A National Study of eHealth Standardization in Finland - Goals and Recommendations

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Abstract

The role of standards is constantly increasing in health services, electronic health records, and eHealth applications. There are many areas of standardization which affect the healthcare work and health information systems. On a national level, the organization of the development and support for standardization should be a key priority. This paper summarizes a national study in Finland which reviewed the current status of eHealth standardization and made recommendations for the national standardization and the use of standards. The recommendations are related to the organization model and balanced participation, international and cross-domain collaboration and quality assurance of standards-related activities. In addition, education and support services and support for introductions and pilots are recommended to improve the know-how of standards in system acquisitions.

Keywords:
standardization, interoperability, eHealth, health information systems

Introduction

The role of standards in eHealth and national initiatives

The provision and use of health services are facing increasing change pressures. The aging population, recruitment problems, biomedical advances, diversity of treatments and examinations, and increasing need of services by the elderly and by those having multiple diseases are seen as international trends [1, 2]. On the other hand, the national and international health and economic policies affect the market of the eHealth solutions. For example, the transition from hospital-centric to patient-centric and local health service provision has been seen as a pan-European trend [3]. On the other hand, specialized services such as clinical laboratories are transferred to large specialized units, for example in Finland. Electronic health information is increasingly used to improve quality and to enable new care models and treatments [1]. Healthcare networks require connections between disparate healthcare units and professionals. These needs are reflected in the requirements of eHealth applications and information systems.

One of the central challenges for electronic health services is the interoperability of eHealth solutions [4]. Health information systems contain lots of diverse information which have to be preserved and used for a long time. Large amount of new information and knowledge is constantly emerging in healthcare [1]. In addition, information is often sensitive or has accountability requirements. It has been observed that in general, the interoperability of eHealth applications and health information systems is far from optimal. This is partially due to the fact that standards are missing, their existence is not known, or they have not been implemented to an adequate extent [2].

A central goal of the national health project in Finland is to produce interoperable national electronic healthcare records. This includes national solutions for the long-term storage of electronic patient records and a secure access to the patient records by health service providers, patients and other actors [5]. The national architecture requires that the electronic patient record systems correspond to the national specifications as well as the establishment of national healthcare IT services. These services include an electronic archive and related services for the registration of documents as well as solutions for messaging. The realization of the architecture requires steering by the authorities and the establishment of an actor that is responsible for the implementation of the national services. Shared standards are a key factor in pursuing these goals. In addition to Finland, similar large-scale projects are underway in many countries. One central component of these initiatives is the promotion of the standardization of the healthcare IT.

This paper presents the central results of a study which aimed to document the current status of the national healthcare IT standardization in Finland and to identify and suggest improvements in the organization and development of standardization and the use of standards.

Dynamics of standardization

To illustrate the context of this work, we briefly discuss some aspects of standardization as a basis for this study. A standard is a document approved by an accepted body which contains rules, guidelines or features for generic and repeated use in products, processes or services [6]. In general, standardization has many meanings and motivations [7]: the uniformity of pro-
duction, the compatibility of technologies, the objectivity in measurement, the means for justice and a form of hegemony. Out of these goals, compatibility in the form of interoperability of software applications has been emphasized in recent years. Rapid change, global connectivity and the need for systems to interoperate are also increasingly evident in the future [8]. However, there is a wide range of interoperability standards available, both on healthcare-specific and domain-neutral levels. The lack of implemented standards hinders the development and use of healthcare knowledge, causes risks to the patients and sub-optimal use of resources [2].

Central tasks related to standards include the organization and steering of the standards work, the production and use of standards (experiments, introduction and use in products and procurements), education and support services, and the evaluation of standards and products conforming to them. The tasks are different in various phases of the lifecycle of standards, and they affect different participants. Standardization organizations are only responsible of some of the costs of these activities.

Most standardization organizations emphasize the creation of standards as a response to the needs expressed by the companies and users. On the other hand, standards are created as a result of complex social negotiations [7]. These viewpoints to the creation of standards (functionalistic and constructivist) emphasize the quality and accuracy, and the acceptance and dissemination of standards, respectively.

