

Report from the CEN/ISSS e-Health Standardization Focus Group

Current and future standardization issues in the e-Health domain: Achieving interoperability

Executive Summary

**Final version
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This is the Summary of the report prepared by the CEN/ISSS
e-Health Focus Group revised after public comment.

Preface

The CEN/ISSS e-Health Focus Group was formed to prepare an overview report on current and future standardization issues in the e-Health domain. This document comprises a draft Executive Summary of that report for Public Comment. The draft Report itself comprises a Main Text (Part 1) and Annexes (Part 2).

The Focus Group's objectives were:

- to consider, with all the relevant stakeholders, priorities and objectives for e-Health standardization and interoperability and how the CEN system and others can contribute;
- to overview the existing achievements and current programme of work of CEN/TC251, starting from the report presented to the Commission in June 2001, and to consider its current achievements and Business Plan;
- to overview other current and proposed e-Health related and relevant standardization activities, in formal standardization and industry consortia, and in particular interface with the recommendations of the e-Health Standardization Co-ordination Group (eHSCG) recently formed by an ITU-T initiative, and which includes CEN/TC251, ISO/TC215, ITU, DICOM and HL7;
- to consider the standards implications of the Ministerial Declaration of 22 May 2003, following the Commission/Presidency e-Health 2003 Conference;
- to take due account of requirements of eEurope Health Online key actions;
- to take due account of other policy and legal requirements in the European context, including initiatives at national and regional level;
- to prepare a draft report, containing proposals and priorities for future standardization work, and present this to a Commission-organised Open Meeting;
- to finalise the report in the light of public comments and the Open Meeting discussions.

Its scope was to cover the concept of e-Health as defined in the context of eEurope – the application of information and communications technologies (ICT) across the whole range of functions and services which, one way or another, affect the health of citizens and patients, specifically:

- delivery of care to patients by healthcare professionals;
- health-related information;
- electronic trading of healthcare goods.

Membership of the Focus Group was opened to all interested parties through a public web announcement. It attracted a large number of participants from a wide audience.

There are many organisations involved in standardization and standards development some formally multinational such as CEN, ISO and ITU and many with an international authority or engagement often with international affiliates or equivalent such as WHO, HL7, IEEE and DICOM. The Focus Group chose to use the term Standards Development Organisations (SDOs) to cover all such bodies.

Executive summary

The goals for the European Community in health are to:

- maintain a sustainable health care for all;
- improve safety of healthcare delivery and reduce the number of errors;
- support secure authorised access to patients' relevant health documentation anytime, anywhere;
- support the mobile citizen in seeking high quality care throughout Europe.

In Europe the demand for care (quality and quantity) is growing while the resources remain limited. Europe needs to improve and refine the supporting processes of health care to gain resources for future demand. e-Health has the potential to improve the quality and effectiveness of healthcare services. This view has recently been endorsed by the Council for Employment, Social Policy, Health and Consumer Affairs, which "Recognises that electronic health cards, electronic health dedicated national and regional networks and the use of other information technology tools can achieve significant improvements in the quality and safety of the health care that is delivered to patients in an environment of increasing pressure on healthcare systems, while contributing to cost savings in the longer term."

Many countries of Europe are increasing their attention on the use of ICT in the health domain. Some have a declared national or regional policy and others have adopted ambitious strategies for the next five to ten years.

The EU Commission is also looking to ICT to realise many of its health-related objectives and is working with Member States in encouraging a range of trans-EU e-Health services.

The most challenging of the services and work practices to which ICT is being directed involve many, and often diverse, organisational entities sometimes located in different countries. Successful application of ICT in these circumstances will not be achieved unless all the organisations concerned agree a set of common standards. Where the services extend between countries, perhaps across the whole EU, those agreements will need to be trans-national. In considering these matters the Focus Group came to the following conclusions.

Health informatics standards are essential to achieve the goals of e-Health in Europe for:

- interoperability between systems and patient information exchange between health organisations;
- market efficiency by providing increased understanding between all players in that market through a common technical framework and terminology for e-Health application development, procurement and implementation;
- meeting non-functional requirements to ensure safety, security and legal requirements e.g. protecting the privacy of the citizens;
- establishing a representative set of multinational interoperable, coordinated and open eHealth services based on a common business and service architecture
- managing eHealth services.

