

CEN/TC 251 Health informatics: Business Plan 2015-2018

EXECUTIVE SUMMARY

Business Environment

Health and social care are in a great state of flux in countries across Europe. Irrespective of their variety, all countries face a formidable challenge in containing rising costs for health and social care, combined with an ageing population and a strained professional workforce. Governments, patients, professionals and provider organizations have high expectations of health informatics to help address these issues. Local, regional and national eHealth initiatives have been set in motion.

European efforts are focused through the Digital Agenda for Europe, the European eHealth Action Plan, and the European Innovation Partnership for Active and Healthy Ageing. Member States are working together with the European Commission in the eHealth Network to support cross-border patient rights on key topics such as Patient Summaries and ePrescriptions. The Horizon 2020 research program also includes strong programs on Personal Health and Care. Much is to be gained by a coordinated effort in the application of Health Informatics.

Health informatics standardization is concerned with the principles of information processing, management and governance of information with the provision of solutions for associated problems in the field of health and care. The health informatics sector is made up of a number of very large software producers, with a great many small and medium enterprises operating primarily either in domain niches or in geographic areas. This disparate global market is reflected within the CEN member states and presents a challenge. It stifles the free flow of knowledge and experience in the health informatics industry, thus presenting health care organizations with mounting costs and health informatics vendors with limited potential for growth. As a consequence, it makes the work of CEN/TC 251 that much harder, both in terms of standardization and of communication about standards.

Benefits

There are many cases of governmental adoption of standards produced, adapted or adopted by CEN/TC 251 into legislation, regulations and procurement requirements. CEN/TC 251 has provided the basis for further work in other SDOs, fora and consortia – and ISO/TC 215 has adopted many CEN/TC 251 standards, making the European input both a valuable contribution and facilitating the uptake of solutions that are relevant for Europe.

CEN/TC 251 plays an active role as one of the currently eight members of the Joint Initiative on SDO Global Health Informatics Standardization. The objective of the Joint Initiative is to achieve a harmonized set of health informatics standards across globally recognized topics. CEN/TC 251 also takes an active part in the Clinical Information Modelling Initiative which is a design authority for common clinical information elements that expects the SDOs to standardize its outputs. CEN/TC 251 is increasingly asked to take part in EU funded projects, reflecting its increasing relevance to EU, so as to ensure that outputs can be taken forward into standardization for the benefit of the member states.

Priorities

CEN/TC 251 delivers and maintains health informatics standards for Europe, preferably by producing them in co-operation with other SDOs at a global level and by adopting standards from other SDOs. CEN/TC 251 will seek to further increase engagement with other standards development organizations, consortia and fora to enhance efforts to coordinate its work with other organizations that have similar goals, such that stakeholder wishes for fewer, but more universal, global standards for health informatics are recognized and delivered in Europe.

1 BUSINESS ENVIRONMENT OF CEN/TC 251

1.1 Background to the topic

Health Informatics (HI) is an interdisciplinary field that develops and deploys the knowledge, skills and tools which enable information to be created, collected, managed, used and shared safely and appropriately to support the delivery and management of health, where 'health' is taken to mean a state of complete physical, mental and social well-being¹. The topic of information in the delivery and management of health *care* is a derived, though integral part of Health Informatics.

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Health informatics uses appropriate methods and tools, especially from informatics generally, to model structures and mechanisms for information control and use in the field of healthcare in order to describe or analyse these systems, or in order to provide possibilities for their construction, adoption, implementation and evaluation.

Health informatics is therefore at the intersection of information science, computer science, management and care professions and services. It deals with the resources, devices, and methods required to optimise the acquisition, storage, retrieval, and use of information in health care. Health informatics tools include not only algorithms, computers and technology, but also concept systems, clinical guidelines, metrics, formal medical terminologies, as well as information and communication systems applied to care.

Health informatics include informatics applied to at least the following subdomains: (bio)medical, clinical (acute, chronic, dental, general, mental and palliative), consumer and personal health, genetics, healthcare management (local, regional and national levels), imaging, laboratory, medical devices, mental health, nursing, practice of professions allied to medicine, public and population health, research (biomedical, clinical and medical), social care, telecare (in its various specialisations), therapy, and veterinary. Its application scope is that of the WHO declaration in 1948.

There are a large number of other terms, both general and specialised, applied to health informatics. Most commonly used are eHealth (with spelling variants) and telemedicine; eHealth is for practical purposes synonymous with the application of health informatics.