In health information systems, standards support the vision of open systems which can be complemented with new products. The direct benefits of eHealth standards provided for healthcare organizations, professionals and patients include the reduction in costs and errors, and improvements in care quality, usability, work practices and the availability of information. In addition, the application developers must attain advantages from the use of standards, such as new markets, consistent and accurate requirements, improved integration with partners, specialization possibilities and reusable models for subsystems or interfaces. In addition, healthcare financiers, medical research and the government benefit from standardization [3,2].

However, several problems related to standardization have been identified. Standards and standard families are incompatible and overlapping. Despite many standards available nationally and internationally, the introduction and assignment of different standards has not been completed. As the participation in the standards work is voluntary, not all relevant areas of standardization have been considered. In addition, the participation has been based on personal interest and it has not been properly coordinated, organized or resourced.

Materials and Methods

In November 2004, the challenges and problems of standardization were considered in a meeting by the representatives of the Finnish Ministry of Social affairs and Health, Ministry of Trade and Industry, the Association of Finnish Local and Regional Authorities, the Technical Research Centre of Finland (also representing HL7 Finland), the National Research and Development Centre for Welfare and Health, the Finnish Agency for Technology and Innovation TEKES, the University of Kuopio and the Savonnia University of Applied Sciences. In conclusion, it was acknowledged that standardization is an important enabler of the health service provision, the development of the national economy, and the growth of the small and medium enterprises. The lack of sustained solutions for the development, utilization and participation in standardization was identified as a central challenge. The action was taken to produce a report which would review the previous studies and recommendations and combine them with a wider view of standardization. The result of the study would be recommendations for the improvements in the development of activities related to standardization on a national level.

The work was scheduled from December 2004 to March 2005 for two projects funded by the Finnish Agency of Technology and Innovation TEKES. A literature survey was first performed, and national and international recommendations for eHealth standardization were reviewed, e.g. [3,4,9,10,2]. The study also produced a description of central international and national actors in eHealth standardization and a description of the different areas of standardization related to eHealth and health information systems. In addition, a previously defined framework for the evaluation and selection of standards was updated. The standardization areas were intentionally described from a wider view than only health IT to identify relationships and improvements beyond healthcare-specific considerations (see Figure 1). The standardization areas were divided in three main classes: the standards requiring specific medical or healthcare knowledge, the standards requiring a combination of IT and healthcare skills, and the IT or domain-neutral standards relevant in healthcare. These classes have some correspondence with the specificity levels and perspectives of the health informatics profiling framework by ISO TC 215 [10]. The notion of complementary standards to allow the modular construction of solutions [4] was one of the guiding principles in the identification and classification work.

After the identification of the main actors and areas, data collection was designed to survey the current status and the target state of the field. A recent web-based survey from the

![Figure 1. Areas of standardization addressed in the study.](image-url)
SerAPI project which included questions related to the responsibilities of integration and standardization was used as a basis. The survey was continued with an e-mail survey to named experts in different organizations (hospital districts, companies, organizations in the board of the project). This survey had four main categories and 60 detailed points. The main categories were the goals and policies, areas of standardization, activities related to standardization and the objectives for improvement. Each respondent received questions from two or three categories to lower the response threshold.

The questions of the e-mail survey were also discussed in several meetings with various experts. The number of responses in the web-based survey was 10 (of 18) and in the e-mail survey and meetings 13 (of 18), the total response rate being 66.7%. In addition to the surveys, interviews were performed with several experts responsible of the different areas of official and industry standardization. Furthermore, the participants of the project board reviewed the work in two mid-project meetings. The results of the literature survey and the data collection were then used by the authors who wrote the descriptions of current and target state, and other parts of the report.

The main result of the study was the description of current status and issues and a set of recommendations related to the standardization of healthcare IT. For the recommendations, the material of the study was combined with the personal experience of the authors. The results of the study were published in a 92-page report in Finnish for further actions [11].

