, or concurrent execution of test components. The TTCN-3 type system is very complex and includes also test verdicts, test system components, and even direct support for time. The core components of the TTCN-3 type system are the TTCN-3 records, TTCN-3 enumerated types, and TTCN-3 templates. These three components are used for storing the information contained in HL7v3 messages in TTCN-3 specific format.

TTCN-3 records are constructs used for grouping related fields in a single type. TTCN-3 records are used to store data in a structured way. Field names within a record must be unique and their types may be either built-in or a user-defined. TTCN-3 records are arguably the most used types of the TTCN-3 type system. TTCN-3 enumerated types are ideal for representing types that have small, finite sets of values. They are used to model types that take only a distinct named set of values, i.e. enumerations. TTCN-3 enumerated types are often used in HL7v3 to encode vocabularies. TTCN-3 templates are used for defining information exchanged between the test system and the SUT. While TTCN-3 types such as records and enumerated types define logical structures for storing information, templates contain the actual information. Subsequently, TTCN-3 records, TTCN-3 enumerated types and TTCN-3 templates will be referred as records, enums and templates, respectively.

When creating test cases, testers define two templates. The first one represents the input that is passed to the SUT, while the second one is the expected output. During test case execution, the TTCN-3 matching mechanism verifies if the expected output matches the one received from the SUT. Based on the similarity between the two,

a verdict is set to the test case, generally indicating if the test failed or passed. The input and expected output templates are defined in TTCN-3 specific format. Using these templates for testing SUTs require the existence of modules for converting data from TTCN-3 to SUT specific formats. For this conversion, two of the TTCN-3 test system components are used, namely the Codec and the Adapter.

An important aspect of testing HL7v3 applications using TTCN-3 is that templates are difficult to create. Their hierarchical structure can span on many levels, usually reaching more than twenty levels, in the case of QED messages, which makes manual definition and maintenance cumbersome.

3 Testing HL7v3 applications

In order to validate the suitability of testing HL7v3 applications using TTCN-3, a case study was considered. The SUT chosen is a mature application that uses the IHE QED profile. During the development of this solution, several decisions have been made to facilitate the communication with this SUT. However, as the paper describes further, the modularity of the TTCN-3 test system allows adapting this solution to testing any HL7v3 based application. The SUT is deployed as a web service, and the communication is performed through SOAP messages. The message flow for testing the interoperability of the HL7v3 based application is depicted in Figure 2.

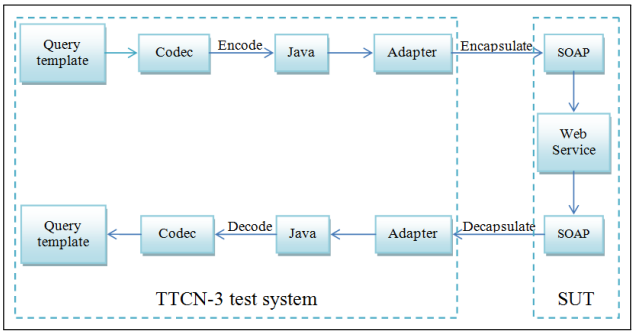

Figure 2: Testing HL7v3-based applications - message flow

When executing the test case, the template that describes the QED Query is sent to the Codec through the TTCN-3 Control Interface (TCI). The message is translated into a Java object and passed on to the Adapter through the TTCN-3 Runtime Interface (TRI). The Java object is then serialized and embedded into a SOAP message. After the connection between the Adapter and the SUT is established, the SOAP message is passed on to the SUT. If the query is valid, the web service replies with a QED Response in SOAP format. The Adapter converts the SOAP message into a Java object and forwards it to the Codec, where it is decoded into a TTCN-3 template. At this point, the TE evaluates the response from the SUT, setting the verdict of the test case.

3.1 Implementation of the Codec

The Codec (Coder/Decoder) is an important TTCN-3 test system component. It is responsible for interfacing the communication between TE and the Adapter. The Codec has two basic functions: encoding and decoding. TE interprets test cases and automatically converts templates representing QED Queries into Java objects, organized as structures. After the conversion, Java objects are sent to the Codec, via the TCI interface. The TCI [5] is composed of three interfaces that define the interaction between TE and TM, CD and CH.

In the encoding phase, the Codec translates the structure generated by TE into a Java HL7 object. In this way the Codec assures that the Adapter receives a set of input data that can easily be handled. The translation is performed at runtime, using Java Reflection. The structure is parsed, each composing element being translated into the corresponding HL7 Java object. These objects are then encapsulated into a Java-based query request.

The Codec is also responsible for sending this query request to the Adapter. TRI [6] defines the interaction between TE and the Adapter. There is an important constraint determined by the usage of TRI. The Java interface TriMessage has to be implemented by any class describing messages that are used in communication between the TE and the Adapter. This constrains messages to be formatted as byte arrays. Since none of the JAXB generated classes implement the Serializable interface, scripts had to be created to modify each class and add "implements Serializable" to their definition, so that requests can be serialized and sent to the Adapter within a TriMessage.

In the decoding phase, the Codec receives a TriMessage from the Adapter, containing the QED Response. The Codec deserializes the message, converts it into a Java structure and then forwards it to TE.

3.2 Implementation of the Adapter

The existence of the Adapter confers the TTCN-3 test system much flexibility. The Adapter is the TTCN-3 test system component responsible for establishing connections and handling communication with the SUT. The same test suite can be executed on SUTs with different platforms just by replacing this component.

The Adapter enables communication between TE and the SUT. It has two different functionalities: encapsulation of the query and extraction of the response from SOAP messages. Simple Object Access Protocol (SOAP) is a protocol specification for exchanging structured information. SOAP relies on XML as its message format.

In the encapsulation phase, the Adapter uses the TriMessage it receives from the Codec as input. The byte array containing the query is deserialized. Given the transparency of the test case to the Adapter, the conversion from Java to XML could only be done dynamically, at runtime, through Java Reflection. For this translation Java API for XML Processing (JAXP) was used. JAXP

[7] provides the capability of validating and parsing XML documents. It offers several parsing interfaces from which Document Object Model (DOM) parsing interface was chosen. DOM [8] enables parsing of XML documents and constructing complete in-memory representations of the documents.

DOM documents have tree-type structure. They are composed of a root element, which represents the XML document, and several nodes, representing XML elements. The translation of the Java message to XML was implemented as following the next steps:

Step 1: a DOM document is created based on the type of the query message;

Step 2: object's fields list is obtained using Java Reflection; each field represents a Java HL7 object;

Step 3: for each field a DOM element is generated and added to the root element's children list;

Step 4: another DOM element containing the preconditions is defined and added to the root's children list;

Step 5: the DOM document is serialized and the XML-formatted message is ready to be forwarded to the SUT.

DOM is used when extracting of the Java object from the XML-formatted response received from the SUT, as well. The transformation follows the next steps:

Step 1: the XML is deserialized into a DOM document;

Step 2: the root element of the DOM is used to generate a Java object representing the QED Response;

Step 3: the document is parsed and each node is translated into the corresponding HL7 Java object; these objects are set as fields of the Java-based QED Response object;

Step 4: after the parsing is finished, the Java QED Response object is serialized to a byte array and sent to the Codec via a TriMessage.

The Adapter is also responsible for handling the communication with the SUT. The communication protocol chosen for exchanging messages was SOAP. The web service used WSDL [9] to define the type of QED messages it can handle, such as Query, Continue or Cancel. In order for the communication to take place, the connection had to be established, and for that a Java client was needed. There are many tools that use the WSDL description to generate stubs and clients. Java API for XML Web Services – Reference Implementation (JAX-WS RI) was chosen. JAX-WS RI [10] was introduced in Java SE 5 to simplify the development and deployment of web service clients and endpoints. Once the client was created, methods for connecting, sending and receiving QED messages were available and the communication was possible.

3.3 Generating testing components

In terms of the TTCN-3 test system, when executing a test case, a template representing the QED Query is sent to the SUT and if the template representing the QED Response matches the expected response template, the verdict is set to pass. As SUTs usually can't handle TTCN-3 templates, they have to be converted to SUT compliant formats. Java was chosen as common language, for portability reasons and for the fact that it is the language in which TTCN-3 test system components are developed. Thus, the template representing the QED Query is encoded into a Java object that is passed to SUT, and the response from the SUT is decoded into a template storing QED Response.

The first attempt was to use a set of Java classes offered by HL7, i.e. the Java SIG Project (jsig) [3]. The main problem of jsig classes is the lack of a generic way to generate Java HL7 objects based on the TTCN-3 templates. Jsig classes offer no generic way of instantiating objects and setting field values at runtime. This was a major problem and another approach was needed.

The second approach was to use a set of XML Schemas that describe the HL7 data types and the QED queries. Java classes were generated based on the XSDs using Java Architecture for XML Binding (JAXB) [4]. Because of the constraints imposed by communication between TTCN-3 test system components, the classes were modified through some scripts, so that all implemented the Serializable interface.

The Java classes were used to generate the corresponding TTCN-3 records and enumerated. The generating tool that was developed and used has two components. The first one is responsible for instantiating the classes and extracting the relevant information at runtime, using Java Reflection. The second one is a TTCN-3 code generator which uses the information provided by the first component to create two TTCN-3 modules, one for the records and one for the enumerated.

After generating the records and enums, templates corresponding to HL7 data types could be defined. Finally, we were able to create query and response templates used in defining the test cases.

To summarize, when testing HL7v3 applications using TTCN-3, the tester defines two templates: the one representing the query and the one representing the expected response. When defining these templates, the TTCN-3 type system should contain types, i.e. records or enums, that describe basic HL7v3 structures, in a TTCN-3 format. Since these types are not part of the TTCN-3 type system, they had to be generated using the automated tools described earlier. These aspects allow testers to define test cases. However, when executing the test cases against a SUT, the TTCN-3 test system is used. In order to adapt the messages from the template format to an SUT known format, two components have to be implemented: the Codec and the Adapter.

4 Conclusions

There are many advantages which come with this approach, and probably the most important one is the technology used for testing. TTCN-3 is standardized, has been

validated as one of the best testing languages for protocol testing, it has a complex verdict assessment and its modularity makes it very flexible.

The proposed solution does not directly depend on the SUT, neither on its architecture, nor on the technology it uses. The Adapter component is responsible for linking the SUT with the test suite, which means that it is the only component that needs to be replaced when testing other systems. Another advantage is the automation. Test suites can be developed to thoroughly test several systems, without user intervention.

