

IHIC 2007 International HL7 Interoperability Conference

ABSTRACTS

ABSTRACTS	- 1 -
Day 1 - Friday	- 2 -
Shared Session	- 2 -
NHS CfH: Care Record Sumary & Entries	- 2 -
Canadian V3 Experiences: ePrescription, Claims & Disease Management	- 2 -
HL7 Version 3 Mission and Strategy in Relation to International Standards and Methodologies for Semantic Interoperability	- 2 -
Stream 1 – Auckland Room	- 3 -
Next Generation Electronic Medical Record Systems – Pioneering Attempts in Japan.....	- 3 -
CDA R2 “Summary of Care” Specification and Addenda in Germany.....	- 4 -
Maintainability of Healthcare Information Systems and the role HL7	- 5 -
Stream 2 – Epsom Room.....	- 7 -
Over the RIM.....	- 7 -
Development of a Nationwide Standard Electronic Health-Document-Exchange based on HL7CDA-Rel.2 in the New National Health-Checkup-Program for Preventing Metabolic Syndrome in Japan.....	- 9 -
Use of HL7 Clinical Document Architecture R2 (CDA R2 And Inclusion of Digital Signature.....	- 11 -
Day 2 - Saturday	- 14 -
Shared Session	- 14 -
HL7 V3 and SOA.....	- 14 -
CDA & CCD Specification & Implementation	- 14 -
Stream 3 - Auckland Room.....	- 14 -
A Unified Approach to Adoption of Laboratory LOINC in Taiwan.....	- 14 -
Development of HL7 Methodology for Medical Data Exchange in Taiwan using the assessment framework provided	- 16 -
HL7 – Review and Guidance for Handling Multiple Versions	- 17 -
Document-Centric Clinical Care: Using ECMA XML to Document Healthcare for Machine and Human readability	- 17 -
Stream 4 - Epsom Room	- 19 -
SS-MIX: An Initiative for Promoting Healthcare Data Exchange by Japanese Ministry	- 19 -
Informatics in the management of metabolic syndrome.....	- 20 -
Clinical Document Registry Framework.....	- 21 -



HL7 New Zealand

See www.HL7.org.nz for presentations
& additional information

Day 1 - Friday

Shared Session

NHS CfH: Care Record Sumary & Entries

Dr Ken Lunn, Data Standards, NHS Connecting For Health

NHS Connecting for Health has adopted HL7 V3 as a core standard for electronic communications for the National Programme. This includes a broad range of clinical applications including demographics, access control, electronic prescribing, and detailed clinical information exchange. We publish a localisation of the V3 standard, which suppliers use to define their interactions in a heterogeneous network of applications. Our current implementations involve the broadest HL7 V3 implementation worldwide, and in some areas the highest number of messages of a particular type. As well as applying the HL7 V3 standard, we are proactive in extending it, participating in HL7 working group meetings and sponsoring projects to further develop the standard. We also have taken a proactive stance with HL7 V3 tooling and have been the main instigators of the HL7 Tooling Collaborative.

Canadian V3 Experiences: ePrescription, Claims & Disease Management

Mr Marc Koehn, Gordon Point Informatics Ltd.

Canada's health jurisdictions are aggressively pursuing e-health initiatives to help improve the delivery of health care to their citizens. Many of the associated initiatives are sustained by investments from Canada Health Infoway Inc., an independent, not-for-profit organization whose Members are Canada's 14 federal, provincial and territorial Deputy Ministers of Health. These initiatives are also shaped greatly by a common architecture framework, namely Infoway's Electronic Health Record Solution (EHRS) blueprint, and compatible data communication standards. This unique business arrangement is beginning to bear fruit and may offer lessons for other jurisdictions seeking to accelerate their e-health agendas.

The presentation will briefly outline Canada's constitutionally driven health delivery system. It will then provide an overview of Infoway's EHRS Blueprint, its key investment programs and, more specifically, the strategy of using contemporary messaging and nomenclature standards to drive EHR developments. Given that so many initiatives are still under development, the presentation will attempt to take stock of progress to date and will surface key challenges and lessons learned.

HL7 Version 3 Mission and Strategy in Relation to International Standards and Methodologies for Semantic Interoperability

Bernd Blobel, Diego Lopez. eHealth Competence Center Regensburg, Germany University of Regensburg Medical Center Franz-Josef-Strauss-Allee 11, 93053 Regensburg, Germany, bernd.blobel@klinik.uni-regensburg.de

With its version 3, HL7 advances from a communication standard to a development framework and workproducts for semantic interoperability. In that context, all paradigms characterizing structure, behaviour and needed infrastructure services for semantically interoperable systems have to be developed step by step. Because there are several very active standards developing organizations in the healthcare domain, but also many others coming from domains directly or even only indirectly related to health. In that context, system analysis tools, software engineering processes and methodologies, but also specifications of systems and component in domains to be considered in the context of integrated care, the development of comprehensive e-society approaches have to be considered. Therefore, open-minded communication and cooperation between SDOs as well as the consideration and harmonization of standards is not only required towards SDOs in the field of Health Informatics such as ISO TC 215, CEN TC 252, DICOM or IHE (in the context of profiling) and their workproducts, but has to include many other ISO TCs, CENELEC, ETSI, OASIS, W3C and its IETF, ASTM, etc. Additionally, relevant international projects or national or international health telematics or eHealth programme have been included. Here, the openEHR work, Eurorec activities and Projects as well as the European eHealth strategy and its Member States derivates will be considered.

The paper first classifies the semantic interoperability paradigms, groups standards from different domain including HL7 for meeting the paradigms' challenges, compares mission and strategies defined, assesses commonalities and differences and finally defines requirements and possible solutions for migration and harmonization.

The presented approach is fundamental for the current and future development of HL7 as well as for the demanding evolutionary and partially even revolutionary process ongoing around the globe towards comprehensively integrated and personalised health setting (i.e. beyond health care including public health, social affairs, etc.).

Stream 1 – Auckland Room

Next Generation Electronic Medical Record Systems – Pioneering Attempts in Japan

Speaker: Ei Murakami

In 2001, Ministry of Health, Labor and Welfare (MHLW) of Japan issued an e-health action plan titled “The Grand Design for Information Innovation in Healthcare Field”*. In this plan, an ambitious goal was set up that 60% of hospitals with over 400 beds and 60% of clinics in Japan should have working Electronic Medical Record Systems (EMRS) by the end of the fiscal year of 2006. Although the resulting rates are not as high as expected, it has contributed to enlargement of the installation volume of EMRS in Japan.

