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Large Scale eHealth Deployment in Europe: Insights from Concurrent Use of Standards

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Abstract. Large-scale eHealth deployment projects face a major challenge when called to select the right set of standards and tools to achieve sustainable interoperability in an ecosystem including both legacy systems and new systems reflecting technological trends and progress. There is not a single standard that would cover all needs of an eHealth project, and there is a multitude of overlapping and perhaps competing standards that can be employed to define document formats, terminology, communication protocols mirroring alternative technical approaches and schools of thought. eHealth projects need to respond to the important question of how alternative or inconsistently implemented standards and specifications can be used to ensure practical interoperability and long-term sustainability in large scale eHealth deployment. In the eStandards project, 19 European case studies reporting from R&D and large-scale eHealth deployment and policy projects were analyzed. Although this study is not exhaustive, reflecting on the concepts, standards, and tools for concurrent use and the successes, failures, and lessons learned, this paper offers practical insights on how eHealth deployment projects can make the most of the available eHealth standards and tools and how standards and profile developing organizations can serve the users embracing sustainability and technical innovation.

Keywords. eHealth, interoperability, governance, standardization, adoption, harmonization

1. Introduction

The convergence towards a fully harmonized set of eHealth interoperability standards at international or European level is a long-term vision, but far from the reality today. Different approaches in terms of technical solutions, standards and profiles used, terminologies adopted, etc., are the natural consequence of the many factors influencing architectural decisions in eHealth deployment, including culture, domain, country, implementation timeline and the interoperability layers addressed. It seems unlikely that international consensus on a common reference information model for eHealth deployment can be reached in a reasonable timeframe and budget and we need eHealth interoperability now! To support large-scale eHealth deployment, we need to tackle the important question how coexistence between competing or overlapping standards and standard options can be achieved to ensure practical and sustainable interoperability.

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The eStandards project [1], funded by the European Commission, has been proposed by leading Standards Development Organizations (SDOs), HL7, CEN TC251, & IHE and is supported by other organizations to advance eHealth interoperability and global alignment of standards by connecting stakeholders in Europe and internationally to accelerate knowledge-sharing and build consensus on eHealth standards. eStandards aims to deliver evidence-based Roadmaps for alignment, iterative consolidation, and broad acceptance of eStandards endorsed by SDOs, the eHealth Network, the providers, and the Industry. The eStandards Roadmaps and associated evidence base, a white paper on the need for formal standards, and guidelines addressing clinical content development and dealing with competing standards in large-scale eHealth deployments will be pragmatic steps toward alignment and convergence.

In the eStandards project a study has been carried out to provide evidence on concepts for *managing the coexistence of competing or overlapping standards* in large-scale eHealth deployment nationally and cross-border. The evidence has been organized as a collection of case studies about technical approaches and real-world eHealth deployment projects offering solutions for the concurrent use of overlapping or competing standards. The case studies have been published as a public project report [2] and are openly accessible. The case studies describe the successes, failures, and lessons learned from the individual projects. Many authors from within and outside the eStandards project have contributed. While it was not possible to find authors for case studies about all relevant eHealth projects in Europe, as large as possible a selection was included.

The insights gained from this analysis aim to serve both as a source from which recommendations for future large-scale eHealth implementation projects will be derived, and as part of the "eStandards Roadmap for Essential Standards Development: Strategic Options and Policy Instruments" that will be defined by the project in 2016-17 to inform collaboration among standards developing organizations (SDOs), competence centers, and eHealth stakeholders.

2. Methodology

A case study template guided the authors in describing the case studies:

- Summary: author, project name and status, location and scale of deployment
- Project Overview offers a brief, non-technical project overview
- Approach refers to the standards and profiles used following the "Layers of Interoperability" in the revised eHealth interoperability framework adopted by the eHealth network established under Directive 2011/24 Art 14 in Nov. 2015 [3].
- Concurrent Use of Standards and Specifications explains how the concurrent use of standards was addressed e.g. providing gateways converting or by mapping (transform) between terminologies, documents or messages.
- *Governance* refers to processes and organizations set-up to maintain the specifications (e. g. mapping rules) for the concurrent use of standards.
- Lessons learned accounts the successes, pitfalls and remedies in the project that could benefit future large scale eHealth deployment projects ending with a list of useful resources and references for further information.

For each case study, available project information was mapped to interoperability layers. Tools and technical approaches to coexistence, and lessons learned were collected. The guiding research question was the use of standards within the projects on the different interoperability layers, issues caused by overlapping/competing standards and the way the projects addressed these issues.

3. Results

Nineteen case studies describing the concepts for managing the coexistence of competing or overlapping standards were solicited from June to December 2015. Six (6) were developed in an R&D project and thirteen (13) as part of a large-scale eHealth deployment and policy support project, national or cross-border. The case studies linked to R&D projects were:

- 1. SemanticHealthNet
- 2. Semantic Mediation in ARTEMIS, RIDE and SALUS
- 3. IHE Cross-Community Profiles
- 4. X-Paradigm
- 5. DICOM SR to HL7 CDA Imaging Report Transformation Guide
- 6. Trillium Bridge Bridging Patient Summaries across the Atlantic.