This approach has been validated on a mature system that is using a HL7v3 profile: QED. However, the authors highlight the adaptability of this solutions to other profiles, as well. Even though during the implementation phase many generation tools had to be developed, these tools can be used to other profiles, as well, since they are not profile-dependent.

This approach requires testers to be familiar to these technologies and to TTCN-3 standard. On the other hand, times and costs of the testing are reduced, since the testing process is completely automatized, and can be used with different SUTs, as well.

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Helping the Cause of Medical Device Interoperability: A standards-based testing approach based on identifying and obtaining testable assertions

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Abstract

We present a black-box messaging test approach employed to achieve a level of rigor which improves, if not assures (given no optionality and fully constrained), correct data exchange. In particular, verifying that physiological information derived and communicated via messaging from a source medical device (e.g., an infusion pump) or healthcare information system, to another medical device (e.g., a patient monitor) or healthcare information system which consumes or make use of the data is syntactically and semantically correct. Our approach for developing a test system to validate messages is based on constraining identified and recognized specifications. The test system validation performed uses codified assertions derived from the specifications and constraints placed upon those specifications. To first show conformance which subsequently enables interoperability, these assertions, which are atomic requirements traceable by clause to the base specifications, are employed by our medical device test tools to rigorously enforce standards to facilitate safe and effective plug-and-play information exchange.

Keywords

Conformance Testing; Interoperability; Health care Information Technology; Medical devices; Testable Assertions

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1 Introduction

At the U.S. Department of Commerce's (DoC) National Institute of Standards and Technology (NIST) researchers are collaborating with medical device experts to facilitate the development and adoption of standards for medical device communications throughout the healthcare enterprise as well as integrating it into the electronic health record. We have developed test tools[1] and a modeling application, including a corresponding electronic representation of an international standard's information model[2], which provides several important capabilities leading toward device interoperability[3].

Conformance testing is a key step leading to, although not guaranteeing, interoperability[4]. Sparked by involvement over the past several years of working with medical device domain experts and vendors who participate in Standards Development Organizations (SDOs) and use established standards such as Health Level 7[5] (HL7) and ISO/IEEE 11073 Health informatics – Point-of-care medical device communication[6] and Personal health device communication[7], an approach used to identify testable assertions derived from such standards and constrained by important use cases is presented.

The black-box messaging test approach addresses how we define and get to a level of rigor which improves, if not ultimately assures – given no optionality, correct data exchange. In particular, verifying that physiological information derived and communicated from a source medical device (e.g., an infusion pump) or healthcare information system, to another medical device (e.g., a patient monitor) or healthcare information system which consumes or makes use of the data is syntactically and semantically correct. In other words, the structure of information exchanged within the healthcare system is compliant to a defined specification(s) and the information meaning con-

veyed and interpreted by the consumer is exactly the same and as intended by the source.

The reality that medical devices need to communicate with tens, if not hundreds, of other devices of varying makes, models, and modalities has large market and substantial healthcare implications. Acute point-of-care settings such as a hospital's intensive care unit, a patient's bedside, or personal telehealth location require each class of medical device to use the same terminology and data organization to seamlessly and reliably communicate physiological data. Healthcare communication standards that address plug-and-play medical device interoperability are critical. While providing the groundwork to enable device communication, standards are developed in an open ended manner (and for good reason). It is our contention, through experience in software testing, that only until standards and defined specifications are constrained (ultimately removing all optionality to create profiles) that the desired "guarantee" of syntactic and semantic correctness can be achieved.

Conformance test methodologies are being employed by NIST via software test tools to help get closer to that "guarantee". These tools are publicly available and being used by the medical device industry to ensure that critical devices correctly implement the medical device standards. A consortium of medical device vendors using these test methodologies to successfully meet a level of compliance to standards sufficient to achieve truly efficient interoperability is the Integrating the Healthcare Enterprise – Patient Care Device (IHE-PCD) domain[8]. Correct implementation of standards lead to effective exchange of critical physiologic data derived from the patient at the device and exchanged throughout the healthcare enterprise. As more and more devices are able to achieve "plug-and-play" capabilities, clinicians are empowered to focus more on the patient and less on the devices. The ability to reliably and effectively integrate data from a broad range of point-of-care devices will ultimately lead to a reduction in medical errors and the associated loss of life.

2 Background

2.1 Medical Device Communication Standard

The ISO/IEEE 11073 Health Informatics – Point of Care and Personal Health Medical Device Communication standards (x73) defines a set of information objects and functions needed for medical device communication. Such a family of standards was developed to address the critical need of enabling medical devices to share physiologic data between devices and computerized healthcare information systems. Two primary parts of these standards used in our approach pertain to the Domain Information Models (DIM)[9, 10] and Nomenclature[11]. The DIM provides the objects and object relationships necessary to abstractly define a device (see Section 4.2 discussion regarding device containment hierarchy). It defines the overall set of information objects as well as the attributes, methods, and access functions which are abstractions of real-world entities in the domain of medical devices and device communication. Nomenclature defines terminology and codes used across classes of medical devices.

2.2 IHE-PCD Integration Profiles, Technical Frameworks, and Integration Statements

IHE-PCD participant vendors define 'use cases' in which at least one 'actor' is a regulated Patient Care Device. IHE Integration Profiles are defined and provide the necessary detail to enable demonstration, through implementation (i.e., specific implementations of established standards to achieve integration goals), of important use cases. The IHE-PCD Integration Profiles, defined in IHE-PCD Technical Framework documents[12], organize and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards such as HL7 and x73. They provide precise definitions of how standards are constrained and may be implemented to meet specific clinical needs[13].

Based on these specifications which constrain the reference standards, the IHE conducts cyclical interoperability testing events; NIST test tools are used in the IHE-PCD domain to evaluate conformance to the specified Integration Profiles and executed test cases. If successful, industry participants publish IHE 'Integration Statements' to indicate their system's conformance which can be useful for medical device procurers during their evaluation.

Currently within the IHE-PCD participants are actively working on several Integration Profiles[14] including Device Enterprise Communication (DEC) with options to Patient Identity Binding (PIB) and Subscribe to Patient Data (SPD) which provides a subscription/data filtering mechanism; Alarm Communication Management (ACM); Point-of-care Infusion Verification (PIV) addressing infusion safety issues such as "five rights of Medication Safety"[15]; Implantable Device Cardiac Observation (IDCO); and Rosetta Terminology Mapping (RTM) which provides a mapping between proprietary device semantics to the x73 nomenclature and associated co-constraints (e.g., associated reference identifier, terminology code, unit(s) of measurement, lead sites where measurements may be taken, and enumerations).

2.3 The Need for Conformance Test Tools

- Conformance and interoperability testing of medical device data communication is essential leading to long term value propositions which include:
- Integrity of data – automatic population of all information systems – reducing medical errors
- Automating systems to capture clinical data into

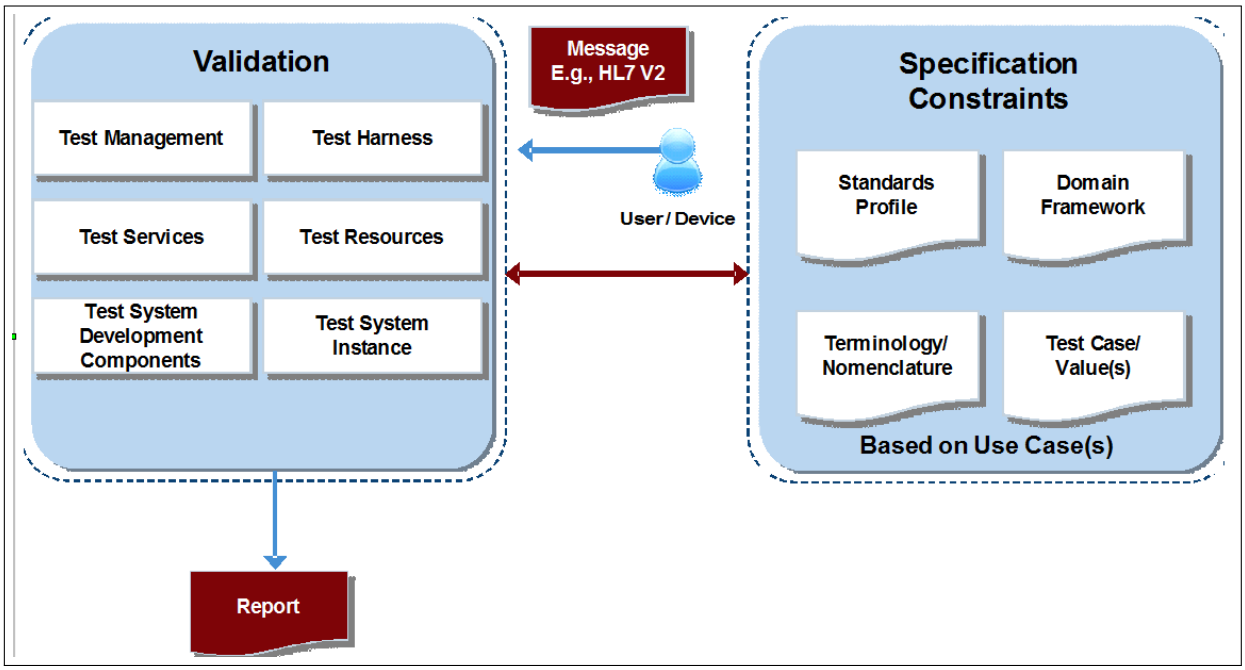

Figure 1: Constraining Specifications to Enable Rigorous Testing

Electronic Health Records (EHRs) thus saving time for clinicians

- Access to patient data across devices and systems so custom communication interfaces can be eliminated thus allowing for best of breed and even plug-and-play devices
- Improving agility of enterprises to meet varied patient loads
- Improving life-cycle cost of ownership

To address real-world semantic interoperability the transfer of data must be (in many cases) near real-time data from a gateway to an Electronic Medical Records (EMR) system in a rich, accurate, and consistent manner. To first show conformance which subsequently enables such interoperability, test tools that rigorously enforce defined specifications to facilitate safe and effective plug-and play interoperability are necessary.

3 Our Approach: Constraining Specifications To Derive Testable Assertions

Our approach for developing a test system to validate messages is based on constraining identified specifications. The validation is defined by assertions derived from the specifications and constraints placed upon the specifications. The premise at getting to any level of rigor is that specifications are complete (as possible) and constrain open ended assertions. The more well-formed, formal, and complete the specifications the greater level of rigor can be achieved by the test system.

