



DELIVERABLE

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Statement of originality

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Executive Summary

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. Standards are essential in this context, but more is needed than just standards. Antilope, as a European initiative, aims to support any project in this field throughout Europe with help in modelling, describing, testing and certifying interoperable solutions on different scales: patient-centred, local, regional, national and crossing borders.

This document sets the scene. It offers modelling of the interoperability world in order to create an environment to describe and discuss interoperability problems and solutions. It establishes the need for a framework for interoperability, building upon and offering a refinement of the eHealth Interoperability Framework (eEIF) as published by the European Commission in 2013.

This document refines the eEIF with a number of “tools” that can be used in solving interoperability challenges. An important element in this framework is the use case driven approach. The framework describes an initial set of interoperability *use cases* that can be used as the basis for national/regional deployment. Wherever applicable and useful, several variants of these use cases are given, to support the different deployment scales. Also, concrete *realisation scenarios*, based on available profiles and standards, are specified for each of these use cases. The linking to standards and profiles in these realisation scenarios provides guidance upon which to build localisation and interoperable implementations.

Another part of the framework consists of a template for the uniform description of these use cases, and for their accompanying realisation scenarios. Also, a refined representation of interoperability levels, and a glossary of interoperability terms and definitions are provided.

The framework increases consistency where possible, across eHealth projects in Europe, reducing project risks, giving higher quality with reused test tools, and offering a broader choice of compatible solutions. Finally, recommendations are given for governance and lifecycle of the interoperability framework described here.

1. Introduction

The need for the exchange of healthcare information is growing, due to factors such as the ageing population and the increase in chronic diseases, specialisation of hospital care and the constant struggle to improve efficiency and quality of healthcare provision. A more collaborative approach to patient care, where multidisciplinary teams work together (and with the patient), also requires an environment where this information can be shared efficiently and safely.

If information is to be shared between healthcare organisations, interoperability between these organisations is necessary. Interoperability entails more than just agreements about the information itself – agreements on different levels are necessary: there are legal, organisational, logistical, informational, technical and infrastructural aspects to consider before interoperability can be realised.

Achieving interoperability requires well-defined sets of rules on the levels of organisation, care processes, content and infrastructure. Using healthcare ICT standards, as defined by SDOs such as HL7, DICOM, IHTSDO, GS1, CEN and others, facilitate the interoperability between systems, and organisations. Standards can be seen as formalised types of agreements, and as basic building blocks for the realisation of interoperability. But standards alone often leave too many degrees of freedom for efficient deployment. For that purpose, organisations such as IHE (Integrating the Healthcare Enterprise) and CHA (Continua Health Alliance) have introduced the concept of Profiles, which can be seen as the cement that holds building blocks together, forming functional modules.

Profiles are guidelines for implementation of specific use cases, by selecting relevant standards and defining how they have to be configured.

The Antilope project follows this methodology: it describes a number of high-level use cases, their functional components and interactions, which are linked to Profiles. Profiles can be tested and qualified against standard test parameters; software that is based upon Profiles can be used interchangeably, have a number of predefined functionalities that can be tested in a standardised manner.

This part of the Antilope project is the basic material that is used in the rest of the Antilope deliverables as referral material for the testing and certification / labelling parts of the project.

The description of the use cases are accompanied by a number of tools and models that support the discussion, the adoption and the realisation of such Use Cases.

1.1 The Antilope project

Antilope is a thematic network of European organisations supporting the adoption and take-up of existing eHealth standards and profiles. The network will promote and drive adoption of use cases, testing guidelines and testing tools on a European and national/regional level. The network will arrange a number of events and workshops across EU Member States. The outcome will be a common approach for the use of the eEIF framework, for testing and certification of eHealth solutions and services in Europe.

The Antilope project provides recommendations and guidelines for the adoption, deployment and standardisation of a number of high-level interoperability Use Cases.

This deliverable (D1.1) of the Antilope project provides the basis for the support for projects on interoperability throughout Europe. This basis is called the eHealth European Interoperability Framework (eEIF). It consists of a number of models, definitions and tools that can be used across Europe to accelerate the ongoing transformation process that will help to increase eHealth interoperability.

2. Objectives

The three objectives of Work Group 1 are:

- Inventory of relevant input
- Refinement of the eHealth European Interoperability Framework
- Creation of education material

2.1 Inventory of relevant input

In the study¹ launched by the DG Connect of the European Commission, Deloitte has gathered the relevant input for consideration in the desk research, collecting input from the (core) members of the thematic network to help identify the relevant sources (both international and national) that should be part of the desk research for the scoping of the EIF refinement. In this study, called the “eHealth Interoperability Framework Study Report”, a number of use cases have been identified including the relevant and available profiles for these Use Cases. But also other inputs have been taken into account, such as eHGI, the Calliope Roadmap for interoperability, M403/1, Renewing Health, etc.²

Furthermore, a lot of practical results and insights have been obtained in the defined Interoperability Specification for the epSOS project, both at the infrastructure, services, technical and semantic level (within the context of the two epSOS Use Cases, Patient Summary and ePrescription). The testing approach by epSOS is also a source of valuable experience.

