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Review Article

Standardization in Medical Informatics

Abstract

This article stresses the importance of standardization in the domain of Health and Medical Informatics, and Telematics. It gives an overview of the current standing of the activities of CEN TC 251 (European Standardization Committee, Technical Committee on Health Care informatics) and describes the scope and content of a number of emerging European standards.

Keywords

Health Care, Informatics, Telematics, Standardization

Introduction

Today, there is a growing need for multi-system connectivity and electronic data transfer in the health-care sector. The necessity for integration of systems and for data communication in this sector becomes evident when studying the variety of interested parties, the multitude of applications and their importance. The potential exchange of data between heterogeneous and independent information systems in hospitals, ancillary departments (e.g., the laboratory, or radiology), private medical offices, public authorities, and the health-care industry is very large and complex. The nature of health data itself (text, coded data, voice, signals and images) is also very diverse [1]. The following list illustrates the most urgent user requirements with regard to health-care telematics:

1 Clinical Messages

- Exchange of laboratory medicine data, especially fast and reliable access to laboratory test results,
- Access to radiology text reports (interpretative comments),
- Prescriptions from physicians to pharmacies,
- Availability of hospital admission data and discharge summaries,
- Interpersonal mail between practitioners (e.g., general practitioners and specialists),
- Access to existing external literature and knowledge bases,
- Communication with public authorities concerning epidemiology, external quality assessment schemes, and utilization review,
- Data transfer from the pharmaceutical industry, e.g., information on new drugs, adverse drug reactions, or pharmaceutical trials.

2 Administrative Messages

- Communication between hospitals and suppliers; purchasing and payment,
- Exchange with insurances agencies and third party payers; billing.

3 Medical Images

- Conventional X-ray images from radiology departments
- Digital images from CT scanners, MRI, DSA, ultra sound images, processed for radiotherapy, neurosurgery, etc.,
- Scanned documents (cf. the multimedia health record).

4 Other

- Digital voice reports
- Signals (ECG, EMG, EEG).

International standards for messages in health care are necessary to maximise efficiency, effectiveness and quality in health care delivery.

Studies have shown that the use of standards is a key promoting factor in electronic communication, which in turn significantly increases the application of informatics and the use of computers. A breakthrough in the medical informatics market will probably result from the introduction of medical telematics applications.

Why Standards in Health-Care Informatics and Telematics?

In conventional sectors of industry, Information and Communication Technology (ICT) Standards are known to increase the market opportunities and to lower the cost of equipment and services to users. These arguments are even more valid for informatics and telematics in health care, where European industry often supplies to local market products which are too customized, i.e., expensive in development, expensive to buy, and with a short life cycle. Agreement on common requirements at an international level will inevitably reduce the price of health-care information systems and open the market. Moreover, in health-care telematics today, heterogeneity in health-care information systems is a reality. There is even a proliferation of heterogeneous and incompatible data exchange solutions, which results in higher maintenance costs and lower user-friendliness.

Consequently, linkage of diverse systems by standard interfaces has been widely recognized as a must. Health-policy makers, involved in medical effectiveness and in health services-research, recognize that the development of standard definitions of medical data is essential, and require common reporting formats and linkages for such data. Especially in Europe, where the information crosses management boundaries and in many cases regional and national boundaries, agreement on information content and message structures is necessary. Last but not least, standards in health-care telematics and informatics will improve the health of individual patients, by improving the ability of public administrations and health-care professionals to share critical safety requirements and other information.

CEN TC 251; Standards in Health-Care Informatics

It is important in standardization to decide the right moment to begin harmonization. This is of particular interest in the case of moving technologies where an intended standard might impede the development; in this case the standardization measures are too early. However, it may be desirable to ensure that unsuitable circumstances (e.g., proliferation of incompatible solutions for electronic data interchange) are not allowed to take root and, in that case, standardization must be started as soon as possible in order to set the developments on the right track. It is only with the introduction of telematics in health-care that such an urgent need was disclosed for organized standardization activities and for a common use of standards in health-care informatics (basic standards securing compatibility, connectivity and interchangeability were especially desired). In order to respond to this challenge, the Technical Board (BT) of the European Standardization Committee (CEN) approved the establishment of a Technical Committee for Medical Informatics (TC 251) in March 1990. The objectives of CEN TC 251 are the organization, coordination and follow-up of development of standards, including testing standards, in health-care informatics, at a European level (12 EC countries, 7 EFTA countries and a growing number of Eastern European countries). Since any standardization activity should begin by identifying the needs, determining the aims of the (pre)-standard(s) to be prepared, and the interests that may be affected, the CEC issued a mandate (BC-IT-SI-05) to assess the actual situation of standardization in medical informatics. The recommendations originating from this mandate are part of the TC 251's 'Directory of Requirements and Programme for the Development of Standards for Health-care Informatics' [2] in which the tasks for the working groups and project-teams are described (see Annex). As with other Technical Committees in CEN, CEN TC 251 is composed of delegations officially appointed through the members of CEN (the national institutes of standardization, e.g., BSI, DIN, AFNOR, etc.) and is responsible for the overall coordination.