Figure 1 shows the specifications used by our test tooling to address message validation in the IHE-PCD domain environment. Messages being exchanged contain physiologic observations. The messages (i.e., defined using HL7 version 2) are tested against the specifications which define the standards used, any domain specific specifications, terminology and nomenclature employed and any specific values or value sets being conveyed as identified in test cases.

It is unrealistic to assume all standards and specifications are correct or mature to a level of 'complete'. However as specifications are implemented and a collaborative, iterative, feedback process occurs - so too can the rigor-level and coverage provided by the test tools via updates, enhancements and issue resolution. Should we consider different enterprise-level testing outside of IHE, other specifications as made available by the domain could be integrated in a similar manner into the test tooling.

Based on the specifications and any constraints identified in those specifications, messages are validated by the test system which employs various test components. For example, an HL7 message derived from an infusion pump (or generated from the pump system or gateway) is evaluated against the HL7 standard for its syntax and semantics, the x73 standard for terminology, terminology co-constraints, and information model (i.e., the device object hierarchy), and the test case for any specific values or attributes.

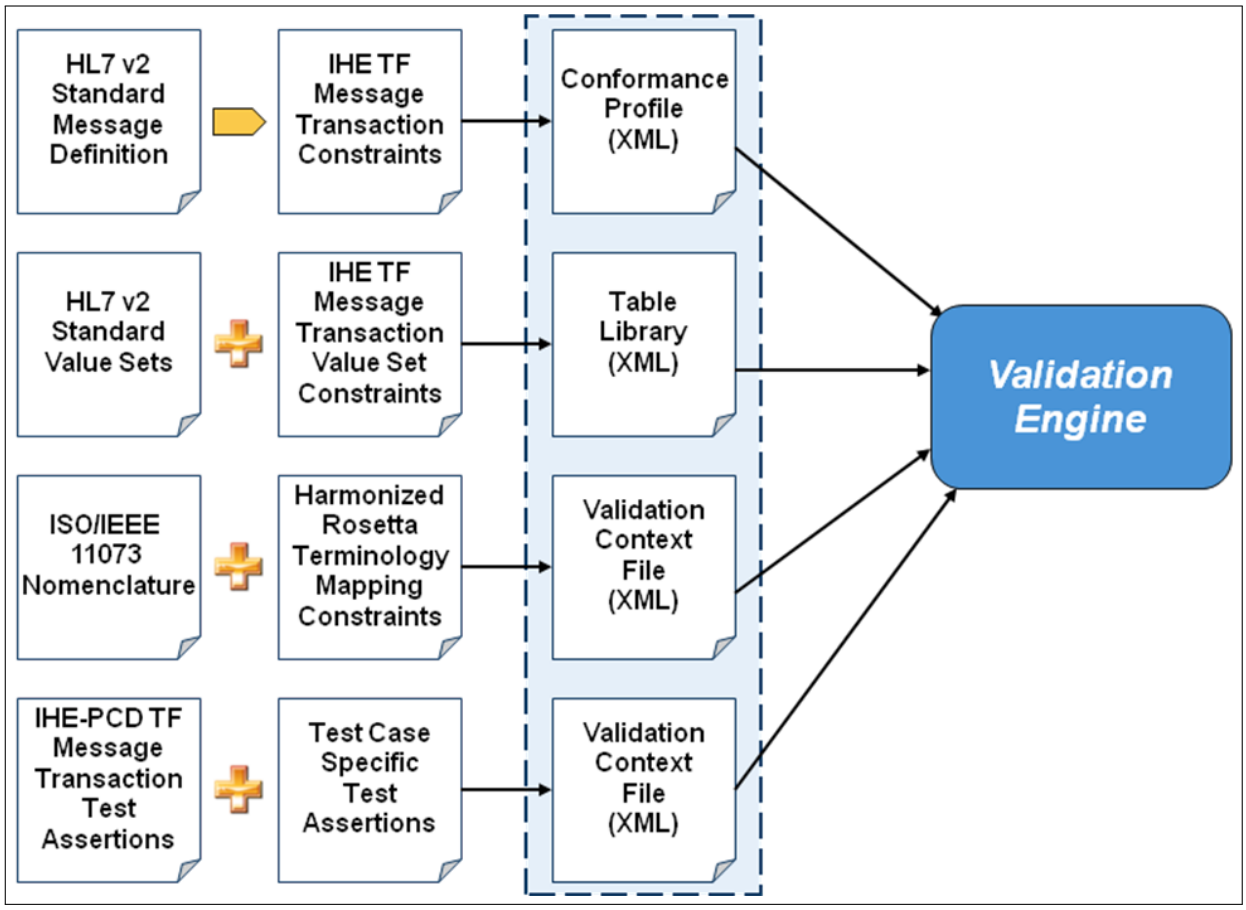

Figure 2: Origin of Test Assertions

4 Specification Ingredients Employed In Our Testing Approach

The recipe for correctly effecting validation of messages in our approach calls for specification ingredients as shown in Figure 2. Given the IHE-PCD domain and integration goals, these specifications include the HL7 Version 2 standard for message definition and value sets, the x73 standard for medical device nomenclature, the IHE-PCD Technical Framework documents for message transaction definition, and the IHE-PCD test cases for specific value definition.

These specifications define and lead to what we call "testable assertions", which are atomic test requirements traceable to the aforementioned specifications. Identified test assertions are codified into "context validation" files. Context validation files are defined in XML and provide the precise assertions that the test system uses as input to a validation engine which performs the validation service (and in the future, other services such as message generation). Each testable assertion references the specific clause in the base specification, or ingredient of our recipe. Test reports are generated by the test tool identifying the specific error within the message along with a reference to the clause from which the assertion is based.

4.1 HL7 Standard, Value Sets, and IHE Technical Framework Assertions

Validation of the device information carried within the HL7 messages occurs at both the syntactic and (low-level) semantic levels. Messages are validated against defined value sets and what we refer to as "failure types". The test tool uses validation context files codified in XML (see Figure 2) to perform message validation checks against the HL7 V2 standard, value set tables, and any further constraints defined by IHE-PCD with the Technical Framework documents (e.g., "local" value sets not defined in HL7) for message transactions. Validation of failure types include:

- VERSION (e.g., the HL7 version and IHE-PCD Technical Framework Integration Profile)
- MESSAGE_STRUCTURE_ID (e.g., the HL7 message type [MSH.9 element] defined in the profile shall match what's in the message)
- MESSAGE_STRUCTURE (e.g., the message shall have a valid HL7 message structure - including correct usage, correct cardinality, and correct element name)

- USAGE (e.g., HL7 'R' elements should be present; 'X' elements should not be present in the message)
- CARDINALITY (e.g., elements shall be present at least the minimum times and at most the maximum times specified in the conformance profile)
- LENGTH (e.g., the value of the element shall have a length equal or less than the value specified in the profile)
- DATATYPE (e.g., for the HL7 data types 'NM', 'DT', 'DTM', 'SI' and 'TM', the value of the element shall match the regular expression defined in the standard)
- DATA (e.g., the value of the element shall match a constant specified in the profile, a value set specified in a table, or a value or a regular expression specified in the message validation context [derived from a test case])
- TABLE_NOT_FOUND (e.g., an error when a referenced table can't be found in the table files - HL7 or local defined set of allowable tables)

The above attributes defined in HL7 are often referred to as 'HL7 Conformance Profiles'. 'HL7 Conformance Profiles' are typically produced using third party software and define the constraints desired when implementing HL7 messages. 'HL7 Conformance Profiles' may be used as input into the test tools and become testable assertions enforced by the validation engine.

4.2 Common Medical Device Information Model and Nomenclature Assertions

In considering and developing our test approach one of the overarching goals is to achieve semantic interoperability – communicate medical device data using a single unified nomenclature and semantic model that can be rigorously defined and enforced to facilitate safe and effective plug-and play interoperability.

This is where the aforementioned x73 Domain Information Model and Nomenclature are an essential ingredient. Today, nearly all vendors have an internal (and often proprietary) representation of device and corresponding device generated information. Vendors can correctly and consistently map information that has been generated, either by the same or another device make or model or system, by applying a common model and nomenclature based on recognized standards. Furthermore from a black-box testing perspective in which medical device observations are exchanged via messaging, rigorous validation can be applied using those very same standards which are constrained via profiles by communicating entities. Profiles may include 'device profiles' as defined in x73 (x73-103[16] series of device specializations for point-of-care health devices - such as an infusion pump or ventilator or x73-104yy[17, 18, 19, 20, 21, 22, 23, 24, 25] series of device specializations for personal health devices - such as a weight scale or pulse oximeter) or 'Integration Profiles' as defined by the IHE-PCD domain.

One of the IHE-PCD domain constrained value sets, Rosetta Terminology Mapping, identifies the nomenclature and provides a 'containment hierarchy' to abstractly represent medical devices as defined in the x73 standard. This set of terminology provides the testable assertions of device information carried within the observation segments (i.e., HL7 Version 2 "OBX segments"). These constraints or test assertions lead to test validation context files as depicted in Figure 2 and provide traceability to the x73 standard's nomenclature and information model.

4.3 IHE-PCD Transaction and Test Case Defined Assertions

IHE-PCD domain defines the technical framework documents and test cases (see Figure 2) in which vendors are evaluated against. The framework documents define and constrain (at the HL7 usage level) 'transactions' (i.e., HL7 messages). IHE-PCD defined test cases identify specific values required in vendor implementations and demonstrated during the test event(s). The corresponding validation context information contained in the test cases is codified in XML as testable assertions.

5 Advancing the Approach

The presented test approach of validating static messages by constraining specifications is foundational. However, there is much work to be done to achieve greater levels of rigor. Test tool enhancements were completed to advance functionality from a static message checker over what we refer to as in an "instance test environment", which essentially evaluates a message(s) against the specification(s) from which the message is based (e.g., conformance testing an HL7 V2 message), to an "isolated system test environment". Ultimately we strive to provide a test infrastructure providing a "peer-to-peer environment"[26].

Isolated system type testing involves real scenarios in which transactions exchanged as well as behavior exhibited by the system under test (SUT) are evaluated by the test system. Typically this involves a meaningful scenario in which transaction exchange occurs between the SUT and test system, thus isolating the SUT. Protocol conformance and functional behavior (including features and operation) are evaluated by the test system according to identified specifications. For example, each step within a scenario may involve one or more messages transmitted to/from the SUT to/from the test system. The test system views the SUT as a black box, evaluating transactions and behavior (i.e., expected syntax and semantic content).

