Refinement of the eHealth European Interoperability Framework (ReEIF)

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Appendices

In a separate document three appendices are included:

A. From EIF model to the refined eHealth EIF model
B. Example of a use case description
C. Glossary of terms

1 Purpose of this document

The objective of this discussion paper is to introduce a common refined framework for managing interoperability and standardization challenges in the European eHealth domain. This framework for interoperability is based upon the output of the Antilope project[1] (and specifically deliverable D1.1) that was closed in Q1 of 2015. The Antilope project took the eHealth European Interoperability Framework (eEIF) as a starting point. The eEIF in its turn should be seen as derived from the society-broad European Interoperability Framework (EIF), tuning EIF more specifically to the eHealth domain. The resulting refined eEIF (ReEIF) will be proposed for adoption on the 8th eHN meeting in November 2015. The ReEIF is expected to be of great structuring value for the decision making process on projects and solutions for eHealth.
The members of the eHN are asked to give guidance to and to provide feedback on the expected value of the Refined eHealth European Interoperability Framework on a European and national level to be endorsed.

2 Introduction

Interoperability has been identified as one of the greatest challenges in healthcare IT. It is about bringing to life fruitful collaborations between different healthcare environments, with electronic means. The use of standards is essential in this context, but more is needed than just standards. The importance for the eHealth Network of enhancing interoperability in the eHealth domain is reflected in the *Multi Annual Work Plan 2015-2018* and in the *Joint Action*. In order to realise the ambitious interoperability and standardisation objectives of the eHN (JA), it is important to create and adopt a common multi-level perspective on this field of work. Achieving eHealth interoperability on a cross border, national or regional level starts with an interoperable frame of mind that reflects the most important areas of interest.

This document offers modelling of the interoperability world in order to create an environment to describe and discuss interoperability problems and solutions. It supports the (latent) need for a framework for eHealth interoperability, building upon and offering a refinement of the eHealth European Interoperability Framework (eEIF) as published by the European Commission in 2013. The refined eEIF (ReEIF) contains a number of “tools” that can be used in solving and discussing interoperability challenges and could be a valuable supporting instrument for the members of the eHN.

First of all, the framework describes the plotting of the interoperability world into a six level model, with actors and activities on each level. Secondly, a template for the uniform description of the use cases, and for their accompanying realisation scenarios, is given. These templates help providing a consistent set of clinical problem descriptions, (which *use cases* basically are). The third asset of the ReEIF is a glossary of terms, for unifying ‘language’ and improving understand-ability.

Chapter 3 is an introduction to interoperability issues in general, chapter 4 provides some background information on the European Interoperability Framework, and its tuning to

[1] http://www.antilope-project.eu

eHealth. In chapter 5, three tools of the Refined eHealth European Interoperability Framework are explained. Chapter 6 provides conclusions and discussion topics.

3 Interoperability in healthcare

Before introducing the interoperability framework and its components, some extra attention is paid to the term “interoperability”. It is generally accepted that improving the ability of organisations, eHealth solutions, systems or entities to work together (i.e. improving their interoperability) enables healthcare professionals to work together in the interest of their patients, increasing the quality and continuity of care through shared knowledge and enabling a more efficient use of that information in the healthcare process.

Interoperability achieves these ends by providing a number of specific benefits:

- It increases flexibility, by allowing the “mix and match” of components.
- It increases cost-effectiveness, by allowing the reuse of existing components and capabilities.
- It creates virtually integrated systems that are easier to use across organisations and countries / regions.
- It facilitates the creation of new capabilities, by composing new functions out of existing ones.

The concept of interoperability is commonly seen as one of the key drivers of eServices in general and eHealth in particular. In practice, this is reflected in the many people, policy documents, projects, activities and solutions aiming to enhance interoperability as an important means to the ends. However, interoperability has the abstract characteristic to become a panacea for the challenges in eHealth. In order to be aware of this fallacy and to create a clear understanding of “interoperability” two relevant perspectives of the concept are presented.

First the difference between “interoperability” and “operability” is elaborated. Secondly “small” and “broad” interoperability is stipulated and a proposal for a definition is presented. Both perspectives represent frequent misinterpretations but do not represent all fallacies and provide valuable insight for the development and use of an eHealth European Interoperability Framework.

