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Joint Action to Support the eHealth Network

REPORT

on

Evaluation and good practice guide for eHealth specifications

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1. Purpose

This report forms part of Task 8.2 of the Joint Action on eHealth. The Description of Work describes the task as follows: "there is much to be gained from awareness of different approaches to specifying the requirements, and how to enable Member States MS in Europe to benefit from the experience of others. This task will source eHealth specifications from across the world, with a view to understanding developments and priorities in different countries, identifying lessons learned and examples of good practice".

The deliverables from this task are as follows:

D8.2.1 Inventory of eHealth specifications - (initial month of delivery: M7, November 2015);

D8.2.2 Evaluation and good practice guide for eHealth specifications - (initial month of delivery: M19, November 2016).

The sub-tasks include the establishment of a repository of specifications and also a good practice guide.

This document is D8.2.2 and provides advice and a good practice guide for eHealth specifications, including quality criteria and a proposed scoring scheme.

2. Scope

The deliverable D8.2.1 described the various types of output that contribute to the overall specification of a product or service.

This guide discusses processes for development and types of artefact and evaluation criteria for the subsequent use of "good" requirements and standards.

Section 3 introduces quality management standards as a basis for any development work and Sections 4 and 5 apply this to the production of specifications and standards.

Section 6 moves onto the subsequent assessment of artefacts for re-use.

Each asset is documented using a standard set of descriptors, developed through an examination of many current methods and metadata specifications for assets, complemented by a wide consultation with many experts, initiatives, SDOs and profile development organisations. These asset descriptors aim to inform a potential downstream user of important aspects of the quality of each asset, as well as specifying its purpose and functional characteristics. These asset descriptors cover the following areas:

- Development process
- Maturity level
- Trustworthiness
- Technical support and skills needed
- Sustainability
- Semantic interoperability
- Cost and effort
- Maintenance.

3. Quality Management

3.1 QMS

Organisations developing specifications would be expected to have formal process for managing quality. A quality management system is a way of defining how an organization can meet the requirements of its customers and other stakeholders affected by its work.

One common approach is to use ISO 9000 series of standards [6]. First published in 1987, ISO 9001 has been around for many years, but it is regularly updated to ensure that it remains relevant to today's business environment. In its latest version, ISO 9001:2015 incorporates elements such as a stronger focus on stakeholders and the wider context of an organization to fit the evolving needs of modern business. ISO 9001 is based on the idea of continual improvement.

ISO 9000 is a series, or family, of standards. ISO 9001 is a standard within the family. The ISO 9000 family of standards also contains an individual standard named ISO 9000. This standard lays out the fundamentals and vocabulary of quality management systems (QMS). The ISO 9000 family contains these standards:

- ISO 9001:2015: Quality management systems - Requirements
- ISO 9000:2015: Quality management systems - Fundamentals and vocabulary (definitions)
- ISO 9004:2009: Quality management systems – Managing for the sustained success of an organization (continuous improvement)
- ISO 19011:2011: Guidelines for auditing management systems

The standard is designed to be flexible enough for use by different types of organizations. For this reason, it does not specify what the objectives relating to "quality " or " meeting customer needs " should be. Instead, it requires organizations to define these objectives themselves and continually improve their processes in order to reach them.

3.2 Quality Management Principles

There are eight quality management principles which complement the ISO 9001 standard. These principles assist in setting a systematic and transparent quality management system. The management principles are as follows:

- Customer Focus – Organisations depend on their customers and therefore should understand current and future customer needs, meet customer requirements and strive to exceed customer expectations.
- Leadership – Leaders establish unity, purpose and direction of the organisation. They should create and maintain the internal environment in which people can become fully involved in achieving the organisation's objectives.
- Involvement of People – People at all levels are the essence of an organisation and their full involvement enables their abilities to be used for the organisations benefit.
- Process Approach – A desired result is achieved more effectively when related resources and activities are managed as a process.
- Systems Approach to Management – Identifying, understanding and managing a system of interrelated processes for a given objective improves the organisations effectiveness and efficiency.
- Continual Improvement – Continual improvement should be a permanent objective of the organisation.
- Factual Approach to decision making – Effective decisions are based on the analysis of data and information.
- Mutually beneficial supplier relationship – An organisation and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.