For the refinement of the eHealth EIF, the main goal was to present a variety of relevant interoperability care processes, in different medical domains, and on different organisational scales. These Use Cases are described independent of organisation, funding and infrastructure. They are examples that can be used as starting points for specific interoperability projects, and for reference in the other Work Packages of the Antilope project. For the refinement of the Use Cases, Work Package 1 has drawn up some requirements. The selected Antilope Use Cases should:

- Be recognised as relevant
- Be mature enough to be promoted as part of the eEIF
- Cover a variety of medical domains and subjects
- Cover different organisational levels, or scales
- Clarify the importance of the use of international Profiles and Standards for their realisation
- Add the possibility of adding more Use Cases in the future.

2.2 Refinement of the eHealth European Interoperability Framework

For the refinements to the framework, a number of requirements were defined by WP1:

- The eHealth EIF should offer models, templates and other educational material for the internationally shared understanding of interoperability processes, models and terms.

¹ [eHealth Interoperability Framework Study Report](#)

² See the Abbreviations and organisations-part for links to the relevant websites

- A refined eEIF interoperability model should provide an overview of the different levels of interoperability, and show the different aspects, processes and responsibilities involved in the realisation of interoperability. It should use non-technical terms that are understandable by all stakeholders.
- There should be a clear link between the description of high-level use cases, and the profiles and standards that could be used in their realisation.
- For a uniform description, and for future addition of the now selected Antelope Use Cases, the eHealth EIF should provide templates for the description of the Use Cases and of the accompanying Realisation Scenarios.
- The terms used in the eEIF should be well defined. For interoperability to work, a shared understanding of the often-used interoperability terms is necessary.
- An overview of the Standards and Profiles mentioned in the Use Cases and Realisation Scenarios should be provided.

2.3 Creation of education material

The goal of the educational material of Work Package 1 is to provide a set of models, templates, use case descriptions and general guidelines that can be used in Europe as a starting and reference point for the adoption of healthcare interoperability projects. The target audience of the educational material are decision makers, policy makers, enterprise architects and ICT management.

3. Deliverables

The goal of this document is to offer a number of refinements to the eHealth European Interoperability Framework. They comprise a set of documents, tools, models, templates and lists that support the development of interoperability at the European and the national/regional levels. Together, they are part of the refined eHealth European Interoperability Framework (eEIF).

The refined framework consists of:

- A set of **Use Cases**, which serve as standardised clinical problem settings that can be used as the basis for interoperability projects. Also, for each Use Case, one or more **Realisation Scenarios** are defined, that link the Use Case to internationally accepted Profiles and Standards. These will increase the interoperability consistency in Europe.
- A set of **templates** for the uniform description of these Use Cases, and of the accompanying Realisation Scenarios. These templates can be used to further expand the set of Use Cases presented by the Antilope project.
- A refined **model for interoperability**. This model will promote a shared model and understanding of interoperability aspects.
- A **glossary** of healthcare interoperability terms and definitions, as used throughout the Antilope documentation.
- An overview of the interoperability **Profiles** that are mentioned in the different Use Cases and Realisation Scenarios. This consists of a short description of the different Profiles, and a schema which groups these Profiles into functionality categories.

Figure 1 shows an overview of these refinements – a more detailed introduction will be given below for each refinement.

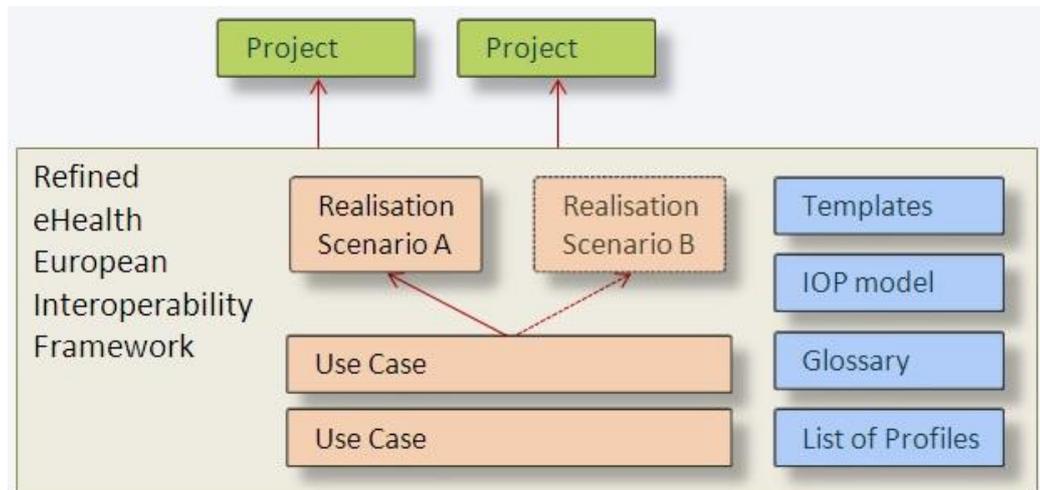


Figure 1 – Refinements to the eEIF

3.1 The Antilope Use Cases

3.1.1 The importance of a Use Cases approach to Interoperability

A common approach for testing and certification of eHealth interoperability solutions and services in Europe starts with the creation of comparable testing environments, processes and information material. These can be described in so-called *use cases*. Interoperability use cases describe specific situations where medically relevant information is exchanged between organisations to support the continuity of healthcare for patients.