Peer-to-peer system testing involves multiple (two or more) SUTs interacting, with the test system involved as a proxy. In addition to the functionality of isolated system

testing, peer-to-peer includes the complete application environment to achieve interoperability testing. Peer-to-peer test environment may include interacting with many services including a database, network communication, other hardware, applications or systems as appropriate.

Another software application[27, 28, 29] we developed at NIST allows users to define medical device profiles in strict accordance to the x73 standard. The resultant XML file provides abstract representations of real devices defined using x73 nomenclature and with an x73 DIM containment hierarchy. Using the application's interface a user can define and constrain the device abstract representation to a particular class of device and furthermore to the specific make and model. We are considering approaches to integrate this device representation with the message validation test tools. Such integration would enable validation of specific device classes for each IHE-PCD use case that is appropriate for that device class. Conformance testing device classes, makes, and models is important as devices exhibit variant behavior, even if when applied to the same test case (within a use case, Integration Profile, or scenario).

In related efforts NIST has developed validation tooling being used in several other domains (including the Health and Human Services' National Health Information Network, the IHE IT Infrastructure domain[30] Cross Enterprise Document Sharing [XDS][31], Patient Identifier Cross Referencing [PIX][32], and Patient Demographics Query [PDQ][33]).

Developing our initial set of test tools has been enhanced through our involvement with industry consortium. As active participants in IHE, standards development organizations and other consortium, NIST researchers have gained invaluable insight into the needs and issues of medical device vendors, clinicians, clinical engineers, and in general the healthcare community. We continue to focus our attention on open consensus forums and processes based on open consensus standards. We are actively monitoring other related work[34, 35] and efforts using related medical device standards[36], focused on critical issues such as patient safety and device risk analysis. We believe our approach offers benefits to most of these efforts, if not all. As we continue to build upon and enhance the test tooling, the likely hood of interoperability increases. It is our hope that "as we build it, they will come. . . "

6 Conclusion

Data communication of device-derived physiologic data captured at the point of care and exchanged in a syntactically and semantically consistent manner is an industry-wide shared objective. To advance the goal of end-to-end, plug-and-play connectivity in healthcare NIST has successfully applied and demonstrated conformance software test tools, based on recognized medical and healthcare data exchange standards that rigorously validate vendor implementation of medical device data exchange solutions. Addressing problematic high-impact use cases, conformance testing information exchange is now possible via an approach which constrains recognized international standards and verifies assertions drawn directly from specifications derived on those very standards. Proving conformance is a key step to enable integrated approaches at the point of care - and downstream interoperability of various device types and particular makes and models of devices. While there is much to do to accomplish a test approach which guarantees peer-to-peer interoperability, the approach described is a solid foundation which may be used to advance research in this area of study.

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If Two Do the Same Thing... Comparing IHE Profiles PIX/PDQ Based On HL7 2.x And HL7 Version 3

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Abstract

Background: IHE integration profiles for managing patient identification, PIX and PDQ, exist in two alternative forms: on the one hand using HL7 2.x, on the other hand based on HL7 Version 3. **Objective:** Knowing differences between the competing integration profiles shall assist the user to choose the one better suitable for their specific deployment. **Methods:** Differences in the set of interactions, the information model, the vocabulary and the required behavior of individual interactions were analyzed. **Results:** A list of specific features and constraints for each of the integration profiles was compiled. **Conclusions:** Not all of the identified deltas originate in the inherent incompatibility between HL7 2.x and 3.0, they also result from the specific constraints imposed by the IHE profile. Identified disparities include the communication pattern, constraints to identifier schemas and pseudonymization capabilities.

Keywords

health communication; medical records linkage; HL7; IHE

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1 Introduction

The international interoperability initiative Integrating the Healthcare Enterprise (IHE) employs standards authored by Health Level Seven International (HL7) throughout all of its technical frameworks. The IHE domain IT Infrastructure (ITI) and its technical framework make use of various HL7 technologies, including HL7 2.x (HL7v2) and HL7 version 3 (HL7v3) messaging.

The profiles Patient Identifier Cross-Referencing (abbreviated as PIX or PIXv2) and Patient Demographics Query (PDQ or PDQv2) are based on HL7 versions 2.3.1 and 2.5 [1]. They describe the management of patient identification information. In the IHE season 2011-2012, two other profiles with the very same purpose have achieved the final status, being referred to as PIXv3 and PDQv3. These profiles depend on HL7v3 (Normative Edition 2008) [2]. The obvious redundancy invites to explore the differences between the old and the new profiles more closely.

A short overview of the profiles within the ITI technical framework [3] is provided here for readers not familiar with the IHE process or the particular integration profiles.

An IHE integration profile typically covers a specific healthcare scenario (use case) by defining roles of the participating systems (actors) as well as the message transmissions or service calls among them (transactions). Transactions defined within the ITI domain are identified by their number of the form "ITI-<integer>" (cf. IHE ITI [3], TF-1, 1.1).

The profiles PIX and PIXv3 specify the communication with a central application, the PIX Manager, which is capable to aggregate multiple identifiers belonging to the same patient person. This actor receives patient information from individual PIX Source actors in form of Patient Identity Feeds (transaction ITI-8/ITI-44). A PIX Consumer actor may subsequently use a locally known patient identifier to obtain associated identifiers from the s (transaction PIX Query, ITI-9/ITI-45). Optionally, PIX Manager may notify the Consumer about changes in an association between two identifiers (transaction PIX Update Notification, ITI-10/ITI-47). The „Patient Identity Feed" transaction is re-used by a related profile Cross-Enterprise Document Exchange (XDS.b) for maintaining

a patient record in a central document index (actor Document Registry).

Demographics queries (transaction ITI-21/ITI-47) are directed from a peripheral client system (PDQ Consumer) to the central PDQ Supplier actor. The latter is often coupled (grouped) with a PIX Manager. Unlike PIX queries, PDQ supports comprehensive patient demographics both as query parameter and in the query result. The scope of the demographics may include pediatric information (Pediatric Option) or visit information (transaction ITI-22, subprofile Patient Demographics & Visit Query).

As incomplete information is allowed as query criteria in PDQ, responses with a large number of matching records may occur, which requires adequate technical means. PDQv2/v3 allows a querying client to explicitly limit the size of the response and to fetch the result in multiple smaller pieces. The complete result set is obtained by incrementally iterating over all fragments. This mechanism is referred to as incremental response or query continuation.

2 Objectives and Methods

Integration profiles PIXv2 and PIXv3 are not in complete alignment, the same is true for PDQv2 and PDQv3. The objective of the work at hand is to identify the differences and their impact on the practical usability of the respective profile.

To achieve the goal, the aforementioned specifications of the ITI technical framework were analyzed. Differences in the set of interactions, the information model and the vocabulary were explored, with consideration of the previous work. The main focus was put on differences in the definition of the relevant IHE transactions „Patient Identity Feed“, „PIX Query“, „PDQ Query“.

3 Results

3.1 Interactions

Both PIX and PIXv3 manage the patient information object through basic life cycle actions: create, read, update and delete (CRUD) [4]. Both PIX and PIXv3 use multiple transaction subtypes: initial query, continuation query, query cancellation. Refer to Figre 1 for an overview of the interactions and their correlation with each other.

IHE Transaction PIXv3/PDQv3	HL7 Ver. 3 Interaction	IHE Transaction PIXv2/PDQv2	HL7 2.x Message
ITI-44 (Patient Identity Feed)	PRPA_IN201301UV02	ITI-8	ADT^A01^ADT_A01, ADT^A04^ADT_A01 ADT^A05^ADT_A05
	PRPA_IN201302UV02		ADT^A08^ADT_A01
	PRPA_IN201304UV02		ADT^A40^ADT_A39
	MCCI_IN000002UV01		ACK^Axx^ACK
ITI-45 (PIX Query)	PRPA_IN201309UV02	ITI-9	QBP^K23^QBP_K21
	PRPA_IN201310UV02		RSP^K23^RSP_K21
ITI-46 (PIX Update Notification)	PRPA_IN201302UV02	ITI-10	ADT^A31^ADT_A05
	MCCI_IN000002UV01		ACK^Axx^ACK
ITI-47 (PDQ Query)	PRPA_IN201305UV02	ITI-21	QBP^K22^QBP_K22
	PRPA_IN201306UV02		RSP^K22^RSP_K22
	QUQI_IN000003UV01		QCN^J01^QCN_J01
	MCCI_IN000002UV01		ACK^J01^ACK

Figure 1: Comparison of PIX/PDQ interactions [3].

4 Information Model And Vocabulary

In the approach of both HL7 2.x and HL7 Version 3 semantic concepts in its implementable form are represented by a combination of an information model element and a vocabulary value. However, each of the standards may use a unique combination and not every concept is expressible in both standards.

This gap is obvious already at the level of data types. See Figure 2 for an example concerning the patient's mobile phone number. Another example of different representation are the specialized patient/person identifiers such as Social Security Number or Driver's License Number. These are modeled as individual elements (fields) in HL7 2.x (PID-19, PID-20), whereas in HL7 3.0 based profiles they are uniformly represented by a single element ("Other ID") with varying values of the assigning authority - i. e. through differentiation by the means of vocabulary.

	HL7 Ver. 2.5	HL7 Ver. 3 (XML)	
Data type used	XTN (Extended Telecommunication Number)	TEL (Telecommunication Address)	
Data element(s) used	XTN-3 (Telecommunication Equipment Type)	telecom/@value (scheme)	telecom/@use (use)
Vocabulary used	Table 0202 (Telecommunication equipment type)	URLScheme (2.16.840.1.113883.1.11.14866)	TelecommunicationAddressUse (2.16.840.1.113883.1.11.201)
Vocabulary value	CP (Cellular Phone)	tel (Telephone)	MC (Mobile Contact)

Figure 2: Representation of the mobile phone number in HL7 2.5 and Version 3.

In general, the information model of a HL7 Ver. 3 domain, based on the Reference Information Model (RIM), is richer and more powerful than the corresponding (implicit) model under HL7 2.x. The scope of the chronologically newer profiles is essentially the minimal coverage of elements required in the „old“ profiles, including profile

options. This approach is reflected in the constraints imposed on the HL7v3 Reference Information Model (RIM) by PIXv3 and PDQv3. Within this narrowed scope, IHE offers an approximate mapping of both data types and higher semantic units between HL7 2.x and 3.0 ([3], TF-2x, Appendix R).