3.3 Overview

The QMS structure consists of six layers [Fig 1] for all Projects. A breakdown of each layer is described below:

http://9001quality.com/wp-content/uploads/2014/02/ISO-9001-4.2.4-contro_of_records_documentation_pyramid.bmp

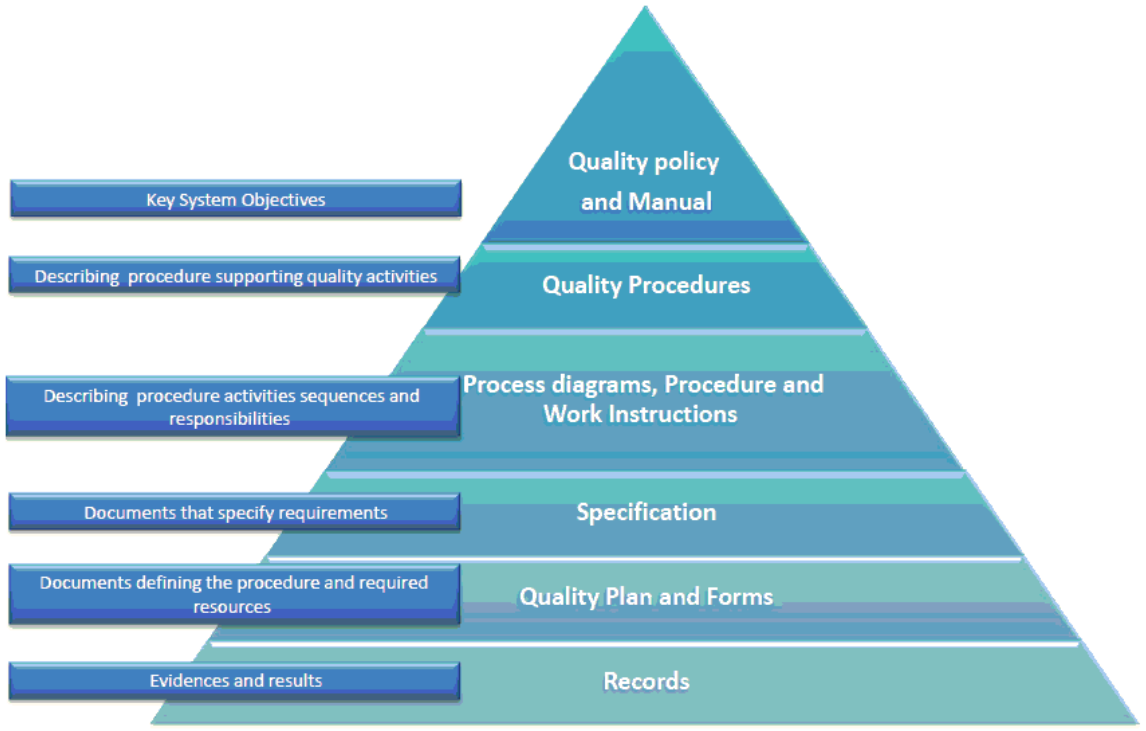

Figure 1. Layers of the Quality Management System

3.4 Quality Management Responsibilities

To achieve and maintain the required level of assurance there will be clear accountability for the overall Quality Management Strategy with routine operation overseen by named individuals. For each area of activity there would typically be:

- An oversight Board for the quality and delivery of products and services;
- A co-ordinator for providing review to achieve control and rigour;
- A named individual with day-to-day responsibility for quality for each product;
- The Quality Manager has responsibility for the maintenance of the Quality Management System.

4. Assessment in Development

4.1 Evaluation of Specifications

This section considers criteria and processes that might be adopted in the development of artefacts.

The evaluation of requirements needs to reflect the stage of the project; at each point, the requirements evolve into more detailed expressions but they are still requirements (vision, functional requirements, non-functional, design documents). So, for instance:

- Sponsor requirements are the 'vision' and the sponsor needs to be kept on board (business case held and managed by the portfolio team);
- Stakeholder requirements need to have a mechanism to fit with these key types and *vice versa,* generally captured in user stories and the agile process.
- Delivery requirements (including non-functional requirements) need formal requirements analysis and documentation (such as tracking releases, currently done by suppliers);
- Contract requirements need good co-ordination and consistency; and are constantly updated (the 'living document'); generally suppliers have their own systems for this, which need to be shared.