This spreading EMRS utilization has improved efficiency of hospital operation in accounting and logistical aspects. On the other hand, it requires practitioners' accurate and enormous direct entry and arises following issues;

- Practitioners find it hard to follow complicated operation sequences in busy clinical situations.
- Entering Japanese text into terminals is not a straightforward task but a task requires interactive converting process.
- Practitioners tend to face more to screens and less to patients and it makes patients feel a sense of alienation.

The presentation will introduce pioneering attempts to design EMRS which may better cope with the above issues. Support for practitioners' thinking process, natural language processing and patients' participation in record management will be featured. Localizations and possible extensions to CDA specifications will be also addressed to accommodate additional information for these purposes.

*English title translation by the speaker. The original in Japanese is "Hoken-iryou Bunya no Joho-ka ni Mukete no Grand Design"

CDA R2 "Summary of Care" Specification and Addenda in Germany

Dr Kai U Heitmann, Chair HL7 Germany

Director International Affiliates - Board of Directors HL7 USA

Heitmann Consulting and Services (The Netherlands, Germany)

In summer of 2006, the final balloted version of the German HL7/Sciphox "Arztbrief" (summary of care) specification based on Clinical Document Architecture R2 (CDA R2) was released. The 150 page implementation guideline defines a kind of "framework" based on three use cases and several storyboards. A set of about 30 business rules expressed in Schematron used as a business rule validation language has also been defined in order to add extra validation opportunities to the created CDA documents.

The largest German vendor's association, VHitG, initiated and sponsored this development, and more than 15 medium and large size vendors helped to actively define the "Arztbrief." The official part (ballot) was conducted by Sciphox/HL7 Germany and, therefore, has now achieved a normative status in Germany. These 15 vendors demonstrated CDA R2 document exchange based on this specification at a large German exhibition that is similar to a small HIMSS. The scenario covered primary care systems, hospital settings, and a rehabilitation setting. The exhibition showcase successfully demonstrated CDA R2 implementations in various care chains.

This presentation summarizes the results and experiences. CDA R2 Levels 1 and 2 are used for the structured and labeled text, and for diagnoses and procedures also Level 3 is defined and implemented by some vendors. An additional implementation guide for the transmission of diagnoses defines information exchange between practitioners, and for reimbursement purposes, public health, and cancer treatment and research in Germany.

This year, work has continued to define the terms "Laboratory Results" and "Medication" that are represented in CDA R2 Level 3. The so-called addenda "lab" and "med" are an extension to the original "Arztbrief" framework specification. While lab results were not difficult to define in terms of structures and codes (for example, LOINC

is used), specifying medication was much more of a problem from the coding perspective. It is difficult to find an unique and commonly used code system to classify medication. Additionally, some other needed vocabularies such as route codes were considered as well as codes from other pharmacy standards organizations.

Meanwhile, a few other projects based on this CDA R2 specification have begun. One of the projects is now busy to define digital signatures to be used in the context of this specification.

Maintainability of Healthcare Information Systems and the role HL7

P. Aggelidis, A. Berler, C. Chronaki

Summary

Maintainability, the ability of a pre-existing operational healthcare Information System (IS) to be retained and smoothly incorporated in an integrated Regional Healthcare Information System (RHIS), is a challenge for large scale implementations covering different healthcare entities, vendors, and diverse user needs. Fostering maintainability can contribute to increased user acceptance, containment of IT costs, and incremental development. Starting from experience gained from tenders in the Greek public health sector, different aspects of maintainability are discussed based on quantitative and qualitative data. HL7 and other interoperability standards can promote maintainability at the technical level, however, business and marketing perspectives need to be accommodated as well for long-term sustainability.

Introduction

In 2001 a reform of the Greek national healthcare system was introduced aiming to enhance the performance of healthcare IT in Greece. Detailed Requests for Proposals (RFP) were issued for each of the newly created 17 regional health authorities (RHA) focusing on pressing clinical, organizational, and managerial needs [1]. The requested RHIS included all levels of the health system e.g. primary, secondary & tertiary care, homecare, etc., addressing interoperability issues as well as data privacy and confidentiality. A major concern for the RHA was maintainability of operational healthcare IS (hospital IS, laboratory IS, radiology IS, etc.) [2]. The RFPs required that pre-existing operational healthcare IS be integrated as component IS of the RHIS. According to the RFP, the contractor “should make every effort to maintain IS components that are compliant with the tender requirements and are well-accepted by the user community.”

Although, pre-existing healthcare IS did not need to be removed, connecting new component IS to existing ones should be an economically viable activity and no unanticipated load should be introduced to existing healthcare IS. From a technical perspective this requirement can be easily met by an asynchronous interoperable and scalable message information exchange infrastructure based on HL7. However, beyond technical requirements and interoperable solutions involving operational healthcare IS, the contractor, the existing vendors, and the RHA should come to a common understanding early in the implementation process as to which healthcare IS will be maintained. The RHA was responsible for the final decision. To facilitate the decision-making process, the contracting authority requested that the independent organization supervising the implementation of the contract, apply an objective methodology, which would result in a ‘maintainability decision’. The methodology and results of this exercise are presented below.

Materials and Methods

According to Iakovides [3], the successful deployment of health IS needs to: (a) attend organizational and cultural matters to endorse continuity of care and structured data collection; (b) bridge the cognition gap between healthcare professionals and

information science experts that creates a proliferation of incompatible information models; (c) address complex legal requirements on the confidentiality of personal and patient related data as well as data privacy; (d) ensure the consistent implementation of interoperability standards in health informatics products; (e) encourage the development of vision and leadership among healthcare managers and health authorities, and the willingness to re-engineer healthcare processes for the benefits of efficiency and quality of care; (f) invest in user education, acceptance and application usability of the introduced IS taking a user-centered approach that places emphasis on speed, quality, and effectiveness of data entry and information retrieval, streamlining complex security procedures.

Maintainability denotes the special characteristic of a component IS that allows it to maintain its position as a functional part of a larger IS that is introduced at a later stage. Thus, maintainability depends not only on the component itself, but also on the larger IS. More specifically, it depends on the functional characteristics of the IS component (F), its user acceptance (U), the cost/benefit factor of replacing the component IS (C), and the interoperability factor (I) of the component IS with the larger IS system. A methodology for the calculation of F, U, C, and I was developed and applied during a technical survey in the region of Central Macedonia which is covered by 2 RHA and includes the 2nd largest city in Greece, and 20 hospitals. The technical survey lasted for three months, took four person months of effort, and involved a series of site visits to gather on-site data concerning already installed and operational component IS.

