G.O. Klein

Centre for Health Telematics
Karolinska Institute
Stockholm, Sweden

Review

Standardization of health informatics - results and challenges

Abstract: A number of standardization initiatives have been in progress for more than ten years in several parts of the world with the aim to facilitate different aspects of the exchange of health information. Important results have been achieved, and in some fields and parts of the world, standards are widely used today. Unfortunately, we are still facing the fact that most healthcare information systems cannot exchange information with all systems for which this would be desired. Either the existing standards are not sufficiently implemented, or the required standards and necessary national implementation guidelines do not yet exist. This causes unacceptable risks to patients, inefficient use of healthcare resources, and sub-optimal development of medical knowledge. This article will review some of the difficulties surrounding standards, as well as highlight the achievements and main global actors, while focusing on the challenges facing the international consensus process.

Introduction

The health sector is still a rather immature user of information technology (IT) compared to other parts of society, especially considering the very strong dependence on information management. While there are many good exceptions where IT is used to provide better quality of care and more efficient use of resources, unfortunately, the over-all picture is different. Many routines still depend on the exchange of paper documents often not available when needed. Most often, information systems excellent in some aspects of the healthcare process are isolated islands, unable to communicate with other systems.

There are several reasons why obstacles may be overcome in the relatively close future.

Healthcare is extremely complex. Even though important international shared scientific background is available, many variations in information exchange requirements exist within the different specialty fields, countries and organizations. The standards that have been developed had to address these diverse requirements and rapidly changing technology. This is paired with a resistance toward change within a large installed basis of different systems owned and operated by different organizations in the network of collaborating healthcare entities.

An increasingly difficult issue for achieving interoperability is the rapid general development of IT with important, radically new software tools, and, not the least, standards from a large number of non-health related organizations. Still, the formal international standards, especially from the collaboration of ISO and IEC in JTC1 (Joint Technical Committee no 1) are very important in providing basic tools for interoperability, both with many lower layer standards, and also for e.g. character encoding (where the gradual introduction of the ISO/IEC 10646 character set, which provides for most international characters, is one important contribution sometimes underestimated by the English language speaking countries). The modern security techniques with public key infrastructures are very much dependent on such basic standards, which are sometimes developed jointly with the ITU (International Telecommunications Union). However, today, we are also seeing the formation of more and more other special bodies targeting the provision of important IT standards. Some examples are the IETF (Internet Engineering Task Force), whichnot only provides basic Internet standards, but also for many aspects of intranet applications. W3C (the World Wide Web Consortium), which developed HTML, and more recently XML, with many additional techniques, such as XSL and XML schemas, is another important actor. The open group OMG has developed UML (unified modeling language) which is now widely used

for healthcare information management and standards. This organization is also behind Corba (Common Object Request Brokering Architecture).

While these inter-sector techniques and standards are very important for interoperability, we also need health specific standards for many issues to achieve interoperability.

In this article some of the achievements of the following organizations will be reviewed: IEEE, which is focusing on device communication; DICOM for imaging; CEN (the European Committee for Standardization) with very diverse objectives; Health Level Seven, based in the US, but with many international affiliates, mainly for messaging; and the relatively recently formed ISO/TC 215 Health Informatics Committee. The reader should be aware of a possible bias by the author, since he has been the chairman of CEN's Health Informatics Committee since 1997, and of the ISO Committee, which he helped establish in 1998. In the latter he leads the working group on security.

Objectives of standardization

Relation between standards and political goals

CEN (Comité Européen de Normalisation), established in 1961, is a federation of official national standards bodies of the twenty European countries. It now has strong links to the political European Union, but is, nevertheless, an independent institution.

Generally, this European collaboration follows two objectives: Their first objective is to facilitate a European market for products and services and to remove the different national standards as barriers to this. This goal has generally been extended to include a global market wherever possible, and CEN is collaborating with the International Standards Organization (ISO) in many areas, now including Health Informatics. However, it is often easier to develop regional technical standards and it has been possible to achieve more precise requirements in Europe than under a global approach. Because of the links to trade policies within the European Union and EFTA, the CEN standards, which have been adopted by a qualified majority (with weighted votes, meaning countries with larger population have more votes than the smaller ones), automatically become valid in all CEN countries, even if a country is actually against a particular standard. This is unlike the situation for ISO, in which each national standards body decides if they want to adapt an international standard in their specific country. Because of this, unfortunately, many examples exist of ISO standards not becoming truly global. Large countries like the USA have often maintained national technical standards in direct conflict with ISO standards. However, in international trade the WTO agreement stresses the importance of the ISO for technical requirements.

The second important objective of the European standardization collaboration is related to the safety of its citizens. In many respective areas, common legislation (national laws following European Union directives) exist, in which the general safety requirements are set out, but to be used in connection with detailed technical specifications which have been developed and maintained by the European Committee for Standards – CEN. In the area of medical devices, many such examples exist, such as surgical implants, pacemakers, and in vitro diagnostics. For such products, a system of controlling bodies exists to ensure the standards are complied with.