3.1.2 Selection of Use Cases

The Use Cases presented by the Antilope project have been selected from several previous EC projects, such as epSOS, HITCH, Calliope, M403/1, Renewing Health and others. The first selection of relevant use cases was made in the Deloitte³ study. To these use cases, and with the defined objectives in mind, the following refinements were made:

- A new ordering and grouping of the Use Cases. The Use Cases are now ordered first on the medical domain, and then on the organisational scale. Due to this reordering, the number of Use Cases seems to have been reduced (from 10 to 8), but this only reflects the fact that some Use Cases were divided into separate Use Cases for different organisational scales (see the schema below).
- Extension of some of the use cases by adding organisational scales.
- A structured and more detailed description of the Use Cases, using the templates defined for the eEIF framework.
- A Use Case (“Medical Board Review”), that exemplifies a multidisciplinary and cross-enterprise process where the exchange of information from different sources need to be available to all participants.

As a result, the selection of Use Cases offers variety on different levels:

- Different domains: radiology, laboratory, patient summary, medical summary sharing, patient data entry, telemonitoring, medical board review
- Different scales of interoperability: international, national/regional, intra-organisational, and citizens (at home and on the move)
- Different Realisation Scenarios for some of the Use Cases

³ [eHealth Interoperability Framework Study Report](#)

The selected and refined uses cases are described in more detail in Chapter 3. Below is the list of Antilope Use Cases:

#	Medical domain	Description	Scale
1	Medication	e-Prescription and e-Dispensing	1a) Cross-border 1b) National/Regional 1c) Intra-organisational 1d) Citizens at home
2	Radiology	Request and results sharing workflow for radiology	2a) National/Regional 2b) Intra-organisational
3	Laboratory	Request and results sharing workflow for laboratory	3a) National/Regional 3b) Intra-organisational
4	Patient Summary	Patient Summary sharing	4a) Cross-border 4b) National/regional 4c) Citizens at home
5	Referral- and Discharge reporting	Cross-enterprise Referral and Discharge Reporting	National /Regional 5a) Referral of patient from primary to secondary care 5b) Discharge report from secondary care
6	Participatory healthcare	Involvement by chronic patients in electronic documentation of healthcare information	Citizens at home
7	Telemonitoring	Remote monitoring and care of people at home or on the move using sensor devices	Citizens at home
8	Multidisciplinary consultation	Medical Board Review	National/Regional

These Use Cases will be described in detail in Chapter 5.

3.2 Templates for the description of Antilope “Use Cases”

Linking high level Use Cases to Profiles through Realisation Scenarios

The high-level *Use Cases* in the Antilope project describe processes between organisations, such as the sharing of medical summaries, laboratory and radiology study requesting and results viewing, telemonitoring, etc. They are functional descriptions of a process, and are independent of organisation, funding and infrastructure. For their realisation on the project level, each Use Case is accompanied by one or more *Realisation Scenarios*. These give guidelines for the use of interoperability Profiles for the realisation of these Use Cases.

For this purpose, the Antilope use Cases will be described in two sections:

- A high-level *Use Case*. This is a functional description of the interactions between the participants in a process, for a certain purpose. The description is on a level that is independent of country specific legal or regulatory requirements, and of architectural choices.

- One or more *Realisation Scenarios*. While solving the same functional problem, the above mentioned constraints may impose different technical solutions. A realisation scenario describes one of the possible solutions, taking these requirements into account. As a consequence, some use cases may lead to more than one realisation scenario. Realisation scenarios can be linked to specific interoperability Standards and Profiles.

Relation between Use Cases and Realisation Scenarios

The schema below explains the relation between Use Case, Realisation Scenario and an actual implementation project. A Use Case is an implementation-independent description that can be adopted by all EC countries. A Realisation Scenario describes, also on a high level, how such a use case could be realised using standards and profiles. The actual implementation of these Use Cases can be based upon the adoption of a Use Case and a Realisation Scenario. For some of the Use Cases, more than one Realisation Scenario is given. In that case, projects can decide which Realisation Scenario best suits the national/regional or local requirements.

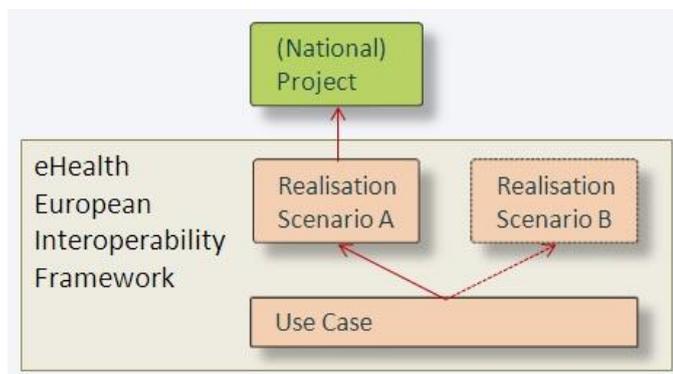


Figure 2 – Projects select a certain Realisation Scenario that fits their needs

Templates for the description of Use Cases and Realisation Scenarios

There are many templates for the description ways of a Use Case. Although some “standard” description formats exist, such as RUP⁴, UML, CEN, the basic thought is, that a template for a specific goal works best: the sections of such a template vary according to the processes they describe, to the scope of the use case (organisation, system, component), and to their level of detail.