A semantic mapping between the v2 and v3 representation is only achievable within a constricted scope and with limitations [5]. While PIXv3/PDQv3 strives for semantic alignment with PIX/PDQ, this effort influences the profile design. For example, both PIXv3 and PDQv3 impose a restriction on the scoping organization of a patient identifier, requiring it to be identical with the assigning authority of the patient identifier ([3], TF-2b, sections 3.45.4.2.2.1, 3.45.4.1.2.2, 3.46.4.1.2.1, 3.47.4.1.2.1). This does not fully comply with the common practice for assigning ISO object identifiers (OID) and restricts the OID assignment policy within the user's organization. Obviously this approach is a compromise to avoid more complicated technical solutions, such as an externalized mapping of object identifiers.

4.1 PIXv2 Versus PIXv3: Patient Identity Feed

The recipient of a PIXv2 ITI-8 transaction is explicitly required to respond with an application acknowledgement. In conjunction with the use of the original acknowledgement mode ([3], TF-2x, Appendix C.2.3) and the synchronous Minimal Lower Layer Protocol MLLP ([3], TF-2x, Appendix C.2.1) this implies that the response shall be generated immediately after the receiving application has fully completed the processiong of the message. The requirement for immediate application response conflicts with the asynchronous processing approach of most interface engines. This issue could only be resolved with an additional implementation effort, such as a asynchronous-to-synchronous converter being a part of the interfaces.

Opposed to this, for PIXv3 a commit acknowledgement (MCCI_IN000002UV01) is sufficient ([3], TF-2b, sections 3.44.4.1.2, 3.44.4.2.2, 3.46.4.1.2), which allows for responses with a simple transport receipt. In this case, message transmission over asynchronous intermediaries is IHE compliant.

As the PIXv2 profile specification references to the generic HL7 2.x guideline within the ITI technical framework ([3], TF-2x, Appendix C), its error handling is more specific than in PIXv3.

4.2 PIXv2 Versus PIXv3: PIX Query

PIXv2 query constraints itself strictly to dealing with patient identifiers (PID-3). Returning other data is explicitly precluded ([3], TF-2b, section 3.9.4.2.2.5). While the motivation of this measure is avoiding inconsistency issues with multiple unequal sets of demographics, its side effect is that the PIXv2 query response becomes de-identified. While the users of an IHE compliant PIX implementation can expect the query response to contain no personal data of the patient whatsoever, in a PIXv3 interface such behavior is not requried and has to be addressed explicitly. Since patient name is a required element in a PIXv3 query response (PRPA_IN201310UV02), the implementer would have to supply an adequate NullFlavor value to achieve de-identification.

4.3 PIXv2 Versus PIXv3: Update Notification

It is to note that on the Patient Identity Consumer side this functionality is expressed as an optional transaction in PIXv3 but represented as a separate profile option „PIX Update Notification“ in PIXv2 (ITI TF-1, table 5.2-1). The practical significance of the transaction is limited, as most implementations favor the query-response communication pattern of the PIX query over the data push approach of the notification.

While PIXv2 update notification ITI-10 is free of patient's personal data ([1]), the analogue PIXv3 transaction ITI-46 is generally not, on the same background as discussed for PIXv2 Query in section 4.4.

Furthermore, recipients of PIXv2 Update Notification are required to support a subscription mechanism with a defined configuration structure ([3], TF-2a, section 3.8.4.1.3.1). Requirement in PIXv3 are substantially less demanding ([3], TF-2b, section 3.46.4.1.2), leaving more freedom to the implementor.

4.4 PDQv2 Versus PDQv3: PDQ Query

PDQv2 only supports the combination of multiple query parameters with logical AND ([3], TF-2a, section 3.21.4.1.2.2.1). Logical OR has to be achieved executing multiple queries and subsequently combining results.

Also, PDQv3 is more specific about partial matches ([3], TF-2b, section 3.47.4.2.2.1). It describes how to specify a particular matching algorithm or how to quantify the alignment of the result with the parameters using a metric (quality of match).

A major difference appears in the specification of the continuation. Continuation is optional in PDQv3. HL7 2.x represents the response increments basically as linked list, using the continuation pointer of the DSC segment ([3], TF-2a, section 3.21.4.2.2.7) as a pointer to the next element. In opposite to this, the generic mechanism of HL7 Version 3 allows to be retrieve any fragment of the result, using the QUQI_IN000003UV01 interaction ([3], TF-2b, 3.47.4, 3.47.4.3). The fragment has an arbitrary position within the result set (parameter startResultNumber) and an arbitrary size (parameter continuationQuantity).

PDQv3 does not possess any counterpart to the optional Visit Information of PDQv2: the corresponding parameters such as Assigned Patient Location or Consulting

Doctor ([3], TF-2a, 3.22.4.1.2.2.1) are not supported.

5 Discussion And Conclusion

Comparing HL7 2.x with HL7 Ver. 3 with respect to the scope, methodology and information model down to the message structures has been subject to both theoretical research and practice driven work since the first Version 3 Normative Edition in 2005. To avoid redundancy, this paper refers to existing publications ([5, 6], [7, 8]) and addresses this aspect only in a limited depth.

It is to note that not all deltas between PIXv3/ PDQv3 abd PIXv2/PDQv2 can be attributed to the incompatibilities between the underlying information models. One reason why PIXv2 and PDQv2 are more restrictive than their HL7v3 counterparts is a higher re-use of the technical framework, e. g. of the framework-wide HL7 2.x guidelines ([3], TF-2x, Appendix C). Also, the HLv3 re-edition of the integration profiles was taken as opportunity for a purposeful re-adjustment of profile features, while maintaining downwards compatibility.

As HL7v3 and HL7v2 will continue to co-exist, the probability of PIXv2/PDQv2 and v3 interfaces being deployed in parallel to each other is likely to increase and technical availability will cease to be the major selection criterion. In such a setting, when deciding on the interface, special traits beyond the implementation technology can be taken into account. Based on the comparison results above, a few recommendations regarding the deployment can be articulated. PIX/PDQ HL7 2.x is to be preferred under the following pre-conditions:

- easy administration is a priority - immediate response and specific error handling increase the maintainability of the interface;
- for privacy reasons, patient demographics data must not occur in PIX query and PIX update notification;
- PDQ continuation must be supported;
- in the local deployment, organizations are not identified by a pure object identifier, instead a combination of an OID and an additional (non-OID) identifier is used.

PIXv3/PDQv3 is to be preferred under the following pre-conditions:

- asynchronous intermediaries (e. g. hospital interface engines) are employed for Patient Identity Feed transactions;
- rich PDQ queries are required, supporting the logical OR and result filtering based on the quality of match;
- comfortable continuation functionality is needed: random access to result fragments (w/ Continuation option).

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A Personal Health Service to Increase Patient Empowerment by Intelligent Use of Electronic Xray-Records

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Abstract

Background: The electronic Xray-Record is the Austrian contribution to the PALANTE project. The Austrian pilot aims to implement a new module into the hospital information system used within the KAGes which includes the summary of the dosage of X-ray examinations in a personal eXray-Record. The main goals are to support the personal health management of the patient and to increase the awareness of patients and physicians for X-ray exposure in healthcare. External access for health professionals and patients will be done via a web portal to provide a comprehensive representation of the X-ray exposure data. Additionally, transparency about radiation doses applied in the context of radiological examinations is provided. **Objectives:** This paper gives a brief description of the web access to radiology data. In particular, the paper outlines the online representation of exposure doses caused by radiology examinations and identifies the challenges. **Methods:** In the analysis, the national regulatory frameworks and standards were considered. Literature research and expert discussions were done to figure out the risks of the radiation exposure in the low-dose range. **Results:** Possibilities for data extraction and data representation were worked out. The architecture of the eXray-Record was designed with consideration of important standards. **Conclusion:** Access to personal health information empowers patients and increases the control over matters concerning their health. Shared decision making would become possible through intelligent use of the eXray-Record and a bi-directional patient-caregiver communication.

Keywords

eHealth, patient empowerment, radiology, X-ray exposure, personal health record, electronic Xray-Record, web portal, web access

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1 Background

Patient empowerment [1] is the situation where a patient plays an active part in his/her disease management. Patient empowerment integrates multiple concepts that allow a patient to effectively self-manage his/her disease. In the context of an aging population and an increasing number of chronic patients, it is considered a key tool to reduce healthcare costs and improve both quality and efficiency of the health delivery process [2]. Information and Communication Technology (ICT) applications already help to empower patients. However, there is still considerable potential to develop this concept much further.

Generally, pilots and projects dealing with patient empowerment each address a single element or mechanism of the whole concept. The approach in the PALANTE (PAtient Leading and mANaging their healThcare through EHealth) [3] project is to maximize the potential of ICT technologies by validating at a large scale a significant number of pilots so that all the mechanisms involved in patient empowerment are addressed. Thus the project approach considers the implementation of seven new pilots and the evaluation of two additional ongoing pilots. Globally, the project mobilizes twenty-one partners in ten different countries and 69.550 new users. The project there-

fore responds to the main challenges that European health systems are currently facing: demographic changes, demand for access to health relevant information, quality of care, and an increasing number of chronic patients.

1.1 Electronic Xray-Record

The Austrian contribution to the PALANTE project is to analyze, implement and evaluate one of the seven pilot implementations, the electronic Xray-Record (eXray-Record). The Styrian Hospital Holding (KAGes[1]) will implement the eXray-Record in 19 hospitals with 270.811 inpatients and 928.015 outpatients per year[2]. Currently, exposure data is not available in the Hospital Information System (HIS), neither electronically nor on paper and even less in a cumulative way. Therefore the X-ray exposure data is not accessible for health professionals and patients. In addition, it is difficult to keep track of all radiology examinations for both health professionals and their patients.

The eXray-Module to be piloted within the PALANTE project will summarize X-ray exposure data for every patient's life time in a personal eXray-Record. The information about the X-ray doses coming from radiology examinations can support decisions about further X-ray examinations.

Besides the knowledge about the cumulative doses of X-ray examinations an economic benefit is expected, because currently very similar or even the same X-ray examinations are often done twice, usually in an inpatient and an outpatient setting. Considering the information available from the eXray-Record the patient as well as the doctors will be aware of this exposure and may reduce the number of X-ray examinations, respectively avoid redundant X-ray examinations. The information stored in the eXray-Record will empower the patients in their personal health management. Furthermore, clinicians and referring physicians are interested in a high quality documentation of radiology examinations and also consider actuality, clarity, and completeness to be very important [5].

