



eHealth Network

Refined eHealth European Interoperability Framework

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth. The Joint Action supporting the eHealth Network (JAseHN) provides scientific and technical support to the Network.

Adopted by consensus by the eHealth Network, Brussels, 23 November 2015

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I. Purpose

The objective of this paper is to present a common refined framework for managing interoperability and standardisation challenges in the eHealth domain in Europe. This framework for interoperability is based upon the output of the [Antilope project](#) (and specifically [deliverable D1.1](#) of that project) 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) described here is proposed for endorsement on the 8th eHN meeting in November 2015. The ReEIF is expected to be of great structuring value for the communication and decision making processes on projects and solutions for eHealth. It offers a framework of terms and methodologies for reaching a common language, a common starting point, for the analysis of problems and the description of eHealth solutions throughout Europe.

II. 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 (eHN) of enhancing interoperability in the eHealth domain is reflected in the Multi Annual Work Plan 2015-2018 and in the Joint Action for support of the eHN (JAseHN). In order to realise the ambitious interoperability and standardisation objectives of the eHN and JAseHN, 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 understandability.

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 eHealth.

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

III. 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 regions / countries.
- 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) organizations operate in line 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 utilize 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. Thus, as an important notice, broad interoperability addresses not only the organization of (technical) interoperability, but also the interoperability of (healthcare providing) organizations. It is this broad definition that is leading for this document.

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. The most general framework is the European Interoperability Framework (EIF), and in the EIF document interoperability is defined as follows:

Interoperability is the ability of disparate and diverse organizations to interact towards mutually beneficial and agreed common goals, involving the sharing of information and knowledge between the organizations, 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, understood and used by actors for the purpose it is shared, by policy level decision.

IV. European Interoperability Framework and eHealth

4.1 The European Interoperability Framework (EIF)

The **European Interoperability Framework** (EIF) 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. This document uses the following definition of an interoperability framework:

'An interoperability framework is an agreed approach to interoperability for organisations that wish to work together towards the joint delivery of public services. Within its scope of applicability, it specifies a set of common elements such as vocabulary, concepts, principles, policies, guidelines, recommendations, standards, specifications and practices.'

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 Health 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.

V. Refined eHealth EIF (ReEIF)

One of the assignments for the EC Antelope 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

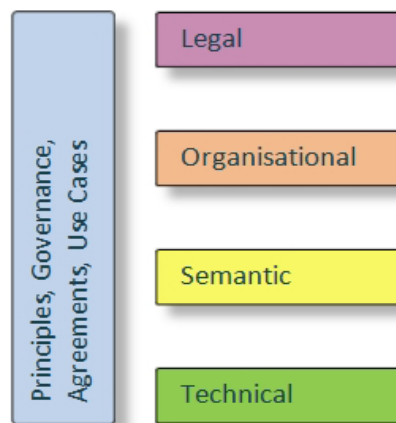
Interoperability involves many different aspects that have to be taken into account. Aspects such as legislation and guidelines, contracts and agreements between exchanging parties, governance and maintenance, shareable workflows, standardised data elements, semantic and syntactic choices, applications, 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:

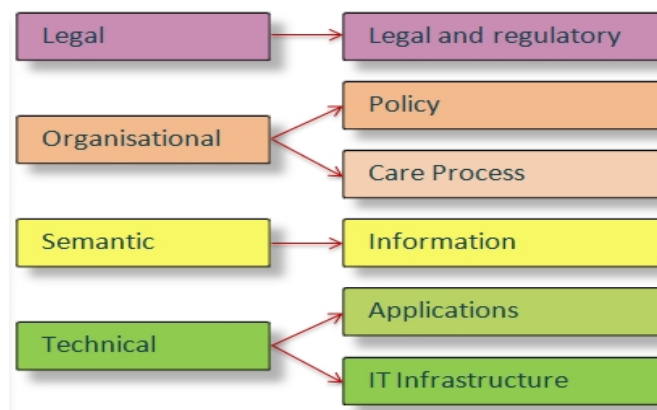


Figure 3: refinement of the EIF model from four to 6 layers

The reason for this splitting is the following:

- The Organisational level is split into Policy making (for the organisation at stake) and Care execution, because these levels require different actors and responsibilities. This policy level anchors the interoperability of organisations. The governance (of the collaboration) is also anchored at the Policy level, although affecting all levels of course.
- 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:

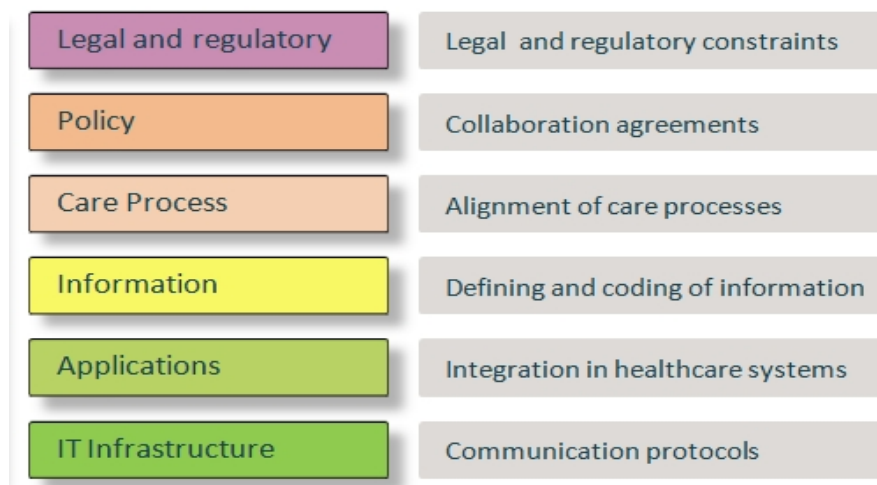


Figure 4: refined eEIF (ReEIF) model

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. The purpose and value of the collaboration must be set. Trust and responsibilities between the organisations are formalised on the Policy level. In governance documents the governance of collaboration is anchored.
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. The shared workflow prescribes which information is needed in order to deliver the integrated care.
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 using these communication standards. Another aspect in this level is the integration and processing of exchanged information in user-friendly applications.
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:

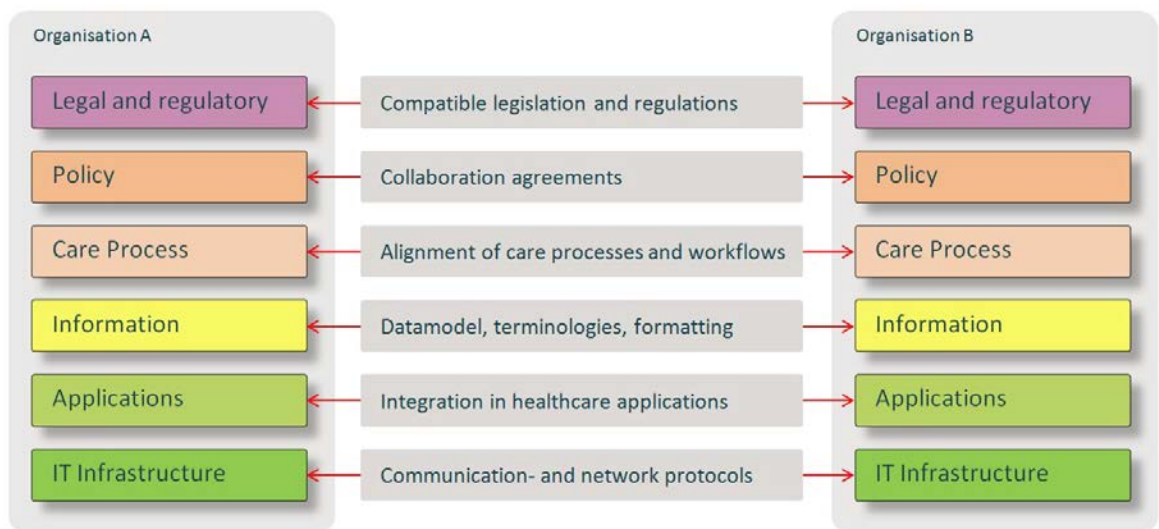


Figure 5: refined eEIF (ReEIF) model – alignment activities between organisations

