Chapter 5
Standards Development Organizations

Healthcare interoperability is based on the application of standards. This chapter introduces some of the major Standards Development Organizations in e-health.

A report produced for the European Union concluded:

> Despite a generally large number of conflicting e-health standards, versions and implementations, there may be a lack of the "right" standards. For particular applications and for concrete processes there may be no well-developed standards. In an expert survey, 80% of the respondents stated that there is a lack of sufficiently developed standards, and 64% said that there is a lack of standards for electronic health records (EHRs). (EU 2008)

5.1 What is a Standard?

ISO defines a standard as a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.[1]

Two of the key terms are consensus and recognized body. Consensus is general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. Consensus need not imply unanimity.

A recognized body is understood to be an internationally recognized standards development organization such as ISO, CEN, BSI, ANSI, and its accredited SDOs including HL7.

There are two main types of standard: exact specifications, which enable interworking of nuts and bolts, paint colors and computers; and minimum thresholds to ensure the safety and quality of processes, materials, and the environment. For healthcare interoperability we need stringent specifications.

[1] ISO/IEC Guide 2:2004, definition 3.2

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One of the limiting factors in market growth for health information systems has been the inability for different systems to interoperate, due to lack of suitable standards. Standards have a multiplier effect, the more people can interoperate, the more cost-effective is every new application and the larger the IT market becomes.

Interoperability standards have already become the foundation of whole industries.[2] This is well-illustrated by the explosive growth of the World Wide Web and mobile telephone markets, and should also be true of healthcare computing. In general, the healthcare standards development organizations have failed to provide sufficiently stringent standard specifications to enable plug and play, leaving this to local implementers.

The benefits of using standards increase exponentially with the number of different systems that need to be linked.

Purchasers of computer systems should insist on open interoperability standards to avoid supplier lock-in and give them choice and flexibility in procurement, allowing them to shop around for whatever meets their needs most closely. Open standards offer a guarantee for future migration, growth and evolution, foster competition between suppliers, drive down costs, and push up cost-effectiveness.

Suppliers also benefit; their criterion for success is return on investment. The actual return is often outside each supplier's direct control, so their priority is always to minimize investment and risk.

5.2 International Standards Development Organizations

The organization of health informatics standards development internationally is complex, changes frequently, and can easily become a fog of acronyms. The intent here is to introduce the most important players and to provide some important information, which does not readily fit into other chapters.

About 100 years ago the International Standardization Organization (ISO) was established to provide a focal point for all international standards. ISO is a membership organization, with one member in each c ountry. In the USA the member is the American National Standards Institute (ANSI) and in the UK the member is the British Standards Institute (BSI). The Vienna agreement specifies how conflicts between different standards should be handled. In particular, work done at the international level takes precedence over national standards.

When the European Union was established, it was agreed that the common market required common standards and the European Standards Organization (CEN) was established in Brussels, along the same lines as ISO as a national member organization.

[2] ISO Strategic plan 2005–2010: standards for a sustainable world. Geneva: ISO 2004

In 1990, CEN set up the first formal international standards organization in health informatics, CEN TC251. Each European country established its own mirror committee; for example in the UK, the mirror committee is BSI IST/35.

In the USA, ANSI acts as an umbrella organization for a number of affiliates with an interest in health informatics.

In 1999, ISO established a committee for Health Informatics (ISO TC215). The main task of this committee is to ratify existing standards, such as the HL7 RIM, as full international standards.

A number of other international organizations have also emerged, which do not fit neatly into the traditional ISO pattern. These include:

- IHTSDO The International Health Terminology Standards Development Organization, responsible for SNOMED CT
- CDISC (Clinical Data Interchange Standards Consortium) responsible for coordinating data capture for clinical trials
- IHE Integrating the Healthcare Enterprise, which develops profiles for specific use cases leveraging existing standards
- Continua, which focuses on home tele-health devices
- OpenEHR which focuses on elements of EHR architecture
- Open Health Tools a collaboration to develop tools for developing and implementing standards

In 2007, a joint initiative on SDO Global Health Informatics Standardization was established to coordinate the work done by ISO TC215, CEN TC251, HL7, IHTSDO, and CDISC. The major SDOs are shown in Fig. 5.1.