Each project would be expected to have clear, unambiguous, statements of requirement, uniquely referenced, supported by user scenarios to explain the context and meaning of the requirement and conformance criteria, by which functionality and features can be subsequently be tested and measured in live use.

In general, good quality requirements should establish a common understanding between the project sponsor, customers, developers and other stakeholders, thus improving customer confidence in the products to be delivered. Requirements would then provide a roadmap to development. As the project develops, the aim is for requirements to be traceable and to be maintained, reflecting any amendments along the way.

Both from a good practice and reputational point of view, requirements need to be baselined for each project. There needs to be traceability of requirements from definition, through procurement, development, implementation and maintenance. To manage across the enterprise, requirements also need to be consistent, accessible, consumable and re-usable.

Poor requirements have an adverse impact on a project. Typical characteristics of poor requirements include unclear or changing requirements, unmet or misunderstood requirements and requirements that have been assumed or missed altogether. The result is likely to have an adverse impact on any or all of cost, timescales, quality and clinical safety.

Many government projects got into difficulty because they attempted to complete requirements before going out to market almost inevitably leading to a bespoke solution rather than looking for a package that would meet "enough" of the requirements.

4.2 Standards

This section describes aspects relating to the high-quality development of standards.

The communication on ICT Standardisation (COM(2009)324) [7] identified a set of attributes that should be respected in standardisation processes:

1. Openness: The standardisation development process occurs within a non-profit making organisation on the basis of open decision making accessible to all interested parties. The open standardisation process is driven by the relevant stakeholder categories and reflects user requirements

2. Consensus: The standardisation process is collaborative and consensus based. The process does not favour any particular stakeholder.

3. Balance: The standardisation process is accessible at any stage of development and decision making to relevant stakeholders. Participation of all interested categories of stakeholders is sought with a view to achieving balance.

4. Transparency: The standardisation process is accessible to all interested parties and all information concerning technical discussions and decision making is archived and identified. Information on (new) standardisation activities is widely announced through suitable and accessible means. Consideration and response is given to comments by interested parties.

Moreover the following attributes should be reflected in the standards themselves:

a) Maintenance: Ongoing support and maintenance of published standards, including swift adaptation to new developments which prove their necessity, efficiency and interoperability, is guaranteed over a long period.

b) Availability: Resulting standards are publicly available for implementation and use at reasonable terms (including for a reasonable fee or free of charge).

c) Intellectual property rights: IP essential to the implementation of standards is licensed to applicants on a (fair) reasonable and non-discriminatory basis ((F)RAND), which includes, at the discretion of the IPR holder, licensing essential IP without compensation.

d) Relevance: The standard is effective and relevant. Standards need to respond to market needs and regulatory requirements, especially when those requirements are expressed in standardisation mandates. There is very little activity tracking the use of standards – and so evaluations of effectiveness and relevance are done on the basis of limited evidence. This impacts the development and effectiveness of standardisation mandates, as well as the standards themselves. There is therefore a great deal of value to be realised by establishing and maintaining effective metrics for the relevance of standards.

e) Neutrality and stability: Standards should whenever possible be performance oriented rather than based on design or descriptive characteristics. They should not distort the (global) market and should maintain the capacity for implementers to develop competition and innovation based upon them. Additionally, and in order to enhance their stability, standards should be based on advanced scientific and technological developments.

f) Quality: The quality and level of detail are sufficient to permit the development of a variety of competing implementations of interoperable products and services. Standardised interfaces are not hidden or controlled by anyone other than standard setting organisations.

5. Assessment in Selection

5.1 Requirements

This section proposes criteria and processes that might be used when considering the use of pre-existing specifications or standards.

