Health Level Seven® International

Unlocking the Power of Health Information

Member of the JIC for Global Health Informatics Standardization

Health Level Seven International (HL7) welcomes the opportunity to contribute to the European Commission Public Consultation on Standardisation. This document outlines the competence of HL7 to contribute and the view of HL7 developed in partnership with its international affiliates.

About HL7

Health Level Seven International is a global authority on standards for interoperability of health information technology. With members in more than 55 countries, HL7 is deeply involved in worldwide efforts to improve healthcare through information technology and is a founding member (with ISO TC215 and CEN TC251) of the Joint Initiative Council (JIC), an international council on global health informatics standardisation that is committed to developing a single standard for a single purpose. The JIC has since also added IHTSDO, CDISC and GS/1 as member standards organizations. HL7 also has an agreement with the International Organization of Standardization (ISO) through which HL7 submits appropriate standards directly to ISO for approval.

Founded in 1987, HL7 is a not for profit organization comprised of more than 4,000 worldwide members who represent hundreds of healthcare system manufacturers, providers, purchasers, government agencies, consultants and others.

Volunteers perform HL7's standards development work. HL7 standards facilitate the exchange of clinical and administrative data among health information systems. Specifically, HL7 provides a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of health information that supports clinical practice and the management, delivery, and evaluation of health services. The most widely used HL7 specifications are messaging standards that enable disparate healthcare applications to exchange key sets of clinical and administrative data.

HL7's Version 2.x messaging standard is arguably the most widely implemented standard for healthcare in the world. In 2009, it was most recently re-published as a current ISO standard.

The HL7 Version 3 messaging standard is used widely in countries such as Canada, the United Kingdom, the Netherlands, Germany, United States of America and Mexico.

The HL7 Version 3 Clinical Document Architecture (CDA) is an important step to achieving interoperability. The CDA is an ISO approved standard that provides an exchange model for clinical documents (such as discharge summaries and progress notes) - and brings the healthcare industry closer to the realization of an electronic medical record. There are large-scale CDA implementations in Europe, Asia, the Pacific and both North and South America.

Our mission

The mission of HL7 is: "HL7 provides standards for interoperability that improve care delivery, optimise 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 transactions we exhibit timeliness, scientific rigor and technical expertise without compromising transparency, accountability, practicality, or our willingness to put the needs of our stakeholders first."

Process for developing this response

This response was developed during an HL7 working group meeting, by the Policy Advisory Committee, an official Board appointed committee within HL7.

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Responses to the consultation questions

Do you think that service standards (including process standards) and alternative standardisation documents should be included in the scope of Directive 98/34/EC or its successor?

HL7 is not in a position to respond to this question

Are you aware of specific cases where national service standards and alternative standardisation documents have caused technical barriers to trade?

HL7 is not in a position to respond to this question

For areas other than Information and Communication Technology (ICT), should it be possible to refer to documents developed by fora and consortia in legislation and public policies? If it should, how should it be implemented?

HL7 is not in a position to respond to this question

How could ESOs and NSOs be encouraged to accelerate their standards development process? Should for example the Community financing for standardisation be subject to conditions in terms of speed of delivery whilst maintaining the openness of the process?

It is not clear that ESOs and NSOs should accelerate standards development processes. Many standards in the healthcare informatics sector have been developed by the ESOs however there is limited evidence of adoption and implementation by manufacturers into their product line. In contrast HL7 products are supported and implemented by many product manufacturers.

ESOs and NSOs should require implementation of the standard to be demonstrated before approving the standard. A standard published with clear evidence of utility and acceptance is more likely to provide manufacturers with the confidence to adopt the standard in the marketplace and for the consumers to appreciate and seek conformance to the standard.

Community financing should be subject to conditions in terms of quality of the resulting standard measured by uptake by market, with conformance assertion, rather than speed of delivery. This would incentivise ESOs and NSOs to produce standards relevant to the market rather than a large volume of standards with restricted adoption and limited benefit.