3.1 Operability versus Interoperability

In the terminology used here, the word operability means the way (parts of) organisations are set up in terms of different aspects like care processes, information structure, etc., in order to provide healthcare services in their specific domain. Interoperability then is the next step: it is used for the situation in which two organizations are lined up to work together in order to provide collaborative healthcare. This lining up requires activities and arrangements, as well on human levels as on more technical levels of information structuring and electronic

communication. It should be noted that the partners in interoperability can be similar in nature (*e.g.* two countries, two hospitals), or dissimilar (*e.g.* a hospital and a community pharmacy).

3.2 Narrow versus Broad Interoperability.

The narrow definition involves the ability of information and communication technology (ICT) systems to communicate with each other so as to utilise each other's capabilities, or to provide composite capabilities to their human users. Even this narrow definition involves compatibility on a number of different levels, from the lowest network communication protocols to the highest semantic interpretation of each system's terminology, computations and results.

A broad definition of interoperability involves more than just ICT systems. From this perspective, interoperability among ICT systems is a means to the end of enabling agencies, organizations, groups of users, municipalities, regions, or even nation states to interact with each other more efficiently and effectively. The overall purpose of interoperability is to improve these organizational and healthcare interactions.

Although this broad view of interoperability provides important context, an Interoperability Framework (IF) is typically thought of as a specific set of standards, protocols, procedures, and policies aimed at helping professionals and patients improve the interoperability of the eHealth solutions that they design, implement, use and evaluate.

Definition of Interoperability Framework[2]:

'Interoperability, within the context of European public service delivery, is the ability of disparate and diverse organisations to interact towards mutually beneficial and agreed common goals, involving the sharing of information and knowledge between the organisations, through the business processes they support, by means of the exchange of data between their respective ICT systems.'

In summary, interoperability is only established when information is exchanged between actors, understood and used for the purpose it is shared.

Both perspectives on "interoperability" represent the main vision on the value creation of eHealth in an international and national setting. Typically this vision is not only applicable to the eHealth sector but the healthcare domain is very complex (in terms of organisational structure, semantic models and application landscapes) and addresses therefore the need for a meaningful and useful framework on eHealth interoperability.

[2] http://ec.europa.eu/isa/documents/isa_annex_ii_eif_en.pdf

4 European Interoperability Framework and eHealth

4.1 The European Interoperability Framework (EIF)

The **European Interoperability Framework** (EIF)[3] is a set of recommendations which specify how Administrations, Businesses and Citizens communicate with each other within the EU and across Member States borders. The first version was published in 2004. The second version, EIF 2, was adopted by the European Commission as the *Annex II - EIF (European Interoperability Framework)* of the *Communication "Towards interoperability for European public services"* on the 16th of December 2010.

The purpose of the European Interoperability Framework (EIF) is:

- to promote and support the delivery of European public services by fostering cross-border and cross-sectoral interoperability;
- to guide public administrations in their work to provide European public services to businesses and citizens;
- to complement and tie together the various National Interoperability Frameworks (NIFs) at European level.

The EIF contributes to the better functioning of the internal market in the EC by increasing interoperability among European public administrations.

4.2 eHealth European Interoperability Framework (eEIF)

In terms of the health and care of European citizens, continuity of care (otherwise referred to as integration of care) is a particularly important domain. Interoperability is needed both in healthcare, and in terms of the supporting information and communication technologies.

The eHealth EIF is positioned as an operational tool kit for implementers and purchasers to deploy eHealth systems. It is intended to be used as a reference guide in calls for proposals and tenders for the Connecting Europe Facility (CEF) deployment, but possibly also for deployment at the national and regional levels. The vision is that the eHealth EIF will be leveraged by the eHealth Network for eHealth deployment that takes place in Member States. The high-level concepts are its governance, principles, agreements, interoperability levels, and high-level use cases.

[3] See: European Interoperability Framework (EIF) for European public services, http://ec.europa.eu/isa/documents/isa_annex_ii_eif_en.pdf

5 Refined eHealth EIF (ReEIF)

One of the assignments for the EC Antilope project was to deliver a refinement to the first version of the eHealth European Interoperability Framework, to extend and refine the set of tools provided by the framework. This framework provides, among other things, an overview of possibly relevant use cases and appropriate links to the existing and available profiles from the major international consortia in the area of standardisation and interoperability.