Ensuring the quality of the assets used to support delivery of systems and services whether nationally or cross-border, is vital to the delivery of safe, timely, evidence-based health and care. Building on the work in EXPAND [1, 2, 3], quality issues may be seen from five perspectives:

- **Meeting relevant requirements:** the "fitness for purpose" of an interoperability asset critically depends upon that purpose. In order to properly assess whether an asset can now be used for a given purpose (e.g. for a given use case), it is important to know and match carefully the scope and purpose for which the original asset was developed, including what kind of end-user was envisaged and how the asset was expected to be used. In the case of health care such scoping may include which care settings, clinical domains and care scenarios (care pathways) were targeted. Examples might include: meeting policy mandates, meeting the end user needs, demonstrating that they meet the needs of patients and healthcare professionals. This implies on-going engagement and involvement by the relevant users at all stages to allow them to contribute to specification and development.

- **Quality development processes:** the asset itself should have been developed through a process of good quality. This includes ensuring that the best possible evidence and experience was used in its design. In the case of health informatics assets, especially semantic interoperability assets, this includes ensuring that relevant clinical evidence was used to ensure that the semantic content is correct. This means consulting published literature, authoritative guidelines (preferably those published at a European level) and engaging key opinion leaders and stakeholder groups to provide requirements input and to critique the evolving and final versions of the asset. These quality processes should be transparently documented, and made available along with the assets itself to any party wishing to assess its use in a new context. A formal quality process may have been used for the development itself, which usually requires the formalised documentation of an iterative process involving assessment checkpoints before progressing to each successive

phase of the development life cycle. There are a number of different published and well respected quality processes that might have been used.

- **Technical quality:** in addition to having been well-designed, it is an important that the asset has also been well made. The most appropriate technical quality processes will vary depending on the kind of asset being developed, but will often include software development practices and the adoption of relevant ICT and/or health informatics standards. Not all assets are made to the same level of robustness: assets intended for adoption in real healthcare settings will inevitably need to be more robust than those developed for research prototype use. For transparency and to ensure that no future user is misled as to the extent of completeness and robustness of the asset, there should be documentation which confirms the extent to which a design specification has been implemented (fully, or which parts) and what testing has been undertaken including software safety testing. Since interoperability assets are only rarely used in isolation, both the design and testing should indicate what other complementary interoperability specifications this asset is known to work alongside. This may include use with security components, since many interoperability assets will deal with patient level data that needs to be capable of being processed and communicated securely. Another important aspect of technical quality is maintenance. The asset should be handled with a formal version management process, making clear to any potential user which is the latest version, and a mechanism for the user to determine if any later version is subsequently produced and how it differs from a version they may have already adopted. It ideally should be clear to any future user whether the asset has been maintained since its original production, and what ongoing maintenance effort is expected to be needed by any future user. All of the above technical quality points are well known to the software industry, and largely adopted seamlessly. However, a number of assets have originated from research projects or other parties who are not professional software developers, and any subsequent user of an asset must therefore take responsibility to check that the appropriate technical quality processes have been followed

- **External quality assurance:** assets are sometimes curated and published by bodies that did not themselves develop the asset, and/or who may have sponsored its production. Such bodies may themselves undertake endpoint quality assurance processes to encourage trust in its wider use. Other (user) organisations may provide subsequent endorsement of

an asset or of a product that has successfully used the asset. This endorsement may come from deployment reference sites, professional bodies, health insurers or health ministries, or through a standardisation process that has taken up and balloted an asset internationally.

- **Adoption, scalability and sustainability: t**here are a number of other considerations that will influence whether a seemingly ideal asset can, in practice, be used in a new context by a new user or community or service. This will include the language or languages and formats in which the asset is made available, its IP and licensing arrangements. If the asset is not available in a suitable form, the potential new user will need to know if a further investment can be made to add new functionality, a further language or carry out a technical enhancement: if this is technically possible, and if it is permitted under the licensing arrangements. A further consideration when deciding whether to reuse an asset may be if it has already been widely adopted, has a strong user community, if there is expertise that may be consulted or employed to support its adoption and use, and if there is already any evidence of beneficial impact to earlier adopters.

5.2 Standards

A further set of criteria might be needed where potentially competing standards need to be compared to identify the most suitable. The list below was used by epSOS to determine appropriate code systems to be used for the patient summary dataset:

- **Internationally Used:** An international code system such as those released by ISO or WHO, for example, has the advantage that it was elaborated by experts having vast experience with terminology implementation and application. The internationally used code systems have implementation guideline that are used at a national level, as well as maintenance guideline. The code system used in the Value Sets Catalogue must be internationally recognized. The suitability should be evaluated by experts in the field, both medical and non-medical.