The collaborative development between ESOs, NSOs, industry fora and other standards development organisations, based for example on the CEN TC251 participation through the Joint Initiative Council, could promote the quicker development of useful, robust standards without duplication of effort or confusing the market place.

Should the WTO principles of transparency, openness, impartiality, consensus, efficiency, relevance and consistency be integrated in the legal framework of European standardisation (especially in EU Directive 98/34/EC or in its successor)? How should this be implemented?

The collaborative development between ESOs, NSOs, industry fora and other standards development organisations, based for example on the CEN TC251 participation through the Joint Initiative Council, could promote the quicker development of useful, robust standards without duplication of effort or confusing the market place.

In general, domains such as healthcare should adopt existing standards from the general market place unless there is a compelling reason to develop a domain specific standard.

Within healthcare and other safety critical industries there is a case for standards designed to meet the requirements of the member states and the citizens of member states, alongside the needs of manufacturers in the market place. These standards may be referenced in member state and EU legislation, such as standards for medical devices, pharmaceutical products and clinical records. The implementation should be sensitive to the societal challenges involved.

Standards should include metrics for the benefits delivered by the standard; these benefits should be quantified using these metrics before review of the standard as part of the standards development process.

How could the participation of consumer organisations, environmental NGOs, trade unions and social partners, and SMEs be best promoted? What should be the role of public authorities (European Commission and Member States) in supporting such a participation in a transparent, open, impartial, consensual, efficient, relevant and consistent European standardisation system?

Engagement with a broad range of stakeholders is important for a standard to have credibility in the market place. ESOs should foster this engagement to promote confidence in their standards. The quality criteria for a standard should include evidence that these stakeholders have been involved.

How could the NSOs (National Standards Organisations) deepen their cooperation, and mutualise their activities? Could the following tasks be shared amongst several NSOs?
1. Management of the Secretariats of Technical Committees?
2. Notification of new national standardisation projects?
3. Promotion/sales of standards?
4. Other?

HL7 is not in a position to comment on the operational practice of NSOs however HL7 affiliates in the EU actively collaborate with the technical committees.

Without prejudice to the national delegation principle, how could the European Standards Organisations (ESOs) manage directly, on a case by case basis, some standardisation activities, especially some Technical Committees?

HL7 is not in a position to answer this question.

What support should the European Commission provide to facilitate the use of European standards as a means to open global markets? What would be the operational means that the Commission should use? (Support experts' participation in international standardisation activities, translation of European standards into extra-community languages?)

HL7 has found that successful support of standards depends on:

Awareness of the standard. This can be achieved by education, training, inclusion in specifications for procurements, engaging manufacturers and consumers in the standards development activity. Low cost or no cost access to the standard reduces the initial barrier to awareness. The whole HL7 standard suite is available to individuals for less than the cost of one standard published by ISO, the ESOs and NSOs.

Growing sufficient competence in the marketplace within member states and in other states to correctly adopt the standard

A clear and credible means of asserting a product has conformance to the standard

Where appropriate, national profiles to ensure the standard is fit for the national market with national adoption guides.

For the HL7 community these criteria are already met, in particular through the HL7 national affiliates.

Under which conditions do you think that the European Commission could launch, on a case by case basis, calls for tenders, open to the ESOs and to other organisations, to develop standards supporting EU policies and legislation?

For such a call, each of the following criteria must be met:

The call for the standard must support European Union policies and legislation

The business processes within the member states should be closely aligned with each other

The proposed standard should support the business processes or lead to an agreed improvement in the business processes

The standard should be required to include clear conformance criteria and a clear process to measure conformance

The standard should have at least one implementation delivering the identified benefits of the standard in at least three member states before becoming an approved standard.

It is likely that HL7 or some HL7 national affiliates will consider the development of standards (or localisation/profiling of international standard) called for on this basis either alone or in participation with other organisations developing standards. HL7 aims to strengthen the European market through collaborative development of standards.

The EU should ensure that such a call includes metrics for the quantified benefits of the standards produced and metrics for the measurement of conformance and adoption of standards.