Both the original author of the term “use case” ([Ivar Jacobsen](#)), and other renowned authorities in the field, such as [Alistair Cockburn](#) and [Martin Fowler](#), agree on a number of particularities about use cases. A few quotes:

- *“There is no standard way to write the content of a use case, and different formats work well in different cases”* (Martin Fowler).
- *“I have personally encountered over 18 different definitions of use case, given by different, each expert, teachers and consultants. They differed along 4 dimensions: purpose, contents, plurality, and structure.”* (Alistair Cockburn)
- *“Use cases appear in the UML in the form of use case diagrams, but these diagrams are of little value - the key value of use cases lies in the text which is not standardized in UML. So when you do use cases, put your energy into the text”* (Martin Fowler).

⁴ See the ‘Abbreviations and organisations’ paragraph at the beginning of this document.

For the Antilope project, a template is introduced for the description of the high-level Use Cases, and for their accompanying Realisation Scenarios. The “sections” of the template were selected from several use case template structures, with the addition of sections that were deemed relevant for the context of these Use Cases.

Note: as an example, the Antilope Use Cases describe processes on the organisational level, and therefore some of the section titles that are more appropriate for the description on the system- or component level were dismissed, such as *trigger*, *pre-condition* and *post-condition*.

The templates for healthcare interoperability Use Cases are described below:

3.2.1 Template for description of an interoperability Use Case

Structure for the description of a Use Case:

Title	(Number and) Name 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	Organisational dimensions of the Use. The following scales have been defined for the Antilope Use Cases: <ul style="list-style-type: none"> • 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

3.2.2 Template for description of an interoperability Realisation Scenario

Structure of a Realisation Scenario description:

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 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 <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

3.3 Refinement of the eEIF interoperability levels model

For the realisation of Use Cases, many aspects have to be taken into account, such as legislation and guidelines, contracts and agreements, a shared workflow layout, semantic and syntactic choices, the different healthcare ICT systems, the technical infrastructure and safety and privacy. For a successful implementation of interoperability, all these aspects have to be taken into consideration. A shared “model” for these interoperability levels is introduced. This model 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 refined 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

Keeping in mind these requirements, the interoperability model introduced here is a synthesis of a number of interoperability architecture models, such as described by the EIF

model, CALLIOPE, HITCH, TOGAF, HL7 SAIF, and others⁵. A refined model is introduced that builds upon the existing eEIF model, does not use technical terms, can be understood by all stakeholders, and shows the high-level aspect categories of interoperability.

The refined eEIF model is an extension of the eHealth EIF model that was defined in the EC projects such as HITCH and epSOS.

The refined model splits the four levels of interoperability from the original eEIF model into six levels:

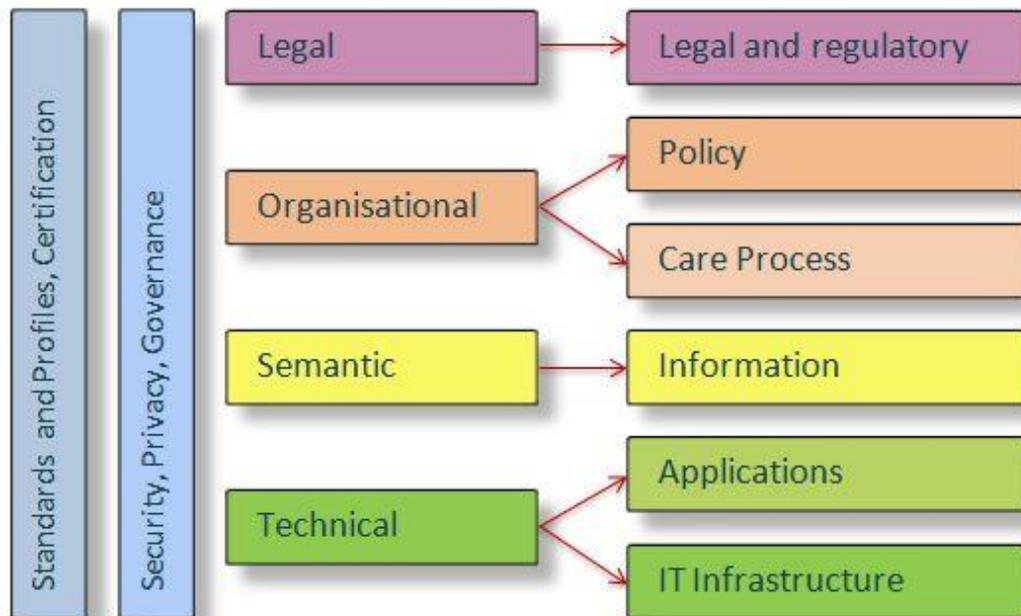


Figure 3: refinement of the EIF model from four to 6 layers

In Appendix D of this document, a rationale and explanation of the refined eEIF model is given. The resulting model is shown below:

⁵ More background information on the model is given in Appendix D of this document

