

CASE STUDY: Health Level 7 (HL7)

Draft 2009-05-05 (Mattias Ganslandt, Jonas Andreasson and Martin Sutinen)

Work in progress, comments most welcome!

Brief facts about HL7

Webpage

<http://www.hl7.org/>

Organization tagline

HL7 is the foremost organization for standardizing clinical and administrative data.

Main standardization areas

Digital healthcare standards.

Best known standards

[HL7 Version 3](#), [HL7 Version 2.x](#)

Organization classification

ANSI-accredited and can be considered formal, international with a broad healthcare agenda.

Does the SSO have any explicit or implicit policy relating to interoperability?

HL7 states its mission as “to provide 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.” Several of the workgroups have interoperability concerns directly incorporated in their charters. Interoperability is regarded broadly, covering technical, semantic and process interoperability.

Is there an explicit strategy to facilitate or contribute to interoperability?

HL7 organizes interoperability conferences and provides testing and certification services. The HL7 national affiliates can provide further interoperability and implementation assistance.

Procedures for testing of a proposed/developed standard with respect to interoperability and backward compatibility?

HL7 standards undergo technical and clinical public review for an extensive period prior to approval.

What are the procedures (internal or external) for implementation?

The national HL7 affiliates can assist with implementation.

How is compliance enforced and what are the consequences of defections and deviations from the standard?

HL7 certifies individuals but not implementations.

Did the SSO develop competing standards for the same or similar type of technical problem?
Although stating its intent to drive adoption of HL7 standards, some of the work done by [IHE](#) could be considered to be competitive with HL7 even though it's provided to be complimentary.

What is the value of interoperability in the specific area in which the SSO is active?
HL7 is the market leader for clinical data management and interoperability. Standardization is of great importance in the area to reach co-operability, which is required to realize the full potential of eHealth.

What is the value of selection and conformity in the specific area in which the SSO is active?
Competing standards could severely inhibit the development of full interoperability in Electronic Health Records systems. Conformity is vital for the success of the HL7 standard.

Standardization Process

- Health Level Seven (HL7) has been active since 1987 and has over 2300 members.
- HL7 have developed about 40 standards in the area of clinical and administrative data.
- All organizations and individuals are welcome as members.
- There are four main membership classes: organizational, individual, student and affiliate. Organizational members can upgrade to become supporter and benefactor members for greater promotional status and further benefits. Individuals pay a flat rate of 600 USD except for non-voting students which pay 125 USD. Organizational members vary from 900-22,000 USD depending on turnover, member type and desired promotional status.
- All members can participate in working groups and vote on approval of standards. Non-member individuals can participate in the balloting procedure for normative voting conditional on an administrative fee and a shown direct and material interest in the specification. Organizational members can receive additional votes in accordance to their dues. Approval of standards requires 75 percent majority and final approval is accomplished with the ballot. Decisions can be appealed.
- Approved standards are not freely available. Instead they are sold by the HL7's document shop but are free for members. Meeting minutes and working material on the other hand is made freely available online. The individual votes are made public.
- To initiate new work there shall be a demonstrated need for a work group, the need shall be within the scope of HL7 and at least five members shall agree to active participation in the work group. The HL7 Chief Technical Officer and the Technical Steering Committee chair will determine if these requirements are fulfilled.

Improvement activities

- There is a Process Improvement Committee which is responsible for monitoring HL7 process and collecting input from members on improvements to the HL7 operation. The PIC is currently updating the Governance Operation Manual and creating a Co-Chair Handbook.
- There is no specific scope for public review of standards in the development process.

- HL7's goal is to create standards for healthcare which are the best and most widely used, to provide standards that facilitate interoperability between stakeholders and produce standards that exhibit timeliness, technical excellence and scientific rigor.
- Strategic imperatives are: streamlining HL7 production and processes, defining HL7's role and position, make HL7 more useful and communicate the ideas worldwide, use Electronic Health Records/Personal Health Records/Public Health Management capabilities as a focus point for technical development and engage the clinical society to a greater extent in the HL7 development.
- Other organizations with a similar focus to HL7 are [ASTM](#), [CDISC](#), [IHE](#) and [ISO](#). Cooperation exists with [ANSI](#), [CEN](#), IHE, ISO, [OASIS](#), [W3C](#) and several others. HL7 affiliate organizations cooperate with National Standardization Organizations. HL7 have formal liaison with ANSI and ISO.