- **In Use:** The second most important criterion in selecting the code system is its use in the Member States. A survey was conducted among the experts working on the epSOS Value Sets Master Catalogue in order to have an accurate representation of the code systems used in each country.

- **Existence of translation in Different Languages:** The existence of translations into different languages is another key element to be evaluated, since it will dramatically reduce the activity of translating the Value Sets Catalogue terms into the local (national) language. If a code system exists in the local (national) version, it is likely that existing translations have been already validated / certified and kept aligned when newer versions are released.
- **Has a Maintenance Process:** A code system that has an official maintenance process is highly desirable. The release of new versions should be taken into account during deciding process. The maintenance process should include specifications for distribution and support.
- **Existence of Transcoding Systems / Services:** The existence of officially defined or at least of consolidated systems / services to perform transcoding from one code system to another one is a desirable element in order to reduce costs and risks. However it is known that this is an important issue that most Standard Organization Bodies are struggling with. Nevertheless, whenever official attempts exist to map one code system to another it is considered very useful as this provides guidance for mapping.
- **Cost of licenses, implementation and maintenance:** Although for research purposes most of the code system licenses are provided for free, the cost might prove to be prohibitive. In addition to the cost of the licenses, the cost of the implementation and maintenance need to be considered.
- **The code system must be easily implementable:** The code system must be easily implementable based on a sound methodology which takes into account both the syntactic and vocabulary aspects.

6. Application to the Inventory

6.1 Asset Descriptors

Based on the previous sections, and in discussion with the team involved in building the EXPAND repository, a set of descriptors has been defined (see Annex A). Aligning with the asset descriptors introduced in D8.2.1, these additional items provide quality criteria in order to be able to test this framework for asset evaluation. The spreadsheet form will be used to evaluate the proposed domains, descriptors and graphical representation, before being implemented as an online register and database. This spreadsheet is organised in 11 domains that are classified into two groups:

- **Domains to support asset discovery and provenance information**. This group includes three domains, represented in a white background colour. They include the description of the purpose and recommended usage, enabling new users external to the asset's development team to determine if the specific asset is suitable to be reused in their projects and systems. Additionally, these descriptors provide information about access to the asset, detailing the organisation that developed the asset and the one that now hosts the asset.
- **Quality metrics.** This set of domains is presented on a pink background colour, and are designed for evaluating the most relevant characteristics that would determine the impact of the asset adoption. Some of these metrics evaluate current performance according to the robustness of the development process, the level of maturity, trustworthiness based on the level of endorsement and communities of use and semantic interoperability capabilities. They are complemented with an evaluation of the impact on an organisation adopting the asset, based on the available level of support, skills required, cost & effort foreseen and maintenance requirements.

All domains include multiple descriptors corresponding to the most representative metrics that are useful to support decision for adopting, reusing or modifying the selected asset. Descriptors are evaluated with a drop-down list that details multiple options ordered according to their level of fulfilment.

6.1 Graphical Representation

A radius diagram representation is automatically calculated according to the answer weights to display the performance of the selected asset in each of the defined quality domains. This representation shows the average fulfilment of the selected asset for each descriptor included in the corresponding domain. Annex B provides an example in which the cross-border Patient Summary for unscheduled care has been assessed.

Further examples were provided in the EXPAND deliverable D4.2 Quality labelling criteria for European eHealth interoperability resources [2]

Annex A: Quality Indicators

The table below gives an example scoring scheme for the criteria. Each option has assigned a weight with % score attached.

	Criterion	Measures	%
200	**Development process**		
201	Evidence used		
		Formal guideline	100
		Supporting references	75
		regional/national practice	50
		local practice	25
202	Consultation process		
		public consultation	100
		multi-stakeholder consultation	75
		peer review	50
		domain experts consulted	25
203	Conformance to standards		
		Conformant	100
		partially conformant	60
		aligns	30
204	Quality processes used		
		External quality process based on (e.g.) ISO9000	100
		External quality control process	75
		Internal quality control process	50
		No verified quality control	0
300	**Maturity level**		
301	Technical completeness		
		live in > 3 sites	100
		conformance tested	75
		validated in equivalent setting	50
		proof of concept	25
302	Domain completeness		
		Full coverage for multiple domains	100
		Full coverage of the stated domain	75
		Partial coverage of the stated domain	50
303	Adoption scale		
		cross-border	100
		National	75
		regional	50
		local	25
304	Market adoption		
		adopted by global vendors	100
		adopted by national vendors	75
		adopted by SMEs	50

