

European Interoperability Assets Register and Quality Framework Implementation

Alberto MORENO-CONDE^{a,b,1}, Geert THIENPONT^c, Inge LAMOTE^c,
Pascal COOREVITS^{d,e}, Carlos PARRA^b and Dipak KALRA^d

^a*CHIME, University College London, UK*

^b*Virgen del Rocío University Hospital, Spain*

^c*RAMIT, Belgium*

^d*European Institute for Health Records (EuroRec), France*

^e*Department of Public Health, Ghent University, Belgium*

Abstract. Interoperability assets is the term applied to refer to any resource that can support the design, implementation and successful adoption of eHealth services that can exchange data meaningfully. Some examples may include functional requirements, specifications, standards, clinical models and term lists, guidance on how standards may be used concurrently, implementation guides, educational resources, and other resources. Unfortunately, these are largely accessible in ad hoc ways and result in scattered fragments of a solution space that urgently need to be brought together. At present, it is well known that new initiatives and projects will reinvent assets of which they were unaware, while those assets which were potentially of great value are forgotten, not maintained and eventually fall into disuse. This research has defined a quality in use model and assessed the suitability of this quality framework based on the feedback and opinion of a representative sample of potential end users. This quality framework covers the following domains of asset development and adoption: (i) Development process, (ii) Maturity level, (iii) Trustworthiness, (iv) Support & skills, (v) Sustainability, (vi) Semantic interoperability, (vii) Cost & effort of adoption (viii) Maintenance. When participants were requested to evaluate how the overall quality in use framework, 70% would recommend using the register to their colleagues, 70% felt that it could provide relevant benefits for discovering new assets, and 50% responded that it would support their decision making about the recommended asset to adopt or implement in their organisation. Several European projects have expressed interest in using the register, which will now be sustained and promoted by the the European Institute for Innovation through Health Data.

Keywords. Interoperability, Electronic Health Record, Quality framework

1. Introduction

According to the four levels of interoperability identified as part of the European Interoperability Framework [1]: legal, organisational, technical and semantic, in order to achieve interoperable EHR systems that support the continuity of patient care, a level of agreement is required between implemented solutions that goes further than

¹ Corresponding Author: Alberto Moreno Conde, Grupo de Innovación Tecnológica, Hospital Universitario Virgen del Rocío, Edif. Centro de Documentación Clínica, Av. Manuel Siurot, s/n. Seville, 41013, Spain; E-mail: albertomorenoconde@gmail.com

adopting published interoperability standards. To address this aim many national eHealth programs, Standards Development Organisations, European projects and other bodies have developed formal specifications, templates, vocabularies, guidelines, and educational resources etc. that are useful and help to ensure the quality of integrated care, also across borders. Unfortunately, these are largely accessible in ad hoc ways and result in scattered fragments of a solution space that urgently need to be brought together. At present, it is known that new initiatives and projects will reinvent assets of which they were unaware, while those assets which were potentially of great value are forgotten, not maintained and eventually fall into disuse. To address this problem the SemanticHealthNet project [2] identified the need for a recognised point of reference at a European level that would contain relevant material for guiding the definition, development and implementation of interoperable eHealth systems and ICT solutions in our continent. As a pioneer initiative to address this need, this research, carried out as part of the EXPAND project [3], aims to define, design and assess the development of a European Register able to contain, classify and quality assess any relevant material for analysis, design, implementation, adoption or benefits realisation of interoperability within eHealth environments, also known as interoperability assets (IA).

2. Method

This research study aimed to identify those relevant characteristics for the quality in use model that is described as the degree to which interoperability assets can be used by end users and developers to meet their needs to achieve specific goals with effectiveness, efficiency, freedom from risk and satisfaction in specific contexts of use. A set of quality metrics was defined and assessed based on the feedback and opinion of a representative sample of potential end users. The definition of functional requirements combined results from studying clinical information modelling processes [4] and tools [5] with two face to face workshops (Athens and Brussels) online meetings and surveys in order to maximise the number of experts involved. The information collected was applied to identify:

1. The types interoperability assets required to support cross border care
2. Elements needed in a quality framework for interoperability asset evaluation. Once quality evaluation framework was defined it was assessed through an online survey that requested participants to review of the defined descriptors, value sets including a set of examples of quality labelled assets.
3. The functional requirements for an IA register. The identified requirements lead to the implemented IA register that already contains an initial set of interoperability assets from some of the most relevant EU projects.

3. Results

3.1. *Types of interoperability assets*

Based on interactions of experts and potential users, the IA Register was implemented as an online register and discovery service for the following kinds of assets:

- Methodological, such as use cases, requirements specification, design guidelines, methodologies.
- Legal and organisational interoperability assets, such as frameworks, policies, agreement templates adoption guidelines, educational or training resources, governance frameworks.
- Technical & semantic interoperability assets, such as information models, XML schema, software, source code, clinical information models, terminology subsets, vocabularies, ontologies.