Three tools are presented here: a refined model for interoperability, a template for the description of high-level use cases, and a glossary of terms and definitions.

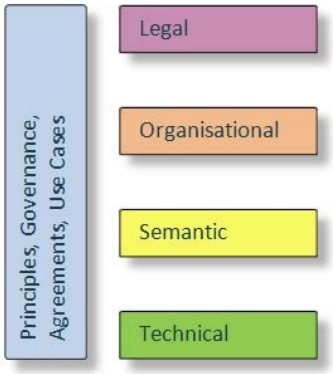
5.1 Refined interoperability model

Interoperability involves many different aspects that have to be taken into account. Aspects such as legislation and guidelines, contracts and agreements between exchanging parties, governance and maintenance, shareable workflows, standardised data elements, semantic and syntactic choices, technical infrastructure, and safety and privacy issues all play a part. Only when all these aspects have been taken into account, and when all stakeholders are involved in the process, implementation can be successful.
A shared model for these interoperability levels is introduced. It is a non-technical model that can be adopted by all stakeholders and participants (policy- and decision makers, IT architects and managers, information analysts, healthcare professionals, software vendors, technicians etc.)

For the refinement of the eEIF, the new interoperability model should:

- Provide an overview of the different levels of interoperability.
- Be understandable for all stakeholders involved in interoperability discussions - technical terms should be avoided.
- Show the relationship between the different levels of interoperability.
- Show examples of the different parts, within the schema.
- Show the stakeholders involved in the different levels of interoperability.
- Build upon existing interoperability models.

The refined eHealth EIF model is an extension of the original EIF model, which exists of four main levels:



The refined model splits two of the original levels into two, yielding six levels:

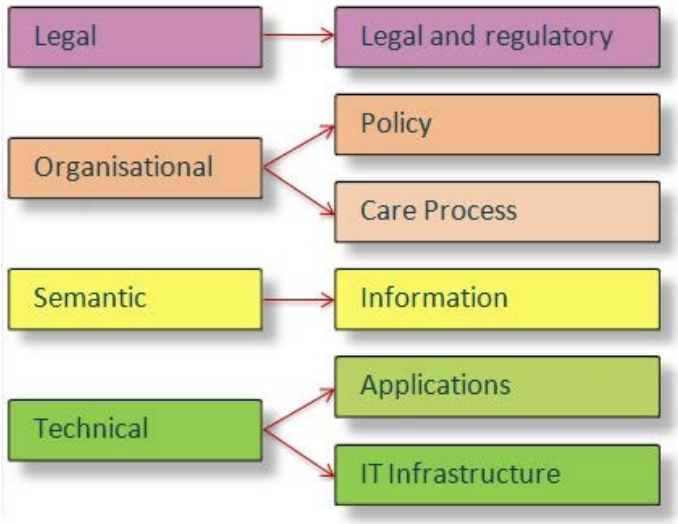


Figure 3: refinement of the EIF model from four to 6 layers

The reason for this splitting is the following:

- The Organisational level is split into Policy making (on the organisational level) and Care execution, because these levels require different actors and responsibilities.
- The Technical level is split into Applications (*i.e.* health-specific technology), and IT infrastructure (*i.e.* general technology, servers, networks, etc.), because these levels again have different responsibilities, and obey to different classes of standards.

The resulting model is shown below:

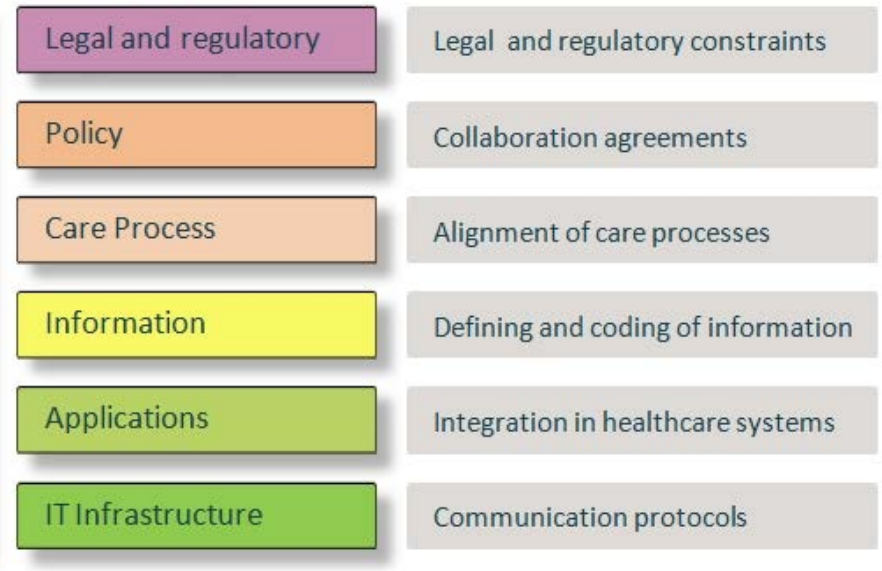


Figure 4: refined eEIF (ReEIF) model

In the following table, the six interoperability levels are explained in more detail.

Legal and regulatory	On this level, compatible legislation and regulatory guidelines define the boundaries for interoperability across borders, but also within a country or region.
Policy	On this level, contracts and agreements between organisations have to be made. Trust and responsibilities between the organisations are formalized on the Policy level.
Care process	After the organisations have agreed to work together, specific care processes are analysed and aligned, resulting in integrated care pathways and shared workflows. This level handles the tracking and management of the workflow processes.
Information	This level represents the functional description of the data model, the data elements (concepts and possible values) and the linking of these data elements to terminologies that define the interoperability of the data elements.
Applications	On this level, agreements are made about the way import and export of medical information are handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards). The information systems must be able to export and import these

	communication standards. Another aspect in this level is the integration of the information and knowledge in a user-friendly way.
IT Infrastructure	The generic communication and network protocols and standards, the storage, backup, and the database engines are on this level. It contains all the “generic” interoperability standards and protocols.

Two extra model representations are shown below. These provide extra information about the different aspects of interoperability.

The first one shows the alignments that are necessary on the different levels of interoperability:

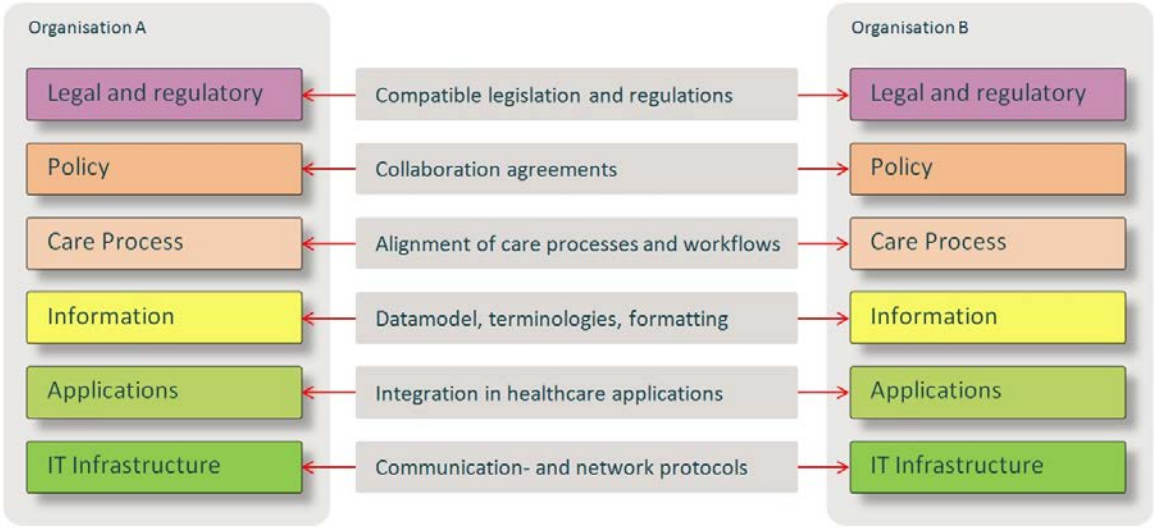


Figure 5: refined eEIF (ReEIF) model – alignment activities between organisations