Interoperability

- HL7 require that IPR is made available on RAND terms. Copyright of submitted material is held by HL7.
- All participants are required to disclose any patent claims related to the technology incorporated in the standard that they are personally aware of.
- The HL7 national affiliate subdivisions provide services related to implementation. HL7 provide training and certification services.
- Interoperability is considered an important goal within HL7. Ensuring interoperability is in turn affected by whether the necessary interoperability is in the form of technical, semantic or process interoperability.

Case study

Health Level Seven (HL7) is a non-profit organization formed in 1987 which develops global standards for healthcare within the areas of clinical and administrative data. This is achieved through creation of specifications which enable interoperable exchange, management and integration of electronic medical data between different systems. The term HL7 is used to refer both to the organization and its most important standards such as HL7 version 2 (published in 1987) and HL7 version 3 (published in 2005). These standards define the content and format for messages which are exchanged between different applications. Version 2 has been revised several times with version 2.6 published in 2008.

HL7 can be described as a global community, with one global organization headquartered in the United States and further affiliate organizations in over 30 countries. Membership in the main organization, Health Level Seven, Inc., is open for all organizations and individuals. The membership fee depends on the size of the member and the choice of membership level. HL7 is organized in a Board and a Technical Steering Committee, which consist of both appointed and elected members, and an International Committee representing all of the affiliate organizations.

The development of standards is done in specific working groups. Any member is allowed and encouraged to take part in such working groups. Each such group has three official meeting each year

and is allowed to define its own procedures. Once a working group has reached consensus on a suggested specification, the members of the technical steering committee and the international committee vote on whether to approve it. The outcome of the vote is sent as a recommendation to the board, which takes the final decision. However, at this stage it can only be passed as a Draft Standard for Trial Use (DSTU). The advancement to a Normative Standard, which is what a HL7 Standard refers to, usually takes approximately two years of further evaluation and review before a ballot is held where approval requires 75 percent of the votes. Throughout the entire development process the working groups are required to consider all negative votes and comments and any HL7 member who is dissatisfied with the work of a group may officially appeal to the Steering Committee and the Board.

Since a HL7 standard contains a large number of specifications they are continually revised. HL7 also offer training sessions and certification services related to the standards. Additionally, part of the purpose of the affiliate organizations is to offer local forums to help to promote the standards and facilitate implementations.

The IPR to any contributions in the development process is generally transferred to HL7. HL7 standards are not made freely available in contrast to many other standards developing organizations but are instead sold by HL7's document shop. All documentation related to the development process though, such as meeting minutes and ballot results, are made publicly available online.

Any contributor in the development process is required to disclose any patent claims related to technologies used in the standards. In order to approve a standard where the implementation requires technologies subject to patent claims it is required that such patent holders offer licenses under Reasonable and Non-Discriminatory terms for as long as the standard is upheld by HL7.

Since 1994 HL7 is accredited by the American National Standards Institute (ANSI), which means that HL7's standards are also adopted as ANSI standards in the United States. HL7 is also actively cooperating with ISO and CEN, and a number of the specifications in the HL7 version 3 standard have been adopted as ISO standards. Additionally, the affiliate organizations are cooperating with the national standard bodies in their respective countries. HL7 also participate in W3C, since the XML standard developed by W3C is implemented in the HL7 standards.

An affiliate organization in Sweden, HL7 Sweden, was established in 2005 and this organization has approximately 30 members. A number of different standards within the eHealth data area have been used in Sweden but nowadays several Swedish health care organizations have started to adopt the HL7 standards.

Key success factors

- Allowing for a long trial period ensures that final standards meet the requirements of the market and builds acceptance for the standards.

- HL7 offers a “one-stop shop” for all related services of standardization, including testing, certification and implementation help. This cements HL7 as the centre point for development of medical data standards
- HL7 closely cooperates with several other influential SSOs which increase the credibility of the organization and guarantees adoption.