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

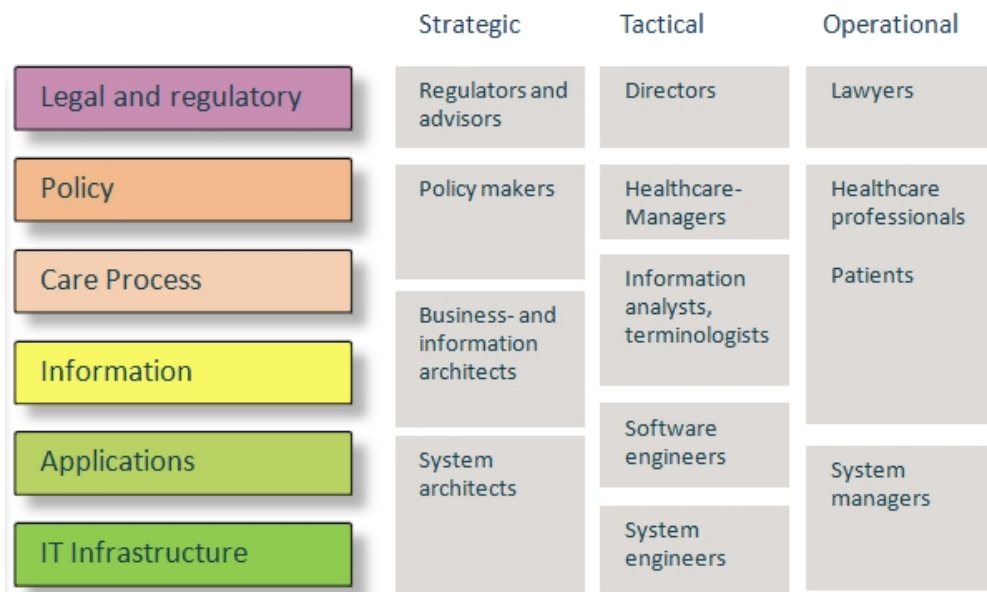


Figure 6: refined eEIF (ReEIF) model – stakeholders

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. Even this 6-layer model can be used to decide on the competences needed for the various activities in interoperability projects.

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 of this document (November 2015), several countries have already adopted the refined eEIF model and translated the terms in the different languages (Dutch, Danish and Portuguese).

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 examples of eHealth interoperability cases have been worked out (further called 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). These templates can be used as a toolkit supporting each eHealth use-case in the realisation and elaboration of interoperability.

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: <ul style="list-style-type: none"> • Medication • Radiology • Laboratory • Patient Summary • Referral and Discharge Reporting • Participatory healthcare • Telemonitoring • Multidisciplinary consultation
Scale	Organizational dimensions of the Use Case. The following scales have been defined for the Antilope Use Cases: <ul style="list-style-type: none"> • Cross-border

	<ul style="list-style-type: none"> • 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 organizational 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 <u>between</u> the systems, and not the steps <u>within</u> 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 realization 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 realization 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 <u>may</u> 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.

VI. Conclusion

The ReEIF, as presented here, is general enough in its definition and scope and 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 mechanism (*e.g.* a document or a message) should be defined: containing the information needed and able to be generated and read 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 meantime 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, which will have to contain (in the cross border case at least) legal interoperability assets like a multi-lateral agreement.

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

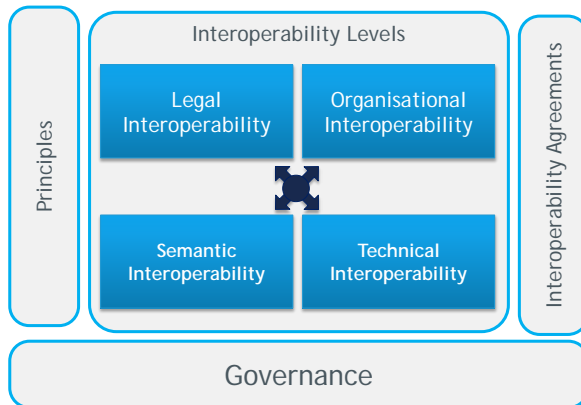
their national environments, secondly this framework can also benefit the work of the eHN itself, by giving structure to documents, decisions, proposals, etc.