The component IS in use were evaluated with questionnaires distributed to users to capture the effectiveness of component IS. The ability of the system to support HL7 and more generally their compatibility to the architectural requirements outlined in the RFPs were discussed with the IT department. An algorithm combining qualitative and quantitative criteria was employed and based on that, the initial decision whether an existing component IS should be maintained or not, was made.

Note that maintainability did not apply to healthcare IS of the same supplier as that would be considered as a system upgrade. It applied to the case where the system is not supported by any contractor and the existing system fitted the technical specifications of the RFP. From an operational (business) perspective, it should be made possible to incorporate the component IS as a subcontractor participating in the Service Level Agreement (SLA) sharing the responsibilities of the contract. Finally, the level of human effort for the integration of the component IS in the larger IS should not affect the time-table of the deployment.

Results

The technical survey proceeded according to the methodology. The protocol application in five hospitals and the personnel application of two hospitals were considered maintainable. Additionally, the ERP application of another hospital was also deemed maintainable. Nevertheless, none of the pre-existing healthcare IS was recommended to be maintained. The approach that maintaining information islands of different suppliers would create greater confusion and complexity in the implementation compared to the effect of changing the applications prevailed, disregarding the human factor. Although, user acceptance ranked high with existing operational HIS, it was argued that the limited experience of most users with different and possibly diverse healthcare IS, hindered their objectivity. User satisfaction was presumably affected by the responsiveness of the vendor in adapting the system to their changing user needs. In some systems, significant custom development resulted in functional features that were acquired 'en route'. Moreover, the majority of operational healthcare IS even if HL7 compliant, lack robust technical specifications. The applications were scattered and

semantically inhomogeneous. Adoption and effective use of terminology standards, ontologies, and coding systems were limited.

Conclusions

Maintainability is a key aspect of quality in an integrated RHIS, as it amounts to investing in knowledge management, reuse, and sharing. However, the business processes associated with maintaining or interconnecting to pre-existing IS are not well-established. Strategies that focus on processes establishing key performance indicators, balanced scorecards, or other metrics that are the upper level of a structured information flow-based model, need to be adopted. Unfortunately, thus far despite their length the RFPs in the Greek public sector did not request a plan for the incorporating pre-existing operational IS, making maintainability a secondary objective.

Overall, the issue of maintaining an IS component inherently points to a paradox as a newer system is presumably a better one. Although HL7 and other health informatics standards provide a viable solution to the issue of integrating islands of IT in healthcare, the business processes associated with this integration in terms of liability and upgrades are not well-established, understood, or trusted. An open dialogue involving policy makers, manufacturers and users, needs to start. Such a process must include interoperability showcases based on robust technical implementation guidelines and should aim to set the scene for the possible alternatives and result into a set of business assumptions and procedures that are widely agreed and accepted by all players. Otherwise, the technocratic approach and the maintainability algorithm presented here will always result into “no maintainability”.

References

- [1] Information Society SA, “Healthcare Information System for the 2nd Regional Healthcare Authority of Central Macedonia”, Request For Proposal co-funded by the 3rd CSF under the EU decision C(2001)551/14-3-2001, Greece, 15 May 2003 [In Greek].
- [2] S.Spyrou, P. Bamidis, I.Chouvarda, G.Gogou, S.M. Tryfon and N. Maglaveras, “Health Care Informatics Standards: Comparison of the approaches”, Health Informatics Journal, 8 (1), pp 14-19, 2002
- [3] Iakovidis I. (2000), Towards a Health Telematics Infrastructure in the European Union, In “Information technology strategies from US and the European Union: transferring research to practice for healthcare improvement”, Amsterdam, IOS Press.

Stream 2 – Epsom Room

Over the RIM

Mike Mair FRANZCO, Timaru, New Zealand

The HL7 Reference Information Model (RIM) has been presented as a “realist” information model based on speech-act theory[1]. The RIM has a “3-layered ontology” structure: the UML classes, the normative ontology and the extensible ontology. It is the close fit between the information model and the ontology that is argued to make the RIM simple and so powerful.

Despite the breathtaking simplicity of the Role - Act - Entity scheme, there have been implementation difficulties. Because of the simplicity of the UML class layer, it has proved necessary to use vocabularies on both the normative ontology and extensible ontology layers to massively extend the RIM.

The designers of the RIM claim that because “we can use the same names for the data structures as for the real world phenomena they represent”, therefore “there is never any ambiguity, hence there is no confusion”[1].

However, when the RIM backbone classes are extended using vocabularies during message design and implementations, confusions do arise. Using the “same names for the data structures as for the real world phenomena they represent” does not always guarantee that there will be “no ambiguity” and “no confusion”. For example:

Observation ->moodCode = RSK, value = DVT

Does this mean that the patient has a risk of DVT? or Does this mean that I have the risk of making an observation that the patient has DVT? When the rules meant to govern the expression of the process of healthcare using Vs3 are applied, many inconsistencies are revealed.

We argue that there's a fundamental flaw in the RIM's epistemology, and that is why the 'fudges' exceed the 'fixes' in making it work. We look again at the roots of the RIM in Austin and Searle's speech act theory, and the philosophical and linguistic paradigms of the early twentieth century. We discuss the tripartite division of the study of language, pragmatics, syntax, semantics. We examine the assertion that Vs3 and speech act theory itself are examples of the 'pragmatics' of human communication. It is anomalous that the RIM which claims to be at the level of 'pragmatics' also is put forward as a model for 'semantics'.

Speech act theory was itself a reaction to the logical positivist view of language, which saw its function as establishing the truth of propositions. Austin [2] rebelled against this 'denotative' view, pointing out that speech does not just establish the truth value of the world, but can also itself constitute a state of affairs, e.g. in a marriage ceremony.

He classified 'speech acts' into 'locutionary', 'illocutionary' and 'perlocutionary'. The notion of 'intentionality' was part of this - illocutionary speech acts were characterized by the intentions of the speaker. These propositions have always been controversial, and have been further elaborated and often changed by subsequent authors, for example John Searle [3]. The adoption of one version of them as the syntax of the RIM involves a breath taking leap. We argue that it is arbitrary and wrong to make this conceptual scheme into the kernel of a global information model.