1.2 Description of the Business Environment

The following economic, political, regulatory, legal, linguistic, social and technical dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of CEN/TC 251, and they significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

The health informatics sector is made up of a number of very large software producers, with a great many small and medium enterprises operating primarily either in domain niches or in geographic areas. The global health informatics sector is influenced by several large national and regional governmental customers seeking to apply health informatics to better manage the cost and effectiveness of providing healthcare to persons within their responsibility.

There is a comparable financial pressure being exerted by private sector insurance and health maintenance organisation interests. Many small health delivery organisations set their own health informatics policies without reference to other organisations and are least able to benefit from the

potential savings that interoperable systems and information might offer. This disparate global market is reflected within the CEN member states and presents a challenge, both in terms of standardisation and of communication about standards.

As a result there are ongoing efforts to coordinate the work of CEN/TC 251 with other standards development organisations, consortia and fora that have similar goals. Much CEN/TC 251 work is therefore carried out in partnership with ISO/TC 215 Health informatics² and its liaison and partner organisations such as CDISC³, DICOM⁴, GS1⁵, HL7⁶, IEEE/11073⁷ and IHTSDO⁸.

Where possible the Vienna Agreement⁹ process is used to ensure that, for each subject matter area, only one standard is approved by ISO and CEN, and is adopted worldwide. This goal is sought at the request of the end-user organisations and presents a number of challenges where regional or informal 'standards' exist and conflict.

Internationally, CEN/TC 251 has been participating actively in the Joint Initiative Council (JIC) on SDO Global Health Informatics Standardization¹⁰. In terms of JIC, CEN/TC 251 was one of 3 founding members, which has just risen to 8 with the inclusion of DICOM. The eight members are: CEN/TC 251, ISO/TC 215, HL7, GS1, IHE¹¹, CDISC, DICOM and IHTSDO.

At a European policy level, there have been concrete attempts to enable more open flows of citizen-related health information in support of personal mobility within the continent. As early as 2003 the CEN/ISSS eHealth Standardization Focus Group was formed and delivered its final report in 2005. The recommendations on priorities and governance for eHealth interoperability are still valid today, In 2007 the European Commission (EC) issued a mandate (M/403-2007) to the European Standardization Organizations (ESOs), CEN, CENELEC, and ETSI, to develop a coordinated work programme for standardization in health informatics (Mandate M/403).

A significant report in response to this mandate was produced in 2008¹² and approved by the ESOs in February 2009, and by the EC in March 2009. Since that time, the eHealth European Interoperability Framework has built on that work, along with a succession of EU committees, projects and groups to attempt better communication and coordination between parties in this domain. One with a broader remit is the Multi Stakeholder Platform for ICT standardization (2013), which we believe has to be complemented by an eHealth Specialisation Platform to achieve these goals within the standardization of Health Informatics. The long standing knowledge and presence of CEN TC/251 suggests that this is one area that both needs support and nurturing, particularly at this important time, both to capitalise on former investment and to avoid competing and fragmenting initiatives that superficially cover the same areas.

In addition, the European Commission adopted the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU) in 2011, making the cross-border flow of information a priority issue for Europe. In line with Article 14 of this Directive, the eHealth Network was formed to discuss, among others, the needs for standardization and interoperability in cross border care. One of the key deliverables from this network are the guidelines for minimal datasets for personal health information in cross-border care, which reflect a professional and governmental consensus on the need to exchange information in specific situations pertaining to the health of every European citizen. The task to provide appropriate health informatics standards and profiles to support this exchange of information has yet to be completed. The eHealth Network is currently working on a set of guidelines for cross-border delivery of medication in specific situations, through the use electronic prescriptions. These two topics are the most prominent examples of the agenda of work that the eHealth Network is contemplating, with concrete and urgent needs for health informatics standards and profiles to deliver the required semantic and technical interoperability.

The global nature of the healthcare market for hardware, software and (especially) regulated devices means that demand-side stakeholders are seeking optimal value for money by

minimising the number of standards, and the supply-side is keen to reduce development and maintenance costs by using the same standards globally.

A significant result of this is that the major global standards organisations (including fora and consortia) have begun to work together to reduce duplication of standards work, minimise overlapping standards products and reduce or remove standards incompatibilities.

1.3 Quantitative Indicators of the Business Environment

No reliable figures exist for the value of the health informatics aspects of the healthcare technology budgets globally although even focussed research on just Electronic Health Records suggest that the sums are significant. Recent research by Accenture (April 2014) suggests that:

... \$22.3bn will be spent on EHR globally by the end of 2015, with 5.5% growth every year. The US market will be worth \$9.3bn, with yearly growth of 7.1%.”