CEN TC 251 decided to constitute the following Working Groups (WGs):

WG 1: Health-care Information Modelling and Medical Records.
WG 2: Health-care Terminology, Semantics and Knowledge Bases.
WG 3: Health-care Communications and Messages.
WG 4: Medical Imaging and Multi-Media.
WG 5: Communication with Medical Devices.
WG 6: Health-care Security, Privacy, Quality and Safety.
WG 7: Intermittently Connected Devices (incl. cards).

In most of the member states 'mirror-groups' have been established, following the same structure as the CEN TC 251 Working Groups.

Each Working Group supervises a number of Project Teams. The work in a Project Team is undertaken by specially assigned experts and is funded. Project Teams have to be duly justi-

fied; they are small groups of trusted people preparing high-quality documents, urgently required.

The present Project Teams (PTs) in CEN TC 251 are:

PT001: Medical informatics vocabulary.
PT002: Terminology and coding systems of medical procedures.
PT003: Model for representation of semantics.
PT004: Investigation of syntaxes for existing interchange formats to be used in health care.
PT005: Procedures for registration of coding systems related to health-care.
PT006: Medical image and related data interchange format standards.
PT007: Standard interchange format and communication protocol for computerised electrocardiography.
PT008: Messages for exchange of laboratory information.
PT009: Identification, administrative and common clinical data content for intermittently connected devices used in health-care.
PT010: Health-care information framework.
PT011: Electronic health-care records architecture.
PT012: Security for health-care information systems.
PT024: (EWOS) Medical image interchange.

About 700 individual experts (representing users, academic centers and industry) are now active in CEN TC 251 through participation at either the working group level, the project team level, or within the national mirror-groups. They constitute a rich network of technically and medically skilled people.

CEN TC 251's statements of principle are:

1. Do not 'over'-standardize.
2. Bottom-up (user needs) and top-down (models) approaches are complementary and both will be followed at all levels (TC, WGs, PTs).
3. The partitioning of the work strongly shapes the effort and will determine its success or failure (cf. importance of a taxonomy of problems).
4. There is a danger that tools may be used for the wrong purpose or outside their working limits and, therefore, a problem-oriented approach is preferred to one which is technology-driven.
5. Medical Informatics must be understood in its broader meaning comprising health-care informatics as well.
6. At the start, attention will be focussed on OSI layer 7 and above, and on the domain data.
7. Duplication of work must be avoided. When the scope of a group is all-inclusive or overlaps the effort of too many others, this group has to accept a narrower range (cf. cooperation with EWOS, CENELEC TC 62, CEN TC 224, WEEB/MD 9, ANSI-HISPP, MITI, ISO-IAeG, etc.).
8. Whenever there are opportunities to work cooperatively on an international basis, one has to use these facilities in order to avoid conflicts and to make the standards more compatible. (cf. cooperation with the ANSI Health-care Informatics Standards Planning Panel in the USA, which was established in December 1992). The establishment of a 'Fortress Europe' and the creation of barriers to trade have to be avoided.
9. Work will only start when a standard is really needed and required by the users. Only realistic and feasible targets will be promoted: near-term and high-yield opportunities will be dealt with first. The reasoning, recognizing that standardization in health-care informatics is an extremely urgent issue, has to be balanced against the fact that it has been overdue for many years.