The medical devices directive has not been applied to healthcare software products, e.g. electronic healthcare records and messaging. Also, no mandatory compliance to standards exists from a safety perspective. However, there is European legislation on public procurement. This means that any organization largely funded by public means (which includes most European healthcare) should apply certain rules for procuring products or services. These includes referencing standards when such exist. Given the strong legal position of European standards, this means that CEN standards should be used for health informatics in Europe. However, the interpretation of these is difficult and not yet fully understood. Therefore, many systems are bought without reference to standards.

The main emphasis for promoting standards in health informatics is that they facilitate, not that they are mandatory.

Table 1: CEN's members

Austria
Belgium
Czech Republic
Denmark
Finland
France
Germany
Greece
Iceland
Ireland
Italy
Luxembourg
Malta
Netherlands
Norway
Portugal
Spain
Sweden
Switzerland
United Kingdom

CEN/TC 251, the technical committee on medical informatics, was formed in 1990 (with the name changed to health informatics in 1997). This committee has a very broad scope, covering most aspects of health informatics, unlike some of the other more specialized organizations. This committee als provided a way to make use of the results of the extensive European joint research program in health telematics. Large funds have been allocated to the projects of this program for developing new methods of using IT and telecommunications in health. In several cases, submitted project results submitted regarding formal standardizations were discussed further and finally matured into technical standards (or pre-standards).

Scope of CEN/TC 251

Standardization in the field of Health Information and Communications Technology (ICT) is aimed at achieving compatibility and interoperability between independent systems. This includes requirements on the structure of health information to support clinical and administrative procedures, technical methods to support interoperable systems as well as requirements regarding safety, security and quality.

This scope is very similar to that of the more recently formed ISO/TC 215 committee, which largely covers the same ground, but has emphasized the objective to not always develop new specifications, but rather to endorse solutions developed by other bodies.

Different stakeholder views

The healthcare sector is one of the largest soietal sectors, accounting for some 8-14 % of the Gross Domestic Product. The main parties interested in standards for health informatics are the *organizations providing healthcare services*, in other words, those buying and operating health information and communications systems, and *their industrial suppliers*. The suppliers of health information system solutions have been rather nationally oriented (with the exception of device related systems), but multi-national actors are increasingly appearing.

Since all people are potential patients at some stage in their life, *every citizen* has a concern for the effectiveness of the health care service system. This applies both when it is used directly for themselves as well as when it is used for others that are close. For the citizens, as payers of services through insurance fees, taxation, or direct payment mechanisms, the efficiency of resource utilization is an issue.

The payment bodies are another important stakeholder in this sector. *Payment bodies*, in many countries private or public insurance organizations, or a regional or national governmental body, are important users of health information, with connections to all types of health service providers, and often directly to the patients/citizens.

The *pharmaceutical industry*, with a truly international market and the need to compile information from clinical trials in different countries, is another stakeholder in health information standardization. Although this stakeholder has not played a very active role in health informatics standards so far, its interest is of growing importance.

Healthcare professionals and other *caregivers* have other interests in the development of this sector and the use of technology to change the working environment, in particular to provide new patterns of collaborative work.

The *national governments*, with responsibility for public health planning is also an important user of health information, which comes from many different sources, and thus is an important stakeholder of standards.

While the patients/citizens have not been directly represented in the standardization activities in this area, there is a growing awareness that patient views are important. In ISO/TC 215 a special ad hoc group has been formed to analyze consumer health issues in relation to the technical standards.

Requirements for standards in patient care

The overall purpose of health services is to provide increasingly good quality care to patients/citizens not only in their home environment, but increasingly to those traveling to other parts of the country or region, such as within Europe, and to some extent globally (although resource constraints make this an impossible luxury for very few). The present lack of standardized ICT communication, which prevents inappropriate access to health records, may result in important clinical risks for patients. This is an important safety issue that has not been recognized sufficiently. E.g. a number of adverse drug reactions could have been prevented if information had been made available on-line that existed elsewhere in another health institution. It is also well recognized that appropriate decision support systems with standard interfaces to the clinical routine situation, e.g. for drug therapy, can decrease suboptimal drug use and reduce costs.

Citizens are increasingly demanding that professional health information related to their case should be available from whatever point of care source, wherever this may be.

Health Information and Communication Systems are essential to improve efficiency by enabling effective integration and co-operation of health professional resources over time and space. ICT systems are required to manage the processes of quality management and control involved in public authority activities, as well as actions

within provider organizations and research institutions. The aggregated health monitoring information should also be made available to the citizens/ patients, as described in the Community's proposed strategy for health.

Implemented standards are often crucial for any communication, They are especially important in open and very complex health care systems, which are made up of many different organizations and units, most often equipped with information systems from different suppliers and providing different parts of the overall ICT support.

Suppliers/developers of ICT systems are the primary users of our standards, but some standards are used directly by the healthcare IT management, e.g. for security and safety issues. The suppliers generally welcome standards that enable modular systems solutions and a well-defined market. However, in many areas of health information standardization, the suppliers alone cannot be the driving force. In this case, it is a task for the health professionals, healthcare service providers and authorities.