The Electronic Health Record is just one of the standardisation areas in which CEN TC251 is active.

In a recent ISO/TC 215 meeting in Japan (May 2014), the Chief Information Officer of the Japanese government pointed to the likely costs of healthcare in the near future in trillions of Yen, taking into consideration the increasingly ‘aged’ demographic trend. Japan believes the only way to tackle this challenge is to focus on standards to support the use of connectivity (interoperability) in networks and data use from health records.

Europe has similar problems, and even single conditions, such as Stroke or CHD, costs member countries millions of Euros per year. If co-morbidity and longevity is taken into consideration, then it is clear that Health Informatics standardization offers a major opportunity and potential contribution to both improving healthcare and reducing costs to member states economies.

There are many cases of governmental adoption of standards produced or adopted by CEN/TC 251 into legislation, regulations or procurement requirements. Several CEN/TC 251 standards have provided the basis for further work in other SDOs, fora and consortia – and many CEN/TC 251 standards have been adopted in ISO/TC 215. Many of the CEN/TC 251 produced standards are cited as normative references in International Standards of other ISO committees such as ISO/TC 76, 121, 150, 172, 194, 198, and 212.

2 BENEFITS EXPECTED FROM THE WORK OF CEN/TC 251

A major focus of CEN/TC 251 is to assist adoption of standards to enable European organisations to achieve optimal use from their health informatics investments. It does this in a global context and where possible cooperates to develop and adopt international standards as the basis for such national or regional European standards. Strategically it is about ‘delivery’ and through its newsletters, and particularly its participation in EU activities and in JIC, it seeks to inform and engage existing and potential partners and members.

CEN/TC 251 offers a channel to produce standards which support the EU policies in the health informatics area and that CEN/TC 251 give Europe a united voice to talk to other SDOs and fora.

The Concurrent Use initiative is one that seeks to harmonise enterprise wide interoperability, and by being based on the quality perspectives and clinical process models establish a sound and attractive basis for interoperable solutions in healthcare. This initiative specifically looks at the 3 CEN initiated architectures now within ISO, regarding the concepts for continuity of care (ContSys), record communication (EHRcom) and services and middleware (HISA). The learning and outputs are intended to be generalized to other interoperability frameworks, and is currently CEN’s contribution to the JIC strategy. The Concurrent Use Initiative maximizes re-use of

existing standards, thereby increasing the return of investment already made, as well as recognizing that one-size, or model, does not fit all requirements and that multiple solutions require to be considered as having a harmonized role within the domain.

3 PARTICIPATION IN CEN/TC 251

All the CEN national member bodies (NMBs) are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, the experts need to contact the national standards organization in their countries.

As indicated in section 2, CEN/TC 251 is actively engaged with many other standards development organisations, consortia and fora to further efforts to coordinate its work with other organisations that have similar goals.

CEN/TC 251 members are those from member states and also include representatives from a number of related organisations.

CEN/TC 251 has established working relationships with:

1. CEN/CLC JTC 3
2. COCIR
3. European Commission
4. GS1
5. HL7 International
6. ISO/TC 215
7. EN13606 Association (formal liaison of CEN/TC 251)

It is evident, however, that only a small number of commercial organizations and not a very large number of user organizations are currently engaged in the work. This, and the small number of NMBs actively participating, has been identified as a weakness of the TC.

4 OBJECTIVES AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of CEN/TC 251

CEN/TC 251 had a strategic rethink after an effort was made to reach out to all our participating NMBs. It was clear from that activity, that assumptions about the homogeneity of all NMBs could not be validated and that this impacted both engagement and adoption. It was agreed that with respect to their standardization activities CEN/TC 251 should consider:

- a) Better communication strategies,
- b) Relevant, proactive engagement: seek active involvement with EU projects in a formative fashion and be
- c) Value driven: consider 'delivery' as a metaphor rather than 'development', which is increasingly happening in other forums such as ISO and HL7; indeed the former seemed to be aligned with the wishes of CEN to limit duplication.

The early conclusion from approaching the member states and considering their response was that each country often had different needs and this required a very different approach from what had been done before. In particular, this conclusion had implications both for understanding the

processes of eliciting requirements and standards adoption and the various needs of raising awareness and promoting the CEN/TC 251 activities and products.