It is not an objective of the eXray-Record itself to derive recommendations on further radiological investigation opportunities. The medical assessment based on the data that the eXray-Record provides will remain within the responsibility of the physicians.

1.2 Integration into ELGA

The Electronic Health Record (EHR, ELGA) [6] is being implemented step by step in modules in Austria. Core applications of the first implementation phase of ELGA consist of the electronic discharge letter, e-Report laboratory, e-Report radiology and an e-Medication tool. In the future all relevant medical findings and documents will be stored in ELGA. Patients and their physicians will be able to access this data. The relevant data is provided by different health service providers (physicians, hospitals, etc.) and by the patient. In this context, data privacy and security are given highest priority, because ELGA contains medical information which is directly assigned to one distinct person. ELGA is a virtual health record, so its data is stored in several different information systems at the health service providers. For authorized persons all medical findings and documents are provided independently of location and time of the treatment. The data provided has to be relevant and up-to-date and is appropriately pre-processed and displayed for the specific user. Every patient has the right at every stage to refuse the storage of his/her data.

The Austrian Health Commission has decided to use established international standards for information and communication in healthcare. As a result, the following frameworks and standards are used for ELGA [7]:

- IHE Framework [8]
- Health Level 7 – Clinical Document Architecture (HL7 CDA) [9]
- Logical Observation Identifiers Names and Codes (LOINC) [10]
- Digital Imaging and Communications in Medicine (DICOM 3.0 incl. Web Access to DICOM Persisting Objects (WADO) [11]
- Health Level 7 V3 RIM as data model [12]

In a first step, the eXray-Record will only be offered to the patients of KAGes via a web portal. The eXray-Record should comply with relevant international technical standards and ELGA-specifications, so that it could be used to implement a further module of the Austrian health record ELGA. The data will be stored in compliance with the standards proposed for the Austrian electronic health record. The pilot project aims to implement the eXray-Record as an independent module. In this way, it can be integrated in other applications based on compliant international standards.

1.3 Web Access

According to a U.S. study [13] most patients are dissatisfied with the current reporting system in radiology. Referring physicians as well as radiologists are aware of this dissatisfaction of patients and think that patient access to radiology data should be provided. Researchers figured out that patients wish to have easy access to their personal health information and like to be involved in medical decision making. The representation of the data is expected to

[1] KAGes is a Styrian Hospital Holding, a non-profit organization and the public welfare promoter. Its core task is the construction and operation as well as the management of regional hospitals in the Federal State of Styria [4].

[2] http://www.kages.at/cms/ziel/2326/DE/ (2011)

be understandable, meaningful and clear. It is generally accepted that such an involvement leads to better clinical outcomes. On the basis of this evidence, it is believed that improved access to radiology information increases both patient satisfaction and clinical outcomes. A system that grants access to personal health data and additionally provides educational information could be expected to increase patients' knowledge and understanding of his/her own state of health. In addition, patients obtain greater autonomy because they take more responsibility for their own health care. A study of the American College of Radiology [14] outlines that patient access to radiology data provides the opportunity to develop better relationship between patient and radiologist.

Although there is reason to believe that the clinical outcomes could be improved, physicians are concerned that online access to radiology data could potentially increase patient anxiety. Furthermore, radiologists and referring physicians worry about patients' ability to understand the complex context of radiology data [13].

2 Objectives

This paper aims to endorse the necessity of an electronic Xray-Record and can be seen as a summary of recommendations for the implementation including issues and resulting advantages. Therefore we have to investigate national regulatory frameworks and standards to guarantee the feasibility of the eXray-Record project. As a result, we want to provide a list of relevant laws which have to be considered during the analysis and implementation phase.

In order to provide web access for patients and external physicians to radiology information, we have to examine possibilities of how to grant secure access to sensitive data. Additionally, we need to investigate the various possibilities of radiology data extraction and the process of transferring the measurement data into the record.

Another main question of concern is how to represent the figures of X-ray dose (milli-sievert) in a way to make them understandable for both patients and physicians. This could be achieved by putting them in relation to other measures like high mountain walks or Trans-Atlantic flights. However, the difficulty about relating dose to other measures is that these may be perceived as too harmless or too harmful. Relating dose to complications like cancer risk is problematic as well, because there is evidence on X-rays causing complications like cancer but not on the precise relation between the dose and the resulting complication. UNSCEAR states that "there is strong epidemiological evidence that exposure of humans to radiation at moderate and high levels can lead to excess incidence of solid tumours in many body organs and of leukaemia. There is also growing information on the cellular/molecular mechanisms through which these cancers can arise. [...] any increase in cancer incidence thought to be caused by low-dose radiation exposures is modest by comparison." [15]

Currently there are no rules on how to represent the X-ray doses to clinicians, not even in the clinical world. The challenge is thus making patients aware of the risk of radiology. However, no clear specification of the risk can be given.

3 Methods

In order to achieve an electronic record for X-rays the main stakeholders of the pilot were identified. For the pilot project, the KAGes officiates as the owner, provider and maintainer. KAGes provides experience in construction, operation and management of regional hospitals and is the end user and thus the validator of the pilot. The GFST (Gesundheitsfond Steiermark) [16] acts as the regional healthcare provider and is responsible for planning, managing and controlling the Styrian health service. The initiator of the project is the FH JOANNEUM University of Applied Sciences which provides the experts for examination and treatment methods in radiology, medical computer science, process management, health economics and public health.

We investigated the national regulatory frameworks and standards for the development of an eXray-Record. Our analysis was limited to laws and regulations in healthcare and technology, with special consideration of data privacy.

The basis for the development of the eXray-Record is a requirement analysis. Requirements were identified through an analysis of the scientific background and the creation of a questionnaire. We were able to involve a range of medical professionals such as physicians, radiology technicians, medical physicists as well as patients into the requirement analysis process.

4 Results

4.1 Regulatory Framework

The regulatory framework includes the data privacy act (Datenschutzgesetz [17]), a law which defines additional data security rules for electronic transactions with health data (Gesundheitstelematikgesetz [18]), a central law to protect people and environment from harm due to ionizing radiation (Strahlenschutzgesetz [19]), an act about the regulation of measures for the protection of persons against ionizing radiation in the field of medicine (Med. Strahlenschutzverordnung [20]), the Austrian Physicians Law (Ärztegesetz [21]), a law for medical-technical professions like e.g. physiotherapists, speech therapists and radiology technologist (MTD-Gesetz [22]) and regulations for the education of medical-technical professions including radiology technologists (FH-MTD-Ausbildungsverordnung).

4.2 Data Extraction

The X-ray exposure data of the specific examinations of patients is the foundation for the core functionalities in the eXray-Record. Different ways of documenting the X-ray exposure data will be necessary, depending on the type of X-ray unit and manufacturer:

- Transfer via DICOM/MPPS interface from the X-ray unit to the eXray-Record (mainly for CT and fluoroscopy)
- Documentation by manual reading of the data from the X-ray unit and entering it manually in the HIS (mainly for CT and fluoroscopy)
- Documentation in RIS (Radiology Information System) supported by default values which are automatically preallocated depending on the weight and sex of the patient and the radiological procedure (mainly for conventional X-rays and mammography)
- Automatic determination of the required data from the header-data of the PACS images (mainly for conventional X-rays and mammography). This process is triggered after a new picture of a radiology examination has been stored into the PACS.

In every case the X-ray units only provide the physical parameters of the examination like dose area product, dose area product rate or tube current. From these physical parameters, the eXray-Record has to calculate the effective dose by using conversion factors.

4.3 Data Representation

Since the discovery of radiotherapy the use of radiology procedures have globally increased. There are a number of current trends in medical use of ionizing radiation, which offers tremendous benefits to the humans. The rapid increase of new technology for medical exposure and the corresponding speed of clinical introduction of this technology show a major trend, but the associated radiation exposure poses a high risk for patients. In particular the increased usage of computed tomography (CT) scanners causes about 42% of the total collective effective dose arising from medical diagnostic radiology [23].

The eXray-Record provides an accurate summary of doses for physicians and radiologist to make them aware of the amount of radiology examinations. To still the fears of radiologist and referring physicians about clear data representation for patients the web portal offers meaningful comparisons of radiation doses. Cumulative or other radiology doses, which are shown in milli-sievert (mSv), are presented in a clear, understandable way and the radiology exposure data is explained on the basis of comparable examples. Figure 1 provides comparisons between doses from radiology examinations and the natural radiation exposure. In Austria the effective dose of natural radiation exposure amounts to 2,5 mSv per year which is equivalent to 0,007 mSv per day [24]. The various examination procedures are normalized by comparing it to a common thorax radiology exposure. Such comparisons support patients to become aware of the risks of radiology. However, a clearer specification of the risk is not possible.

Examination Procedure	Effective Dose (mSv)	Equal to n pa-Thorax-Xray	Equal to Natural Radiation Exposure in Austria
Thorax pa	0,02	1	~ 3 days
Skull 2 planes	0,07	~ 3,5	~ 1 week
Abdomen ap	1	~ 50	~ 5 months
CT skull	2,3	~ 115	~ 1 year
CT thorax	8	~ 400	~ 3 year
CT abdomen	10	~ 500	~ 4 year

Figure 1: Typical effective doses, based on VBDO [24]

4.4 Architecture

Figure 2 shows the framework of the eXray-Record. Every X-ray examination in a patient life is stored in the personal eXray-Record. Physicians within the KAGes are able to access the eXray-Record through the hospital information system. External physicians and the patient can access the data through a web portal. Based on this data they are able to make an informed shared decision about future X-ray examinations. The collected data of radiology examinations is stored in the Clinical Document Architecture (CDA) format. The standard used is based on the latest implementation guidelines for CDA reports of imaging diagnostic in Austrian healthcare [9]. The usage of the standard provides a harmonized, structured and standardized way to transfer medical documents from health services to patients.

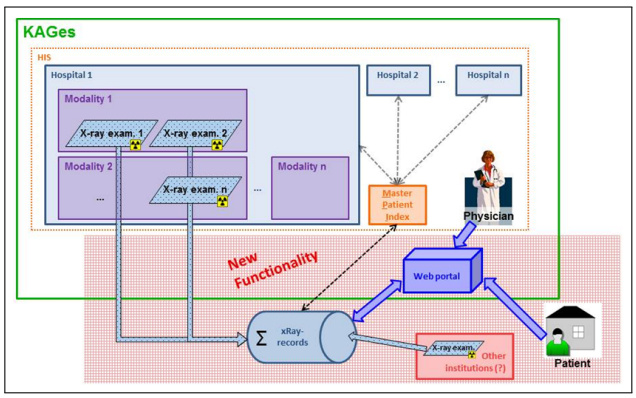

Figure 2: eXray-record architecture

5 Conclusion

Promoting the deployment of new information and communication technologies in the health care system is the explicit aim of a series of international and national strategies in Austria, the majority of which are related to the Europe initiatives and the eHealth action plan of the European Union. Austria is participating in the European PALANTE project to maximize the potential of ICT technologies and to achieve patient empowerment.

