DISCUSSION PAPER
ON SEMANTIC AND TECHNICAL INTEROPERABILITY

Proposed by the eHealth Governance Initiative

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Introduction

Continuity of care is a key priority for modern healthcare delivery. It enables a high quality of care, in particular for citizens with chronic conditions. Continuity of care in turn relies on seamless communication between all actors involved in the healthcare process.

This paper is submitted by the eHealth Governance Initiative (eHGI) to the eHealth Network as a basis for discussion. Building on CALLIOPE[1], and following the roadmap of the eHealth Network set up under Article 14 of the Directive 2011/24/EU on patients' rights in cross-border health care, it suggests a pragmatic approach to semantic and technical interoperability and provides a set of recommendations that can be agreed by the Network as essential first steps.

Defining interoperability

Interoperability in eHealth means the ability of two or more eHealth systems to use and exchange both computer interpretable data and human understandable data and knowledge. Three aspects characterise interoperability:

- **Legal interoperability** covers the broader environment of laws, policies, procedures and cooperation agreements needed to allow the seamless exchange of information between different organisations, regions and countries.

- **Semantic interoperability** refers to the ability to ensure that the precise meaning of exchanged information is unambiguously interpretable by any other system, service or user.

- **Technical interoperability** means the ability of two or more information and communication technology applications, to accept data from each other and perform a given task in an appropriate and satisfactory manner without the need for extra operator intervention.

To achieve interoperability in eHealth for a given use case, all aspects of interoperability have to be concerned and should be based on common technical and semantic standards.

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[1] The CALLIOPE project listed these under four distinct areas: semantic, technical, legal/ethical and political. While the eHGI agrees with the proposition that all areas must and should be addressed by member states, only the first two are addressed here.

Benefits of semantic and technical interoperability

Semantic interoperability, in conjunction with technical interoperability, can deliver the following benefits including:

Mobile and ubiquitous access to medical information

Semantic and technical interoperability enables access to, and correct interpretation of, medical information by different health care providers and medical disciplines as well as in different countries, regions and nations. Furthermore, it ensures that, as patients access care from a variety of health care providers, there is a seamless flow of a patient's medical history.

Enhanced quality of care

Semantic and technical interoperability assure a common understanding of medical information and subsequently lead to a reduction in medical and prescription errors. They also enhance the quality of care by enabling better and faster coordination between the different healthcare professionals and providers. This in turn improves continuity of care through enhanced communication of the patient's health status, performed procedures, family history and personal history.

Improved cost efficiency

Semantic and technical interoperability provide the basis so that the right information can be available in the right way at the right time. This improves medical decision making while at the same time reducing risks and cost. In particular, it avoids duplicate, medically unnecessary (laboratory) tests and imaging procedures.

Enhanced choice for healthcare providers

Interoperability of vendor systems enhances the choice for healthcare providers: if the solutions are interoperable, providers have more choice in buying what they need in a competitive market and at lower costs, while at the same time vendors can introduce their products to more markets, thus reducing further development investment.

Challenges of interoperability in eHealth

Linking the different actors, IT systems and institutions across different medical disciplines, cultures, languages and jurisdictions is still a major problem. The eHGI has identified the following main challenges of interoperability in healthcare including:

Complexity of the health domain

The human body itself is characterised by an unmatched degree of complexity as are the deviations of function and their descriptions. A skilled medical professional can easily describe a pathological deviation, a chain of cause or a holistic view of a patient in free text but it is often challenging to produce a structured report using standardised terminologies.

Heterogeneous landscape of healthcare systems in Europe

Healthcare in Europe is for historical reasons and by definition of the European Treaties a pluralistic field: each country and even regions have their own healthcare system. Different national or regional health systems use different laws, policies, terminologies. This further increases the complexity of communicating effectively and efficiently.

No universal coding systems

A variety of classifications, nomenclatures and ontologies have been developed. Coding systems originate from national efforts, international organisations, professional organisations or private vendors and were often designed for specific usage. Subsequently, vendors have to cater for a variety of coding systems while healthcare providers may have to encode even the same fact in different coding systems.

No systematic acceptability, adoption and use of existing standards

Interoperability of IT systems depends on the use of recognised standards describing the technical specifications, methods and processes. However, finding the standard or profile that fits a use case requires time and effort. In addition the 'not invented here' syndrome and the desire to keep control over the technical specifications of one's IT system motivate organisations to maintain or develop proprietary custom solutions.

