Trends in Healthcare Information Standardization

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Abstract

Standardization of medical information systems by industry associations such as ISO/TC 215 and CEN/TC 251 is currently underway internationally. In Japan, too, participation in and the dissemination of international standardization are being actively promoted. This paper is intended to summarize trends in standardization and to discuss the activities that are being conducted at NEC.

Keywords

medical information system, standardization, ISO/TC215, CEN/TC251, HL7, DICOM, IHE, HELICS

1. Introduction

Medical institutions are the settings for the operation of a large variety of systems including: core systems such as electronic medical record, order entry and medical accounting systems as well as departmental systems such as clinical examination, radiation information management and medical image management systems. These systems are naturally not supplied from a single supplier but are based on a multi-vendor system and the information handled across these systems extends very widely indeed. It includes basic data such as patient names, dates of birth and gender to numerical data such as: body temperature, blood pressure and test results, image data of CT and MRI examinations as well as electrocardiographic and electroencephalographic data, which is displayed in waveform format. The importance of standardizations is emphasized in support of the accurate and safe transmission of such medical information across different systems and facilities. At NEC, we are positively promoting the activities based on a thorough recognition of its importance. In the following we will summarize the standardization trends and activities being conducted at NEC.

2. Organizations Engaged in Standardization

(1) ISO/TC 215

The Technical Committee (TC) that controls the standardization of medical information systems at The International Organization for Standardization (ISO) is TC 215 on Health Informatics. This committee was established in 1998 as the 215th TC. At present, TC 215 has 24 P-member (participating) countries and 21 O-member (observing) countries and includes 9 Working Groups (WGs) under its control as shown in **Fig.** Japan acts as one of the P-member countries and is supplying experts selected from associated academic societies and industries. TC/215 has already published a total of 47 documents including international standards (ISs), technical specifications (TSs) and technical reports (TRs), and a further 46 documents are currently under deliberation. In Japan, an independent committee has been established within the Medical Information System Development Center (MEDIS-DC) in order to take various measures including the determination of international policies.

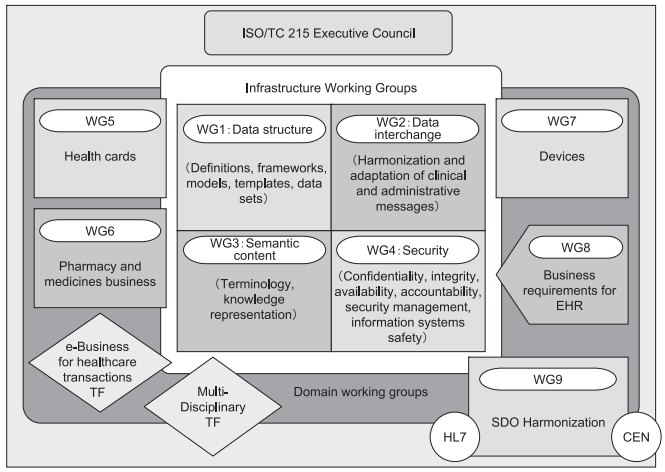

Fig. ISO/TC215 organization.

(2) CEN/TC251

Comite Europeen de Normalisation (CEN) is the European body established in 1961 for the standardization of matters other than electronic and communications technologies and currently participated by 29 countries. Its technical committee in charge of medical information is CEN/TC 251 on

Health Informatics, which was founded in 1990. TC/251 has 4 working groups, which deal respectively with information models, terminology and knowledge representation, security, safety and quality, and the technology of interoperability.

(3) HL7 Inc.

Health Level Seven Inc. (HL7) is a voluntary, non-profit-making organization established in 1987 in the United States with the aim of promoting the development and dissemination of international standards for information interchange between medical information systems. HL7 currently has branch offices in 32 countries worldwide, which include HL7 Japan [1] , established in July 1998 as the seventh overseas branch. The secretariat of HL7 Japan is positioned in the Japanese Association of Healthcare Information Systems Industry (JAHIS). It develops activities for reflecting Japanese opinions on HL7 standards through its participation in international conferences and for disseminating and promoting HL7 standards in Japan by holding seminars and by publishing journals.

(4) DICOM Standards Committee

The Digital Imaging and Communications in Medicine (DICOM) Standards Committee is an organization for developing and maintaining international standards for communication of medical digital images and associated information. It was established in 1983 jointly by the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA). The first version of the standard was issued in 1985 as the ACR/NEMA standard but its name was changed to the DICOM standard following publication of a third version in 1993. In Japan, participation in the development of the DICOM standard and promotion of its dissemination are under the control of the DICOM Committee of the Medical Imaging Systems Division of Japan Industries Association of Radiological l Systems (JIRA) [2] .