The case studies linked eHealth Deployment or policy support Projects were:

- 1. Patient Summary & ePrescription/eDispensation: epSOS, EXPAND, eSENS
- 2. Nation-wide EHR System in Romania
- 3. National eHealth network in Denmark
- 4. Documentation at the Source Program in the Netherlands
- 5. EHR Interoperability in Italy
- 6. Delivering 21st Century IT to the English NHS
- 7. Greek National Patient Summary Design
- 8. Spanish Implementation of the EU Patient Summary
- 9. e-SENS ePrescription and Patient Summary pilot for Greece
- 10. Electronic Prescription of Drugs and Pharmaceutical Products
- 11. LIGHt Local Integration Gateway for eHealth
- 12. Portuguese eHealth National Contact Point
- 13. Portuguese National Broker.

Ten of the studies were national, bringing insights from Greece, Portugal, Spain, the UK, and the Netherlands. There was remarkably little evidence on the use of competing and overlapping standards in the real-world eHealth deployment projects other than a mapping between different controlled terminologies. Terminology mapping is a critical issue, because a direct mapping is usually possible only for a subset of the terms. In Denmark (#9), International Classification for Primary Care (ICPC) codes are mapped to ICD-10 diagnoses when a GP sends a referral to a hospital, or a hospital sends a discharge letter to a GP. In the Netherlands (#10), a mapping between ICD-10 and SNOMED-CT has been defined. In Italy (#11), work is ongoing to map terminologies defined by, and used in regional implementations to a nation-wide terminologies used for patient summary content are mapped to the epSOS Master Value Catalogue. In Spain (#14), mapping of SNOMED-CT procedures and ICD-10 PCS (procedure coding system) classification is planned.

The epSOS project (described in case study #7) developed the concept of the pivot document as an intermediate format for the document conversion, for which a mapping from and to each national format was defined. The *pivot document* was used to convert the patient summary, ePrescription, eDispensation, or patient consent document in the sending country's format and language to the same document in the receiving country's format and language. Pivot documents are exchanged between epSOS actors and it is the responsibility of national contact points to "hide" the conversion process to/from national formats. The Master Value Set and Master Transcoding Catalogue support national contact points in the terminology mapping necessary to convert between a national document format and the epSOS pivot document. As a safety measure, the original document is always delivered along with the translated document in PDF format, offering a human-readable representation of the document prior to conversion. After the end of the epSOS project, the Master Value Set and Master Transcoding Catalogue were handed off to the EXPAND and eSENS project in preparation for the Connecting Europe Facility program. eSENS (#7) actively refines and improves the epSOS software architecture, and has replaced several standards and specifications with improved more recent ones like the PEPPOL Service Metadata Locator and the eIDAS regulation for identification. The case study indicates that National Contact Points will have to migrate to the new version of the software infrastructure to maintain interoperability.

Powerful and elaborate algorithms for converting between clinically equivalent representations of messages or clinical documents have been developed in the frame of R&D projects and follow a Gateway, Semantic Mediation, or Model driven approach:

- *Gateway*: IHE Cross-Community Profiles define protocols for connecting Electronic Health Record (EHR) deployments into a federated network. Profiles cover protocols required to locate, retrieve, or submit documents across communities. The profiles imply that a conversion between local value sets and document formats can be performed by the Gateway, but do not specify how such a conversion could be implemented.
- Semantic mediation: semantic mediation technologies can be used to convert between representations of clinically equivalent information by expressing the content of the messages or documents in ontologies. It requires a common ontology for both source and target format, or complete bidirectional mappings between ontologies. The main advantage is that equivalent clinical information can be identified irrespective of the representation used. However, complete ontologies that can represent the full meaning of the clinical documents are not yet available today for real-world use cases such as patient summaries.
- *Model driven*: a clinical information model is first developed to represent the clinical knowledge to be exchanged, independent from concrete EHR implementations. Transformation rules are created for documents formats conversion. They are based on the underlying clinical information models and specific mappings to EHR standards.

These three approaches are not mutually exclusive, but actually complement each other. Case studies on semantic mediation have identified the clinical information models, represented by a set of archetypes or templates, as the level on which semantic mediation should be defined. Thus, semantic mediation can be considered as an extension of the model-driven approach. Both approaches are independent from the actual communication protocol used to locate and access clinical documents. This is a gap that is filled by the Gateway-based approach exemplified through IHE XCA or through protocols under development in the X-Paradigm project. Nevertheless, if there is one important conclusion from the collection of case studies, that is the fact that a conversion between eHealth standards such as document formats, terminologies, or communication protocols, will rarely produce a "perfect" solution. This can be exemplified through the Trillium Bridge project, which tried to develop a mapping between two very similar specifications: two patient summary specifications (EU and US), both based on the same document format (HL7 CDA). Still it was not possible to find a complete mapping for all codes and subject matters in these two patient summaries. In Trillium Bridge, the terms for which a correspondence could be found varied from 6% to 87%, depending on the terminology [4].

4. Recommendations

Several of the case studies have expressed pragmatic, practical recommendations for future eHealth deployment projects, which are explained in detail in [2], but can only very briefly summarized here:

- Do not "reinvent the wheel", use existing standards, architectures and tools.
- Think big, start small: build a small system and grow over time.
- Make sure that more than one end user application can be built.
- There are useful components developed outside the eHealth community.
- Be pragmatic with regard to content formats.
- Develop your architecture layer by layer.
- Decouple components by defining clear interfaces.
- Ensure developer training and experience.

5. Conclusion

It can be concluded that there is no "magic bullet", no simple solution for solving the challenge of interoperability in large-scale eHealth projects – but nobody involved in the field would expect this. The combined experience of the case studies collected, both positive and negative, is a valuable source of information for future eHealth projects. This leads to an additional recommendation: make your approach and lessons learned publicly accessible and permit others to learn from your experience!

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