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

VII. Appendices

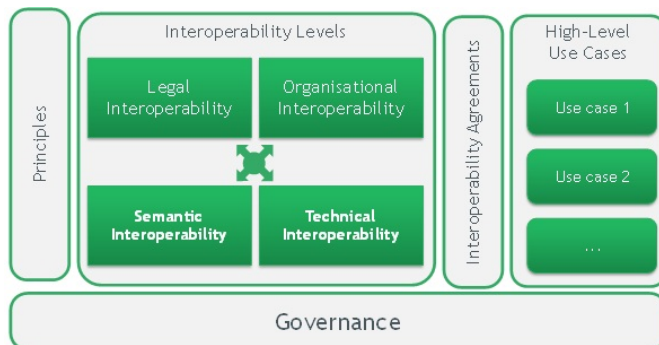
7.1 Appendix A - from EIF model to the refined eHealth EIF (ReEIF) model

Below is a schema of the generic EIF model:



The task of WP1 was to refine this model. Looking at the starting points described above, WP1 proposes another representation of the same framework, and an extension to the framework.

Here is a first draft of the eHealth EIF model :



For the refinement of the model, a more “hierarchical” orientation of the interoperability levels is restored. It also combines the parts that are valid across all interoperability levels, such as Principles, Governance, Security, Use Cases and Interoperability Agreements, into vertical bars, to show that they are relevant for all interoperability levels.

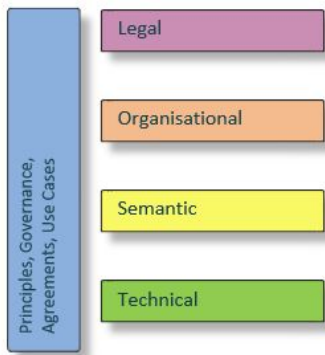
Inventory of current interoperability models

Below are a number of models and schemas that have been compared and studied for the refinement of the current model:

- [AIOS](#)
- [NIST Enterprise Architecture Model](#)
- [LCIM model](#)
- [MDI](#)
- [TOGAF](#)

The new model/schema is presented in two steps.

In the first step, the EIF framework is shown in another visual representation:



In the second step, some interoperability levels are renamed, and some are extended for more clarity. The model should explain all aspects of interoperability to all stakeholders, in non-technical terms. The extended eEIF framework can be used as a practical tool by architects, ICT managers, information analysts and technical professionals.

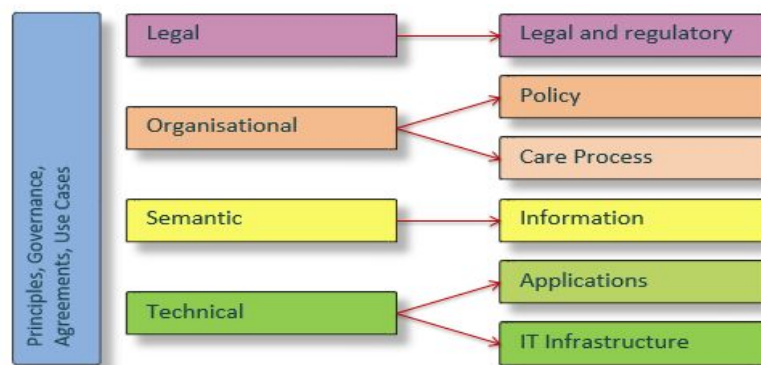
These refinements are described below.

The interoperability model is a synthesis of a number of interoperability architecture models, such as described by the European Interoperability Framework, CALLIOPE, HITCH and others.