(5) JAHIS

The Japanese Association of Healthcare Information Systems Industry (JAHIS) [3] was established in April 1994 with the aim of promoting standardization of healthcare information systems, improving the related technologies and securing quality and safety. It has been continuing its activities for these aims with 343 corporate members as of May 1, 2008. Since FY2006, it has been participating in the Japanese METI's 3-year project known as the "Healthcare Information System Interoperability Verification Program" and has made contributions to it under the four themes of; 1) data compatibility; 2) system interconnectability; 3) system-common platform; 4) survey operations. At NEC, we have also contributed to this project as administrator of the projects promoted by JAHIS. As a result of its efforts, JAHIS has succeeded in several standardizations including the radiation data interchange standard, prescription data interchange standard, disease name information data interchange standard, clinical examination data interchange standard and the guidelines for electronic storage of medical records that should result in mandatory conservation.

(6) MEDIS-DC

The Medical Information System Development Center (MEDIS-DC) [4] is an incorporated foundation established jointly by Japanese MHLW and METI in July 1974. The center conducts fundamental and comprehensive research, study, development and experimentation related to medical information systems as well as promoting operations for the dissemination of their results and organizing staff training. Specifically, it is promoting the development of various master/code tables and undertakes approvals of privacy mark certifications in the healthcare field. It is also acting as one of the certification authorities for issuing electronic certifications in the healthcare field.

3. Trends of Standardization in Medical Information Field

The fields of standardization related to medical information systems can roughly be classified into the terms and codes, the message interchange protocols and security & safety issues. These are being promoted internationally by ISO, CEN and other industry associations. In addition, efforts are also being made domestically to establish standards as well as to participate in international standardizations and to promote the dissemination of international standards.

3.1 Terms and Codes

The best-known international standards relating to terminology and coding are the International Statistical Classification of Diseases and Related Health Problems (ICD) endorsed by the World Health Organization (WHO) and the Systematized Nomenclature of Medicine/Clinical Terms (SNOMED/CT), which is the clinical medical terminology/concept database developed by College of America Pathologists (CA). [5] The latest version of ICD which is used widely at present is the Version 10 (ICD-10). However a revision of this version is underway and publication of ICD-11 is aimed at

by 2015.

In Japan, the masters/code lists most often used include: the Classification & Coding of Clinical Laboratory Tests (JLAC10) developed by the Japanese Society of Laboratory Medicine (JSLM,) Image Examination Order Codes (JJ1017) developed by the Japan Industries Association of Radiological Systems (JIRA) and the Japanese Association of Healthcare Information Systems Industry (JAHIS,) the ICD-10 Based Disease Name Master, Operation/Treatment Master, Clinical Test Master and Pharmaceutical Products Master (Hot Reference Numbers.) developed by MEDIS-DC under entrustment by the Japanese MHLW. In addition, MEDIS/DC also defines the data item sets for use in the interchange of electronically stored medical record information called J-MIX.

On the other hand, in consideration of the interchange of medical information between hospitals, regions or nations, discussions have been active about the interoperability in terms of semantics of the terms used as well as of interoperability between systems. This issue is represented by the fact that linkages maintaining compatibility of clinical meanings are important for the quality and safety of medical care. In this context, a standard known as CEN/EN 13606. "Health informatics - Electronic health record communication" was established in February 2007. This standard features definition of the archetype, which is the structure for isolating that part of the data that is directly concerned with clinical practice in traditional systems and for reflecting accurately the contents defined exclusively by clinical experts for changes in the clinical field [6] . For the implementation of EN 13606, openEHR (http://openehr.jp/) is preparing a library. This standard is also under deliberation for international standardization at ISO.

3.2 Message Exchange Protocols

The representative standards on message exchanges between systems are the HL7 and DICOM standards.

The name of HL7 derives from its purpose of standardization related to what is called the application layer by ISO OSI for message exchanges between medical information systems. This standard handles a wide range of information including: patient administration, ordering, various inquiries, test reporting, information management, reservation, patient referral, patient care and laboratory automation. The Version 2.x series is currently being widely disseminated but Version 3 is being standardized, aiming at systematization of the standard by applying appropriate object-oriented and modeling techniques. It is also expected that Version 3 will also define an electronic medical document interchange standard using XML representation, called Clinical Document Architecture (CDA). At present, Version 2.5, CDA, the data model called Reference Information Model (RIM) and the data format and functional model are under deliberation at ISO.

The DICOM standard defines the formats of medical images captured with imaging devices such as CT and MRI and associated information, and the communication protocol between imaging devices and systems handling them. DICOM3 features definition of images and information based on object-oriented models and has widely been used all over the world during the 15 years since publication. In this period, technical innovations have been dealt with by issuing Supplements. At present, a revision into DICOM4 is being studied in order to deal with XML description and websites.