It is widely accepted that the access to their own health

information empowers patients and increases their control over matters concerning their own health. However, access to personal health records is just the first step in the process of patient empowerment. The ultimate goal is the evolution into a system where bi-directional patient-caregiver communication is possible and shared decisions can be made within disease management.

The development of the eXray-Record was initiated first of all to summarize the X-ray exposure data for every patient's life span in a personal record. An additional goal is to make the X-ray exposure data available for patients and health professionals. The eXray-Record provides doctors with additional information to decide about further X-ray examinations which help to minimize the total X-ray exposure of a patient. The online representation of the eXray-Record for patients and external physicians is a crucial point.

Online access to sensitive data is always assumed to be critical, because high security standards have to be ensured. Therefore a smartcard and SIM card based approach is a possible way to ensure secure access to the eXray-Record [25].

In the end, the implementation of an electronic Xray-Record can be seen as another step towards patient centered integrated care and patient empowerment. It is highly expected that this project will generate economic, medical and social benefit for patients, physicians and ultimately the healthcare system.

6 Acknowledgements

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Sound Foundations: Leveraging International Standards for Australia's National Ehealth System

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Abstract

Background: Australia is currently in the process of deploying a national personally controlled electronic health record (PCEHR). This is being built using a combination of international standards and profiles as well as Australian Standards and with specifications developed by the National eHealth Transition Authority (NeHTA). **Objective:** There exists a poor appreciation of how the complex construction of the overall system is supported and protected by multiple international standards. These fundamental underpinnings have been sourced from international standards groups such as Health Level Seven (HL7) and Integrating the Health Enterprise (IHE) as well as developed locally. In addition, other services underlie this infrastructure such as secure messaging, the national Health Identification Service and the National Authentication Service for Health (NASH). **Methods:** An analysis of the national e-health system demonstrates how this model of standards and service integration results in a complex service oriented architecture. **Results:** The expected benefits from the integrated yet highly dependent nature of the national ehealth system are improved patient outcomes and significant cost savings. These are grounded and balanced by the current and future challenges that include incorporating the PCEHR into clincial workflows and ensuring relevant, timely, detailed clinical data as well as consistent security policy issues and unquantified security threats. **Conclusions:** Ultimately, Australia has designed an ambitious yet diverse and integrated architecture. What remains to be seen is if the challenges that the medical software industry and clinical community face in leveraging the political process in order to encourage provider and public participation in ehealth, can be achieved despite the sound underpinnings of international standards.

Keywords

Medical Informatics Computing, Health Communication, Data Sharing, Health Level 7, Electronic Health Records

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1 Introduction

In Australia there is an undeniable uniqueness to the healthcare environment that has resulted in a complex approach to the development of a national e-health system. It is important to appreciate what these distinct drivers are if there is to be an understanding of the structure and functionality of such an ambitious project. The development and implementation of the Australian national e-health system represents an important and radical change to the healthcare system and critical societal infrastructure.

The uniqueness arises from a number of drivers and characteristics peculiar to healthcare. The drivers in Australia are heavily influenced by the political landscape and the time deadlines imposed by the government. From the perspective of the characteristics of the healthcare delivery environment, the imperative is to have the right data in the right place at the right time, and an urgency driven by clinical need and conditions. Added to this is the complex sequencing of clinical steps and the coordination of parallel patient care, complicated by difficulties with infrastructure and availability of trained personnel across diverse care settings from major cities to remote Aborigi-

nal communities.

This impact of these factors on the applications and software used to delivery and support ehealth is that there is an inimitable complexity of data and documentation, and a labyrinth of data requirements across a distributed system. The distribution is not merely in location but of time and person given the dispersed web of healthcare providers. This environment requires a complex construction of governance because of the public (40%) and private (60%) split in service delivery and due to its multi-tiered, distributed arrangement. This governance structure creates a disjunction between costs and benefits. The electronic age where information, both good and bad, is not in short supply, demands a medico-legal practice of defensive medicine, in addition to the primary prerequisite of medical practice to 'first do no harm'. The need to tame this clinical information tsunami means it is increasingly important to provide effective and readily adoptable clinical decision support. The relevance of these factors to the development of software applications, services, and the supporting information exchange architecture [1] means that developers are wading into a highly complex and contextualised environment. This situation is further complicated by the consideration of privacy and security [2] and the sensitivity about government concentration of personal information.

This paper explores the complex underpinnings of Australia's national ehealth system and the Personally Controlled Electronic Health Record (PCEHR). The basis for using standards and their impact is discussed to preface the analysis of the challenges that such a national system presents to those who have to deliver it – the software industry; those who are to use it - the clinical community; and those who are the consumers of it - the public, and how these challenges create tensions despite the sound foundations that the system is built upon.

1.1 Background to the Personally Controlled Electronic Health Record

Australia, like many countries, is facing increasing challenges in delivering high quality healthcare to an aging population and increases in chronic disease whilst attempting to control spiralling costs [3]. As part of Australia's national health reform Australia is introducing a Personally Controlled Electronic Health Record (PCEHR) [4, 5]. The PCEHR is a primary constituent of the national health reform agenda and as such has been the focus of the development of Australia's ehealth architecture [6]. The PCEHR "aims to place the individual at the centre of their own healthcare by enabling access to important pieces of health information when and where it is needed by individuals and their healthcare providers" [7].

In the Australian healthcare environment there are a number of complementary bodies involved in and impacting the development of the national ehealth system as shown in Figure 1. These include the government sponsored organisations charged with the delivery of the overarching architecture namely National eHealth Transition Authority (NeHTA), the Federal Departments of Health and Ageing (DoHA) and Human Services (Medicare); and the standards and stakeholder communities comprising of national and international standards organisations and technical stakeholders. The national and international standards organisations work underpins the establishment of this architecture such as Health Level 7 (HL7), the International Standards Organisation (ISO) - Health Informatics Technical Committee TC215, Integrating the Health Enterprise (IHE) and Standards Australia (SA) – IT-014 Health Informatics Technical Committee. The technical stakeholders include the Medical Software Industry Association (MSIA) who represent the clinical and supporting system suppliers.

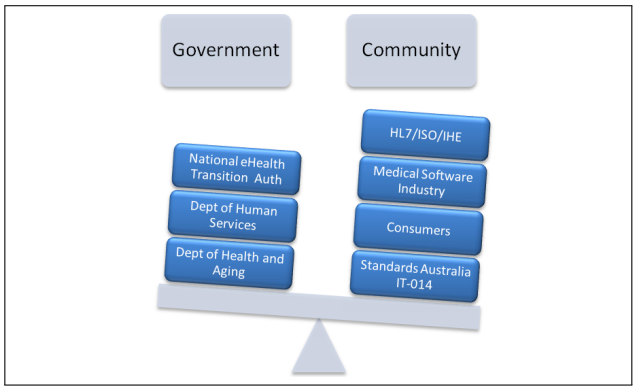

Figure 1: Contributing national organisations and groups in the Australian ehealth standards process.

As with any major government initiative there are inevitable tensions in meeting the needs of the various stakeholders. The tensions have been exacerbated by short politically driven time frames, the enormity of work involved, confusion over leadership roles, the difficulties arising from reliance on a community of volunteer experts to deliver outcomes and key performance indicators for government sponsored organisations. This volunteer community is arguably the ehealth community's most valuable yet undervalued asset. This method of harnessing volunteer experts, who work in the health informatics and related industries, only functions effectively because such people are committed to the outcomes trying to be achieved for Australia nationally. The involvement and collaboration of all stakeholders in Figure 1 is essential to avoid duplication of standards and to obtain engagement and support particularly where the end-user vendor community is bearing a large percentage of the costs. Further, it promotes transparency and harmonisation in a sector that uses multiple models for development, and has a diversity of healthcare delivery requirements. The standards need to ensure that they support all sectors of the healthcare community and do not create unnecessary barriers to innovation and market competition.

2 Standards as a Basis for Systems Development

A standard is an expert consensus document that provides a benchmark for a product or service [?]. Such consensus "represents the best knowledge in the field" and essential contribution by people who are regarded as the technical experts in their field, and in this case are experts in health and health informatics [?]. Standards are practices that are recognized for their quality and can be used as a measure for comparison. Like laws, they need to be monitored and enforced to be effective. Standards provide guidelines for best practice, consistency and interoperability [10] and are an essential feature in a minimally regulated field such as computer and information science. Thus, when this field and the healthcare environment are combined, the requirement for standards is imperative to mitigate potential for safety issues. Further, standards are essential for consistent outcomes to security reusability and end-point security stability, even though the approaches may vary. This is also important as one solution does not meet all the needs.

The use of standards, not to be confused with standardisation, is to facilitate the effective interoperability in communications. One of the underlying drivers for creating uniformity through standards is to address the issues of safety and quality which is of particular importance in the healthcare application environment. Further, standards in software development are beneficial in the ability to reuse specifications from consistent, expert evaluated documentation. Informed, independent and objective professional review also contributes to increased clarity of requirements specification [11]. Further, it contributes to lowering integration costs, fosters vendor innovation and competition with no specific vendor lock-in for users, which are all important factors in the development of a nationwide interoperable system in Australia's free market economy. These are all benefits of using local and international standards where multiple but integrated services are required. This also fosters an independent plug and play approach to software and service integration – a goal of services oriented architecture (SOA).

Designs of formal electronic health records have focused on the integration of intra-enterprise applications. This severely limits the scalability and interoperability required for distributed systems [12]. Thus the move to SOA is attractive, although complex and a major challenge to design on a national scale. There are examples of SOA designs at an organizational level, but few at levels wider than this. What SOA potentially provides is an overarching architectural framework which allows the functionality of multiple competing but complementary services to be brought together. The reuse and enterprise application integration is an attractive proposition supporting modularity and interoperability, using services as the building blocks for development of flexible but reliable system components [13]. In addition, SOA can forge a pathway for migration from legacy systems as it permits software solutions at different levels of technical maturity to effectively interoperate.