Many health informatics standards from CEN, ISO and other bodies such as DICOM, HL7 and IEEE exist, or are being finalised, to meet many of the requirements but:

- their existence is not well known, (this statement applies particularly to formal standards);
- they are not used enough;
- their interoperability is often not proven;
- they rarely explicitly take account of whether their requirements are suitable for small enterprises;
- some of them conflict.

European or whenever possible global standards (as opposed to no standards or conflicting national standards) are essential for an open market to:

- allow suppliers to market throughout Europe or globally without designing for each country;
- assist buyers in specifying exact requirements with assurance;
- facilitate cross-border communications and applications;
- meet the obligations of EU Directives and World Trade Organisation (WTO) principles.

Standards activities need positive and active support from:

- Member States in pursuing their national or regional strategies and policies and particularly in regard to their obligations to EU Directives and WTO agreements;
- the Commission in promotion and in financial support;
- healthcare professionals and other users in participation in standards creation and requirements specification;
- suppliers in participation in standards development and implementation of standards in products.

Moreover there is a lack of guidance on where and how to use standards.

Commitment to European and global standards is generally weak in the health domain and there is an increasing tendency for Member States to create national standards. This is despite:

- EU Directives and Commission Communications making clear the advantages of using European or global standards;
- obligations on EU Member States to use such standards in national applications and procurements;
- obligations not to create national standards where European or global standards exist.

The Focus Group was commissioned to address these matters and to make recommendations for actions that should be taken in the area of standardization to enable health policies and strategies to be efficiently realised at local, regional, national and EU levels.

It would not have been possible, or useful, for the Focus Group to have attempted to consider all the features of all policies and strategies across Europe or all the many

applications of ICT to health services which are being pursued. Instead the Group determined to identify and concentrate solely upon those matters and issues which appeared to have a high level of commonality and priority within the countries of Europe in the context of:

- those strategic aims and policies which have high commonality;
- the highest priority ICT applications needed to achieve such aims;
- the highest priority ICT infrastructure elements to underpin those applications.

The key strategic aims identified were:

- improving access to clinical records;
- enabling patient mobility and cross-border access to health care;
- reducing clinical errors and improving safety;
- improving access to quality information on health for patients and healthcare professionals;
- improving efficiency of healthcare processes.

ICT has great potential to assist the achievement of these aims. An analysis of national and EU priorities, stakeholder concerns and a number of case studies demonstrated that there are some particular ICT applications and infrastructure elements that are critical to meeting all or a number of these objectives. The Focus Group concluded that these should be the priorities to pursue.

Critical applications for achieving strategic aims:

- electronic health/patient records including health record and business architectures;
- electronic transfer of prescriptions;
- electronic health data messages between hospitals and primary care particularly communication of service requests and reports for laboratory investigations, discharge summaries and patient referrals;
- digital imaging and associated service requests and reports;
- e-prescribing with decision support;
- core data sets e.g. for public health and assessing quality of clinical care.

Infrastructure to underpin applications:

- management of patient identification including:
 - EU Health Insurance Card perhaps containing a medical emergency data set and controlling access to data in a patient's country of residence;
 - a common approach to patient identifiers;
 - access control and authentication;
- protecting personal information (with emphasis on Public Key Infrastructure and data cards for identifying and authenticating professionals and citizens/patients);
- terminological systems for clinical records and medicines;
- data cards and portals.

The Focus Group considered what would need to be done if these priorities are to be supported by the necessary standards with assured interoperability. It was conscious of the fact that the world of standardization is complex and comprises many different standards development organisations which often overlap and conflict. The Main Text lists

the bodies involved, the standards available and those in work programmes. There is a variety of co-ordinating and collaborating mechanisms in place but their effectiveness varies.

Whereas there are many standards available from these organisations which might meet the needs of applications, there can be no guarantees that standards will inter-work unless proven in practical applications and/or pilots. Even where two vendors have implemented the same standard, there are similarly no guarantees that their products will inter-operate without adequate interoperability tests due, for example, to allowable options within the standard. There are bodies such as IHE (Integrating the Healthcare Enterprise) and its regional chapters whose aim is to specify focused profiles based on standards and to test interoperability. They often take standards from different 'stables' in order to build a complete set and can provide an essential feed back to standards developers. Nevertheless the amount of such interoperability testing and its scope needs to be expanded. At present scope is centred on workflows inside hospitals although new profiles include exchange of documents across enterprise borders. The Main Text addresses the challenges to achieving interoperability and the critical need to address them.