EIF	Refined eEIF	Argumentation
Legal	Legal and regulatory	The “...and regulatory” part has been added to indicate that regulatory guidelines, together with legislation, define the boundaries for interoperability
Organisational	Policy	The term “Organisational” covers two areas that have different stakeholders. On the level of organisations, agreements are formalized in

	Care process	contracts. After the organisations have agreed to work together, specific care processes are analysed by physicians and information analysts, resulting in integrated care pathways and shared workflows
Semantic	Information	This is a broader and also less technical term, understandable by all stakeholders. This layer represents all aspects of the data model, coding and terminology, and the formatting of the medium for transportation of the information. Terms like semantic and syntactic interoperability are hard to explain, even amongst information architects, so for the other stakeholders, this is the level where the data is “moulded” and standardised
Technical	Applications IT Infrastructure	Here, a distinction has been made between interoperability between healthcare ICT systems (which often need proprietary connections and mapping of content), and the generic communication and network protocols and standards, the storage, backup, and the database engines. For the IT infrastructure, it is often enough to align already existing standards and protocols

Here is the visual representation of the second step:



7.2 Appendix B – Example of a use case description

Antelope Use Case 4a: Patient Summary sharing on a cross-border scale

This use case represents a high level of consensus on what constitute European eHealth services, as this use case was described by the Directive 2011/24 of 9 March 2011 on the application of patients' rights in cross-border healthcare.

Use Case description:

Title	Patient summary sharing on a cross-border scale
Purpose	Sharing information about the medical background and history of a patient by a healthcare professional in another country
Relevance	Many people request medical help when travelling, working or living abroad. Medical information from the country of origin should be available to all citizens in Europe (in their native language). The current solutions (if any) for getting medical information from another country are often cumbersome, unsafe, incomplete and non-standard. The treatment of patients without proper medical background information is hazardous and should be avoided. Benefits can be gained from increased quality of care (e.g. patient safety) (both medical and economical) and from decrease in effort of gathering health information/exchanging health information. This Use Case proposes a way towards solving this problem.
Domain	Patient Summary
Scale	Cross-border
Context	<p>The definition of a patient summary was laid down by the epSOS project as a starting point for the development and pilot testing of a patient summary for citizens who are travelling abroad and need medical help (unplanned).</p> <p>Challenges are related to the level of data required and the quality of information relevant to support patient treatment effectively across different participating European countries. Different countries operate different health care systems. Each country follows its own respective national jurisdiction, supports a different culture for healthcare provision, and uses a different (or several different) language(s) (which may also involve different connotations of similar medical terminology in literal translation).</p> <p>A patient summary provides background information on important aspects such as allergies, current medication, previous illnesses and surgeries, et cetera. These are necessary for the proper treatment of a patient abroad, especially when there is a language barrier between the HCP (healthcare provider) and the patient.</p> <p>Actually two use cases are possible with regard to the Patient Summary (PS). The first is the one in which an occasional visitor needs his/her PS in country B. The second is the one in which the person is a regular visitor in country B (i.e. someone who lives in one country but works in another country). The distinguishing characteristic is that this type of occasional</p>

	<p>situation where the HCO may have some information available from previous encounters. Both a PS of country A as well as one from country B needs to be consulted. In this use case the use case of the occasional visitor is described. More extensive information about this use case and Patient Summary requirements can be found in epSOS Deliverable 3.2.2. Information about identification, authentication, authorisation, and consent sharing can be found in epSOS D3.6.</p>
Information	<p>Patient Summary (in patient’s language and country B language) Patient consent</p>
Participants	<p>Patient HCP in country of origin HCP in another country</p>
Functional process steps	<p>(With reservation that preconditions are met – can be found in D3.2.2.) The patient consults a health professional in country B (= not home country) The patient is identified (identity confirmed by country A) The patients gives consent; either before travelling to country B or at country B via information paper (except for emergency cases)(reference: epSOS Deliverable 3.6 Identity management)</p> <ul style="list-style-type: none"> • The patient gives consent to the health professional. The health professional will then register this confirmation to participate in the epSOS network <p>The HCP is identified, authenticated, authorised.</p> <ul style="list-style-type: none"> • The patient confirms his/ her willingness to participate • The health professional retrieves the patient summary and uses it for the consultation. The patient summary is electronically transferred from the patient's country of origin to the health professional in the country that s/he is visiting (the "visiting country") in a secure way. <p>PS is received in both the language of the patient (PDF of original PS) and a translated version for the HCP.</p>

Realisation Scenario description:

Title	Patient Summary sharing on a cross-border scale (epSOS)
Related Use Case	Patient summary sharing on a cross-border scale
Scenario context	<p>More information about this Use Case, including the full description of the requirements and different versions of it, can be found in the epSOS deliverable “D3.2.2 Final definition of functional service requirements - Patient Summary”.</p>
Actors	<p>Identity Checker Authorisation Checker</p>