Lack of balance between the allocation of the costs and the benefits of semantic interoperability

The provision of meaningful, comprehensive and interoperable data incurs considerable indirect and direct costs for healthcare professionals acting as information providers whereas often distinct information consumers (other medical professions, hospitals, clinical researchers and public health officials) profit from it.

Enablers of interoperability

A stepwise approach

It is almost impossible to achieve full semantic and technical interoperability that can enable the connectivity and exchange of interpretable data between all conceivable eHealth actors, services and devices in all European countries.

A study by Semantic Health suggested that the cost of full semantic interoperability would spiral out of control and that a partial interoperability level would deliver the best cost benefit ratio[2]. Therefore, a stepwise approach is a cost efficient, quality oriented and clinically relevant path forward in order to balance efforts and benefits.

Research projects, initiatives, pilots

Interoperability has been the topic of many research projects, initiatives and pilots. Notably, CALLIOPE delivered the 'eHealth Interoperability Roadmap'[3] in December 2010.

Currently, 'Semantic Interoperability for Health Network (SemanticHealthNet)' aims to develop a scalable and sustainable pan-European process for semantic interoperability.

Smart Open Services for European Patients (epSOS) is a European eHealth Pilot in which semantic interoperability standards are being tested in a reference implementation.

The eHealth European Interoperability Framework (eHEIF) aims to propose an eHealth-specific version of the generic European Interoperability Framework (EIF) to identify technical

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[2] SemanticHealth 2008: D3.1, Comparative Analysis and Initial Socio-Economic Recommendations for Improving Semantic Interoperability
[3] CALLIOPE CALL for InterOPErability 2010: eHealth Interoperability Roadmap, Final European Progress Report

specifications for eHealth use cases and to propose recommendations for organisations developing those technical specifications.

Best practice in Member States

Understanding and learning from interoperability strategies in Member States is a prerequisite for successful collaboration at the European level. A preliminary analysis of a questionnaire by the eHGI indicates, as an intermediate result, similar challenges in all Member States (Appendix).

Recommendations and proposed policy decisions

Semantic interoperability is a challenge requiring policy decisions at European and national level while respecting national initiatives and the principle of **subsidiarity**. The eHGI stresses that the following policy decisions need to be operationalised both **on a national and European level**. All measures should be implemented on a **voluntary basis.**

1. Encourage greater cooperation between Member States

Member States who share a common strategy shall be strongly encouraged to collaborate in order to avoid redundancy and minimize costs. This collaboration can take the form of common investment in expensive tools (e.g. terminology server), exchange of tenders, exchange of methodology, cross-validation of translations, training of experts and evaluation of pilots.

In order to make this possible, a common understanding of the strategies chosen by all Member States is an essential prerequisite.

2. Encourage greater cooperation between national authorities and standardisation bodies

Member States and the European Commission shall encourage standardisation bodies to enhance their strategic and operational cooperation – in a coordinated approach. Furthermore, co-operation between standardisation organisations and competent national authorities in Member States shall be fostered.

3. Enable the recommendation of standards and (harmonised) profiles based on selected use cases

Based on (selected) use cases, an organisation[4] shall be in charge of

   a) the evidence-based selection of use cases

   b) the recommendation of standards and profiles for these selected use cases.

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[4] This organisation could be set up similar to the European Multi-Stakeholder Platform on ICT Standardisation. In order to maximise the involvement of users at every stage, the work already undertaken to create a new pan-user stakeholder group should be enhanced by closer co-operation with the eHGI.

The selection process for both use cases and recommendations shall be run jointly by domain experts and end users.[5] Particular consideration should be given to those use cases mentioned in articles 11 and 14 of the Directive 2011/24/EU on patients' rights in cross-border health care.

4. Use purchasing power of public sector as enabler for semantic and technical interoperability

The public sector – as a major purchaser of eHealth applications and systems – shall require vendors to use recommended standards, profiles and coding systems in public tenders.[6]

5. Foster data portability

5a. Data portability for healthcare providers

Vendors shall be required to implement an import/export function in a recommended standard based on a recommended data model in order to facilitate the re-hosting of medical data. This measure mitigates the risk of failure of the IT infrastructure, enables the re-hosting of medical data and avoids the lock-in of healthcare providers.

5b Data portability for patients

Vendors and healthcare providers shall be required to provide patients access to their data (in particular images, lab results, health records) in a recommended standard. [7]

6. Link and harmonise coding systems

Organisations responsible for the development and maintenance of coding systems as well as Member States and the European Commission shall work towards linking, harmonising and converging coding systems in healthcare.