What is, in your view, the most efficient level of participation in the process of standards development: national, European, international?

The most efficient level of participation will depend on the business circumstances. HL7 operates at national and international levels (and has established a European office for European developments). Ideally a standard would be developed as an International Standard by an accredited standards development organisation with comprehensive contribution by a wide range of nations. In reality not all national communities will be able to contribute to all developments for a number of reasons:

They may not yet appreciate the issue being addressed

They may not have the competence to contribute

They may have a fully worked up national solution but not wish to assign their intellectual property to ISO, ESOs or a NSO. This is particularly common in healthcare where government funded standards development has been successful. Where a substantial contribution of intellectual property is made by a government, industry organisation or standards development organisation, the contributor should have shared rights to the developed standard.

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A significant option, particularly where responsibility for the sector lies with the member state, is to develop standards internationally supported by national profiles of use designed for the economic environment of the member state. Alternatively, an EU profile of standards, meeting the needs of all of the member states, would enable the EU marketplace to become less fragmented, more open and competitive.

In your opinion, where is the major added value in European standardisation with respect to national standardisation?

There is little development and sharing of national standards within the European Union throughout the healthcare informatics sector (and the majority of standards are developed at an International level). Regional standards are developed within member states. For example, within the United Kingdom standards are developed separately for England, Scotland, Wales and Northern Ireland. These standards are rarely compatible and reflect the different architectures of the healthcare delivery environments in these regions.

The European Union should adopt a profile of the International Standards to accommodate the constraints of the EU marketplace (if any) whilst enabling EU manufacturers to compete in the international marketplace. Such a European standard, with sufficient specificity, would enable cross-border interoperability and safe population migration within and beyond the EU however to date the standards developed by ISO and the ESOs have not had sufficient specificity and have not had clear conformance criteria. The NSOs should work to provide a national profile of such a European Standard where this is necessary to accommodate the specific needs of the national community.
HL7, through its national affiliates, operates on this basis. It additionally collaborates with ESOs, ISO and NSOs to ensure the standards developed are appropriate to the European marketplace.

What are, in your view, the most serious barriers to the use of standards by enterprises: costs of standards (purchasing price)? Costs of operational implementation? Access to information? Knowledge of existing standards?

There are six key barriers to the adoption of standards by manufacturers of healthcare informatics products.
Awareness: In the main, manufacturers are not aware of the standards available to use. Where they are aware of standards, these are often those specified by nations for the products deployed in their realm. The free movement of healthcare case notes is essential for the free movement of citizens within and between member states and for the free market in healthcare service provision across member   states.

Where standards supporting this objective have been set a number of nations have specified HL7 developed standards.
Cost: The current financial model for ISO, the ESOs and NSOs is based on free development and a separate charge to gain awareness or understanding of each standard. This incentivises the authorship of standards and specifications at the expense of the adoption of the standards and specifications written.
Education: Within the field of healthcare case notes and health informatics it is exceptional for ISO, the ESOs or NSOs to undertake any marketing initiative. Without marketing, education and training it is unlikely that manufacturers will be aware of the standards and specifications and even less likely that they will have the competence to adopt them. HL7 undertakes a wide range of educational activities to support the adoption of its standards and specifications. HL7 standards are adopted in many member states.
Conformance assessment: For any standard to be of value to the purchaser of manufactured product (for HL7 these are typically organisations delivering healthcare) needs to either benefit from the self-evident benefits of the standard or to be assured that the product conforms to the standard. Conformance is typically asserted in one of three ways:
Self-assessment by the manufacturer
Third party assessment
Assessment by the consumer

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For health informatics there are no competent third party assessors for the ISO, ESO and NSO developed standards and it is rare for a manufacturer to demonstrate conformance. HL7, through the IHE consortium, is able to demonstrate the use of HL7 standards and the conformance of products to HL7 standards is evidenced by the interoperation of different manufacturers products using IHE profiles.