The RIM theorists have the notion that the creation of an entity by an act means that the entity IS an act. We argue that this is mistaken. Acts make Signs, not Signs Acts. Searle, who developed 'speech act theory' beyond Austin, argued in a chapter entitled 'a general theory of institutional facts' that the 'constituted' nature of all systems of classification was a manifestation of collective intentionality. This philosophy is deeply assumed in the RIM. However this need not have made an instance of such a constituted class itself an 'action', as the RIM theorists suggest.

We also query the place of 'collective intentionality' itself in explaining the persistence of signs and classes. We can weave a different lineage from the same founding fathers. Instances of signs are the 'harvest' of the clinical process, and may be considered the persistent 'debris' of actions, material to make meaning and sense out of. Under this paradigm, manifestations of signs are physical, and this is consistent with the tripartite nature of signs (semiotic triangle). We explore this and other definitions of signs and concepts current in health informatics. The CDA as a persistent universal attestable

unit would need to be modified to accommodate a non RIM derived semantics, but the un-hitching of the CDA from the RIM could lead to its rapid universal deployment.

REFERENCES:

- [1] Gunther Schadow: The HL7 Reference Information Model Under Scrutiny (2006)
- [2] J L Austin: How to Do Things with Words (1975)
- [3] John Searle: 'A General Theory of Institutional Facts' In 'the Construction of Social Reality' (1995)

Development of a Nationwide Standard Electronic Health-Document-Exchange based on HL7CDA-Rel.2 in the New National Health-Checkup-Program for Preventing Metabolic Syndrome in Japan

Hiroyuki Hoshimoto(a), Yuki S.Nittami(a), Yukinori Konishi(b), Masaharu Ohbayashi(b), Ei Murakami(b) Takeshi Kubodera(b), Hiroki Watanabe (a), Izumi Yamaguchi a, Katsuya Tanaka a, Kengo Miyo a Ryuichi Yamamoto c, Kazuhiko Ohe a

(a) Department of Planning, Information and Management, the University of Tokyo Hospital, Japan (b) Japan Association of Healthcare Information Systems Industry, Japan (c) Graduate School of Interfaculty Initiative in Information Studies, the University of Tokyo, Japan. Address for correspondence: Hiroyuki Hoshimoto, MHSc, Hongo 7-3-1, Bunkyo-ku, Tokyo 113-8655, JAPAN; e-mail: hhoshi@hcc.h.u-tokyo.ac.jp

Abstract

We have developed the standard electronic format based on HL7CDA-Rel.2 in the nationwide standard electronic health-document-exchange that is the indispensable infrastructure of the new national health-checkup-program (NHCP) in Japan. HL7CDA-R2 was proved to be an applicable message standard to the NHCP in Japan. The exchange has been under the test phase since F.Y.2006 and the real phase is supposed to start in the beginning of F.Y.2008. This is the first nationwide standard health-document-exchange based on HL7CDA-R2 and the estimated number of participants is between 10 million and 50 million citizens.

Introduction

In recent years, life-style related diseases such as diabetic mellitus, hypertension and hyperlipidemia are greatly increased in Japan. This is considered as one of the causes of great increase of healthcare costs. For this reason, the Japanese government formed the policy which goal is a 25% decrease of the prevalence of the life-style related diseases and the number of pre-disease state persons by F.Y.2015[1].

In accordance with this policy, the Ministry of Health, Labor and Welfare, Japan (MHLW) has decided to start the new national health-checkup-program (NHCP) which is specific for preventing metabolic syndrome from F.Y.2008. Recent studies have shown that the Metabolic syndrome is a key pre-stage followed by the life-style related diseases. All the health insurers that support the universal health insurance system in Japan are obligated to provide all the insured persons and their dependent family members aged between 40 and 74 with a routine health-checkup. They also have a obligation to conduct a health consultation program which is specific for preventing metabolic syndrome in the standard method.

In NHCP, all the stakeholders (i.e. health-checkup providers, health consultation providers, insurers, and so on.) are required to exchange the health checkup and consultation data in a standard electronic format. Therefore, we developed the standard format and the guideline of its application under a special working group sponsored by the MHLW. The purpose of this project is to show problems and its solutions in applying HL7 Clinical Document Architecture, Release2 (CDAR2)¹ to the standard data format in NHCP.

Methods

In NHCP, there will be 4 major events such as health checkup, first-time consultation, mid-term evaluation and final evaluation consultation. Since the information to be exchanged are different in each event, specified message formats are required for each message exchange.

In order to reduce development and management costs, we have developed a standard message model based on the HL7 CDAR2 specification [2]. The message format and XML schemas are derived from the model we have developed.

Results

Figure 1. shows the NHCP R-MIM derived from the HL7 CDAR2 R-MIM. We have defined one message type for health checkup results exchange and three message types for health consultation results exchange from this model. XML schemas for each message type are generated from this message model, as well. Each message has basically one section to describe each health checkup and consultation events. Additional sections will be used to describe optional information, such as a health insurance policy holder specified health checkup results. In addition, a specification for the logical structure of the directories and the location of data files for bulk mode message transaction are defined. This specification is conformant with the Portable Media for Clinical document Specification, defined by HL7 Japan [3].

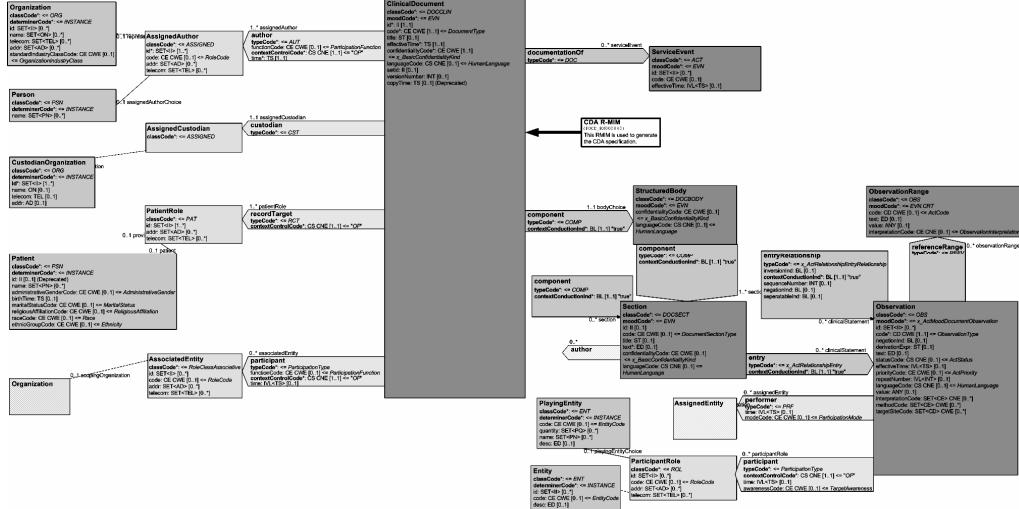


Figure 1. The NHCP R-MIM. This model is derived from original CDAR2 R-MIM.
(see electronic version for readable figure)

Discussion

In the NHCP, although it was found that the author, the custodian and the participants-information elements in the CDA message header have to be rewritten as the exchanging phase progresses, the HL7CDA-R2 was proved to be an applicable message standard to the NHCP.