Another possible representation shows the stakeholders who can be involved in the different levels of interoperability:

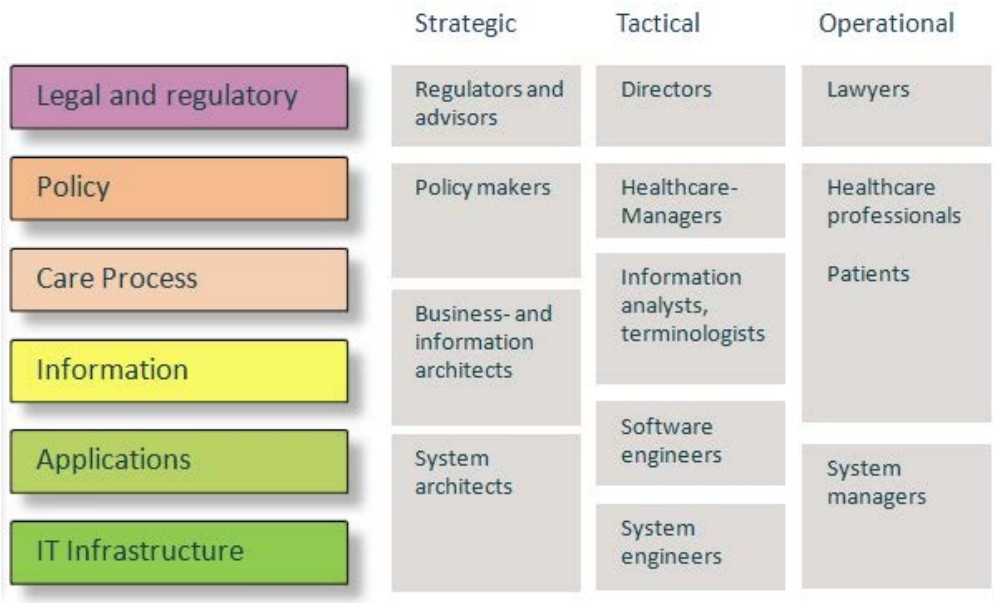


Figure 6: refined eEIF (ReEIF) model – stakeholders

Other representations in the "grey part" may be used - for instance, the use of standards and profiles in the different levels for specific use cases.

The basic purpose of the eEIF model is to explain to different stakeholders that interoperability needs cooperation and effort on different organisational levels and requires different levels of expertise. It avoids technical terms, making the model understandable by all stakeholders. For maximum readability, localised (translated to the language of the country) versions may be defined. At the time of publication, several countries have already adopted the refined eEIF model and translated the terms in the different languages (Dutch, Danish and Portuguese at this time).

In Appendix A a rationale and explanation of the refined eEIF (ReEIF) model is given.

5.2 Template for the description of high-level Use Cases and Realisation Scenarios

In the Antilope project, a number of recognisable healthcare processes (high-level use cases) have been worked out. Below is a list of these use cases:

#	Medical domain	Description
1	Medication	e-Prescription and e-Dispensing
2	Radiology	Request and results sharing workflow for radiology
3	Laboratory	Request and results sharing workflow for laboratory
4	Patient Summary	Patient Summary sharing
5	Referral- and Discharge reporting	Cross-enterprise Referral and Discharge Reporting
6	Participatory healthcare	Involvement by chronic patients in electronic documentation of healthcare information
7	Telemonitoring	Remote monitoring and care of people at home or on the move using sensor devices
8	Multidisciplinary consultation	Medical Board Review

For the description of these high-level use cases, a template has been designed, so that all use cases can be described in the same manner. A distinction has been made between the functional description of the process (Use Cases), and a translation into technical process steps (Realisation Scenarios).