Absence of useful standards: ISO, the ESOs and NSOs have rarely developed the standards required by the manufacturers of health informatics products. There are some standards with no evidence of adoption in the market place. Other SDOs such as HL7, GS1, IHTSDO, World Health Organisation and CDISC are able to show implementations of their standards and specifications. Nevertheless, through the Joint Initiative Council, several implemented HL7 standards have been published by ISO and CEN.

Engagement in the development of standards: Manufacturers engaged in the development of standards are likely to adopt the standards. Although the cost of engaging in Standards Development through ISO, the ESOs and NSOs is notionally free, the meetings are often held outside Europe. This increases the cost of participation significantly. HL7, through its international affiliates, is able to bring the standards development practice closer to the manufacturer. In addition, HL7 couples Standards Development with its extensive range of educational and competence assessment activities, subsidising the cost of participation and providing a broader range of benefits.

What could the standards organisations do, in addition to their current practice, to facilitate the access to standards, especially by SMEs?

Healthcare organisations rarely operate in isolation. Patients will usually access healthcare services from a range of healthcare providers (hospitals, general practices, social services and schools to name just a few). Each of these businesses needs to be able to work in partnership with the other organisations chosen by the patient or selected by the purchaser of healthcare for the patient.

Within healthcare providers it is rare for a provider to use a single solution for case notes. Often small and medium sized organisations are able to provide niche solutions which address the needs of the clinical department and support the delivery of specialist clinical care. The deployment of a case note solution for a general practice in an intensive care unit or emergency department is not likely to yield success.

For SMEs focusing on healthcare case notes to benefit from the use of standards there is a range of additional requirements:

The standards need to be appropriate. Historically, the standards developed by ISO and CEN have addressed problems which were not relevant to the SME market without addressing the need for standards to enable SMEs to participate in the market. The standards developed by HL7 are widely used by SMEs to link to other providers of case note systems and to link to exchange case notes, schedule service provision etc. with products provided by other SMEs. It is for this reason that ISO and CEN are increasingly working with HL7 to provide pertinent standards

The SME needs to be aware that the standards are available. Currently there are several models for sharing standards with consumers (purchasers of product and product developers).

ISO, CEN and NSOs publish their standards either in printed form or as electronic copy and charge for each copy. Although schemes exist to ease the cost of access to the standards it is not possible for SMEs to determine whether they should invest in the document without purchasing the document. The NSOs do not invest in marketing the standards for CEN TC251 and ISO TC215. It is not clear that, at least for case note products, the standards published in this form are widely read by SMEs

Standards are funded by a variety of member nations and other states. A concept model and terminology for use in healthcare case notes is published by the International Health Terminology Standards Development Organisation (IHTSDO) on this basis. Some, but not all, member states contribute to IHTSDO. SMEs based in these member states have free access to the standards and the products based on the standards. Product manufacturers shipping to other states pay a licence fee for the deployments in those states.

HL7 provides its standards free of charge to members of HL7 or any of the national affiliates. Individual membership of an HL7 affiliate typically costs less than one standard published by the NSOs. Adoption of HL7 standards and specifications by SMEs is widespread. This is one of the reasons HL7 standards and specifications are being used a number of EU projects and large scale pilots co-funded under the framework programmes of the European Commission.

The standards must address the needs of the manufacturer and the needs of the purchaser of the product being manufactured. In particular, for healthcare, the standard needs to support the tailoring of the product to suit the bespoke needs of each member state's economy and healthcare delivery

system. This is particularly true of detailed business and clinical process; business, healthcare provider care delivery and payment differences that exist between countries and even individual facilities within a country. For these reasons national and often local profiles of use for the standards or specifications are often required. Within HL7 this is achieved through national affiliates. It is rare for a NSO to provide a national profile for an ISO or CEN standard or specification.

HL7 recommends that ISO, ESOs and NSOs work in partnership with the member states and the SDOs with domain specific expertise, such as HL7 and IHTSDO. This form of public-private partnership is likely to have the capacity to both develop and publish standards suitable for large scale adoption throughout the market.