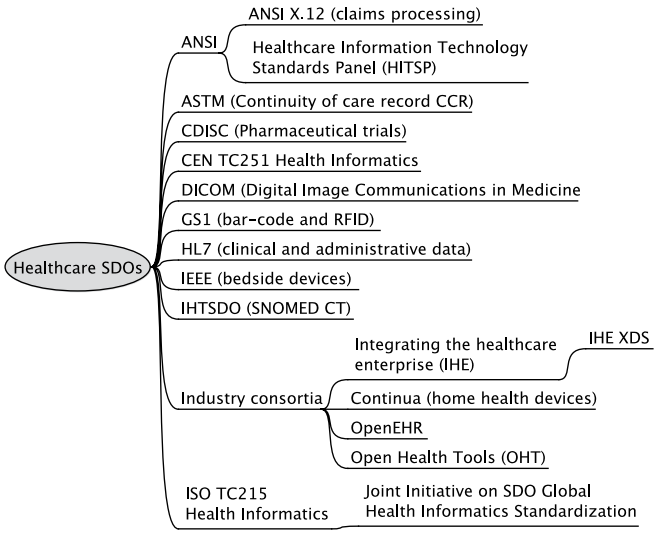

Fig. 5.1 Healthcare Standard Development Organizations

5.3 Health Level Seven

Health Level Seven (HL7) is an international standards development organization (SDO), with Affiliates in 31 countries.[3] Health Level Seven produces the world's most widely used standards for healthcare interoperability. Most of the leading suppliers use and support the development of HL7 standards across six continents.

HL7's vision statement is "to create the best and most widely used standards in healthcare." Its mission reads:

> HL7 provides standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among all of our stakeholders, including healthcare providers, government agencies, the vendor community, fellow SDOs and patients. In all of our processes we exhibit timeliness, scientific rigor and technical expertise without compromising transparency, accountability, practicality, or our willingness to put the needs of our stakeholders first.

HL7 creates standards for the exchange, management, and integration of electronic healthcare information for clinical and administrative purposes. HL7 does not develop software, but simply provides healthcare organizations with specifications for making their systems interoperable. It develops coherent extensible standards using a formal methodology. It collaborates with and provides a meeting place for healthcare information experts from the healthcare IT industry and healthcare providers to work together and with other standards development organizations. And, it promotes its own standards and provides education for the healthcare industry and policy makers.

HL7 is accredited with the American National Standards Institute (ANSI). It is one of several SDOs operating in the healthcare IT domain. HL7 focuses on the domain of clinical and administrative data. Other ANSI-accredited SDOs have responsibility for pharmacy (NCPDC), medical devices (IEEE), imaging (ACR/NEMA), insurance (claims processing) transactions (X12), and dentistry (ADA). These SDOs are all working with the Health Information Technology Standards Panel (HITSP), which was established in 2005 under contract to the US Department of Health and Human Services (HSS) to:

> achieve a widely accepted and useful set of standards specifically to enable and support widespread interoperability among healthcare software applications, as they will interact in a local, regional and national health information network for the United States.

HL7 also collaborates with international (ISO TC215) and European (CEN TC251) standards development organizations, and with other specialized SDOs such as IHTSDO (SNOMED terminology) and CDISC (clinical trials) through the Joint Initiative on SDO Global Health Informatics Standardization.

HL7 is a voluntary standards organization; most of the work in developing the standards is performed by volunteers, working over many years. Much of the work is done in small committee meetings and is then presented to a much larger group to achieve a consensus. HL7 volunteers meet together three times a year in

[3] More information about HL7 is available on the HL7 web site www.hl7.org.

week-long working group meetings at which more than 30 specialized committees meet face-to-face. Work continues throughout the rest of the year coordinated by regular telephone conferences.

