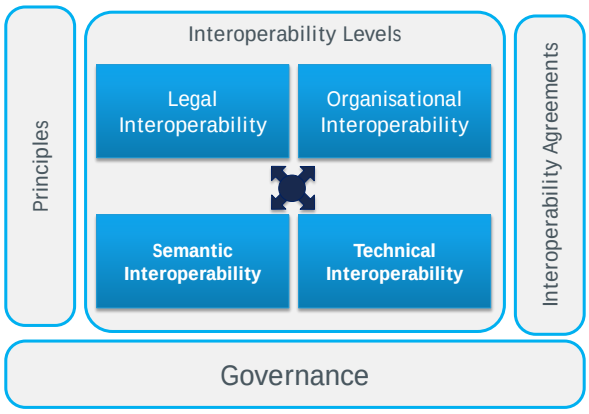
APPENDICES TO THE EHN DISCUSSION PAPER REEIF

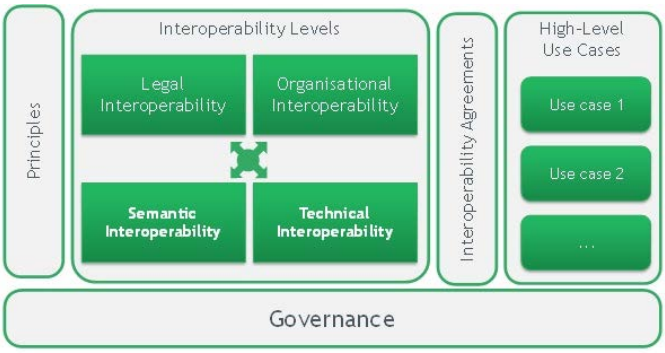
CONTENT

Appendix A – from EIF model to the refined eHealth EIF 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, Work Package 1 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.

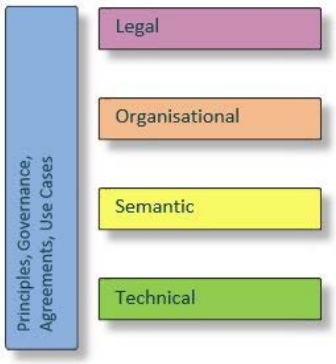
Inventory of current interoperability models

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 three steps.

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



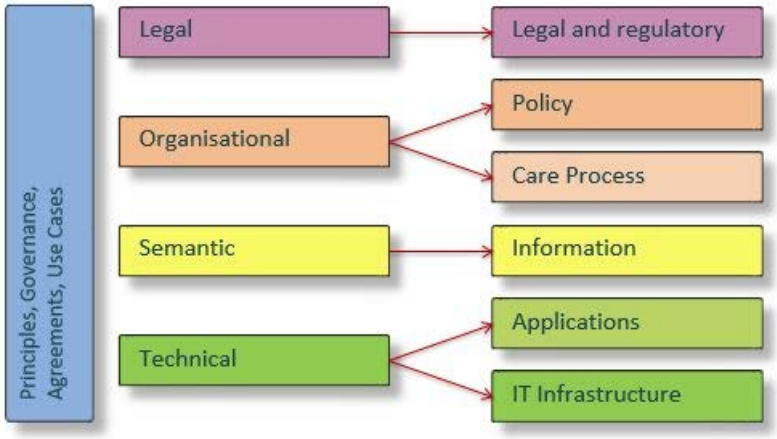
In the second step, some interoperability levels are renamed, and some are extended for more clarity. The model should explain all aspects of interoperability to all stakeholders, in non-technical terms. The extended eEIF framework can be used as a practical tool by architects, ICT managers, information 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 Care process	The term "Organisational" covers two areas that have different stakeholders. On the level of organisations, agreements are formalized in 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:



In the third step, the “cross-level” aspects are divided into two bars that represent the following aspects:

Appendix B – Example of a use case description

Antilope 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	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). 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). 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. 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 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.
Information	Patient Summary (in patient's language and country B language) Patient consent
Participants	Patient HCP in country of origin HCP in another country
Functional process steps	(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) • The patient gives consent to the health professional. The health professional will then register this confirmation to participate in the epSOS network The HCP is identified, authenticated, authorised. • 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. PS is received in both the language of the patient (PDF of original PS) and a translated version for the HCP.

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	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".
Actors	Identity Checker Authorisation Checker HCP EHR System HCPO (Health Care Provider Organization) National Contact Point Semantic Services Transaction Logger
Transactions	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
Technical process steps	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
Associated profiles	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
Possible issues	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
Implementation examples	epSOS (see http://www.epsos.eu/)

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	Generic EIF

	high-level function providing leadership, organisational structures and processes to ensure that the interoperability frameworks sustain and extend the organisations' strategies and objectives."	
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	"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."	Generic EIF
Organisational Interoperability	"Coordinate processes in which different organisations achieve a previously agreed and mutual beneficial goal"	Generic EIF
Profile	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. 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. 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.	IHE
Profile Development Organisation (PDO)	"An organisation developing profiles is called a Profile Development Organisation (PDO)."	ISO TR 28380-1 IHE Global Standards Adoption

Quality Management System	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. 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). 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.	
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	"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: - 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	European legislation (Article 1, paragraph 6, of Directive 98/34/EC)

	national standardisation body and made available to the public."	
Standards developing organisation (SDO)	"A chartered organisation tasked with producing standards and specifications, according to specific, strictly defined requirements, procedures and rules. Standards developing organisations include: - recognised standardisation bodies such as international standardisation committees such as the International Organisation for Standardisation (ISO), *International Telecommunication Union* (*ITU)*, 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), *International Health Terminology Standards Development Organisation (IHTSDO).*"	Generic EIF *(italic: addition of study team)*
Technical Interoperability	"Discuss technical issues involved in linking computer systems and services"	Generic EIF
Technical specifications: profile and guideline	"A technical specification means a document that prescribes technical requirements to be fulfilled by a product, process, service or system" (Regulation of European Standardisation). *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). *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.*	Regulation of European Standardisation ETSI standard ETS 300 406 *(italic: addition of study team)*
Use case	"A textual and graphical depiction of the actors and operations that address information exchange in the context of a set	ISO TR 28380-1 IHE Global Standards

	of specific tasks for a workflow performed by different systems or devices." (ISO TR 28380-1 IHE Global Standards Adoption) *In the context of our study, a use case can be trigged 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.*	Adoption *(italic: addition of study team)*
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