However, since the CDA is originally an adaptable standard for the various medical documents, plural message notation exists to the identical contents. In addition

to it, the NHCP requirements may be changed in the future. To guarantee the interoperability, development of a new mechanism to verify the message conformance to the standard is required.

The real phase of using the proposed standard is supposed to start in F.Y.2008. This is the first nationwide standard health-document-exchange in Japan. The estimated number of participants (i.e. the insured) is nearly 50 millions in the near future.

This message model and message types will be used for information exchange of the Health Checkup for Labors under the Occupational Health and Safety Law of Japan, and Health Checkup and Management Program for School workers under the School Health Law of Japan, as well. The authors believe that the proposed HL7CDA-based exchange program will not only contribute on the success of the NHCP in Japan but also serve as a useful reference for health document exchange in other countries and HL7 communities.

Conclusion

In this paper, we described an outline of the new national health-checkup-program and NHCP message exchange specification. The exchange has been under a test phase since F.Y.2006 and the real phase is to start in the beginning of F.Y.2008. It will be the first nationwide standard health-document-exchange based on HL7 version 3 in Japan.

References

- [1] <http://www.mhlw.go.jp/> (Japanese)
- [2] HL7 Clinical Document Architecture, Release 2.0., May 2005. Ann Arbor, MI: Health Level Seven, Inc., 2005
- [3] <http://www.hl7.jp/intro/std/HL7J-CDA-004.pdf> (Japanese)

Use of HL7 Clinical Document Architecture R2 (CDA R2 And Inclusion of Digital Signature)

Dr. Humberto Fernán Mandirola Brieux¹ (4) , Lic. Sebastián Guillen¹⁽⁴⁾, Diego Kaminker (2,4) Lic. Adrián Gomez (3), Lic. Fernando Campos (3).

(1) BIOCOP, Buenos Aires, Argentina (2) Kern Information Technology SRL, Buenos Aires, Argentina (3) Hospital Italiano (Italian Hospital), Buenos Aires, Argentina (4) HL7 Argentina. Address for correspondence: Dr. Humberto Fernán Mandirola Brieux , Email: hmandirola@biocom.com

Introduction

Digital signature (DS) is an unquestionably needed component for Electronic Health Records (EHR). The HL7 Clinical Document Architecture Release 2 is an ANSI standard that specifies the structure and semantics of clinical documents for the purpose of exchange. It became very important to define what to sign, when, and how to sign it, for several reasons regarding legal aspects including non-repudiation, wholeness and non-alteration of the contents of the documents.

DS allows ensuring these three legal aspects with off-the-shelf tools and libraries available in most computing languages and platforms, and using proven and standardized algorithms.

Digital Signature Technology (DST) and the different Digital Signature Legislation (DSL) available in our countries are the technical and legal elements making possible for us that the Electronic Health Record is not questionable from the legal point of view. It is not necessary to wait for a law that regulates Computerized Clinical to achieve legal value, since DSL equates paper signature to digital signature.

We need to digitally sign the components of an EHR (Electronic Health Record) because this is the only way to legally guarantee who generates the information according to DSL.

This paper addresses our experience implementing digital signature in CDA R2 documents.

Materials and Methods

Our Objective is to present the issues we faced when we applied digital signature for CDA documents, the pitfalls involved and the decisions that were needed to accomplish.

The HL7 CDA R2 clinical document exchange specification defines instances that may contain observations and services, and it has the following characteristics: persistence, stewardship, context, wholeness, human readability, and potential for authentication.

This last characteristic, intrinsic to the specification, was not sufficient to achieve our desired results, we needed to include this digital signature in the document, so we decided to use a W3C standard, XMLDSIG, intended to digitally sign any type of XML documents, to enable the inclusion of the digital signature into the CDA instance.

The XMLDSIG allows the developers to choose between three different types of transformations in the process of signing the document: enveloped, enveloping and detached.

Other issues where the scope of the signing (just one document instance, several document instances, sign different sections of the CDA instance by different authors, etc).

Other problems were whether or not to sign the XML style-sheets used to render the content of the documents and the multimedia images referenced by the document as part of the authenticated content.

Another item worth commenting is the use of the Time Stamping protocol to ensure the sequence of the document generation and the accuracy of time and date.

Results

We decided on the XMLDSIG enveloped transformation (the signature becomes an indivisible part of the document) enabling us to leverage the other CDA features (context, wholeness and stewardship)

Although the CDA model gives us the possibility to include information about several “authenticator” elements, we decided on the inclusion of just one signature inside of the header of the document in the unique “legal Authenticator” element of each CDA instance, since this element represents the person who is legally responsible for the content of the entire document.

Our DSL demands that the legally responsible entity must be a physical person, not an organization, because only physical persons can physically sign documents and the DSL equates the digital signature to the physical one.

One of the pitfalls was that the generated instances that included elements in the XMLDSIG namespace were not valid against to the CDA R2 schema, so HL7.org published a clarification on the CDA spec remarking that “a conformant CDA document is one that at a minimum validates against the CDA Schema once all extensions have been removed from the instance” .

This approach is perfectly compatible with (furthermore it requires) a digital certificate based in PKI infrastructure standards, because it travels inside of the signature element that XMLDSIG defines.

Performance issues regarding the use of this technology are negligible, since the legal authenticator of the document needs to visually inspect its contents before signing, and times to physically sign each document using common off the shelf computers (Pentium IV 128 MB RAM). It is below the time he/she needs to inspect the document (time from the moment the authenticator push the ‘sign’ button until he/she regains control of the application is under one second)

We couldn't identify the signed documents, because it will be against the CDA R2 standard, since it clearly defines that the context and completitude of the document must be included in the document itself, and this means that the patient's, hospital's and physician's identifications must be included and be process able by other applications and rendered in any internet browser, and the document recipient must see the same document that the legal authenticator saw.