4.2 Identified strategies to achieve CEN/TC 251's defined objectives

CEN/TC 251 identified three strategies to achieve the three objectives (a-c); and these are on-going. The three are:

- a) CEN/TC 251 uses social media (e.g. 'Linkedin'), a specific web site and twice annual newsletters to inform and stimulate interest. These have proven successful, but this third year is proving challenging to create and publish due to lack of resources. We are also in the process of developing other outreach materials, such as the Concurrent Use video, available on YouTube in at least English, Italian and Norwegian. We are investigating developing courses around our standards to socialise their use, to promote uptake and to receive feedback from the market. Core resources for communications will be made available through the CEN/TC 251 secretariat, with more dedicated resources being contributed through projects and other subsidized initiatives.
- b) CEN/TC 251 participates in SHN, Trillium Bridge and Antilope projects, either as individual experts or official partners; we took part in the eEIF work and have entered into the current round of EU funded projects, i.e., the CSA PHC/1 & PHC/34 initiatives that have various 'standardization' components. A first European Summit was organized to encourage the formation of the eHealth Specification Platform (eSP) to specialize and complement the eHealth Network and Multi-Stakeholder Platform activity. Together with the Commission, it was investigated as to how we might use the CEN Workshop Agreement activity to support the eHealth Member State activities on Patient Summary Guidelines that emerged from the epsOS work. Now that HL7 International and ONC have modified their proposals and are now looking for the specification of an International Patient Summary, CEN is working with the European Commission and the Joint Initiative Council to secure firm European representation in the work to be carried out.
- c) The third strand in the strategy on 'deliver' rather than 'develop', was the creation of the CEN/TC 251 Concurrent Use Initiative. Three of CEN/TC 251's major architecture projects (ContSys, HISA and 13606), which have now become full EN ISO specifications co-exist, but were not originally designed to work concurrently with each other. A common architectural framework is under development, which will also inform the scheduled revision of both 13606 and HISA. CEN/TC 251 has been actively pursuing this goal by organizing workshops, reports and publicity materials both to demonstrate value and to provide guidelines on implementation. Our link with the SHN project was also exploited to hold a joint workshop to align ContSys and 13606 with the semantic assets required for interoperable systems. This is on-going, as is the eSP activity, which is also part of the 'deliver' philosophy. Building upon this work we look to extend our cross-SDO 'deliver' strategy by actively participating in projects (from demonstrator and pilot to full-scale implementation) and through the advancement of tooling that supports the selection, implementation and testing of standards implementation. The work on the Common Assessment Method for Standards and Specifications (CAMSS) serves as an example, as well as the testing and quality management tools developed as part of the Antilope project.

The CEN/TC 251 Health Informatics will continue stimulate the development of ISO standards in areas where there is specific need and in doing so ensure they meet European requirements. Where necessary it may develop European standards to address regional legislative demands. For example, the existing success which has seen Identification of Medicinal Products (IDMP) be adopted after the EU initiative, and seed-corn resource; which has shown active collaboration

between regulators, industry and other SDO's such as HL7 on the 'Individual case safety reporting' and the input to the new EU OpenMedicine project.

Specifically, CEN/ TC 251 will work in and around EU Directives as there is great need for this in our European healthcare enterprises, and these Directives differentiate our work and should characterise our contribution to the member states.

To achieve these objectives in an effective work program it is proposed to transform the current working group structure from the formal four (including two currently dormant groups) into just two working groups, one focused on interoperability/connectivity and the other on the use of clinical information (record structures, big data, apps). These would effectively funnel work from the international arena into the European space and vice versa. In particular, the two groups would be task oriented and interact on common initiatives, thus avoiding any organisational overhead. Wherever possible, the workgroups initiate or participate in projects to achieve tangible results with end-user involvement within reasonable timeframes.

These two working groups, given their broad mandate, are well positioned to form the focal point for collaboration with European projects as well. The way in which CEN/TC 251 will and can engage with these projects needs to be detailed and publicized. Transparency toward and engagement of the NMBs is crucial to achieve the desired level of impact with these participatory and delivery oriented activities.

More specifically, the workgroups will develop activities that address the following key topics.

Standards coordination:

- Support the priority topics of the European Commission and Member States in the eHealth Network:
 - Patient Summaries;
 - ePrescriptions;
 - Patient and Professional Registries.
- Contribute to the closed loop deployment of standards through specification, testing, certification, adoption and maintenance in relation to CEF and NCP efforts to achieve cross border interoperability for health information, building upon the experience provided by epSOS, Antilope and other EC projects.
- Act as a European point of reference for health informatics standards serving both research and industry in their search for relevant expertise and solutions.