The template for the description of a use case is given below:

Title	Title of the Use Case
Purpose	The Purpose describes the main functionality of the use case – what is it, what does it do?
Relevance	The Relevance explains the “why” of the Use Case. It describes the rationale of the Use Case: both medical (what problem does it solve?) and economical (business case, costs and benefits)
Domain	The functional domain of the Use Case. For the Antilope project, the following domains have been used: • Medication

	• Radiology • Laboratory • Patient Summary • Referral and Discharge Reporting • Participatory healthcare • Telemonitoring • Multidisciplinary consultation
Scale	Organisational dimensions of the Use. The following scales have been defined for the Antilope Use Cases: • Cross-border • National/Regional • Intra-organisational • Citizens at home and on the move
Context	Describes relevant aspects and influencing factors on the non-technical level
Information	High-level description of what type of information is shared, like "patient summary" or "medication prescription"
Participants	List of the main participants in the process. These can be individuals or organisational units. They are real-world parties.
Functional process flow	Real-world, functional description of a sequence of interactions between the participants in the different interaction steps of a process

And the template for the description of a Realisation Scenario:

Title	(Number and) Name of the realisation scenario.
Related Use Case	Use Case identifier and name that this Realisation Scenario is related to.
Scenario context	Information and background about the real-world scenario.
Actors	List of the main participating systems, also (confusingly) called Actors, in the process. In this context, an Actor is an ICT system, as opposed to a participant (see above). Actors are involved with each other through transactions.
Transactions	Interoperability workflow steps describing the process steps between systems.
Technical process flow	A numbered list of process steps (optionally accompanied by a schematic overview), describing transactions between systems (actors), and the information "units" that are exchanged. The technical process flow describes the interoperability steps, i.e. the steps between the systems, and not the steps within the systems. It can be linked to IHE and/or Continua Profiles.

	This part may also contain “swimming lanes” and other schemas.
Associated Profiles	Profiles that can be used in the realisation of the use case. The relevant profiles are listed for each interoperability layer (see Chapter 3.3). This list of profiles is meant as a guideline, showing directions to what profiles may be used for realisation of the use case. As an example, depending on national/regional legislation and norms, choices have to be made between for instance BPPC and / or XUA. In other words, the list of Associated Profiles gives direction to what profiles may be used, depending on the actual situation.
Possible issues	Issues such as legislation and guidelines, social acceptance, language issues, architectural flaws, et cetera, that may affect the realisation of this scenario.
Implementation examples	Real world examples of use case implementations. Different regions and countries can mention projects

Appendix B (in the Appendix document) shows an example of how these templates were used for the description of one of the high-level use cases.

5.3 Glossary of interoperability Terms and Definitions

Interoperability starts with a shared understanding of the terms that are used. Appendix C in the Appendix document provides a list of terms and definitions used in interoperability. The list is not exhaustive, and can and should be extended.

6 Conclusions and discussion

The ReEIF, as presented here, is general enough in its definition and scope to be useful for any cross-border, national, regional or local interoperability project in Europe. Consistently using it will bring unity of concepts, thus providing better and clearer communications between all parties involved: decision makers, health care providers, health professionals, architects, software providers, IT professionals, etc. The value of it has been proven by the usage of (parts of) the framework in different national and regional projects over Europe.

It is strongly recommended that any activity on interoperability starts with the description of the wanted outcome in terms of care processes, *i.e.* in terms of what patients and health professionals want to achieve with the interoperable solution to be created. This is where the use case description template comes into play, it will give a formal description of the use case as the starting point, and the template enforces completeness and homogeneity in the form of the description.
With this use case in mind the focus shifts to the content of the information, and the needed standards in terms of structure and semantics. Then the applications of both organisations should be aligned and an information exchanging document or message should be defined: containing the information needed and able to be read or generated by the applications, and meaningfully presented on the receiving side. Then the technical pathways for these information packages need to be defined in order to communicate correctly and safely.
In the meanwhile these use cases with their technical and financial consequences should be secured at the policy level between the two organisations (or regions, or countries, etc.) by making agreements, etc. Then, finally, everything should be checked against the legal and regulatory environment(s) relevant to the project.

The reason to bring this framework to the level of the eHN is twofold: first of all it gives the members of the eHN the possibility to bring this framework to the attention of relevant actors in their national environments, secondly this framework can also benefit the work of the eHN itself, by giving structure to documents, decisions, proposals, etc.

Of course, this framework is not a law in itself. It is a set of tools, helpful descriptions. And ways must be found to improve it over the years to come.