ICT solution buyers often want to refer to existing relevant standards when requesting proposals from suppliers according to the public procurement directive. Technical standards enable a better working market with competing offers from suppliers active in several countries. However, health care information systems, in many cases, need national adaptation. Standards on the market will decrease costs for ICT support, particularly when the requirements to integrate different systems are considered. Integration through communication is a key factor for improving the health systems.

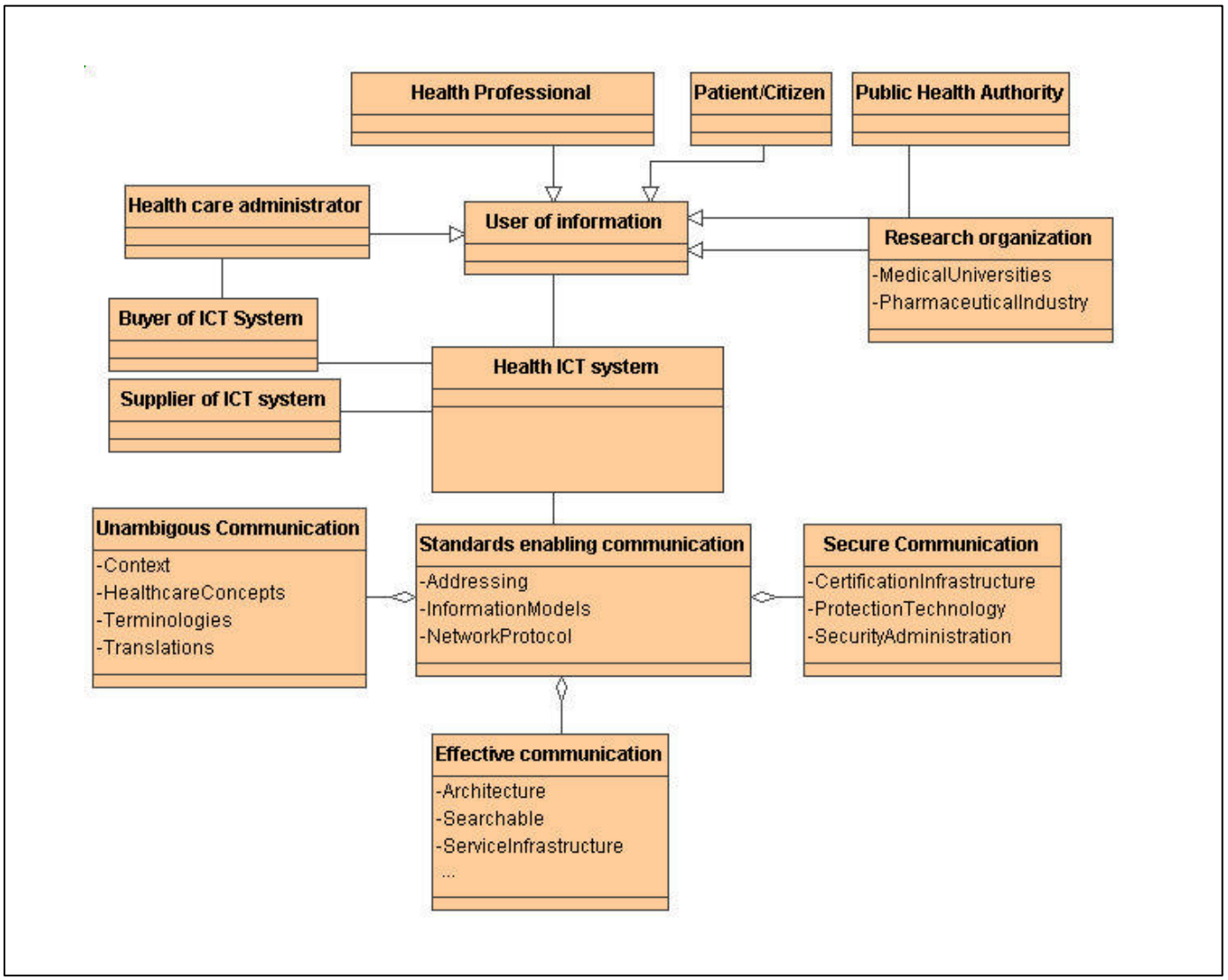

Fig.1. A model of the stakeholders of standards and the main classes of standards

Information models for healthcare processes

A major activity of CEN/TC 251 has been and will remain the specification of detailed information models for various healthcare processes. These correspond to the various clinical documents in the paper world, such as referrals, medical prescriptions, lab reports and healthcare records. A good example is the European standard for Electronic prescriptions completed in 1999.

However, available standards need refinement based on available experiences and the process of global harmonization. Also, there are a large number of healthcare processes for which information models have not yet been standardized.

Syntax specific implementation guidelines are required. In Europe, we are currently in the process of switching from EDIFACT to XML.

Standardized concept representation for processable medical content

Available European standards require additional support in many areas to enable safe and unambiguous communication. The medical content of communication must be *processable* , not just viewed on a screen. This is crucial, because it enables added value use of the information for administrative follow up, improves quality of care, and supports medical research. Defined information structures and concepts are also required for the use of intelligent context-dependent decision support in the clinical situation when treating the individual patient.