Standards production: a coherent set of architecture standards, featured in Concurrent Use

- produce revised versions of EN ISO 13606 EHR Communication, 5 part standard;
- produce revised version of EN ISO 12967 HI Service Architecture, 3 part standard;
- update the EN 1064 SCP-ECG standard and forward the result to ISO;
- standardise the results of the European HI cross-border initiative and relevant outputs from the EU projects that CEN/TC 251 is involved in;

In addition CEN/TC 251 will produce technical reports of use case templates for eHealth and enterprise architectures.

Standards delivery:

- promote the 5 IDMP standards and approve related medicinal product standards coming from ISO/TC 215/WG6;
- publish EN ISO 13940, the standard for continuity of care (ContSys), socialise its use, and maintenance;
- publish CEN ISO/TS 13972, the technical specification for Detailed Clinical Models;

- approve ISO TR 14639-2 'Capacity-based eHealth architecture roadmap - Part 2: Architectural components and maturity model';
- approve the updated DICOM-originated medical imaging standards;
- approve the IEEE 11073 originated medical device communication and Personal Health Device (PHD) standards;
- approve the Health Informatics security standards produced in ISO/TC 215/WG4.

4.3 Environmental aspects

The standards products of CEN/TC 251 have no direct impact on environmental sustainability matters. However, it would be possible to imply indirect impact by reduction of materials usage where the standards are deployed e.g. in telemedicine, home based care, better public health; improved continuity of care; greater efficiency and effectiveness measures, indicators etc.

The working practice of CEN/TC 251, particularly at the task-group level, has been to reduce in recent years the negative environmental sustainability impact of its standards production activity by increasing the use of telephone and web conferencing technologies to hold meetings. This is a trend we expect to continue for both environmental and economic reasons.

Any indirect negative environmental sustainability impact would likely be restricted to the effects of manufacture and disposal of the materials used to provide the operational environment of health informatics software.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC 251 WORK PROGRAMME

Specific factors that could negatively impact the completion or business community acceptance and use of the CEN committee's standards include:

1. Expert resources are not sufficiently available due to lack of stakeholder support – There are a variety of reasons for this: competition from other SDOs; the lack of involvement of competency centres in the more strategic aspects of standardization; unclear support from the EU as to how standardization in eHealth should be resourced; the difficulty of proving value propositions in the absence of suitable feedback mechanisms. Insufficient financial prioritization and resourcing for secretariat and experts involvement (particularly Small Medium Enterprises, who find involvement punitive). Specific expertise for a project is lacking, which could affect the project's development as well as the credibility of the resulting standard in the business community;
2. Validation of test methods is dependent upon funding being available to undertake the necessary pre/co-normative research and development;
3. Establishment and maintenance of semantic resources is dependent upon funding being available to undertake the necessary pre/co-normative research and development;
4. Legal/regulatory uncertainty and fragmentation concerning how best to use CEN/TC 251 to support European objectives within the international market.
5. The lack of knowledge about how standards are used, where they are used, and their impact and value across Europe. It would be beneficial to have an accurate overview of what standards (organizations in) the member states are really using.

Although CEN/TC 251 has produced a number of standards, many members have chosen alternatives as the basis for their national HI infrastructure. In future, CEN/TC 251 will endeavour to take this into account and aim at promoting all standards which serve our member states, regardless of who originally developed them.

Through our collaborative working relationships with other organisations and through our membership of the JIC, CEN/TC 251 is committed to strive for harmonization of standards, as exemplified by our participation in the eStandards project¹³.

While it is true that this important work is currently constrained and hampered by a lack of resources, and that the current agenda cannot be fully delivered by a volunteer workforce only, no matter how capable and committed. Furthermore, part of the awareness activity in our strategy is to manage unrealistic expectations, which often lead to dissatisfaction of the SDO contribution, be it CEN or the others.

Nevertheless it is also true, and important to emphasize, that CEN/TC 251, through its position, influence and contribution, is ideally placed to deliver, socialise and maintain a European targeted and timely response to international Health Informatics standards and to be a focal point for collaboration and leadership in delivering relevant standards for our member states.

¹ See WHO definition: www.who.int

² ISO/TC 215, Health informatics: www.iso.org/iso/iso_technical_committee?commid=54960

³ www.CDISC.org

⁴ www.DICOM.org

⁵ www.GS1.org

⁶ www.HL7.org

⁷ www.11073.org

⁸ www.IHTSDO.org

⁹ Vienna Agreement process: www.iso.org/va

¹⁰ www.JointInitiativeCouncil.org

¹¹ www.IHE.net

¹² www.eHealth-INTEROP.eu

¹³ Horizon 2020 CSP project for Personalizing Health and Care, to be started in 2015.