400	**Trustworthiness**		
401	Endorsements		
		national policy	100
		national guidance	75
		regional policy	50
		local practice	25
402	Reliability of access		
		long-term commitment by asset owner	100
		short-term commitment by asset owner	70
		temporary asset owner	30
		no owner	
403	Communities of use		
		user and developer communities	200
		user community	75
		sources of knowledge available	50
		developer available at cost	25
500	**Support & skills**		
501	Extent of documentation and training		
		documentation and certified training with examples	100
		documentation and training program with examples	75
		documentation with examples	50
		documentation	25
502	Extent of tool guidance		
		tools to support the definition, validation and certification	100
		tools to support the definition and validation	70
		tools to support the definition	30
503	Commercial Support		
		third-party support 24/7	100
		third partly support office hours	50
504	Skills required		
		no previous skills required	100
		general background required	75
		specialist background required	50
		trained specialists required	25
600	**Sustainability**		
601	Viable business model		
		established adoption model	100
		formal business plan	75
		business model	50
		propositions	25
603	Extensibility		
		designed to be regularly extended by others	100
		designed to be extended by others	75

		designed to be extended by others but without review cycles	50
		other examples to refer to	25
700	**Semantic interoperability**		
701	Clinical information model specification		
		standard	100
		specification	70
		local	30
702	Clinical information model terminology binding		
		all mapped to international standards	100
		some mapped to international standards	70
		all mapped to local standards	30
703	Value sets		
		all mapped to international standards	100
		some mapped to international standards	70
		all mapped to local standards	30
800	**Cost & Effort**		
801	Validation Cost		
		Third-party validation	100
		third-party tools	70
		own tools	30
802	Asset Cost		
		free for any purpose	100
		free for non-commercial use	70
		costs covered by formal agreement	30
803	Effort for required implementation		
		little mapping required	100
		some mapping required	75
		much mapping required	50
		full configuration required	25
804	Maintenance effort		
		Minimal	100
		effort required	50
900	**Maintenance**		
901	Problem resolution by the asset custodian		
		prioritisation with users	100
		Prioritisation by team members	50
902	Updating process		
		frequent (6 month) updates	100
		regular updates	75
		new releases at some point	50
903	Response to incidents by the asset custodian		
		SLA in place	100
		potential to fix	50

Annex B: Example of Patient Summary

The proposed structure also allows for an overview assessment of maturity. This Annex provides a worked example of the cross-border Patient Summary for unscheduled care.

Asset name	epSOS Patient Summary
Asset type	Technical / information model
Use cases supported	Patient summary, chronic diseases, continuity of care
Scope/purpose	Supporting cross border access to patient information for emergency purposes
Domain coverage	Trauma (Emergency, Injury, Surgery)
Targeted user groups	IT developers

The assessment was carried out prior to the establishment of the eHealth Member States' Expert Group. A re-assessment might indicate different scores (e.g. for maintenance), but the intention here is to give an example.

	Criterion	**Measures**	**%**
200	**Development process** Fairly good. It could be improved with external quality assurance and open consultation. Moreover it is based on common practice but not supported by guideline (we expect that in future guidelines will promote the use of information models)		
201	Evidence used	regional/national practice	50
202	Consultation process	multi-stakeholder consultation	75
203	Conformance to standards	Conformant	100
204	Quality processes used	Internal quality control process	50
300	**Maturity** Maximum level based on the implementation on multiple countries, full coverage of the multiple domains addressed		
301	Technical completeness	live in > 3 sites	100
302	Domain completeness	Full coverage for multiple domains	100
303	Adoption scale	cross-border	100
304	Market adoption	adopted by global vendors	100
400	**Trustworthiness:** It has the support of national healthcare providers but it is not sure who will support this asset in the future and there is not a community of support		
401	Endorsements	national guidance	75
402	Reliability of access	temporary asset owner	30
403	Communities of use	user community	75
500	**Support & skills:** There are certified training programs, technical documentation and examples but this documentation is directed for experts in the selected specification and there is not commercial IT support for the selected specification		
501	Extent of documentation and training	documentation and training program with examples	75
502	Extent of tool guidance	tools to support the definition, validation and certification	100
503	Commercial Support	no support	0
504	Skills required	specialist background required	50
600	**Sustainability:** short-term measures in place (but note subsequent developments		