Information should be represented by controlled terminologies based on concepts that are well defined by their relations. *Reference terminologies* should be developed nationally or by cross-national specialist groups. An important use of advanced terminology services is the mapping between different terms and codes used by different institutions and professional groups. This is very useful for the aggregation of data, e.g. for pharmaceutical trials.

Mapping surgical deeds and outcomes to a reference terminology allows cross-border comparison of surgical outcomes, enabling the European citizen to make an informed choice of treatment.

National terms mapped to a reference terminology enable translation between national languages.

Security is essential for health-on-line

The use of ICT can also introduce new, not yet well-controlled risks. While medical devices are controlled through the implementation of directive 93/42, medical software systems and information directly targeting citizens and available on the Net are without proper quality controls. Actions are needed, both to investigate and define proper amendments to European and national legislation, and to introduce measured means for improving the present situation without disturbing the need for innovation and recognition of the importance of "in-house" solutions, which are not available on the market and, therefore, not covered by such legislation.

The eEurope action plan 2000 includes, as its first priority, work for Community action an initiative to ensure a quality certification for medical Websites. CEN has started to work on technical standards supporting this process. A first work item is aimed at defining a Metadata structure to describe the intended scope and quality assurance process of the presented information.

CEN/TC 251 has established important security standards for technical protection mechanisms and for supporting security management. Continued sector specific activities in close collaboration with inter-sector developments are important to ensure secure, broadest interoperability, and to ensure the special privacy concerns of the sector are supported by technical measures, as well as security management guidelines and *certification infrastructures*. CEN is already working on a standard for Data Protection Contract Guidance to assist meeting the European requirements for communicating personal health information to countries outside of Europe. Standards are essential to establish certification procedures that ensure the safety and privacy concerns in relation to health information systems when necessary.

Summary of Targets

Standards should **exist**,

- **be validated**,
- **well known** and
- **implemented by major actors** to enable:

- The transfer of most types of patient centered information between all European healthcare organizations including complete health records, medical prescriptions, referrals and results of all types of investigations performed.
- Support of multimedia communication for the above purposes, including direct videoconferencing
- The safe integration of wireless medical devices of all types, both those capable of information provision (measurements) and those requiring computer control from external health systems.
- The integration of various knowledge sources into patient centered health information systems. These knowledge bases should be available across borders in multilingual form.
- Processing of medical content to support clinical research and intelligent behavior of information systems, including medical alerts and other forms of decision support.
- Meeting the security requirements for confidentiality, integrity (including electronic signatures added to various document parts), availability and accountability.
- Interoperability and bridging policies which ensure that security services can

be provided, including access control between healthcare organizations across borders. This should allow pan-European recognition of digital certificates of professional qualifications and registration. This should also allow the patient using the Internet and appropriate security techniques at home to have direct access to health professionals and their personal health data.

- The build up of appropriate quality control measures in certain cases with appropriate third party testing and certification of health information systems to protect patient safety and to ensure interoperability of products

Work areas and organization

In 1997, CEN/TC 251 restructured its work into the following four working groups, shown in Figure 2 with the corresponding ISO/TC 215 working groups.