Hammond and Cimino have described the process as follows:

> The writing of the draft standard is usually the work of a few dedicated individuals – typically people who represent the vendors in the field. Other people then review the draft; controversial points are discussed in detail and solutions are proposed and finally accepted. Writing and refining the standard is further complicated by the introduction of people new to the process who have not been privy to the original discussions and want to revisit points which have been resolved earlier. The balance between moving forward and being open is a delicate one. Most standards-writing groups have adopted an open policy; anyone can join the process and be heard. (Hammond and Cimino 2006)

5.3.1 What Does the Name HL7 Mean?

The name Health Level Seven is derived from the seventh level of the ISO's Open Systems Interconnect (OSI) model: the application layer, which provides a framework for communication between disparate computer systems. The OSI model has seven layers; the top three layers are concerned with applications (interworking); the lower four layers are concerned with the transmission of data (interconnection):

Layer 7 – Application: addresses definition of the data to be exchanged, the timing of the interchange, and the communication of certain errors to the application.
Layer 6 – Presentation: is concerned with the syntax of information transfer between end systems.
Layer 5 – Session: provides mapping between physical and logical sessions, including checkpoint recovery and restart.
Layer 4 – Transport: provides end-to-end transmission of data to the required quality of service (e.g., error-free).
Layer 3 – Network: is concerned with routing and relaying between multiple subnetworks.
Layer 2 – Data-link: transmit a stream of bits from one network node to another with indication of errors and limited error correction.
Layer 1 – Physical: provide the interface to the physical communications medium.

Enveloping is a key concept in the OSI model. Data from a source system enters the OSI stack at layer 7 (application) and is encapsulated by another envelope at each layer, so that by the time it reaches the communication medium (the wire) at Layer 1, it has collected seven envelopes. At the destination, each envelope is checked and removed, one by one, so that the data exiting from layer 7 at the destination is exactly what the source system sent.

Layers 1 to 6 of the OSI model deal with various aspects of technical interoperability. The only domain-specific aspect is the application layer – Layer 7, which deals with the semantics or meaning of what is exchanged. This is why the founders of HL7 chose the name Health Level Seven.

5.3.2 HL7 Products

HL7 produces four types of document:

- Normative Standard: content is balloted by the general membership and is considered a structural component of the HL7 Standard. Negative ballots must be resolved.
- Draft Standard for Trial Use (DSTU): content is balloted by the general membership as the draft of a future standard which will, following a prespecified period of evaluation and comment (usually 2 years), be expeditiously incorporated into normative standard.
- Reference: content is harmonized during HL7 meetings or approved by the HL7 Board. It is not subject to ballot acceptance.
- Informative: content is balloted by the general membership. However, it is not considered to be a structural part of the Standard but only supporting information.

All HL7 Balloted Standards are introduced first as a DSTU and must show some successful implementation before being advanced as a Normative Standard.

5.3.3 Ballot Process

Ballots normally progress through two or more cycles of ballots. The ballot pool is limited to declared interested members. Negative votes must be accompanied with a specific reason justifying the negative vote. Work Groups must resolve negative votes either by accepting the voters comment and recommended solution, negotiating with the voter and getting them to agree to withdraw their negative or declare the vote nonpersuasive.

Voters may appeal to the TSC and Board. They can also revote their same negative vote on the next round of balloting. Substantive changes to a ballot (either to fix a negative or add new material) merit another ballot round. When 75% (for normative documents) of the responses are registered as affirmatives and (hopefully) all negatives withdrawn, a document is ready for publication as a HL7 Standard.

5.3.4 Language

HL7 has produced a "Version 3 Publishing Facilitator's Guide," which is a style guide for v3 documentation.

The stringency of conformance statements is specified by use of SHALL, SHOULD, and other modal verbs. For example, the word SHALL conveys the sense

of being mandatory or required; SHOULD implies best practice or a recommendation, and MAY implies acceptable or permitted.