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	<p>HCP EHR System HCPO (Health Care Provider Organization) National Contact Point Semantic Services Transaction Logger</p>
Transactions	<p>Patient identification (by Identity Checker) HCP identification (Identity Checker) Patient consent checking (Authorisation Checker) Understandable (structured and translated) Patient Summary All transactions should be logged</p>
Technical process steps	<p>Patient visits a HCP in Country B (not country of origin) HCP has to be authenticated and authorised for this patient by his local system Patient has to be authenticated Patient consent has to be validated PS (Patient Summary) requested at NCP country A PS translated by semantic services PS sent to NCP country B Patient summary has to be retrieved</p>
Associated profiles	<p>Policy : -- Care process : XDS-SD, XCF (planned) (Ref: D3.A.1. EED 2) Infrastructure: XDR, ATNA, CT Infrastructure, cross-community : XCPD, XCA Security : XUA (++) , BPPC</p>
Possible issues	<p>By the end of epSOS (June 2014) no legal framework exists for exchanging PS. The coding system is not complete which may cause missing information</p>
Implementation examples	<p>epSOS (see http://www.epsos.eu/)</p>

7.3 Appendix C – Glossary of Interoperability Terms and Definitions

Concept	Description	Source
Certification	“Based on ISO 9001:2000 (or ISO 9001:2008) and ISO 14001:2004, certification could be defined as an independent accredited external body issuing written assurance (the “certificate”) that it has audited and verified that the product or software conforms to the specified requirements.”	HITCH D6.4 Final Report
eHealth Interoperability project	“An eHealth interoperability project, taking place in a EU cross border, national, regional, or local context.”	Mandate 403 study
Interoperability	The ability of organisations to share information and knowledge, by means of the exchange of data between their respective ICT systems.	Generic EIF (shortened)
Interoperability	ISO/IEC 2382-01 , The capability to communicate, execute programs, or transfer data among various functional units in a manner that requires the user to have little or no knowledge of the unique characteristics of those unit	see: http://jtc1sc36.org/doc/36N0646.pdf
Interoperability Agreements	“Written interoperability agreements are concrete and binding documents which set out the precise obligations of two parties cooperating across an “interface” to achieve interoperability.”	Generic EIF
Interoperability Framework	“An interoperability framework is an agreed approach to interoperability for organisations that wish to work together towards the joint delivery of public services. Within its scope of applicability, it specifies a set of common elements such as vocabulary, concepts, principles, policies, guidelines, recommendations, standards, specifications and practices.”	Generic EIF
Interoperability Governance	“Interoperability governance covers the ownership, definition, development, maintenance, monitoring, promoting and implementing of interoperability frameworks in the context of multiple organisations working together to provide services. It is a high-level function providing leadership, organisational structures and processes to ensure that the interoperability frameworks sustain and extend the organisations’ strategies and objectives.”	Generic EIF
Interoperability Levels	“The interoperability levels classify interoperability concerns according to who/what is concerned and cover, within a given political context, legal, organisational, semantic and technical interoperability.”	Generic EIF
Legal Interoperability	“Align legislation so that exchanged data is accorded proper legal weight”	Generic EIF

Memorandum of Understanding	<p>“A bilateral or multilateral written agreement between two organisations which sets out a number of areas and means by which they will cooperate, collaborate or otherwise assist one another. The exact nature of these activities depends on the nature of the two organisations, the domain of activity in question, and the scope of the cooperation envisaged.”</p>	Generic EIF
Organisational Interoperability	<p>“Coordinate processes in which different organisations achieve a previously agreed and mutual beneficial goal”</p>	Generic EIF
Profile	<p>A Profile is a guideline for implementation of a specific process, by providing precise definitions of how standards can be implemented to meet specific clinical needs.</p> <p>IHE Profiles organize and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards, such as DICOM, HL7, W3C and security standards.</p> <p>IHE Profiles provide a common language for purchasers and vendors to discuss the integration needs of healthcare sites and the integration capabilities of healthcare IT products. They offer developers a clear implementation path for communication standards supported by industry partners and carefully documented, reviewed and tested. They give purchasers a tool that reduces the complexity, cost and anxiety of implementing interoperable systems.</p>	IHE
Profile Development Organisation (PDO)	<p>“An organisation developing profiles is called a Profile Development Organisation (PDO).”</p>	ISO TR 28380-1 IHE Global Standards Adoption
Quality Management System	<p>A Quality Management System is a set of interrelated or interacting elements that organisations use to direct and control how quality policies are implemented and quality objectives are achieved.</p> <p>A process-based QMS uses a process approach to manage and control how its quality policy is implemented and quality objectives are achieved. A process-based QMS is a network of several interrelated and interconnected processes (elements).</p> <p>Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single process-based QMS.</p>	