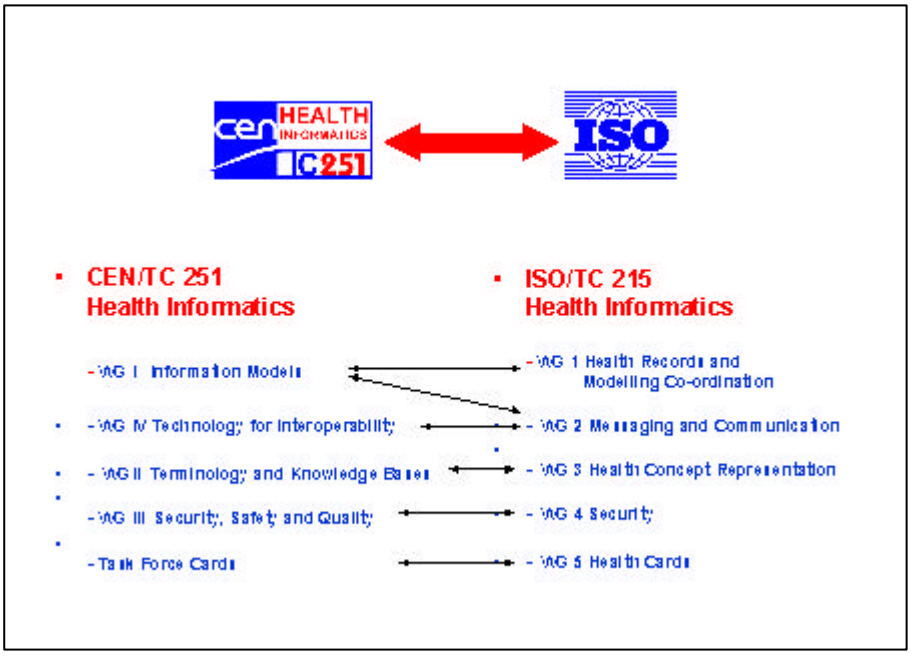

Figure 2. CEN/TC 251 and ISO/TC 215 working groups

Highlights of CEN results

ENV/CR/ No. year	Title/Acronym	Use of the standard
CR **1350** 1993	CEN Report: Investigation of syntaxes for existing interchange formats to be used in healthcare - **MEDIF**	This has guided CEN/TC 251 as well as a large number of message developers in various European countries. However, it is now out of date, since XML is not included.
ENV **1613** 1995	Medical informatics - Messages for laboratory information exchange - **LABMES**	This is the basis of national profiles and large-scale implementations at least in Denmark (50 % of all lab reports are sent using it), the UK and Norway.
ENV **12018** 1997	Identification, administrative, and common clinical data structure for Intermittently Connected Devices for use in healthcare (including machine readable cards) - **DCICD-HC**	This has been the basis for all major European and international healthcare specifications. Through the G8 countries collaboration the US government has used a further development of it. It is presently the basis for the ISO/TC 215 joint development with CEN, according to the Vienna agreement.
ENV **12443** 1998	Medical informatics - Medical informatics healthcare information framework - **HIF**	This is a framework for standardization activities in the field and not intended for direct implementation by industry. The standard is now undergoing major revision.
ENV **12538** 1997	Medical informatics - Messages for patient referral and discharge - **MPRD**	This message standard, with further national implementations in EDIFACT, has been used in national large scale implementations and in Denmark and in several smaller projects in different countries. Currently revised.

ENV **12539** 1997	Medical Informatics - Request and report messages for diagnostic service departments **DIAMES**	This message standard, with further national implementations in EDIFACT, has been used in national large scale implementations and in Denmark and in several smaller projects in different countries. Currently revised.
CR **12587** 1996	CEN Report: Medical Informatics - Methodology for the development of healthcare messages - **METHODOL**	This standard has played an important role for a lot of CEN and EBES-EG9 work and has also had major influence on HL7 in the US. The basic idea has jointly been developed further and is now a CD in ISO/TC 215.
ENV **12612** 1997	Medical Informatics - Messages for the exchange of healthcare administrative information - **ADMES**	This message standard, with further national implementations in EDIFACT, has been used in national large scale implementations and in Denmark and in several smaller projects in different countries. Currently revised.
ENV **13606-1** 1999	Health Informatics - Electronic healthcare record communication - Part 1: Extended architecture – **EHCR-EA**	This is series of standards for the representation of a healthcare record, and is a milestone without international competition. It is, however, complicated and implementation requires national guidelines and considerable work. National strategies intending to use this are underway in the UK, Sweden, Denmark, Norway, Scotland and the Netherlands. It is presently being considered in Belgium for national implementation. Companies that have implemented it include Siemens and Tieto-Enator. Part of this standard is also used in the national Australian record specification under the name GEHR.
ENV **13606-2** 1999	Health Informatics – Electronic healthcare record communication - Part 2: Domain term list – **EHCR-DT**	This is an important part of the record structure that gives meaning to the headings of the record. National guidelines required.
ENV **13606-3** 1999	Health Informatics – Electronic healthcare record communication - Part 3: Distribution Rules – **EHCR-DR**	This part is used less than other data structures.
ENV **13606-4** 1999	Health Informatics – Electronic healthcare record communication - Part 4: Messages for information exchange – **EHCR-ME**	This is a summary message using all the structural elements used in parts 1 –3. This part is actually what is implemented in products. A DTD for an XML implementation is included and used in the products mentioned above.
ENV **13607** 1999	Health Informatics - Messages for information exchange on medical prescriptions– **DRUGPRES**	This is implemented in Denmark in EDIFACT and in Sweden, Netherlands and the UK in XML versions with national adaptations.
ENV **13609-2** 1999	Health informatics - Messages for maintenance of information support in healthcare systems - Part 2: Updating of medical laboratory-specific information – **SUPINFMES2**	This is used by many laboratories in Denmark