5.3.5 Membership

HL7 offers two main types of membership:

- Individual for those with a personal interest in the standards.
- Organizational include benefits crucial to those who rely on the standard as part of their business plan – the most critical of these being the right to distribute excerpts of the standard to clients (as part of technical documentation or proposals) – or distribute the standard within your organization. Organizational members may also elect to be Supporters or Benefactors.

Members of HL7 who meet together electronically or in person are collectively known as the Working Group and are self-organized into a number of different technical committees. There are usually 3-week-long working group meetings each year.

5.3.6 International Affiliates

Internationally, HL7 is organized into a set of International Affiliates in 32 countries, in addition to the USA, where HL7 HQ performs the affiliate role (Fig. 5.2).

5.3.7 The Technical Steering Committee

The HL7 Technical Steering Committee oversees and coordinates the technical effort contributed by the HL7 volunteers who make up the HL7 Working Group. Its mission is to assure that the efforts of the Working Group are focused on the overall HL7 mission. There are four steering divisions:

Foundation and Technology work groups provide the fundamental tools and building blocks for all HL7 activities.

Structure and semantic design focuses on creation of basic patterns and common messages that could exist on their own, but are mostly used by others.

Domain Experts committees and projects in this space focus on creation of messages, services, documents using many of the common structures in place, yet expanding it in key areas as well.

Technical & Support Services committees support to the Technical Steering Committee and Committees of the Working Group (Fig. 5.3).

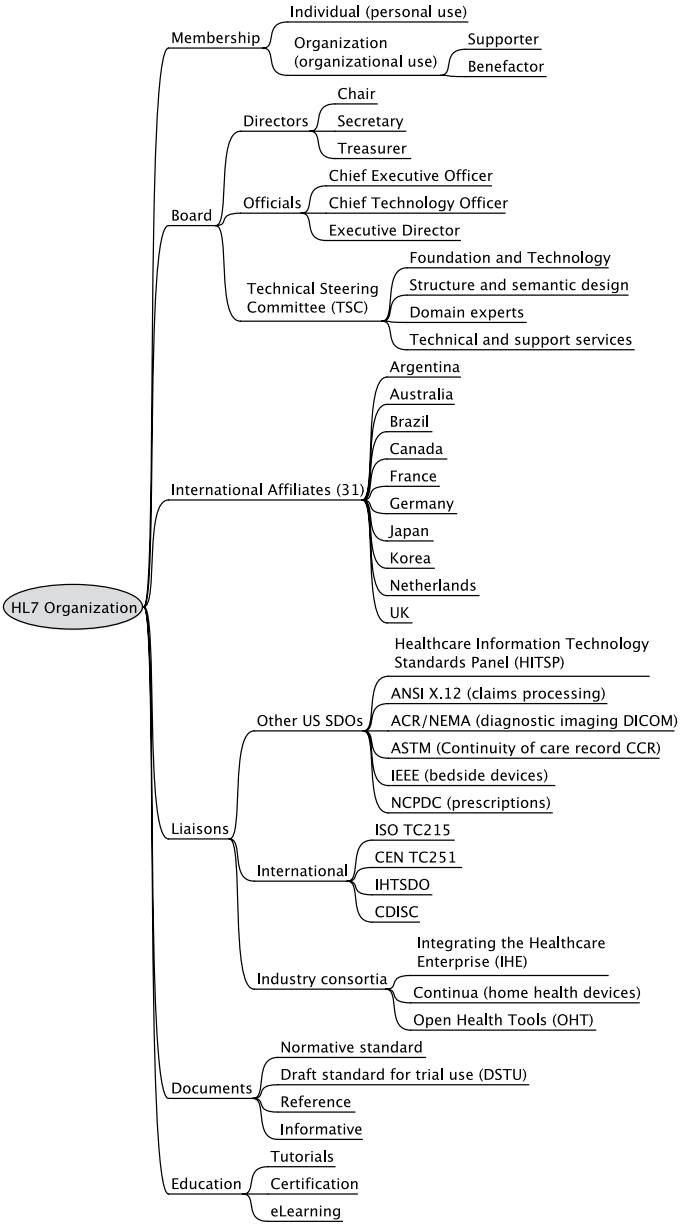

Fig. 5.2 HL7 Organization

Fig. 5.3 HL7 Technical Steering Committee

5.4 Other SDOs and Consortia

5.4.1 IHTSDO

IHTSDO (International Health Terminology Standards Development Organization) is an international not-for-profit organization, based in Copenhagen. IHTSDO was established in 2007, when it acquired the IP of SNOMED CT from the College of