3.2. *Quality framework for interoperability asset evaluation*

The defined quality framework identified eight domains:

- **Development process:** refers to the process of defining and validating the evaluated asset according to how stakeholder engagement activities, quality assurance practices, evidence adopted and alignment with standards.
- **Maturity level:** refers to the readiness of an asset for operations in the specified scenario with a final objective of transitioning it to the user. This is evaluated according to the technical and domain completeness, the scale of asset application and market adoption.
- **Trustworthiness:** refers to the level of confidence and reliability of the asset according to the volume of users supporting the implementation and the organisations committed to implement it and make it available.
- **Support & skills:** evaluates how difficult could be to obtain the required skills to apply the asset according the background that end users require and the level of available support from documentation, training, tools and external commercial companies.
- **Sustainability:** evaluates how the asset contributes business value to the achievement of the targeted interoperability use cases, and what evidence exists for the size of the actual market and extensibility capabilities.
- **Semantic interoperability:** assess the capabilities of the asset to be computable by computer systems to exchange data with unambiguous, shared meaning. This is evaluated according to the technical specifications adopted and the level of adoption of international terminologies for the structure data and metadata.
- **Cost & Effort:** This domain refers to the evaluation of the resources required for asset implementation, maintenance, validation and use.
- **Maintenance:** refers to the processes adopted to support the evolution of the asset according to the updating process, problem resolution methodology and expected time response to incidents.

3.3. *Assessment of the proposed quality framework*

A total of 20 of the 33 invited experts participated in the survey. They had 17.20 ± 8.65 years of experience in their field. Most of them were considered health informatics experts (85.00%) that could be combined with complementary roles such as IT developer, business analyst, terminologist or decision maker. In addition, 3 of the participants had the following roles clinician, eHealth Strategist and decision maker without being recognised as health informatics expert.

Table 1. Overall evaluation

Overall evaluation	Agree	Neutral	Disagree
Register would be useful to discover interoperability assets	70.00	10.00	20.00
How important to make decision to use the interoperability asset	55.00	20.00	25.00
Recommend to use the register to your colleagues	70.00	25.00	5.00

3.4. Implementation of the interoperability asset register

The IA register has been implemented and it is accessible online [6]. The register includes the following functionalities. The register is open to individuals and representatives from the multiple organisations interested in eHealth. The collected interoperability assets and associated description will be accessible for any individual without the need for being logged in. Users can create their own account in order to allow them to register any interoperability resource that their organization has produced. The information collected about this interoperability resource (through self-declaration) will be used to provide an assessment of its quality according to the defined quality framework, which will be reviewed by an editorial board in charge of establishing and applying the governance policy over the interoperability assets. Moreover, the IA register allows users to interlink multiple interoperability assets that would be required to fit together to satisfy a specific use case or supporting the evolution of technical solutions, such as incorporating new assets that provide additional evidence, complement or supersede an existing asset.

It is planned that register will allow external organisations the possibility of hosting their own repository of assets if they adhere to consistent operating and governance rules. The register will include a published technical interface to permit multiple instances of the register to federate, and to permit other kinds of asset register or repository to import and export register entries in an automated or semi-automated way.

4. Discussion

4.1. Overall evaluation of the quality framework

70% of survey participants responded that they would recommend using the register to their colleagues, with minimal disagreement. This result provides promising information about the possible good acceptance of the proposed framework.

Moreover, a good sample of participants identified that the IA register could provide relevant benefits discovering new assets (70%) and supporting decision making (55%) about a suitable asset to adopt or implement in their organisation. Nevertheless, there were between 20-25% of participants who were reluctant to believe that the IA register could provide these benefits. They claimed that there is not enough evidence about the possible benefits of the register and the broad scope could impact on their acceptance.

After carrying out two workshops, direct consultations to more with more than 18 internal experts applying the quality framework for evaluating real interoperability assets and the assessment survey with 20 end users, it is determined that the level of

acceptance and support is sufficient to maintain and grow the IA register, so that further content could be added and a more substantial evaluation carried out in about a year.

It is recognised that the adoption of this proposed new methodology for asset discovery and assessment will require it to be implemented in real practice to strengthen the evidence of its value. Multiple factors such as the availability of valuable interoperability assets would impact on the capability of the register to include the desired benefits. The eHealth community only will use the register if they can find useful assets to be incorporated in their projects and programmes. As a limitation, it is recognised that this developed quality framework was primarily designed for the evaluation of technical and semantic interoperability assets. In the future, additional research is recommended to better characterize organisational and legal assets.

4.2. Implemented IA register

The classification of interoperability assets developed by projects and initiatives, through a consistent quality assessment framework, aims to benefit the eHealth community users by making it easier to discover those interoperability assets that could meet future project and organisational needs. Although the evidence of its potential value is still limited, several EU projects have expressed their interest in using the register, and additional promotion will be carried out by the the European Institute for Innovation through Health Data in the near future. The Register is expected to contribute towards the gradual harmonization of interoperable solutions across Europe.

References

- [1] European eHealth Interoperability Framework. <https://ec.europa.eu/digital-single-market/en/news/ehealth-interoperability-framework-study-0>
- [2] SemanticHealthNet project <http://semanticealthnet.eu/>
- [3] EXPAND project <http://expandproject.eu/>
- [4] Moreno-Conde, A., Moner, D., da Cruz, W. D., Santos, M. R., Maldonado, J. A., Robles, M., & Kalra, D. Clinical information modeling processes for semantic interoperability of electronic health records: systematic review and inductive analysis. *Journal of the American Medical Informatics Association*, **22**(2015), 925-934.
- [5] Moreno-Conde, A., Jódar-Sánchez, F., & Kalra, D. Requirements for clinical information modelling tools. *International journal of medical informatics*, **84** (2015), 524-536.
- [6] Interoperability Asset register <http://interoperabilityassets.ramit.be/>