Even though the work covered many areas, the application of standards was delimited to consider mainly health information systems. This was due to the fact that the majority of challenges of the national project and of the hospital districts were related to the interoperability of these systems. Excluded were also the devices and device interfaces, for example the medical equipment. In addition, the scope of the work was limited to open standards and specifications, and it did not consider internal implementation technologies of applications or development models such as open source.

## Results

### The results of the surveys and interviews

The respondents of the surveys and interviews saw the quality assurance and applicability of standards as a key factor in relation to the goals and policies of standardization. In addition, the usability requirements and pragmatism of standards were emphasized. Fast introduction and implementation were highlighted by software companies, as well as consistent solutions across different business domains. However, the opportunities of international markets were not among the most central goals. There were conflicting views regarding the special consideration of the existing systems in relation to standards, as well as the need for accurate identification of specific fine-grained standards versus widely applicable frameworks.

According to the respondents, the most central areas of standardization were the consistency in the support and specification of healthcare processes, the structure of information, data types, semantic consistency and the storage of electronic patient documents. In addition, unified information models and desktop integration were among the most important areas in some responses. Terminologies, codes, knowledge, shared IT services and workflow support were advocated to some extent. There were different opinions about the necessity of the standardization of architectures, security solutions and many technical or domain-neutral aspects. The code sets and information models were seen as enablers for more advanced standards such as guidelines and processes. According to the responses, eHealth solutions should be based on generic technologies and cross-domain standards, but the specific requirements of healthcare were identified in relation to security, safety and privacy, for example.

Many respondents saw a clear need for many different types of participants in the standardization. Healthcare organizations were emphasized in the standardization of healthcare-specific information, processes and guidelines. In the technology standardization (including healthcare IT), the role of companies and standardization organizations was highlighted. The role of authorities was also seen central, especially in relation to the healthcare-specific aspects and architectural guidance.

### Goals, problems and challenges

Based on the literature survey and the results from the data collection, the national problems and challenges were identified and the target state was specified. In eHealth standardization, no organization can master all areas. This stresses the importance of coordination, the utilization of experts in different areas and the relationship between international and national standardization. In addition, clear relationships between healthcare information and processes, healthcare IT and technical standardization, and the requirement to base the solutions on the actual needs of the market are central. Some research results suggest that global standards succeed only if they can be adjusted to the local processes and activities, and they are applied or modified according to the local requirements [7, 12]. This observation was supported by our study.

The local or national definition of responsibilities, guidelines and resources is needed for the selection and production of standards and recommendations [9]. The selection and production of specifications, steering of these activities, support for their use in products and procurements, and education and conformance evaluation are central parts of these activities.

The coordination and ownership of standardization activities was identified as one of the key challenges in standardization. The various earlier recommendations for the organization models of standardization have not been realized. The collaboration and knowledge of different activities should be increased. Even though standardization requires participation from the industry and their customers, the government can maintain a working standards infrastructure. This support can be realized as clear recommendations about the selected standards, clarification of responsibilities and guidelines such as

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1 This statement has been emphasized also in other research [7].
national architecture for electronic health records. The linkage between the standardization and system introductions, and the creation of conditions which balance the participation in standards activities can also be centrally supported [9].

The quality assurance and the evolution of requirements require special attention in standardization. There is a contradiction between the fast introduction of standards and their quality [9]. The subtle balance between accuracy and flexibility depends on the type of the specification. The conformance and certification require accurate specifications and dedicated services. Implementation examples, support for the projects which introduce standards, and guidelines for the procurement are useful means for the quality assurance.

The relationship between official and industry standardization has not been clearly defined. Industry standardization has been more agile in responding to the needs of the users. The free availability of key specifications promotes their use. In addition, the commitment and participation in standards-related work has been increasing very slowly. In particular, the companies and healthcare organizations have not participated actively in the international standardization. In general, successful standards require demand from the market, and standards can not be easily enforced by the officials.

New standards and specifications which are potentially relevant for healthcare, health IT or technology aspects, are continuously emerging. Constant learning by the users and developers is required. The careful selection of the specifications to be studied, and education about standards are necessary to keep the workload reasonable. The knowledge of key areas and activities of standardization should be included in the education of healthcare IT professionals.