American Pathologists (CAP). CAP-STS (SNOMED Terminology Services) still provide an important support service for IHTSDO and provides support in the USA.

The IHTSDO vision is to enhance the health of humankind by facilitating better health information management; to contribute to improved delivery of care by clinical and social care professions and to facilitate the accurate sharing of clinical and related health information, and the semantic interoperability of health records.

The achievement of this vision for broad, demonstrable, and successful use of SNOMED CT requires a globally coordinated effort to gain agreement on a core terminology for recording and sharing health information, pooling resources to share costs and benefits relating to the development of terminology products and consistent promotion of the uptake and correct use of the terminology.

An important strand is active harmonization activity with other SDOs, including HL7 and the Open Health Tools consortium.

Current (2009) members include Australia, Canada, Cyprus, Denmark, Lithuania, The Netherlands, New Zealand, Singapore, Sweden, United Kingdom and United States. IHTSDO is responsible for the core content of SNOMED CT, while each member country has a National Release Centre, which distributes SNOMED CT and has responsibility within its territory for liaison with IHTSDO, licensing and distribution of SNOMED CT, quality assurance and conformance with IHTSDO standards, issues tracking, change control and monitoring IP (products, trademarks, etc.).

5.4.2 IHE

IHE (Integrating the Healthcare Enterprise) was established in 1999 by the Healthcare Information Systems and Management Society (HIMSS) and the radiological Society of North America (RSNA) to help improve the way healthcare computer systems in share information, initially in the imaging domain where there was clear overlap between the HL7 and DICOM set of standards. IHE's initial focus was interoperability between equipment in clinical departments with hospital information systems. The starting point was radiology, where it developed profiles which specify how to use DICOM and HL7 together and it has moved on to cardiology, clinical laboratories, and other specialties.

The second dimension to IHE's work has been the development of IT infrastructure standards for use across departmental and institutional boundaries. The XDS (Cross-enterprise Document Sharing) profile, described below, is one example of this.

The next stage was to develop a set of integration profiles for healthcare IT infrastructure.

Systems developed in accordance with IHE profiles can communicate with one another better, and may be easier to implement.

IHE has established a four-stage approach:

- Identify Interoperability Problems. Clinicians and IT experts work to identify common interoperability problems with information access, clinical workflow, administration, and the underlying infrastructure.

- Specify Integration Profiles. Experienced healthcare IT professionals identify relevant standards and define how to apply them to address the problems, documenting them in the form of IHE integration profiles.
- Test Systems at the Connectathon. Vendors implement IHE integration profiles in their products and test their systems for interoperability at an annual IHE Connectathon. This allows them to assess the maturity of their implementation and resolve issues of interoperability in a supervised testing environment.
- Publish Integration Statements for use in RFPs. Vendors publish IHE integration statements to document the IHE integration profiles their products support. Users can reference the IHE integration profiles in requests for proposals, simplifying the systems acquisition process.

5.4.3 Continua Alliance

The Continua Health Alliance[4] is a nonprofit, open industry coalition of healthcare and technology companies working to establish a system of interoperable personal health solutions. The driver is that use of tele-health solutions in the home can foster independence, empower individuals, and provide the opportunity for personalized health and wellness management.