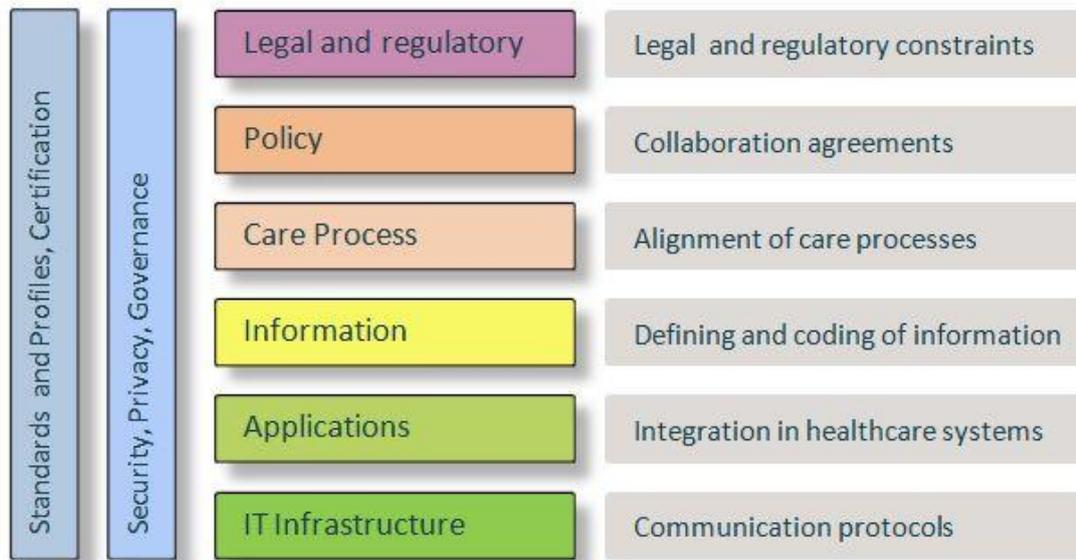


Figure 4: refined eEIF model

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.
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.

For interoperability to work, some aspects are relevant for all interoperability levels. These are shown in vertical bars. These “cross-level” aspects are divided into two bars that represent the following aspects:

- Security, Privacy, Governance
 - Security: authentication, authorisation, integrity, encryption
 - Privacy: patient consents (depending on the opt in / opt out situation)
 - Governance: organising, maintaining, updating and validating all elements of interoperability
- Profiles and Standards, Certification
 - Profiles and Standards are used in all levels of interoperability. They are the foundation upon which interoperability is built. Certification and quality labelling make sure that the requirements of the Profiles and Standards are met, and that they are implemented correctly at the project level.

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:

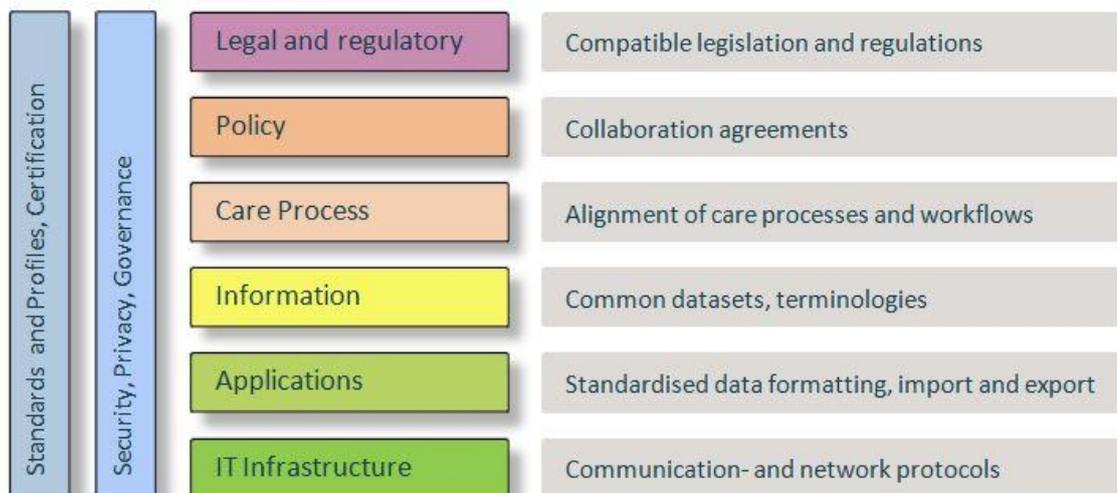


Figure 5: refined eEIF model – alignment activities to undertake

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

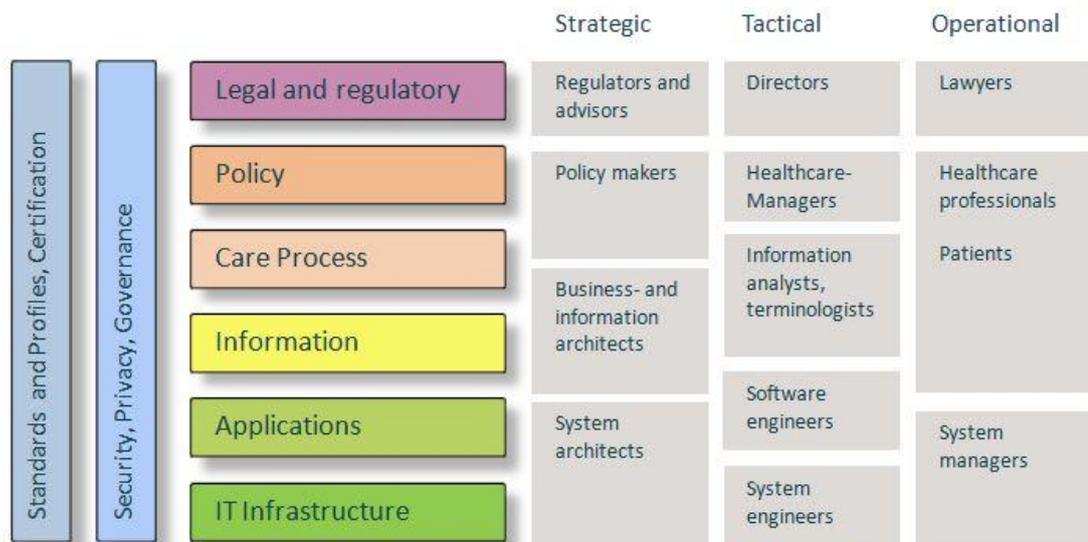


Figure 6: refined eEIF model – stakeholders

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.

Localisation

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 the 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. Translations of this model are already made in Dutch, Danish and Portuguese.

3.4 Definitions for interoperability terms

Interoperability can be seen as the exchange of mutually understandable information. But strangely enough, many of the terms used for the description of interoperability aspects do not have a uniform, shared definition. For this, a glossary of frequently used interoperability terms and definitions is provided, with the purpose of creating a shared understanding of their meaning. This is not a definite list, but it does offer a definition for each of the terms used in this project. The list can be found in Appendix B: **Glossary of Terms and Definitions**.

3.5 Overview of the Profiles used in the Antelope Use Cases

For the Antelope Use Cases, a number of standards and profiles from IHE and Continua have been recommended. An overview and categorisation of the selected Profiles is given in a schema. This schema is presented in Appendix C: **Overview of the identified IHE and Continua Profiles**.

4. Governance and lifecycle

The core elements of an eEIF (use cases and the profiles selected in the realization scenarios) have to be as widely adopted as possible to become effective enablers towards greater technical and semantic interoperability. They need to be placed under lightweight but effective governance in order to ensure:

- Their initial creation in response to the priorities shared by the European member states, and the commitment of these member states to share such assets for their mutual benefits.
- Their stability to be relied upon across the eHealth projects of European Countries as a long-term investment. Unwanted changes would destroy interoperability
- Their time responsive maintenance for minor technical or semantic errors, that avoid the emergence of incompatible corrections and deliver the best value and quality to their adopters
- Their controlled evolution and extensions to meet broader use cases or new development in medicine.

The objective of this section is not to decide which entities should be designated, but to allow those that will be empowered to for such a governance to understand clearly what assets need to be governed.

4.1 What needs to be governed

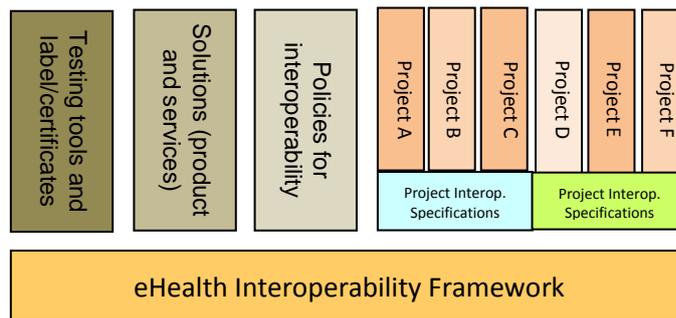
The eEIF is not a project specific interoperability specification. There will be many more, cross-border (such as epSOS), at the national or regional levels, and an even larger number at the local level (e.g. within a hospital). The eEIF sets a framework that provides flexibility along three axes, each one being a type of asset to be governed:

1. A choice of use cases.
→ Not all eHealth projects may find all use cases in the eEIF relevant
2. For each Use Case, a realisation Scenario.
→ There may be cases where alternatives are justified. But the governance must ensure that interoperability between these alternatives is robust and cost effective, otherwise interoperability would be defeated.
3. A list of profiles for each realisation scenario.
→ Not all eHealth projects may find all profiles suitable to meet their requirements. They may be able to only adopt a subset of the eEIF recognised profiles and create ad-hoc profile or design extensions to some of the profiles.

Some examples include:

- Testing tools and label/certificates may be defined to quality control the implementation of these profiles (and their underlying standards) as unified building blocks of interoperability.

- Solutions (product and services) can be designed and brought to a wider market where these building blocks or profiles are used to construct the interoperability specifications of a large number of eHealth projects.
- Policies for interoperability may be established by authorities and health delivery organizations with higher confidence by reusing proven profiles as building block of their standardization strategy
- Project can proceed with fewer risks and greater confidence over time that their interoperability choices will be supported more easily by existing systems and in a more cost effective way with future systems.



4.2 Governance of Use Cases

The initial and evolving scope of an eHealth European Interoperability Framework is set by a list of interoperability use cases. Adding a new use case with a scope at the European level requires a well-established governance to ensure that proposals are submitted with the backing of one or more key stakeholders (e.g. regional or national authorities), and are reviewed to reach a consensus of a sufficient number of qualified stakeholders (e.g. regional or national health authorities, clinicians and industry).

Once approved, new use cases are added to the accepted Use Cases within the eHealth European Interoperability Framework.