Conclusions

Digital Signature Technologies, applied to the robust and flexible CDA R2 model, allowed us to make this advance technically possible.

Day 2 - Saturday

Shared Session

HL7 V3 and SOA

Dr Dan Russler VP Clinical Informatics, Oracle

Solutions based on the HL7 Reference Information Model (RIM-based) have been specified by multiple governments internationally. These government specifications will be described and selected implementations will be reviewed. Implementations that illustrate the opportunities for success and for difficult issues as a result of these government decisions, including transition strategies from HL7 V2-based solutions to RIM-based solutions will be discussed.

CDA & CCD Specification & Implementation

Dr Bob Dolin, Kaiser Permanante

CDA has been the most successfully HL7 V3 standard artefact and has wide international implementations since its inception. CDA Release 2 is a major step forward in addressing structured and complex clinical information exchange needs. The recently released Continuity of Care Document (CCD) implementation guide, which is based on CDA R2, is another significant step forward which will propel further the adoption and implementation of CDA. Dr Bob Dolin is one of the chief CDA architect. He will present a history of CDA and the recent development of CCD implementation guide. He will also share with us the experiences of CDA implementations, discuss relevant key issues and paths forward.

Stream 3 - Auckland Room

A Unified Approach to Adoption of Laboratory LOINC in Taiwan

Chien-Tsai Liu*(1), Liang-Wen Wang(2), Yu-Sheng Lo1, Li-Li Wen2, Jin-shin Lai(3).

(1)Graduate Institute of Medical Informatics, Taipei Medical University, Taipei, Taiwan (2) Department of Pathology and Laboratory, En Chu Kong hospital, Taipei, Taiwan (3) National Taiwan University Hospital, Taipei, Taiwan *Correspondence author: Chien-Tsai Liu, Professor, Graduate Institute of Medical Informatics, Taipei Medical University, Taipei, Taiwan Address: 250Wu-Xing Street, Taipei, Taiwan Email: ctliu@tmu.edu.tw Phone: +886-2-27361661 EXT 3342

LOINC (Logical Observation Identifier Names and Codes) has been recommended by Taiwan's Department of Health as a standard for pooling and combining of patients' laboratory test results from different healthcare providers for integrated care. There is only one single national health insurance agent, the Bureau of National Health Insurance (BNHI) that provides a code set for naming laboratory tests and results in Taiwan. However, the code set is mainly for billing and reimbursement purpose. One NHI code may represent one or more tests with similar cost. They can

hardly be used for clinical purpose. Thus, most clinical laboratories and hospitals have developed their own code sets and create mapping databases between their internal codes and the NHI codes. We take this advantage, and use NHI codes to bridge the mapping from hospital internal codes into the corresponding LOINC codes.

We have created NHI-LOINC mapping database (now containing 9104 records) and developed a web-based NHI-LOINC mapping assistant system (NiLoMAS) to facilitate the adoption of the LOINC,. However, most clinical laboratories provide services including not only the items covered by the BNHI but also those paid by patients themselves. As such, they need the NHI-LOINC database (through the NiLoMAS) for mapping the tests covered by NHI program and the RELMA for mapping self-paid tests. This mapping approach is inconvenient, and cannot support the mapping efficiently. For this reason, in addition to the NHI-LONC mapping database, we have developed a keyword mapping database in which each keyword (including both English and Chinese) is associated with a set of possible LOINC codes. Currently the keyword mapping database contains about 60000 records. Having the keyword mapping database, the NiLoMAS can accept NHI codes or a set of keywords from a user, and then query the corresponding LOINC codes using the NHI-LOINC mapping database or the keyword mapping database, respectively. Thus, any laboratory test (covered by BNHI or self-paid) can be mapped to the corresponding LOINC using only the NiLoMAS.

The NHI-LOINC and keyword mapping databases has been successfully adopted to establish the Local-LOINC mapping database by En Chu Kong Hospital in Taipei. The Local-LOINC database can then be used to online map the ;laboratory tests and results with internal codes to the corresponding LOINC codes. Since the information of a test order may not be fully recorded into a computerized physician order entry system to support an exact mapping to the LOINC, some information may need to be supplied by the physicians who issue the test order, and some supplied by laboratory professionals who perform the laboratory tests.

In order to evaluate the online mapping effectiveness, we collected 160,000 records of tests performed in the clinical laboratory of En Chu Kong Hospital for mapping to the corresponding LOINC codes. About 65% of the tests can be uniquely mapped into the LOINC codes automatically, and other 35% need human intervention to supply the information required for unique mapping. . There are 2 types of such information: lack of or insufficient information contained in “challenge or any standardization or adjustment” part in the component; and ambiguous test methods of an instrument. For example, the methods of an instrument for HBsAg test can be configured to EIA or AFP. However, if the instrument is configured to AFP, then the mapping may failed because the method of the test is represented as blank in the LOINC. In order to understand the impact of online mapping, in this year (2007) we recruit six more hospitals for pilot study on the feasibility of automated mapping of a test with local code into the corresponding LOINC code.

Development of HL7 Methodology for Medical Data Exchange in Taiwan using the assessment framework provided

Shih-Chan Fan*, Jin-Shin Lai# *Secretary-General, #Chair

HL7 Taiwan

HL7 has been accepted as the national standard (CNS: 14232) for healthcare informatics in Taiwan since 1998. Many governmental projects, for example, Communicable Disease Reporting System, Death Reporting System, & Available Beds in ICU Reporting System, etc., have used HL7 as one of protocol for exchanging medical data. According to a governmental report published in 2005, 44 hospitals (8.18%) have adopted HL7 and 26 hospitals (4.83%) were planning to use HL7. However, 468 hospitals (86.99%) representing a majority of hospitals in Taiwan did not have any plans to adopt HL7. There are three critical issues affect these hospitals which didn't adopt HL7: (1) HL7 is not legally required in Taiwan yet, (2) Lack of obvious benefits or incentives in most hospitals or clinics, (3) There are barriers to be overcome. According to NTU Hospital's experience, cost, training, and performance issues are the major barriers.

Another research had found that there were many important issues affecting hospital to adopt HL7. These issues include the environment pull, CEO's attitude and knowledge of IT, employee's ability in deploying information technologies, the size of hospital, their relative advantages, the systems integration.