ENV **13730-1** 2000	Health informatics - Blood transfusion related messages – Part 1: Subject of care related messages Part 2: Production related messages	This is quite recent but is being implemented in France by the national blood transfusion service
ENV **1068** 1993	Medical Informatics – Healthcare information interchange - Registration of coding schemes - **RCS**	This standard was implemented with the World Health Organization as the registration authority, but then put on hold to await a general ISO procedure. It has now been revived and is to become an EN.
ENV **1614** 1995	Healthcare informatics - Structure for nomenclature, classification and coding of properties in clinical laboratory sciences - **PROCT-L**	This is the basis for the major international classification scheme maintained by IUPAC used in many, but not all, European countries.
ENV **1828** 1995	Medical informatics - Structure for classification and coding of surgical procedures - **PROCT-S**	This has been the basis for the French national classification of surgical procedures while other countries have maintained older less structured systems.
ENV **12381** 1996	Health care informatics - Time standards for health care specific problems - **TSMI**	This is being forwarded to an EN without change and will provide a basic common concept system for standards and other specification work.
ENV **12435** 1999	Medical informatics - Expression of the results of measurements in health sciences - **UNITS**	This is being forwarded to an EN without change and will provide a basic common concept system for standards and other specification work.
ENV **12610** 1997	Medical informatics - Medicinal product identification - **CDRUGS**	This is being revised to an EN in collaboration with the European Medicines Evaluation Agency, EMEA
ENV **12611** 1997	Medical informatics - Categorical structure of systems of concepts - Medical Devices - **TCMD**	This vocabulary structure is used in standards works, but not yet in other contexts to our knowledge
ENV **13940** 2000	Health informatics – System of concepts to support continuity of care - **CONTSYS**	This rather recent standard is being implemented nationally with health authorities in the Scandinavian countries and is guiding the development of a number of IT products not yet released. It has also been translated into Dutch and will be the basis for discussions about continuity of care.
ENV **14032** 2000	Health informatics - System of Concepts to Support Nursing - **NURSYS**	This is a step towards international harmonization of Nursing terminology and is the basis for an ISO/TC 215 work item developed in liaison with the International College of Nursing Professional Societies.
ENV **12388** 1996	Medical Informatics - Algorithm for Digital Signature Services in health care - **ADDS**	This standard algorithm (RSA) has been the basis for most trials and implementations of systems for digital signatures in European countries, e.g. in France, Germany, Belgium, Sweden, Norway, Finland and Greece.
ENV **12924** 1997	Medical Informatics - Security Categorization and Protection for Healthcare Information Systems - **COMPUSEC**	This standard guide to information security has been used in training and management mainly in France, the UK and the Netherlands, but it has also influenced regional and local policies in other countries. It is now considered a candidate for an ISO standard.

ENV **13608-1** 1999	Health Informatics - Security for healthcare communication - Part 1: Concepts and terminology – **SEC-COM1**	Part 1 of the SECOM series is used in several countries to guide requirement analysis and specification work. France is probably the leader here. It is also an important basis for much of other TC 251 security work.
ENV **13608-2** 1999	Health Informatics - Security for healthcare communication - Part 2: Secure data objects – **SEC-COM2**	Part 2 specifies a profile of the well-known IETF standard for secure messaging. Most modern healthcare security protection schemes using a PKI are in fact implementing this standard. Known examples are in France, Germany, Belgium, UK, Sweden and Norway
ENV **13608-3** 1999	Health Informatics - Security for healthcare communication - Part 3: Secure data channels – **SEC-COM3**	Part 3 specifies a profile of the well-known IETF standard for secure web access. Most modern healthcare security protection schemes using a PKI are in fact implementing this standard. Known examples are in France, Germany, Belgium, UK, Sweden and Norway
ENV **12251** 1999	Health Informatics - Secure user identification for healthcare - management and security of authentication by passwords (Healthcare oriented security functionality classes) – **SEC-ID/PASS**	This standard is not very well known, but the principles specified are followed by the industry in many countries
ENV **13729** 1999	Health Informatics - Secure user identification - Strong authentication using microprocessor cards – **SEC-ID/CARDS**	This standard specifies the basic principles of using microprocessor cards and has been followed in the major projects using such cards in e.g. France, Germany and Sweden. Will need an update now that more generic standards are available.
FM-HSP/FR	Health Informatics - Framework for formal modeling of healthcare security policies	This CR provides a basis for further work but is not directly implemented by industry
SAFE-ID	Health Informatics - Safety procedures for identification of patients and related objects	This CR has generated considerable interest for addressing these important safety problems. In the pharmaceutical area, this CR provides a conceptual foundation of the European DRIVE project which involves the pharmaceutical industry as well as hospital pharmacies and information system solution suppliers. EN work has been proposed as a follow-up, but has not yet started.
ENV **1064** 1993	Medical informatics - Standard communication protocol - Computer-assisted electrocardiography – **SCP-ECG**	This standard has been taken up by most major companies producing ECG machines not only in Europe but also worldwide. It has now been revised and is forwarded to an EN.
ENV **12052** 1997	Medical Informatics - Medical imaging communication - **MEDICOM**	This and ENVs 12623 and 12922-1 are European contributions and endorsements of the world leader in imaging standards for health, DICOM. The global DICOM specs now incorporate European contributions and a revised standard for EN as a general endorsement is being prepared.
ENV **12967-1** 1998	Medical Informatics - Healthcare Information System Architecture - Part 1: Healthcare middleware layer - **HISA**	This provides the basis for one successful commercial product (DHE) from Italy which is used in several countries. The standard is now undergoing major revision.

ENV **13728** 1999	Health informatics - Instrument interfaces to laboratory information systems – **INTERMED**	This standard, developed with major industries in Europe and the US, has now been agreed on to be fast-tracked as an ISO standard parallel to the EN process under the Vienna agreement.
ENV **13734** 1999	Health informatics -Vital Signs Information Representation– **VITAL**	This standard and ENV 13735 has been developed with major industries in Europe and the US, working in IEEE, and has now been agreed on to be fast-tracked as an ISO standard (in two parts) parallel to the EN process under the Vienna agreement
ENV **13735** 1999	Health informatics - Interoperability of patient connected medical devices	See above (ENV 13734). Now fast-tracked as an ISO standard parallel to the EN process under the Vienna agreement

ISO/TC 215

In August 1998, ISO/TC 215 "Health Informatics" was started with a scope similar to that of CEN/TC 251. These international efforts have been welcomed by Europe. An active collaboration between the European and international level is encouraged and has been started. A general co-operation agreement exists between ISO and CEN, the Vienna Agreement regulating how close collaboration can be achieved, avoiding different solutions but often allowing CEN results to be processed as formal ISO standards, possibly modified after international review.