New EC projects, such as EXPAND and others, are collecting assets from project deliverables and suggest methods and funding for their long-term governance. As the number of projects grows, the urgency for a “standing body” increases. The core group of the Antelope project strongly advises a discussion on the subject of governance, as this is a problem recognised by project participants in many EC projects.

4.3 Governance of realization Scenarios

Once a new Interoperability Use Case has been approved for inclusion in the eEIF, a corresponding realization scenario needs to be established. Proposals, based on existing and widely accepted profiles need to be submitted with the backing of one or more key stakeholders (e.g. regional or national authorities), and reviewed to reach a consensus of a sufficient number of qualified stakeholders (e.g. regional or national health authorities, clinicians and industry).

In this process, a number of gaps (need to extend an existing profile, lack of profile and gaps in underlying standards) may be identified and an appropriate approach need to be selected (e.g. request the development/extension to a profile and/or standard, defer the selection of a profile in this area for this realization scenario supporting this use case).

4.4 Governance of recognized profiles and supporting Standards

This governance needs to apply criteria to the profiling organization that is the source of profiles, to the candidate profile specifications as well as to the base standards organization and its referenced standards. Preference should be given to internationally defined profiles and standards.

A maintenance agreement should be established with the source profiling or standards organization.

When profiles or standards that were identified as missing or having gaps, the governance should favour the engagement of the source organization for any additional development, so that the eEIF framework governance remains a lightweight process, without the need to maintain deep level of expertise over time, as the profiling and standards organizations are expected to sustain.

5. Antilope Use Cases description

This chapter presents a variety of eHealth interoperability Use Cases that have the following characteristics:

Different eHealth “domains”:

- Medication
- Radiology
- Laboratory
- Patient summary
- Referral and Discharge Reporting
- Participatory healthcare
- Telemonitoring
- Multidisciplinary consultation

Different organisational “scales”:

- Cross-border
- National/regional
- Intra-organisational
- Citizens at home or on the move

Different examples:

- Some Use Cases are divided into separate Use Cases for the proper description of specific processes. For example, Use Case 5 describes two examples of the same basic Use Case, one for a referral process, and one for a discharge report.

General remarks on the Antilope use cases

- NOTE: although the use cases are described for a certain “scale”, some may also be used in other scales as well. In fact, some use cases may be scaled to local, regional/national and international scale, using the same scenarios. As a matter of fact, as the maturity in interoperability will grow, some of the use cases described here will fit more than one scale.
- NOTE: the “National/regional” scale describes the organisational level, and has no direct relation to the *Affinity Domains* that are described in the IHE architecture. Within a National/regional level, both “cross-enterprise” and “cross-community” implementations can occur.
- NOTE: The use cases presented are the result of a selection process. There are many more use cases out there, and so, this set of use cases is just a first start. It is expected that, using the template for the description of use cases (see chapter 3.2), more use cases will be added to this first selection.
- The Associated Profiles described in the realisation scenarios are references, suggestions to look at. The actual use of profiles will depend on many factors, and have to be specified at the project level.
- Although usability is an important factor in the realisation of interoperability solutions, the use cases described here do not offer guidance towards usability issues. This is partly due to the scope of the project, but also to the fact that the use cases described here can be realised in many ways and presentation formats, so that guidelines for would be too generic to be practical. It is up to the vendors to come up with innovative solutions to integrate information from different sources in a manner that supports the healthcare professional in the daily practice, and hides the underlying technology.

Below is an overview of the Antelope Use Cases:

#	Medical domain	Description	Scale
1	Medication	e-Prescription and e-Dispensing	1a) Cross-border 1b) National/regional 1c) Intra-organisational 1d) Citizens at home
2	Radiology	Request and results sharing workflow for radiology	2a) National/regional 2b) Intra-organisational
3	Laboratory	Request and results sharing workflow for laboratory	3a) National/regional 3b) Intra-organisational
4	Patient Summary	Patient Summary sharing	4a) Cross-border 4b) National/regional 4c) Citizens at home
5	Referral- and Discharge reporting	Cross-enterprise Referral and Discharge Reporting	National /regional 5a) Referral of patient from primary to secondary care 5b) Discharge report from secondary care
6	Participatory healthcare	Involvement by chronic patients in electronic documentation of healthcare information	Citizens at home
7	Telemonitoring	Remote monitoring and care of people at home or on the move using sensor devices	Citizens at home
8	Multidisciplinary consultation	Medical Board Review	National/

5.1 Use Case 1: e-Prescription and e-Dispensing

The electronic prescription and dispensing of medications can have different Use Cases on different organisational scales, and each scale presents different organisation of the process.

Therefore, Use Case 1 is divided into four separate Use Case descriptions for e-Prescription and e-Dispensing, on different organisational levels. Each level presents different requirements and context, on organisational and technical level.