7. Facilitate access to existing standards and medical vocabularies

License conditions of existing standards and medical vocabularies are sometimes highly restrictive and may not be affordable for all business cases.

In order to facilitate their adoption, mandatory semantic standards and medical vocabularies shall be provided by public authorities.

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[5] This recommendation is in line with article 13 of the 'Proposal for a Regulation of the European Parliament and of the Council on European Standardisation' which foresees the identification of technical specifications that could be referred to in public tenders. Furthermore, it supports Action 22 (Promote standard-setting rules) and Action 77 (Foster EU-wide standards, interoperability testing and certification of eHealth systems by 2015) of the Digital Agenda.

[6] Recommendation 2 is in line with the 'Proposal for a Regulation of the European Parliament and of the Council on European Standardisation' which will specify a legal basis for identified specifications that could be referred to in public calls for tender. It also facilitates Action 23 (Provide guidance on ICT standardisation and public procurement) and Action 77 (Foster EU-wide standards, interoperability testing and certification of eHealth systems by 2015) of the Digital Agenda.

[7] In line with this recommendation, article 18 of the 'Proposal for a Regulation of the European Parliament and of the Council on Data protection' introduces the right of a citizen (data subject) to transfer data from one electronic processing system to and into another in a structured and commonly used electronic format.

The documentation of technical standards and in particular standards emerging from publicly funded projects shall be provided for free on the internet and – wherever applicable – be supported by one or more reference implementations that are preferably open source.

8. Stimulate usability engineering for structured and encoded data

The limited usability of user interfaces for the entry of encoded and structured data turns out to be an additional burden for healthcare professionals. Member States and the European Commission shall stimulate research on the development and use of scalable interfaces for structured and encoded data.[8]

9. Consider incentivisation of healthcare providers

Providing medical records that can be semantically shared incurs costs for healthcare professionals. Member States should therefore identify and calculate the value proposition of healthcare providers with regard to interoperability and consider sustainable incentivisation schemes to encourage healthcare providers to provide data in an interoperable way and to invest in interoperable software.

Next steps: refinement and implementation

The eHGI shall be mandated by the eHealth Network to refine the proposed policy actions and to recommend measures towards their implementation.

The implementation shall follow these key principles:

- Measures shall not interfere with Member States' competences in eHealth and shall not harmonise any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

- Existing ICT infrastructure in each Member State shall be respected. Measures towards interoperability shall evolve from existing ICT infrastructures.

- Users and in particular healthcare providers shall be involved at every stage in the refinement and implementation of these policy actions.

- A stepwise approach shall be followed.

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[8] This includes technologies to automatically derive codes for diagnoses and procedures from free text using natural language processing.

Semantic interoperability in Member States
– a preliminary analysis -

Background

The eHGI surveyed Member States and associated countries of the eHGI in August 2012 by means of a questionnaire. 22 out of 26 countries replied. The following analysis can therefore only be considered as a preliminary and first step. The list of challenges is not exhaustive. By way of example, this first questionnaire does not reveal well-known interoperability challenges relating to different versions, national adaptations and translations of coding systems.

National strategy and electronic health records

A minority of 8 (out of 22) countries have developed a national strategy for semantic interoperability while 11 countries are going to develop one within the next three years. 15 countries have defined a national strategy for the introduction of electronic health records (EHRs). 11 out of these 15 countries require from healthcare professionals that their EHR systems comply with at least one interoperability standard. The healthcare professionals in almost all countries (21 out of 22) enter a mixture of structured information and free text into EHR systems.

Coding systems

Coding systems refer to medical terminologies, classifications and thesauri.

All countries (22) take advantage of coding systems and each country has at least one mandatory coding system. At the same time, almost all countries (21) set coding rules for healthcare professionals despite the fact that a majority are running into hurdles while introducing national coding systems. 11 countries noted the demand for the development of new coding systems, although most recipients emphasised selecting, qualifying and implementing existing ones.

Coding systems used in many countries include: ICD-10 (15 countries), SNOMED-CT (9), LOINC (8), ICD-9-CM (8) and ATC (7). Over 42 different standards were identified as being made available in at least one country. Most probably a much higher number is being used in these 22 countries to enable documentation in EHRs. 11 out of these 42 coding systems were used by more than 1 country.

The majority of countries (17) cooperate with other countries to validate their coding systems. In 16 countries, public authorities pay the licensing cost of at least 1 coding system. A minority of countries (8) offer incentives for the use of coding systems.