Quality Manual	A Quality Manual documents an organisation's quality management system (QMS)	
Semantic Interoperability	“Precise meaning of exchanged information which is preserved and understood by all parties”	Generic EIF
Service Level Agreement	“A formalised agreement between two cooperating entities; typically, a service provider and a user. The agreement is expressed in the form of a written, negotiated contract. Typically, such agreements define specific metrics (Key Performance Indicators — KPIs) for measuring the performance of the service provider (which in total define the “service level”), and document binding commitments defined as the attainment of specific targets for certain KPIs, plus associated actions such as corrective measures.”	Generic EIF
Standard	<p>“A standard is a technical specification approved by a recognised standardisation body for repeated or continuous application, with which compliance is not compulsory and which is one of the following:</p> <ul style="list-style-type: none"> - international standard: a standard adopted by an international standardisation organisation and made available to the public, - European standard: a standard adopted by a European standardisation body and made available to the public, - national standard: a standard adopted by a national standardisation body and made available to the public.” 	European legislation (Article 1, paragraph 6, of Directive 98/34/EC)
Standards developing organisation (SDO)	<p>“A chartered organisation tasked with producing standards and specifications, according to specific, strictly defined requirements, procedures and rules.</p> <p>Standards developing organisations include:</p> <ul style="list-style-type: none"> - recognised standardisation bodies such as international standardisation committees such as the International Organisation for Standardisation (ISO), <i>International Telecommunication Union (ITU)</i>, the three European Standard Organisations: the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI); - fora and consortia initiatives for standardisation such as the Organisation for the Advancement of Structured Information Standards (OASIS), the World Wide Web Consortium (W3C) or the Internet Engineering Task Force (IETF), <i>International Health Terminology Standards</i> 	<p>Generic EIF</p> <p><i>(italic: addition of study team)</i></p>

	<i>Development Organisation (IHTSDO)."</i>	
Technical Interoperability	"Discuss technical issues involved in linking computer systems and services"	Generic EIF
Technical specifications: profile and guideline	<p>"A technical specification means a document that prescribes technical requirements to be fulfilled by a product, process, service or system" (Regulation of European Standardisation).</p> <p><i>In the study, profile (term used by IHE) and guideline (term used by Continua) are technical specifications that identify "a consistent set of chosen options from a base standard or from a set of base standards, in order to provide a given function in a given environment" (ETSI standard ETS 300 406).</i></p> <p><i>Profiling is usually conducted in order to achieve interoperability between different products and implementations as a profile aims to harmonise all systems implementing it to use the same standards and contents.</i></p>	<p>Regulation of European Standardisation</p> <p>ETSI standard ETS 300 406</p> <p><i>(italic: addition of study team)</i></p>
Use case	<p>"A textual and graphical depiction of the actors and operations that address information exchange in the context of a set of specific tasks for a workflow performed by different systems or devices." (ISO TR 28380-1 IHE Global Standards Adoption)</p> <p><i>In the context of our study, a use case can be triggered by a business event (i.e., a business / high-level use case) or by a technical event (i.e., a technical use case). One high-level use case can (re)use one or more technical use cases.</i></p>	<p>ISO TR 28380-1 IHE Global Standards Adoption</p> <p><i>(italic: addition of study team)</i></p>
Use Case (high-level, Antilope)	A functional description of a process, as seen from the end-user's point of view. It describes interactions between the actors in the process, in a non-technical way.	Antilope