In an ideal world health ICT policy makers, stakeholders including in particular health professionals, vendors, patient organisations/representatives and standards developers would come together within Europe and

- define the priorities for the application of ICT to health;
- establish the business requirements;
- identify the areas where standards are required;
- establish what existing standards might fulfil the needs;
- identify gaps in the standards required and determine how they might be filled and by what body (or bodies);
- develop standards for the gaps to an acceptable time-table;
- bring the standards together for interoperability tests and prove the application through pilots;
- promulgate the results.

This ideal is, at present, far from reality, not least because of the lack of a strong, authoritative European position on the minimal requirements for interoperability and quality for European e-Health systems and a formal EU organisational structure which would bring together all the major players at a senior level.

In that context, the "Open method of co-ordination" needs to be employed where the Commission, together with the recently established High Level Group on Health Services and Medical Care, should help those responsible for health systems to work together at European level [34]. The "open method of co-ordination" will contribute to involving the many actors in this sector particularly health professionals and their associations as well as patient representatives whose role is becoming ever more important

The Focus Group considered these matters at length and its most important recommendation is as follows.

Focus Group Main Recommendation

Establishing an Interoperability Platform

The Member States, with the Commission, should establish a permanent platform with a mandate, and the necessary resources to promote e-Health interoperability based on standards and to facilitate co-operation between Member States.

This eHealth interoperability platform should:

- pursue the implementation of the recommendations made in this report;
- establish a Europe-wide view on the requirements for standardisation and its implementation in specific domains, in collaboration with standards organisations, based on input from relevant stakeholders communities;
- encourage and promote an environment for detailed specifications testing, evaluation or certification, to achieve interoperability of systems based on standards;
- establish a means for tracking and promoting good practice, and foster pilot implementations in compliance with the aforementioned environment;
- encourage agreements across national borders and between professional groups;
- encourage the further development of an appropriate European legal and regulatory framework;
- promote the establishment of infrastructure services such as for the creation and maintenance of terminology systems and knowledge repositories.

This eHealth interoperability platform should report to the High Level Group on Health Services and Medical Care set up by the EU Health Council.

This eHealth interoperability platform should be driven, at a senior European level

- by relevant stakeholders at a senior level, including patients/consumers, vendors, health professionals, and other experts in the domain of interoperability in health working with standards organisations both in ICT and health care generally;

Other recommendations¹

Note: *When the phrase "The Member states and the Commission should" is used in the recommendations below, it is intended that the high level interoperability platform to be established should become involved in the evaluation and pursuing of the actions needed.*

Recommendation 2: Improving access to records

The Member States, with the Commission, should give significant momentum to national and Europe-wide secure access to clinical records and to achieving full semantic interoperability of personal health data and information through strong support to existing and emerging European standards for electronic health record communication.

Recommendation 3: Reducing medication-related errors and e-prescribing

In order to reduce medication-related errors, the Member States, with the Commission and the eHealth interoperability platform, should implement technical measures to:

- uniquely identify and link the patient, the medication administered, the prescriber, the dispenser and the administrator of the medication (in order to achieve this, a common European identification of medicinal products is deemed necessary);
- formalise and present medical and procedural knowledge, such as medicinal product characteristics in relation to clinical findings, rules, clinical practice guidelines, clinical order sets;
- promote means for creating and distributing such knowledge using appropriate high quality, evidence-based, peer-reviewed content libraries including tools for creating and managing their content;
- facilitate the widest use of prescribing decision support software, based on interoperable data structure;
- trigger the development of representative practice models for a number of business cases.

In relation to these measures, the Commission should mandate the European Standards Organisations to develop the necessary relevant standards, in co-operation with ISO/TC 215 and other organisations.

Recommendation 4: Safety of health informatics products

The Commission, with the Member States, should consider a EU Directive addressing the need to control the safety of health informatics products in a similar way as for medical devices, and mandate the European Standards Organisations to prepare the safety standards which should be applied.

Recommendation 5: Quality of information - Metadata for knowledge resources

The Commission should mandate the European Standards Organisations to work with ISO through the Vienna agreement to produce a standard on metadata for knowledge resources and guidelines ensuring quality of health information on web sites to be based on guidelines published by the Commission and on work under way in WHO.

¹ The numbering and order of the recommendations does not indicate importance or priority.