3.3 Security & Safety

Since the medical field handles critical personal information such as the health information of patients, full consideration is required for security of information. The general technical standard on information security is under study by ISO/SC 27, while the medical-specialized technical standard and the guidelines for using such a standard are under development by ISO/TC 215 WG4, CEN/TC 251 WG3, HL7 WG13, etc.

In Japan, the MHLW published the "Guidelines for the Safety Management of Medical Information Systems" (Safety Management Guidelines) in March 2005 to indicate the guidelines on the instruction of information systems in medical institutions and on the handling of data stored externally. Under this trend of placing emphasis on the use of medical information and of advancing linkages of various medical information platforms, HEASNET (Healthcare Information Secure Network Consortium) was established in collaboration between industry and academia in February 2005 in order to promote the dissemination of secure network platforms to enable the linkages. The Safety Management Guidelines were revised as Version 3 in March 2008. While Version 2 featured clarification of the security requirements for the Internet connection mode, Version 3 features definitions related to the wireless LAN. The details on the security have also been compiled in HEASNET reports.

Meanwhile, standardization discussions are also being conducted regarding software security in information systems as well as on security of information. ISO/TR29321: "Application of clinical risk management to the manufacture of health

software" and ISO/TS29322: "Guidance on the management of risk to ensure patient safety of health software systems in deployment and use" are the drafts for the risk management standards related to the software safety of the non-medical device vendors (covering the field of medical information systems) and the medical institutions respectively. Nevertheless, since such standards are closely related to the regulations of individual countries that differ depending on their national situations, it is expected that adequate discussion will be required before final establishment of the standards.

4. Toward the Dissemination of Standardization

(1) IHE

In general, there is always the potential that linkages between programs designed on the same standard may not work properly in a case in which the standard has too wide a coverage or involves optional settings. In order to avoid such troubles, Integrating the Healthcare Enterprise (IHE) was established in the United States in 1999 jointly by the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). The activity of IHE is not to develop standards but to define the operation workflow (Usage Cases) and to provide the specifications defining how to use such standards to support implementation of the workflow. IHE calls this workflow the "Integration Profile," and the specifications are the "Technical Framework."

Every year, vendors perform connection testing in order to mutually confirm compliance to the Technical Framework and this meeting is called a "Connectathon" (from "Connection" and "Marathon"). The Connectathon in Japan held in February 2008 was attended by 41 vendors for testing a total of 22 integration profiles in the four fields of: radiological examinations, clinical examinations, circulatory organs and IT infrastructures. In particular, in the domain of IT infrastructures IHE has led to the development of integrated profiles such as: the Cross-Enterprise Document Sharing (XDS) profile for the sharing of medical documents between medical institutions, the Patient Identifier Cross-Referencing (PIX) profile for mutual referencing of patient IDs that vary between medical institutions, the Patient Demographic Query (PDQ) profile for query of basic patient data, and the Portable Data for Imaging (PDI) profile for saving image data in media such as CD-R discs for loading, display and output on other systems.

Table HELICS standardization guidelines.

No.	HELICS Standardization Guideline Name
HS001	Standard Master for Pharmaceutical Products (HOT reference numbers)
HS002	Agreement on Clinical Laboratory Data Communication. JAHIS. Ver. 2.0
HS003	Agreement on Clinical Laboratory Data Communication. JAHIS. Ver. 2.0 <online>
HS004	DICOM Standards
HS005	ICD-10 Based Standard Disease Code Master for Electronic Medical Records, Ver. 2.30
HS006	Patient Referral Document & Clinical Data Document V.1.00
Under deliberation	Referral Document V1.0 (For Inter-Enterprise)
Under deliberation	IHE: PDI(Portable Data for Images) Integration Profile, and Its Application, Guideline

In Japan, IHE Japan (IHE-J) [7] was established in October 2001 and was subsequently reorganized into a limited intermediate corporation in March 2007. Its operations include: promotion of the dissemination of integrated profiles and Technical Framework, establishment of the Japanese extended version of integrated profiles and Technical Framework, and the holding of domestic Connectathon meetings.

(2) HELICS Board

The Health Information and Communication Standards Board (HELICS) [8] was established in 2001 in order to enable consistent activities among standardization institutions for the electronic conversion of information handled by healthcare information systems, definition of the description formats including codes and definition of storage formats. Its aims include discussions on policy and the detailed content of standardizations, recommendations of the standard to be adopted for each purpose of use and indications of guidelines (Medical information Standardization Guidelines) for use of the standards. Up to the present, it has established or put to deliberation the standardization guidelines shown in **Table** .

5. Conclusion

Issues of major concern in the field of medical care relate to its quality and safety aspects. Although standardization alone is not sufficient for securing quality and safety, there is no doubt that it is a critical factor in their implementation. Collaborations with people in the clinical field as well as among

industry, government and academia are more important than ever for promoting the dissemination of standardizations. At NEC, we are also determined to promote awareness of these systems and to support further standardizations in the future.

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