Continua has set out to develop an ecosystem of connected technologies, devices, and services that will enable the more efficient exchange of fitness, health, and wellness information. The foundation of this ecosystem is a set of interoperability guidelines which specify how systems and devices made by different companies can work together. Such products are expected to become common over the next few years. The first set of Continua standards includes specifications for using existing standards such as Bluetooth, USB, medical devices (IEEE 1173), and HL7 to enable people to use home-based devices to monitor their weight, blood pressure, glucose, and blood oxygen levels and share this with their healthcare professionals.

Continua has developed a product certification program with a recognizable logo signifying interoperability with other certified products, intended to build trust and confidence among customers.

5.4.4 OpenEHR

OpenEHR is a not-for-profit foundation, which has developed a technology-independent architecture, including a Reference Model, Archetypes, and Templates. The main activities are to promote the uptake of openEHR technologies globally;

[4] See www.continuaalliance.org/

to maintain the openEHR specifications and control the change management process for the openEHR model; to protect the copyright of open source software components based on openEHR; and to act as a forum for discussion and contribution on openEHR and related technologies.

5.4.5 Open Health Tools

A new generation of tools is being developed by the Open Health Tools collaborative (OHT), which uses the Eclipse framework and OMG standards.[5]

Eclipse is an open source community, which builds tools for building, deploying, and managing software across the life cycle. Licensing uses the Eclipse Public License (EPL). The EPL allows organizations to include EPL-licensed software in their commercial products, while at the same time requiring those who modify derivative works of EPL code to contribute the modifications (but not the derivative works) back to the community.

The vision of the Open Health Tools collaboration is to produce machine-processable artifacts, spanning through all stages of the message design cycle (requirements, design, implementation, and testing) along with a framework for publishing documentation about the artifacts generated throughout the process.

It will standardize the type and quality of the information conveyed between each stage and between communicating organizations. It will also produce coherent, traceable, and versioned concepts from analysis to implementation and facilitate consistent workflows and project management /oversight.

This will reduce message development time and allow the automatic translation of message designs to supplier-specific formats and support end-to-end automated testing of interoperability solutions. It will facilitate direct involvement /feedback in international standards and tools development, ensuring ongoing alignment of implementation specifications with industry standards, including HL7 V3.

A number of projects are already underway in OHT, but this number is expected to grow, if only because the needs of those involved in developing and authoring standards are quite different from those who implement and test them.

The OHT HL7 Tooling Project is an open software development project which aims to provide second generation tools to support the HL7 version 3 message modeling methodology. The toolset is based on the Eclipse Platform and Tools. The HL7 tools supporting the v3 message modeling methodology will be designed to be an integral part of a wider suite of tools covering conformance/testing, clinical modeling, and terminology maintenance.

Deliverables from this project are expected to include:

- Static model designer, to replace the V3 Visio RMIM editor
- XML schema generator with tight vocabulary binding, data type specializations, and cross-references for vocabulary, CMETs, data types and templates

[5] See www.openhealthtools.org

- Instance editor
- Vocabulary tooling to edit and maintain value sets for HL7 V3 message specifications

The OHT Conformance Services project set out to develop a set of tools and services to support the implementation of applications, which conform to standards such as HL7 in a consistent way with reduced effort and cost. Conformance testing is just one of a set of tests that includes testing the implementation, interface, integration, user acceptance, nonfunctional aspects (e.g., security), and unit.

Conformance services cover test authoring, tools and test execution related to test data, vocabulary, business rules, message structure, and the conformance profile. A conformance profile is a constrained set of standards, based on expected product functionality, grouped into testable units.

A repository is needed to hold the structured conformance profiles, test cases, test data, business rules, etc.

The OHT SNOMED CT Tooling Project is an open software development project, which aims to provide second generation tools which can be used to develop, maintain, promote, and enable the uptake and correct use of SNOMED CT in health systems around the world.

5.4.6 CDISC

The Clinical Data Interchange Standards Consortium (CDISC) has been founded by the pharmaceutical industry to develop worldwide industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. The CDISC mission is to lead the development of global, vendor-neutral, platform-independent standards to improve data quality and accelerate product development.