Recommendation 6: Efficiency of healthcare processes - Workflow models and clinical pathways

The Commission should mandate the European Standards Organisations to prepare standard workflow models and clinical pathways, which would facilitate the application of ICT and improve efficiency. It will be critical for such development to include the appropriate healthcare professionals.

Recommendation 7: Electronic transfer of prescriptions

Member States, rather than developing national standards, should positively support the collaboration between CEN/TC 251 and ISO/TC 215 to:

- define the business requirements for the electronic transfer of prescriptions;
- identify the necessary standards required to implement the service in full and to identify the standards bodies which should produce them if new or amended ones are required;
- create interoperability arrangements to prove interoperability.

Recommendation 8: Information exchange to support inter-working and the mobile citizen

Member States, with the Commission, should provide the necessary means:

- to establish the pan-European business requirements for the interworking of health organisations and cross-border communication to support the mobile citizen;
- to exchange interoperable information structures such as for electronic health records extracts, patient referrals, discharge summaries, and laboratory results, also integrating point of care medical and test devices;
- to create an inventory of those standards that are necessary to achieve these business requirements;
- to ensure that the appropriate European Standards Organisations are mandated to develop them, in so far as they do not already exist;
- to establish arrangements for testing interoperability based on these standards and to ensure that they are, where appropriate, accounted for in conformance testing, quality labelling and certification processes.

Recommendation 9: Case-mix groupers based on diagnoses and procedures

The Member States, with the Commission, should provide the necessary means for the development of tools for mapping between case mix groupers used in Europe including the underpinning coding systems for diagnoses and procedures.

Recommendation 10: Quality indicators

The Member States, with the Commission, should mandate the European Standards Organisations to develop a standard for communicating the priority indicators of quality of care, based on measurements of health care outcomes and patient safety issues, as well as the definition and matching data elements.

Recommendation 11: Improving availability of standards

The Member States, with the Commission, should consider means for making all e-Health standards available free of charge to users in Europe as well as globally (as recommended by the eHSCG) particularly supporting less resourced developing countries and as has been requested by the Commission in COM 356. It is recognised that the national standards bodies in Europe derive income from the sales of standards, but we suggest that ways be explored as to how to overcome this in order to be able to implement the recommendation.

Recommendation 12: Commission's support to European standardization

The Commission should without delay initiate discussions with the European Standards Organisations concerning the implementation of the relevant recommendations of this report. Implementation of the mandated recommendations will require continuing support to the technical groups concerned. The ESOs should also establish an appropriate and co-ordinated mechanism, possibly under the ICT Standards Board auspices, to address and respond to the requirements emerging from the eHealth Interoperability Platform.

Recommendation 13: Towards an international multilingual reference terminology

The Member States, with the Commission, should:

- ensure the Europe-wide referencing and easy access to the content of existing health coding systems based on registration of such systems by the Eurorec Institute;
- support the international convergence towards a common framework for formal representation, and eventually the development and maintenance of a multilingual clinical reference terminology. This effort should build on existing efforts in formal representation as GALEN, FMA and SNOMED, and be carried out in liaison with the WHO Family of International Classifications
- make the targeted reference clinical terminology publicly available free of charge;
- support a common approach to link national classifications of procedures, to support cross-border reimbursement of health care.

Recommendation 14: Security services

As a step to achieving a secure information infrastructure, the Commission should mandate and fund a study of the Business Requirements for measures and services to support the management of patient identification and access control to patient identifiable data by patients and by professionals with patient authority, and to delineate the set of standards required to support those Business Requirements. This study should take into account the many existing community initiatives, as well as standards for inter-sector use, and focus on the need for actions specific for eHealth. The study should include services such as:

- ensuring secure data exchange:
 - common interpretation;
 - data integrity;
 - safe and secure systems;
 - secure communication;
- patient and professional identity management (e.g. processor based ID data cards);
- Public Key Infrastructure for health care;
- Privilege management and access control including:
 - policy bridging between organisations;
 - organisation based authorisation and access control policies;
 - role definition;
 - audit trails;
- identifying a suitable means for testing interoperability.

Recommendation 15: Health cards

Member States should utilise the existing CEN/ISO health informatics standards for health cards and the Commission should, in particular, seek to ensure the use of these standards for the EU Health Insurance Card by member states planning electronic interoperability or multiple applications for the EU Health 'Insurance' Card. Further the Commission should consider data card applications in relation to access through portals to the relevant and actual information.