In Taiwan medical institutions are classified according to their number of hospital beds and capabilities for clinical service, research, and training into four levels, which are Medical Center, Regional Hospital, District Hospital, and Clinic, and each of them has very different IT environment, manpower, programming skill and budget. Facing with this situation, the governmental sector is rather reluctant to enforce excessive pressures upon hospital. Moreover it is not possible for the governmental sector to establish an unified guideline for the implementation of HL7 standards. Most of hospitals would transfer pressures from the governmental sector on HL7 connectivity to their IT vendors. We have found that it is not practical to make every hospital adopt HL7 in Taiwan through the governmental enforcements because most of them would expect to receive financial or technical support from the government.

The goal of our study is to devise a versatile methodology for different regime of hospitals to choose the most suitable practice for HL7 adoption. We divide the cycle of developing HL7 message into four phases: the preparation phase, the setting phase, the implementation phase, and the testing phase.

In the preparation phase, the objective is to understand the skill set and IT environment of the hospital. Based on standard profiling, which may be HL7 v2.x, v3, or CDA provided by HL7 Taiwan Association, at first we need to know whether those required fields had been digitized in hospital or not. If some of required fields can't be provided in digital format, we need a new plan in implementation phase. In most situation we just collect relevant information, for example, the URL of the servers, account, password, database, table name, field name, field type, and the technical contact window, etc.

In the setting phase, the objective is to create a translation table that can be defined through ETL or XML mapping tools. In most hospitals their IT staffs have database knowledge but they are not familiar with HL7. So, we use ETL or XML mapping tools help them to mapping legacy system's data with the required fields based on the outcome in the preparation phase. The focus is being placed on the mapping rather than to get the real data. Sometimes we need to use translation function to cope with special data type or format field.

The implementation phase will be done on site for each hospital. We will actually connect to data source for getting data and create a new interface for staff to input the fields that can't be provided by the hospital. By combining two types of data sources into one table, we would accomplish the transmit table, and use other available HL7 software or library to generate HL7 messages. Up to now this study just provides HL7 v2.x Mini-gateway based on HAPI library. In the future we will provide CDA generator. Regardless of HL7 v2.x or v3.0, there are only database skills for IT staff of hospital needed.

Finally, in the testing phase, the objective is to make the message pass through validated HL7 profiling. For ER7 message format type, we can first use HL7 Messaging Workbench to test sample message at each hospital and next send HL7 message to HL7 message validation and index server which is provided by the Department of Health of Taiwan. For XML message format type, we just use schema file to validate message for hospital. After completing two types of message validation we can set schedule plan or condition of trigger event to transmit HL7 message.

Using this methodology, every hospital can recognize what fields their data format have and choose the best tools that they can handle in a step by step approach. Finally, hospitals can generate real HL7 messages for communications with governmental projects and eventually the majority of hospitals will achieve to adopt the HL7 standard.

HL7 – Review and Guidance for Handling Multiple Versions

K Ananda Mohan, Tata Consultancy Services

Mailto: ka.mohan@tcs.com, Website: <http://www.tcs.com>

In this paper, we present the concepts involved in development and deployment of HL7V2.x and HL7V3. We will present the strengths and weakness of each of the versions while examining the current status of these versions. We will try to define when each of these versions need to be used based on the current market trends. Finally we discuss the possibility of a transition path between these different versions of messages and an architecture based on SOA principles which allows both these versions to co-exist.

Document-Centric Clinical Care: Using ECMA XML to Document Healthcare for Machine and Human readability

Werner van Huffel, Microsoft Asia Pacific, Phone +65 6882 8666

Mobile +65 9674 2263 One Marina Boulevard, #22-01, Singapore 018989

Abstract

The use of healthcare messaging, in the form of HL7, to deliver data within the information technology architectures has opened up the potential interoperability of such data to drive information interchange. As humans involved in the healthcare environment – specifically that orientated around the technology of delivering healthcare information – we seek to perpetually improve upon the abilities of our solutions to present clinical information in meaningful and relevant ways. This delivery of solutions has been hampered in the past due, in part, to the non-structured nature of HL7 version 2 messaging. With the advent of the use of xml-based healthcare messaging, in the form of HL7 version 3, a structured infrastructure can be applied to information interoperability.

The patient-clinician data interactions prevalent in healthcare are not HL7 message based. At the highest level interactions occur verbally human-to-human and are then transcribed to the technology level, from human to computer, through a graphical user interface. There the data is stored in a structured form till required by a relevant party at which point appropriate data is extracted from the data store and presented in a domain relevant manner. The primary domain relevant manner for clinical data exchange is structured as a document – for example discharge summaries and referral notes.

In a move aimed at marrying the requirements to store data and display such in domain relevant manners, Microsoft has been working with the ECMA XML standard document format to incorporate data and document structure. The basis of this ability is the use of a XML-based reference implementation model.

Healthcare Messaging based on a XML-based reference implementation model and represented in the form of XML Schemas has led to the ability for IT to begin to look at delivering value to healthcare that is orientated around the operational structure of the patient-clinician interaction –Document-Centric Clinical Care.

In this paper we will look at various technological aspects in the use of ECMA XML and its impact in the delivery of Document-Centric Clinical Care through the use of desktop technologies.

XML standards derivates, such as Schemas (xsd), XPath and Style sheets (xslt), has become core functionality in all healthcare computing desktops.

Assumptions:

To create your own customised version of this template:

1. Insert your company information in the company name, contact, address and release date frames, and change the header text on page 2 to reflect the contents of your story.
2. Choose File Save As. At the bottom of the menu, choose Document Template in the Save File as Type: box (the filename extensions should change from .doc to .dot).
3. To create a document, choose File New to re-open your template as a document.

The standards used:

To create your own customised version of this template:

4. Insert your company information in the company name, contact, address and release date frames, and change the header text on page 2 to reflect the contents of your story.
5. Choose File Save As. At the bottom of the menu, choose Document Template in the Save File as Type: box (the filename extensions should change from .doc to .dot).
6. To create a document, choose File New to re-open your template as a document.

The standards used:

To create your own customised version of this template:

7. Insert your company information in the company name, contact, address and release date frames, and change the header text on page 2 to reflect the contents of your story.
8. Choose File Save As. At the bottom of the menu, choose Document Template in the Save File as Type: box (the filename extensions should change from .doc to .dot).
9. To create a document, choose File New to re-open your template as a document.