In general, the ISO committee is still somewhat in a phase of trying to define its role. Relatively few work items have been formally approved, although a number projects have been started. To date only two technical specifications (corresponding to prestandards) have been approved by the ISO committee: quality criteria for controlled health vocabularies, and public key infrastructure respectively. The first formal standard in the pipeline is scheduled for publication mid 2002. It is called: Health Informatics - Clinical analyzer interfaces for laboratory information systems - Use profiles based on a previous European pre-standard.

A number of device related standards, developed by CEN and IEEE, have also been submitted to become formal standards in ISO, with necessary refinements.

While the general scopes of the ISO and CEN committee overlap, the major emphasis of international efforts has focused on some basic aspects of health informatics in which global consensus is probably achievable in a near future. This includes, but is not restricted to, methodology for message development (but not messages) and vocabulary of terminological systems.

In a few areas, more specific standards where there is already a clear international market of products such as in the area of medical device communication and where an informal collaboration already existed, European and US previous results and new development are now replacing regional efforts. However, at least in the beginning of the ISO work, it has been decided to leave many specific areas of standardization closely related closely to different business practices and standards heritage outside of the ISO work. Notably, for instance, in both Europe and e.g. the US, a large use of standardized healthcare messages already exists that can not be converted to a common global structure easily.

However, the enthusiasm is great, with over 30 countries participating. Many interesting but difficult projects have been started in various areas, including the security field and health cards, where much common global understanding already exists.

IEEE

IEEE – the Institute of Electrical and Electronics Engineers has been developing standards in its areas for more than 100 years. In what is now called point-of-care medical device communication (the 1073 committee) a considerable history of developing standards for device communication can be looked back on, the most famous being the "Medical Information Bus" standard. For more information see http://www.ieee1073.org.

IEEE has had a long and very lively collaboration with CEN/TC 215. Together, much work has been channelled to ISO/TC 215 for consideration as international standards.

DICOM

The American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) decided to form a joint committee in order to create a standard method for the transmission of medical images and their associated information in 1983. The first version was published in 1985. The release of version 3.0 in 1993 saw a name change, to Digital Imaging and Communications in Medicine (DICOM). For more information see: http://medical.nema.org/dicom.html

Scope

The DICOM Standards Committee exists to create and maintain international standards for communicating bio-medical diagnostic and therapeutic information in disciplines that use digital images and associated data. The goals of DICOM are to achieve compatibility and to improve workflow efficiency between imaging systems and other information systems in healthcare environments worldwide. DICOM is a cooperative standard. Therefore, connectivity works, because vendors cooperate in testing via scheduled public demonstration per Internet and during private test sessions. Major diagnostic medical imaging vendors worldwide have incorporated the standard into their product design. Most actively participate in the enhancement of the standard. The majority of the professional societies throughout the world supports and participates in the enhancement of the standard. DICOM is used, or will soon be used, by virtually every medical profession that utilizes images within the healthcare industry, such as cardiology, dentistry, endoscopy, mammography, opthalmology, orthopedics, pathology, pediatrics, radiation therapy, radiology, surgery, etc. DICOM is even used in veterinary medical imaging applications.

Table 2. DICOM Working Groups

WG 1 (Cardiac and Vascular Information)
WG 2 (Digital X-Ray)
WG 3 (Nuclear Medicine)
WG 4 (Compression)
WG 5 (Exchange Media)
WG 6 (Base Standard)
WG 7 (Radiotherapy)
WG 8 (Structured Reporting)
WG 9 (Ophthalmology)
WG 10 (Strategic Advisory)
WG 11 (Display Function Standard)
WG 12 (Ultrasound)
WG 13 (Visible Light)
WG 14 (Security)
WG 15 (Digital Mammography)
WG 16 (Magnetic Resonance)
WG 17 (3D)
WG 18 (Clinical Trials and Education)
WG 19 (Dermatologic Standards)
WG 20 (Integration of Imaging and Information Systems)
WG 21 (Computed Tomography)

HL7

HL7 was founded in 1987 in the US as a developer of healthcare messages. It developed its own syntax for representing information in a rather simple structure of named segments and fields (each of which has a defined data type). This has been further developed and covers a large number of different clinical and some administrative areas. Much of the focus has been placed on communication needs within organizations, such as hospitals. This specification is used particularly in US and Canadian hospitals in various forms of the version 2 (version 2.4 is approved, but most use version 2.3 or 2.2).

For more information on HL7 see http://www.hl7.org.