In Europe, CEN TC 251 closely liaises with EWOS/EG-MED (European Workshop for Open Systems, Expert Group Medical) and WEEB MD9 (Western European EDIFACT Board, Message Development group for Health-care). EWOS/EG MED's focus is on ISO's OSI and on Functional Profiles to be used in health-care (e.g., application profiles, transport profiles, and management profiles). WEEB is an associated body of CEN; WEEB MD9 specifically works on the development of message standards for health-care, following EDIFACT syntax rules and directories. The agreement with WEEB MD9 stipulates that the study of the user-requirements, the design of domain information models as well as the definition of interchange format-independent General Message Descriptions (GMDs) is the responsibility of CEN TC 251 (especially of its WG3).

Worldwide, CEN TC 251 coordinates with ANSI-HISPP[1] (American National Standards Institute, Health-care Informatics Standards Planning Panel), with IT/14- Standards Australia, with MEDIS-DC within MITI (Ministry of Trade and Industry, Japan), with WHO, with the ISO IAeG (InterAgency edi Group of ISO[2]) and many others. CEN TC 251 was the first established committee standardization in health care informatics. Since

[1]ANSI-HISPP now serves as an umbrella organization and coordinates the activities of ASTM, IEEE/MEDIX, HL7, ACR-NEMA and others in the USA.

[2]Recognizing the risk of divergent approaches to standardization efforts for electronic data interchange (edi), the chief executives of ISO, IEC, CCITT and UN/ECE have agreed on this joint initiative to coordinate the future development of EDI standards among their organizations.

then the USA, Australia and other countries have mirrored, more or less, the structure and organization of its work programme and working groups, as established in Europe [3].

Synergy between R & D and Standardization

The creation of CEN TC 251 and the establishment of the AIM (Advanced Informatics in Medicine) European Research Program is not a coincidence. Already within the exploratory action of the Program of DG XIII-F, funding for international research in medical informatics, several projects addressed very directly standardization or pre- standardization. Both research and development, and standardization will undoubtedly cross-fertilize each other and be of great significance to all future health-care informatics and telematics efforts in Europe. Coordination of AIM and CEN projects is now possible through an Accompanying Measure on Consensus Formation and Standards Coordination and Promotion, called ACOSTA. R & D and Standardization go hand in hand. The one influences the other, e.g., AIM projects and their deliverables can serve as inputs for CEN TC 251 or EWOS EG MED. The standard-making bodies can, on the other hand, make AIM projects aware of the existence of available standards (in order to avoid duplication or the production of incompatible solutions).

Although parallelism between activities of R & D and Standardization programs is beneficial, there is no room for overlap in the responsibilities : CEN does not undertake research; its sole function is to develop and to maintain standards by drafting documents (ENVs, ENs, TRs) after having obtained pan-European consensus. Since CEN only supports the development of much needed and relevant standards, there is a need for R & D projects to prove the practicability of their products and solutions through pilot implementations. The approach to the organization of R & D programs is different from that of standardization activities, which is a good reason for coordination. In R & D, such as in AIM, consortia are invited to submit proposals whereafter an overall selection follows. In CEN, the starting point is always consensus formation regarding the needs of standardization. This then serves as a basis for the workprogram (choice of items, prioritization, target-dates, etc.). For high- priority items, CEN TC 251 then constitutes Project Teams, by launching calls for experts (and not calls for project proposals) and by sending to candidates well-specified Terms of Reference.

Emerging European Standards in Health-Care Informatics

As a consequence of the CEN TC 251 activities, Europe will soon have its first medical informatics standards. The following summaries describe only those reports which are been finished and are ready for ballot, or those close to the final stage.

Registration of Coding Schemes

The first European pre-standard (ENV) specifies procedures for the registration of coding schemes and an unambiguous designator to identify coding schemes used in health-care communications. The Health-care Coding scheme Designator (or HCD) is a six-character identifier issued to each coding scheme on registration. Issuing Organizations (producing and maintaining existing coding schemes) are responsible for making the initial request for registration. Sponsoring Authorities take responsibility for accepting and checking requests for registration from the Issuing Organizations. It is proposed that recognised national standards' bodies or ministries act as Sponsoring Authorities. A single Registration Authority will process at an international level the requests forwarded by the Sponsoring Authorities and will be responsible for allocating the designators (HCDs) as well as maintaining the register. The World Health Organization has agreed, in principle, to act as the Registration Authority and will make the information in the register accessible to interested parties.