The Process used:

To create your own customised version of this template:

10. Insert your company information in the company name, contact, address and release date frames, and change the header text on page 2 to reflect the contents of your story.
11. Choose File Save As. At the bottom of the menu, choose Document Template in the Save File as Type: box (the filename extensions should change from .doc to .dot).
12. To create a document, choose File New to re-open your template as a document.

Understanding by example:

To create your own customised version of this template:

13. Insert your company information in the company name, contact, address and release date frames, and change the header text on page 2 to reflect the contents of your story.
14. Choose File Save As. At the bottom of the menu, choose Document Template in the Save File as Type: box (the filename extensions should change from .doc to .dot).
15. To create a document, choose File New to re-open your template as a document.

Doing it yourself:

To create your own customised version of this template:

16. Insert your company information in the company name, contact, address and release date frames, and change the header text on page 2 to reflect the contents of your story.
17. Choose File Save As. At the bottom of the menu, choose Document Template in the Save File as Type: box (the filename extensions should change from .doc to .dot).
18. To create a document, choose File New to re-open your template as a document.

Stream 4 - Epsom Room

SS-MIX: An Initiative for Promoting Healthcare Data Exchange by Japanese Ministry

Michio Kimura, Hamamatsu University School of Medicine, HL7 Japan Chair.

HL7 Japan CDA for referral document standard (formerly called MERIT-9, reported in former HL7 IAM and CDA conferences) is a standard for CDA R2 patient referral document, with pointers to prescription and lab result contents (HL7 v2.5) and images (DICOM). It passed HL7 Japan vote as HL7 Japan standard. And now it is recommended as HELICS standard (HELICS is Japanese version on HISB in US).

Use cases for this are not only for patient referral document, but also for handing out patient information in CD. Shizuoka prefecture EHR project made use of this standard and already used in real clinical settings. Last year, Ministry of Health Labor and Welfare employed a joint project with Shizuoka prefecture to proceed additional development and deploy nationwide. By this, from small clinics to large hospitals, referral documents and patient data handout CD are standardized in CDA R2. The joint project aims to expand its scope of “documents” to disease registrations, surveillance, and clinical trials. It is SS-MIX project (Standardized Structured Medical Information eXchange).

Products of Shizuoka prefecture project, whose results can be used by hospitals in Shizuoka, comprise progress note description, nursing note description, formatted document submission, PACS, and patient referral. The joint project with Ministry was to promote electronic referral document and patient data CD, which is the last part of the products.

The expected ripple effect is to promote basic data export in HL7 v2.5 format from Japanese vendors' HIS. To make use of SS-MIX software, i.e. to make standardized referral document or patient data CD, hospitals have to have their HIS able to export patient ID data, lab, prescription in v2.5 format. Reimbursement premium for electronic standardized referral is expected in near future, which will be a strong incentive for introducing this feature.

Informatics in the management of metabolic syndrome

David Menkes (FRANZCP, Waikato Clinical School, University of Auckland) Michael Mair (FRANZCO, Timaru Eye Clinic, Timaru)

People with severe mental illness, notably schizophrenia and bipolar affective disorder, have increased mortality rates compared with the general population. Much of this excess mortality, particularly among patients treated with antipsychotic drugs, is attributable to cardiovascular disease. It is now understood that 'metabolic syndrome' (impaired glycaemic control and dyslipidaemia, often with hypertension) plays a key role in the genesis of cardiovascular disease, and is often caused or aggravated by treatment with antipsychotic drugs. Dyslipidaemia, for example, may lead to diabetes; both conditions interact to increase risk of heart attack and stroke.

The serious threat to public health posed by metabolic syndrome, while recognized, is yet to be effectively managed by health services around the world, including NZ. The problem is multidisciplinary; its solution will require active collaboration of various clinicians (mental health, pharmacy, general practice) across primary and secondary care. The information requirements of such collaboration are extensive, and may explain why a solution has remained elusive.

Based in Hamilton, we are in 2007 launching a pilot study of a cohort of 260 chronic patients, their clinicians and available records. The pilot aims are to:

1. inform a planned national programme of options for clinical data capture and management. These data would be used in screening, intervention, and monitoring using database-linked algorithms.
2. appraise the physical health of the cohort, specifically considering evidence for metabolic syndrome.
3. analyze risk factors, particularly in terms of drug history, laboratory and anthropometric measures, for metabolic syndrome in chronic patients.
4. specifically assess the role of ethnicity (Maori v. Pakeha) in the genesis of metabolic syndrome in this cohort.

In this paper we explore how a RIM-based repository may be useful for this project and its implications for a national screening database with linked intervention and monitoring algorithms. We describe the required application functionality, and discuss how CDA and

other relevant V3 standards can assist information exchange in the screening and shared care environment.

Clinical Document Registry Framework

Il Kwang Kim, Jong Hyuk Lee, Il Kon Kim, Yun Sik Kwak. Intelligent Health Information Sharing System Development Center Kyungpook National University, Daegu, Republic of Korea +82-53-422-8182 dinosa@daum.net, jleeiilab@hotmail.com, ikkim@knu.ac.kr, yskwak@knu.ac.kr

Due to the rapid advancement in the Health Information Technology, the needs of customer have increasingly become diverse. Especially, the needs of sharing clinical documents in order for health professionals to provide better healthcare have been tremendously increasing. However, to achieve this common goal, it is required that the standardization to overcome the incompatibility among heterogeneous systems. The HL7 (Health Level 7) CDA (Clinical Document Architecture) is standardized technology in purpose of creating and exchanging various clinical documents. In this paper, we propose the useful framework named DRF (Document Registry Framework) for exchanging, storing, and utilizing clinical documents and present the work of development and implementation of the DRF. The DRF is based on ebXML standards and can give a good solution for clinical institutions to implement and deploy a document management systems. And also, even the heterogeneous HIS (Hospital Information System) is able to communicate and manage the CDA documents via this DRF. In DRF framework, we especially propose a new method to enhance the CDA security level for supporting pseudonymization of CDA. Usually, CDA header can be used for containing patient identification information, and CDA body can be used for diagnosis or treatment data. So, if we detach each other, we can get good advantages for privacy protection. Because even if a hacker is successful to get the separated CDA body, one will not normally be able to identify whose clinical data that is. The other way, even if someone successes to get separated CDA header; one doesn't know what kind of CDA body that is related to. This is the way to achieve protecting privacy by disconnecting association of relative information and reducing possibility of leaking private information. In order to achieve this goal, the method we propose is to separate CDA into two parts and to store them in different repositories in the DRF.