2.1 The Australian Experience

As has been shown in other countries, the challenge is to integrate standards nationally and internationally that support the needs of the environment to which they are applied [14]. In order to avoid the case where proprietary developed standards hamper national interoperability, Australia has taken a 'standards based approach' to the development of the ehealth architecture. Further, the collaboration between the government sponsored organisations and the standards development and implementation community in Australian healthcare, as in Figure 1, has been used to enhance interoperability among the multiple stakeholders and the standards making communities. This is important as it has been demonstrated that the numerous standard development organisations themselves may create confusion for standards adopters, namely industry, instead of promoting interoperability [15]. Collaboration at any level is a beneficial objective to pursue, to avoid gaps in requirements and unnecessary overlap of standards and subsequent disparity between them.

In creating Australia's ehealth interoperable environment a number of standards are used including HL7 Clinical Document Architecture (CDA) and Integrating the Health Enterprise - Cross Enterprise Document Sharing (IHE XDS.b) profile, specified for the Australian PCEHR and associated conformant repositories. The standards upon which the Australian ehealth system is based are well established and used internationally. For instance "the IHE IT Infrastructure (ITI) domain addresses the implementation of standards-based interoperability solutions to improve information sharing, workflow and patient care" [16]. It achieves this with the harmonized use of established international standards such as DICOM and HL7 within an SOA framework.

These international standards are core to ehealth interoperability and supporting services such as the National Authentication Service for Health (NASH), Health Identifiers Service (HI), Secure Message Delivery (SMD), Endpoint Location Service (ELS), Health Care Provider Directory (HCPD), Audit and so on. Some have been modified and extended by NeHTA, for instance, the CDA standard has been extended in a manner permitted by the CDA standard but may not result in adoption internationally and may not end up being incorporated into the international standard. At present these extensions are localised to Australia.

2.2 A Service Oriented Architecture for the PCEHR

There is an increasing push to adopt services oriented architectures across organisations [17]. This is partic-

ularly pertinent to the healthcare environment as SOA addresses some of the common problems that healthcare computing faces in a complex work environment with a need for legacy system re-use, and requiring linkage of multiple interfacing systems [18].

Figure 2 provides a representation of how primary services are integrated for the PCEHR, and how they are moving towards a service oriented architecture. This diagram indicates how technical specifications and standards underpin the national PCEHR.

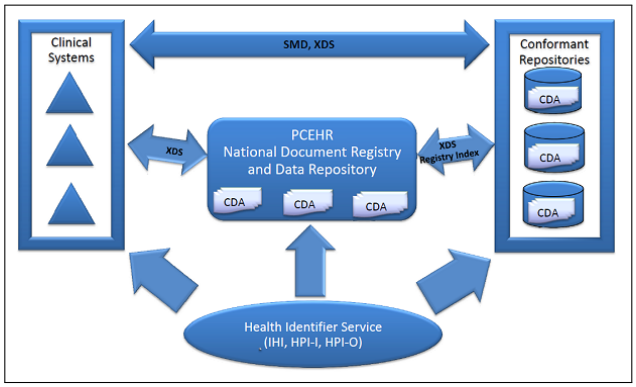

Figure 2: Diagrammatic Representation of the PCEHR

The PCEHR architecture consists of the following services and standards:

- Health Identifier (HI) Service – service specified by NeHTA and implemented by Medicare
- Secure Message Delivery (SMD) – Standards Australia Technical Specification
- Clinical Document Architecture (CDA) – Health Level 7 (HL7) Standard
- Cross Enterprise Document Sharing (XDS) – Integrating the Health Enterprise (IHE) Profile
- ISO 27790 Health informatics: Document registry framework - International Organization for Standardization
- National Authentication Service for Health (NASH) – service specified by NeHTA, implemented by IBM under a government contract.

The proven combination of CDA and XDS.b as a secure clinical document exchange facility, should provide core capability that will reward future investment in functionality and content. This is an ambitious, diverse and integrated architecture whose local components are as yet unproven, however they are based on proven widely deployed international standards and profiles. Significant changes have been made for the Australian implementation, some of which have not yet been fully disclosed and hence it is difficult to evaluate the total impact on functionality, performance and security. It is clear that the variance is sufficient to place a barrier in the path of participation by international vendors as well as potentially limiting export opportunities for local implementers.

Of concern is that in any electronic records system it is the control of all information, but particularly sensitive and patient confidential healthcare data that needs protection. The manner that this is dealt with from a security perspective is through established security policy. This requires that all participants in the information sharing domain in question must have methods of informing each other of their respective policy and ensure they are consistent [19]. This extends further than just trusted end-to-end communication. Privacy of information has been, and is, a major issue for all countries in developing shared healthcare data systems [20]. Whilst there exists a National Ehealth Security and Access Framework (NESAF) [21] intended to provide an overall architectural solution for security, it is the application of this aspect that is currently unclear in Australia's deployment. The NESAF itself is based primarily and extensively on ISO standards and whilst still under development themselves, refers to the HL7 PASS and SAIF frameworks [22].

A recent article by NeHTA's Chief Clinical Lead and other well respected co-authors suggest that there may be critical unmitigated risks with the current implementation [23]. The need for bespoke tool kits for development and conformance testing is a flow-on from the variations to international standards and represent a further risk in terms of possible uncaught implementation errors and ongoing maintenance costs. There will be a necessary trade off between complexity of regulations, conformance and compliance requirements, and an implementation barrier and cost that may prove difficult to manage. This is likely to lead to delays in implementation as has been evidenced already by the Health Identifiers Service. Delays of up to two years for significant uptake have been forecast in DoHA and NeHTA presentations. These important factors result in a number of challenges for those who are to engage with the implementation and use of the national PCEHR system in a commercially sustainable environment.

3 Community and Stakeholder Challenges

The situation described above has led to a number of tensions between government and industry. Numerous personnel changes and strong political drivers pushing for short time frames have detrimentally impacted collaboration with the stakeholders and made quality development challenging. It has seen short term planning, decision making and frequently changing goal posts, which create frustration and uncertainty about what can and will be delivered. Indeed the scope of what will be deliverable on July 1st, 2012 has been constrained considerably from its original specification over the period from April 2012.

From a software industry perspective the tensions are compounded by the issues resulting from the government's inflexibility on time frames and initial scope creep followed by a rapid reduction in scope in the months prior

to launch. There is considerable pressure to realise return on investment as despite being a national initiative, the majority of the software industry is not being funded to implement the attached systems. Given the changes, delay in some specifications and lack of budget for long term development of specifications, the scope has now been so constrained and it may prove difficult to make a sustainable business case for implementation for many vendors in the short or medium term.

One significant issue that has arisen is that some standards have been varied during implementation. For instance, the HL7 CDA standards have been extended, the impact of which is that the standard tools and testing methodologies do not work with the NeHTA versions. The IHE XDS payload and XML packaging have been altered from the international profile. The security in the PCEHR has not been disclosed other than in the broadest terms. There are issues of late modifications to both the PCEHR electronic (B2B) interface and content specifications which will ensure that implementation will take time once the specifications are available, correct and stable. Lastly, the delivery of associated but fundamental services, for instance the NASH, has been delayed, and now is only due for delivery sometime after the 1 July PCEHR launch date, necessitating the adoption of interim security arrangements which have recieved little external scutiny. It is very difficult to retrofit security and there is no information provided on the extensions to standard PKI certificates that will be employed. There are concerns that appropriate Health Identifiers Service functionality may not be in place prior to PCEHR launch. For instance, the ability to assign patient individual health identifiers (IHIs) to neonates in a timely manner.

In regard to the clinical community, there are many issues that have yet to be fully addressed associated with clinical workflows and sustainability. Firstly, the incentives to use the PCEHR are not clearly defined from the clinician perspective though there has been some clarification about use of claimable service fees (called item numbers in the Australian context). Secondly, there are risks to the information being shared and available in many places but uncertainty that it is complete. The quality of the patient summaries may be variable since patients can nominate any provider to submit this information at any time. This may not be their usual practitioner or one that has the majority of relevant information for the patient. This is complicated by the potential commercial incentives for a variety of providers to undertake this activity. The currency of data and any implied obligations on the practitioner who submitted it to the PCEHR have not been widely discussed. The willingness or ability of clinicians to construct appropriate summaries for upload has been assumed rather than tested in any large scale deployment. This was not possible in the test implementation (Wave 2) sites as they did not connect to the PCEHR and employed a completely different interface technology to separate repositories.

From the public's viewpoint there has been little published testing of the impact of the PCEHR and in particular the consumer entered information including what impact this may have on the patient/consumer themselves. There are two parts to the patient entered information - a private and a clinical section. The consumer has control of this information and to whom it is visible. What if inappropriate comments about their treating clinicians or GP are entered? For example a disgruntled patient posted information of a detrimental nature about their doctor. Whether there are adequate safeguards is unclear at present.

Secondly, the decision making ability of the consumer in regards to the control of their information also raises concerns. How are the general public (not medically trained or aware) to decide what clinical information, which they may or may not understand, is relevant or meaningful. Would a patient understand that an x-ray report of pneumocystis pneumonia would be primary evidence for most medical practitioners that the patient has HIV? It is clear that patients will have to understand complex medical data in order to put in place effective and desired access control. For some sections of the community this may cause anxiety in the decision making and distrust influencing the decision to conceal or not conceal certain information. Patients making these choices may not completely understand the implications of hiding data on their future treatment.

4 Conclusions

The development of a service oriented architectural solution on a national basis is ambitious yet necessary. The successful deployment of a national health records system, regardless of any technological issues, is dependent ultimately on the user acceptance and use. Putting the legal, workflow and security barriers aside, the standardisation of healthcare information (yes more standards) is a key element to its adoption.

The initial facilities will be basic and any uptake will be dependent on funding to extend and prove the system. This is likely to take a significant time and in the current political environment may not even be possible. Of greater concern is the lack of a live test environment, similar to a live deployment but with populated dummy data with which to test the security, access and performance. Any large implementation that has a high reliance on and integration of security services, as the Australian national ehealth system undoubtedly has, should have a coordinated and defined security test plan. To date no such plan has been released or reported on. In fact the security deployment has been kept confidential. In a system that reflects a security based services oriented architecture, the necessity to test the individual components and the integrated end-to-end system is vital. Whilst the underpinning of the system and its reliance on standards will provide some assurance, what is untested is the variation from these established international standards. Post

1 July, 2012 will provide some of these answers.

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