Investigation of Syntaxes

There has been a long discussion in health-care telematics community as to which Interchange Formats (IFs) to use for message exchange. This technical report (TR) is the result of an investigation of existing syntaxes for interchange formats to be used in health-care. The evaluation was done against a set of properties, including efficacy, richness, complexity, ambiguity, flexibility, cost, and practicality. The selected formats for investigation were ASN.1, ASTM E1238, EDIFACT, EUCLIDES, and ODA. The results of the evaluation show that none of the IFs support all the functional requirements defined. For some health-care domains, a combination of the functionalities from different IFs is needed (use of encapsulation is then recommended). CEN TC 251, therefore, does not recommend any specific IF for the whole health-care domain but has adopted a message-development method resulting in Interchange Format-independent General Message Descriptions (GMDs) (i.e., implementable in any syntax). This is a guarantee of more stable message standards.

Standard Communication Protocol for Computer-Assisted Electrocardiography

The primary aim of this standard (ENV) is to ensure that ECG reports and data from any vendor's computerised ECG recorder can be transmitted on a direct connected serial line to any other vendor's central ECG management system. The standard covers the two-way digital transmission of remote requests and results between ECG carts and hosts.

Structure for Classification and Coding of Procedures

This two-part pre-standard defines a (multi-axial) structure for classification and coding of surgical procedures and provides a system of concepts for the systematic naming, classification and coding of quantities in laboratory medicine.

Medical Informatics Vocabulary

A Medical Informatics Vocabulary is invaluable for the coordination of work among medical informaticians. The main objective was to produce a list of concepts and definitions, and to construct a tree that would represent the logical relations among concepts. The seven relations chosen as appropriate to place between terms were : part-of, kind-of, instance-of, method-for, required-for, support, and use. The vocabulary is presented both as a glossary and as a tree. The glossary is an alphabetically sorted list of more than 250 terms with definitions and other information.

Medical Image and Related Data - Interchange Format

This standard specifies the logical format to be used when medical images and related data are transmitted by on-line or off-line means. It includes a data model, the definition of various data object classes and services classes, necessary to ensure interoperability of application entities.

Messages for Exchange of Laboratory Information

This European pre-standard defines standardized messages to enable electronic data interchange to send laboratory service orders (requests) and reports (results). The normative parts of this ENV are the scope, the list of concepts, the domain information model and the general message descriptions. The domain information model is built according to the technique described by Coad and Yourdon [4]. The informative parts include the scenarios description and also EDIFACT messages and their implementation guidelines are included.

Profiles for Medical Image Transfer

Because of the urgency of this work (due to user needs) and the fact that the American College of Radiologists and the National Electrical Manufacturers' Association (ACR/NEMA) have produced a specification for "Digital Imaging and Communications in Medicine" (DICOM), it was felt necessary to set up a Project Team to undertake this work. The Project Team uses the method of working as defined in the Technical Guide of EWOS [5], which will in its turn provide valuable input to this guide to determine whether it is usable in practice.

Other standards (see list of ongoing CEN TC 251 Project-Teams) are under development. Among these is the very challenging Electronic Health-Care Record Architecture (PT011) which can be considered as a cornerstone affecting all other modelling efforts.

Conclusions

The successful exchange of information in health-care, both clinical and administrative, between disparate systems is at present one of the major challenges facing medical information science and computer technology. The general acceptance of the importance of telecommunications which forms together with informatics, the area of telematics, served as a catalyst for standardization in health-care informatics, which was urgently needed. It is hoped that today's beneficial synergy between research and development, standardization, and industry will continue to exist and will facilitate the implementation of a growing number of emerging standards.

References

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[5] *EWOS Technical Guide. A Method for Defining Functional Profiles for Health-care*. European Workshop for Open Systems, 1992.

Annex

Work-items in CEN TC 251's Directory (version 1.7) : Codes Titles

1.1 Health-care Information Framework
1.2 Medical Informatics - Vocabulary
1.3 Health-care Information Systems Architecture
1.4 Common Conceptual Schemes

1.5 Health-care Information Model and Transaction Set Coordination
1.6 Electronic Health-care Records Architecture
1.7 Medical User Interface
1.8 Electronic Health-care Records
1.9 Health-care Standardization Framework
1.10 Health-care Information Analysis and Design Methodologies
1.11 Medical Informatics Scenarios