	through CEF)		
601	Viable business model	business model	50
603	Extensibility	designed to be extended by others but without review cycles	50
700	**Semantic interoperability:** maximum level		
701	Clinical information model specification	standard	100
	Clinical information model terminology binding	all mapped to international standards	100
702	Value sets	all mapped to international standards	100
800	**Cost & effort:** This specification is free and certification can be done by third party but it requires to implement a large volume of clinical concepts and it is recommended to include cost for maintenance		
801	Validation Cost	Third-party validation	100
802	Asset Cost	free for any purpose	100
803	Effort for required implementation	much mapping required	50
804	Maintenance effort	effort required	50
900	**Maintenance:** change management is directed without collecting open consultation from end users for prioritisation, uncertainties about the future release process and there is not maximum time to address incidents and problems with the specification		
901	Problem resolution by the asset custodian	Prioritisation by team members	50
902	Updating process	new releases at some point	50
903	Response to incidents by the asset custodian	potential to fix	50

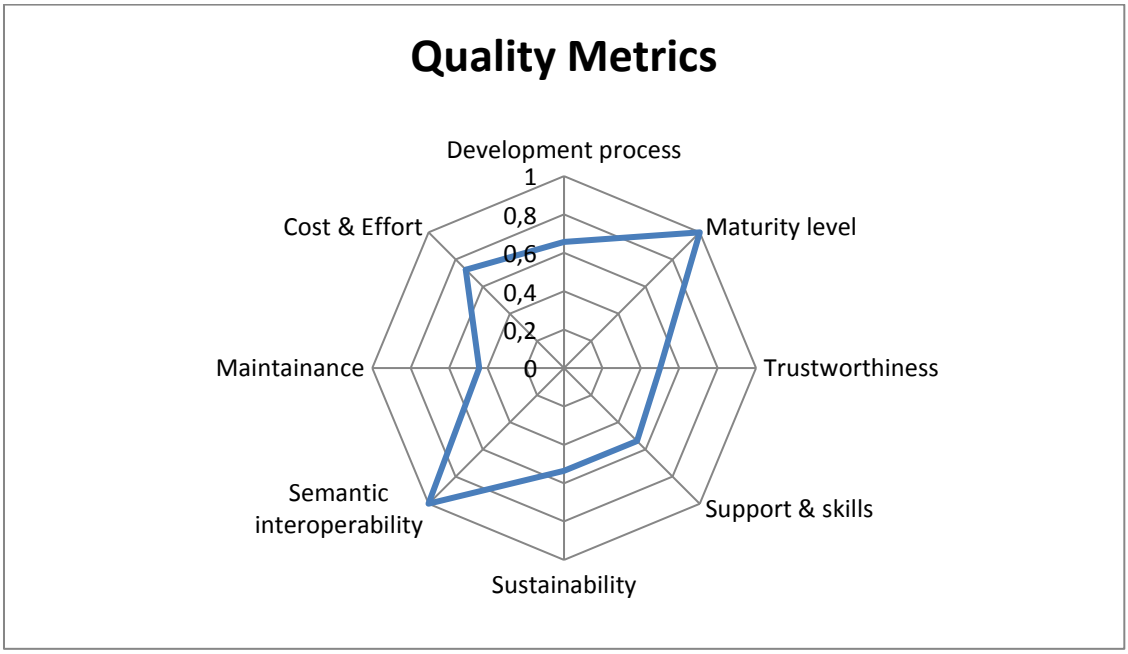

Figure 2. Graphical representation of epSOS patient Summary quality evaluation

Annex C: References

[1] EXPAND: D4.1 Classification of, and inclusion criteria for, European eHealth interoperability resources, WP 4 Assessment model, 14-11-2014 , Version 1.0

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