Discussion

Main recommendations

Based on the surveys and previous parts of the study, the following eight main recommendations were made:

1. The standardization relationship between the healthcare IT and the domain-neutral IT must be intensified. Shared national goals, policies and procedures for IT-related standardization must be specified. National standardization steering groups are proposed for over-all coordination and the healthcare-specific standards.

2. The continuity of domain-neutral and healthcare-specific IT standardization must be assured using permanent funding from various departments.

3. The primary preference for all domains, including healthcare, must be given to cross-domain and generic standards. Healthcare-specific standards should be developed and introduced cautiously and only on areas where they are essential.

4. The participation to the international standardization work and the observation of international key developments in standardization must be intensified and resourced. The goal is to identify mature standards which solve current local needs and to avoid contradictions with the international standardization.

5. The participation of healthcare application vendors and health service providers in the development, localization and introduction of standards must be supported by funding projects which aim at standards compliance and by developing models to support the balanced participation to the standardization.

6. The national standardization in healthcare IT must primarily support the goals of the national health project, especially the interoperable electronic health records. This requires a quick prioritization of the most immediate areas and goals, and the establishment of realistic funding and scheduling for them.

7. The status, normativeness and mutual relationships of healthcare IT standards, guidelines and recommendations must be defined unambiguously and accurately.

8. To ensure the interoperability of information systems and to support the introduction of standards, a support and education network must be created with adequate expertise to promote these recommendations and to support the steering groups.

In addition to these high-level main recommendations, the report identified 51 detailed goals and 127 recommended actions to support these goals. The policy recommendations were related to the organization of the standards-related activities, steering and funding. The relationship recommendations focused on improving the international and cross-sectoral linkages in standardization. For the quality assurance of standards and guidelines, 20 recommendations were made. Central recommendations were also related to the improved know-how for the system acquisitions and to the establishment of education and support related to standards. In addition, the support for the introductions and pilots involving standards, and balance in the participation of standards activities received recommendations. In addition, detailed recommendations were made for many areas of standardization and national policies. The most urgent recommendations were related to the core information sets, clinical documents, architecture and security of the national electronic health records.

Current trends of interoperability standardization

Some central trends of standardization are related to the evolution towards advanced eHealth interoperability. Information systems are increasingly evolving towards networked and service-oriented solutions, which increases the role of standardization. In technical standardization, the aim is to increase the flexibility of systems to support different processes and adaptability. On the other hand, accurate functional and semantic interoperability is pursued, and processes and workflows themselves are increasingly standardized. In particular, profiles which constrain the standards are increasingly used to promote plug and play interoperability or automatic adaptability. Such profiles are emerging on the technology level [13], on the functional level [14], on the semantic level [4] and in
the field of application of interoperability standards [15, 3]. In addition, emerging support services such as conformance testing and certification are closely related to standardization.

**Conclusions**

Achieving the benefits of standardization in the eHealth domain requires coordination, the selection and development of standards on many areas, the identification of central actors and close collaboration between them. The different areas require specific expertise and multidisciplinary collaboration. The success of standards is measured only through their utilization on the market. The support for the introductions of standards, the clear scope of standards, quality assurance, and the availability of standards and their support services create a vortex of successful standardization activities. The national participation in international standardization and the evaluation and selection of standards are necessities in this process.

The rapid evolution of IT and complementary standards offer many opportunities. However, generic standards require healthcare-specific profiling and evaluation, and healthcare also has specific standardization areas. In a wider context, standardization and the use of standards promotes competition and open market, and progresses economy as a whole.

The recommendations of this study were published and given to the project board after the report was finalized in 2005. Since then, the Social Insurance Institute of Finland has been selected as the national actor for the development of national healthcare IT services. HL7 CDA (Clinical Document Architecture) R2, DICOM and HL7 version 3 Medical Records have been recommended as some of the key standards of the national EHR in relation to clinical documents, medical imaging and messaging, respectively. In addition, some technical specifications such as X.509 for certificates, http(s) and SOAP for data communications and WS-Security for mediated secure messaging have been recommended. Furthermore, some of the key recommendations related to the steering model of standards-related work are being refined as of March 2007.

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