2.1 Integration of Medical Data and Knowledge Base Systems
2.2 Terminology and Coding System of Diseases
2.3 Terminology and Coding Systems of Drugs
2.4 Terminology and Coding Systems of Medical Procedures
2.5 Terminology and Coding Systems of Manufactured Health-care Articles
2.6 Standards for Notation of Units for Quantities in Clinical Sciences
2.7 Time Standards for Health-care specific Problems
2.8 European Machine Dictionary and Multilingual Medical Terminology
2.9 Integrated System of Concepts
2.10 Certification of Knowledge-Based Systems, development and evaluation
2.11 Interchange Formats for Knowledge Bases
2.12 Model for Representation of Semantics
2.13 Meta-language for Data Manipulation and Information Retrieval in Medical Databases and Knowledge Bases
2.14 Statistical Databases for Medical, Epidemiological and Administrative Purposes
2.15 Standard Drug Databases

3.1 OSI Application Profiles for Health-care
3.2 OSI Transport Profiles for Health-care
3.3 OSI Management Profiles for Health-care
3.4 Multi-media Medical Data Interchange
3.5 Messages for Exchange of Laboratory Information
3.6 Interchange Format for Reference to Articles Published in Biomedical Books and Journals
3.7 Investigation of Syntaxes for existing Interchange Formats to be Used in Health-care
3.8 Procedures for Registration of Coding Systems Related to Health-care
3.9 Registration of Data Sets
3.10 Request and Report Messages for Diagnostic Services Departments
3.11 Messages for Exchange of Health-care Administrative Information
3.12 Support for the Coordination of Health-care elements, Messages and Associations of Elements
3.13 Methods for Patient Referral and Discharge
3.14 Health-care Messages Standards Development

4.1 Functional Profiles for Medical Image Interchange
4.2 Medical Image Management Standard
4.3 Medical Image and Related Data Interchange Format Standards
4.4 Standard Classification and Codes for Medical Image processing
4.5 Patterns for Calibration of IMAC Components
4.6 Characteristics and Specification Standards for IMACS Components and Systems
4.7 Medical Image Interchange : Conformance Testing of Standards Implementations
4.8 Medical Image Interchange : Compression Schemes in Telemedicine
4.9 Medical Data Interchange : HIS/RIS-PACS and HIS/RIS-Modality Interface
4.10 Medical Multi-Media and Related Data-Format Standard

5.1 Vital Signs Information Representation
5.2 Standard Interchange Format and Communication Protocol for Computerised Electrocardiography
5.3 Interoperability of Medical Devices within Acute Care Units
5.4 Clinical Analyser Interface to Laboratory Information Systems

6.1 Safety-Related Standards for Health-care
6.2 Security for Health-care Information Systems
6.3 Harmonization of Ethical/Legal Issues
6.4 Secure User Identification for Health-care
6.5 Software Quality Assurance for Health-care
6.6 Evaluation of Physiological Analysis Systems
6.7 High-Level Security Policy and Regulations Framework
6.8 User Authentication and Access Control : Technology Impact for Medical Informatics

7.0 Intermittently Connected Devices : Data Content
7.1 Off-line Device Interchange Format

List of acronyms

ACR/NEMA	American College of Radiologists and the National Electrical Manufacturers' Association
AIM	Advanced Informatics In Medicine (CEC, DGXIII-C3)
ANSI	American National Standards Institute
ANSI-HISPP	ANSI Health-care Informatics Standards Planning Panel
ASTM	American Standard and Testing Materials
CEN	Comité Européen de Normalization
CEN-BT	Comité Européen de Normalization - Bureau Technique
CEN-PT	Comité Européen de Normalization - Project Team
CEN-TC	Comité Européen de Normalization - Technical Committee
CEN-WG	Comité Européen de Normalization - Working Group
CENELEC	Comité Européen de Normalization Electrotechnique
COCIR	Comité de Coordination des Industries Radiologiques et Electromédicale
EN	Europäische Norm (European Standard)
ENV	Europäische Norm Vorausgabe (European Prestandard)
EWOS	European Workshop for Open Systems
HL7	Health Level Seven Group
IAeG	Inter Agency edi Group (ISO)
IEC	International Electrotechnical Commission
IEEE/MEDIX	Institution of Electrical and Electronics Engineers (USA), Medical Data Interchange Committee
ISO	International Standards Organization
TR	Technical Report
OIW	Open Implementors Workshop
WEEB	Western European EDIFACT Board