HL7 is now an American National Standards Institute (ANSI) approved Standards Developing Organization (SDO) and has its main base in the US. In recent years, it has, however, greatly expanded its international presence. Affiliated organizations exist in the following countries: Argentina, Australia, Canada, China, Czech Republic, Finland, Germany, India, Japan, Korea, Lithuania, the Netherlands, New Zealand, Southern Africa, Switzerland, Taiwan, Turkey and the United Kingdom. In most of these countries, some parts of HL7 version 2 have been adapted and are used with national implementation guides in some contexts.

In 1997, it was realized that the development model of HL7 had serious problems in achieving consistency between different parts. It was also noted, which is still a great problem, that different HL7 compliant implementations are not fully compatible since they choose to use options in different ways.

HL7 was influenced by European standardization work regarding building of object-oriented information models separate of implementation syntax. HL7 began the work towards version 3, which at the time of writing, fall of 2001, is not yet finished. That is no messages for implementationhave been approved, and, even if installations conforming to this may begin to appear in 2002, it will take considerable time before version 2 is actually replaced.

The work of HL7 with version 3 has resulted in great improvements of the principles of message development. Also, the methodology developed has largely been accepted by CEN, and is about to become an ISO standard. The Reference Information Model (RIM) is the cornerstone of the HL7 Version 3 development process. An object model created as part of the Version 3 methodology, RIM is a large pictorial representation of the clinical data

(domains) and identifies the life cycle of events a message or group of related messages will carry. It is a shared model between all domains and, as such, is the model from which all domains create their messages. Explicitly representing the connections that exist between the information carried in the fields of HL7 messages, RIM is essential to our ongoing mission of increasing precision and reducing implementation costs.

While the principle of a reference information model is sound, it is far from trivial to achieve consensus on the most useful model for healthcare information. The HL7 RIM has been revised completely several times, and is now very concise and abstract. This is elegant, but requires agreements on health specifics on another level. In HL7, this is done as part of message development with so called CMETs, Common Message Element Types. This partly corresponds with what the CEN group is working on, the so-called General Purpose Information Components.

In March 2000, a memorandum of understanding between CEN/TC 251 and HL7 was signed hich recognizes:

"There has been a number of fruitful exchanges between experts of the two organizations in the past years, with, e.g., US experts participating in CEN project teams, European experts participating in HL7 meetings, and the CEN principles for message development were adopted and further developed by HL7 in its work on Version 3.0. The organizations have fundamental common goals and many similarities in their solutions, and it is clear that the present incompatibility between the major European and US set of standards is neither beneficial nor desirable from a long term and global perspective. The need for a global family of standards has been apparent for some time, and both CEN TC251 and HL7 agree that collaboration and co-operation is the most effective way to approach this goal.

CEN/TC 251 and HL7 agree to collaborate in the spirit of mutual appreciation, respect and openness to seek pragmatic solutions to obtain unification of their set of standards for healthcare communication and to make the results globally available to ISO."

Since this agreement for collaboration was made, a lot of fruitful interchange has taken place, and CEN has decided to use part of the HL7 RIM achievements in its restructuring of message standards. It has, however, not been possible to agree on the more healthcare business related areas, and the working modes of the US dominated organization. For HL7, it is very important to encompass the old HL7 Version 2 content in the new messages, but other requirements from the European side have been difficult to accommodate. A particular problem relates to the complex structures of the Electronic Healthcare Record Architecture, which has not at all been taken up by HL7, even if an interest group was formed recently to push this aspect. In a NHS sponsored Project, the UK decided to develop t heir own GP to GP record transfer model using the HL7 RIM but deeming the construction of record containers necessary, and based on the thinking of the European standard ENV 13606.

CEN, on the other hand finds the record structure essential in health informatics and has decided to collaborate with the Open Electronic Healthcare Record Foundation, taking onboard important Australian contributions to the CEN architecture.

Conclusions

Standards now exist from several sources that cover many requirements for health information exchange. They deserve to be used much more, even if they are not perfect, and are in a stage of global development and harmonization. Procurers of health IT solutions should request standard conformant products for their domains, and industrial suppliers of solutions must consider the benefits of standards to meet customer requirements and to enable the construction of modular solutions.

The major bodies having an international impact in this area, CEN, HL7, IEEE and DICOM, all collaborate in different ways, and with ISO/TC 215. It is a long-term process and probably will never completely end, as different standards bodies learn from each other and gradually harmonize wherever possible. The users of standards eventually decide which standards to use. In several European countries, special governmental committees have been formed with the aim to clarify which standards should be used in their healthcare domain for different purposes if there are several candidates to choose from. However, to a large extent, the different standards initiatives complement each other more than they compete.

References

CEN/TC 251: www.centc251.org contains results and ongoing work for a review of the work done 1991-2001 see: doc N01-022 under TC documents 2001.

ISO/TC 215: http://isotc.iso.ch/livelink/livelink?func=11&objId=529137&objAction=browse&sort=name

HL7: http://www.hl7.org

IEEE: http://www.ieee1073.org

DICOM: http://medical.nema.org/dicom.html

Adress of the author:
Gunnar O. Klein
Centre for Health Telematics
Karolinska Institute
Stockholm, Sweden
E-mail: gunnar@klein.se