5.1.1 Use Case 1a: e-Prescription and e-Dispensing on a cross-border scale

Use Case description:

Title	e-Prescription and e-Dispensing on a cross-border scale
Purpose	To support the processes of prescription and dispensation through the electronic exchange of supporting data for citizens who are travelling inside Europe
Relevance	This Use Case represents a high level of consensus on what

	<p>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.</p> <p>Benefits in both medical and economical terms can be gained from increased quality of care (e.g. improved patient safety) when they travelling abroad and still are able to pick up (lost/forgotten/other necessary reasons) medication and to decrease the effort of gathering/exchanging health information.</p>
Domain	Medication
Scale	Cross-border
Context	<ul style="list-style-type: none"> e-Prescribing is defined as prescribing medicines through the support of software by a health care professional who is legally authorised to do so, so that the medicine can be dispensed at a pharmacy; e-Dispensing is defined as the act of electronically retrieving a prescription and reporting on giving out the medicine to the patient as indicated in the corresponding ePrescription. <p>Once the medicine is dispensed, the dispenser will report, via software, information about the dispensed medicine(s) to the prescription provider. To appropriately define the context of the use case relevant aspects require consideration. These aspects include:</p> <ul style="list-style-type: none"> Is an existing prescription filled out in a different European country from where it originated or is a new medicine prescribed in a country visited by the patient? The different legislative contexts in the various European countries have led to the decision of the epSOS project that information about a newly prescribed medicine, in a country visited by a patient, will not be transferred back to the country in which the patient resides. <p>The use case which is described below is one (the most common situation) of 5 possible scenarios that are described within epSOS D3.1.2. Other scenarios that the prescription is written and dispensed in country B, or a prescription written in country B dispensed in another country (C). More extensive information about this use case and ePrescription requirements can be found in epSOS Deliverable 3.1.2. Information about the profiles can be found in epSOS D3.A.1 EED II. Information about identification, authentication, authorisation, and consent sharing can be found in epSOS D3.6.</p>
Information	<p>Consent – information about patient's consent</p> <p>Prescription – information necessary to prescribe the medication</p> <p>Dispense – information about the dispensed medicine(s)</p>
Participants	<p>Prescriber – person responsible for the prescription of some medication</p> <p>Dispenser – person who can hand over the medication to the patient</p> <p>Patient – person who gives consent and requests medication</p>
Functional process steps	<ul style="list-style-type: none"> (With reservation that preconditions are met – can be found in D3.1.2.) The patient visits an epSOS Health Professional and gives his/

	<p>her consent to share his/her medical information in country A</p> <ul style="list-style-type: none"> • The patient then travels abroad where s/he requires medication in another epSOS pilot country • S/he visits a pharmacy that is participating in the epSOS network • S/he identifies himself/herself to the pharmacist/ staff at the pharmacy • Pharmacist is identified, authenticated, and authorised. • The patient asks for his/ her ePrescription. By doing so, the patient gives the dispenser/ pharmacist his/ her consent to access his/her personal information • The pharmacist requests the patient's ePrescription via the pharmacy's computer in a secure way • The prescription is received by country A via the NPC, NCP checks patient consent, is translated by the semantic services, sent back to the NCP of country B • Pharmacist receives the ePrescription both translated in his own language as an original copy of the prescription. • The requested medication is then dispensed to the patient • The dispensed medicine information is sent back to country A.
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Realisation Scenario description:

Title	e-Prescription and e-Dispensing on a cross-border scale in the epSOS Project
Related Use Case	e-Prescription and e-Dispensing on a cross-border scale
Scenario context	e-Prescription has been used by the epSOS project as the overall term for supporting the processes of prescription and dispensation through the electronic exchange of supporting data for citizens who are travelling inside Europe.
Actors	<ul style="list-style-type: none"> • Consent checker • Identity checker • Prescription provider • Prescription viewer • Dispense provider • National Contact Point (NCP) • Semantic services • Transaction Logger
Transactions	<ul style="list-style-type: none"> • (Record consent) • (Record e-Prescription, in country A) • Authenticate end-user (patient, in country B) • Authenticate end-user (pharmacist) • Receive e-Prescription • View e-Prescription • Send e-Dispense (back to country A) • Log all transactions
Technical process steps	<ol style="list-style-type: none"> 1. The Consent Source records the patient's consent 2. The ePrescription Consumer shows the epSOS ePrescription to the patient

	<ol style="list-style-type: none"> 3. The pharmacist logs in to the ePrescription Consumer 4. The pharmacist selects the patient in the ePrescription Consumer 5. The pharmacist retrieves the patient's ePrescription via the pharmacy's computer in a secure way. The requested medication is then dispensed to the patient 6. Information about the dispense is written and sent
Associated profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: XCPD • Information: PRE, DIS • Infrastructure: XDS (Consumer), XDR (reference: epSOS D3.A.1_EED_II), ATNA, CT • Access control: BPPC, XUA(++)
Possible issues	<ul style="list-style-type: none"> • The epSOS Use Case does not provide guidelines for the implementation of the Use Case. This may lead to different approaches in the participating countries. • Not all the drugs are allowed to be included in epSOS. E.g. Given that European countries have different legislation about possible replacements in drug dispensation, Andalusia didn't allow to dispense some kind of medicines • In some countries, the reimbursement is also an important part of the medication system.
Implementation examples	<ul style="list-style-type: none"> • ...

5.1.2 Use Case 1b: e-Prescription and e-Dispensing on a national/ regional scale

Use Case description:

Title	e-Prescription and e-Dispensing on a national/regional scale
Purpose	Nation-wide access to the current medication of a patient.
Relevance	Healthcare professionals need an accurate and actual overview of the patient's medication.
Domain	Medication
Scale	National/regional
Context	<p>Information about the current medication should be accessible by all participants that are involved in a healthcare setting. Besides a list of the medication the patient is currently using (or has used in the last period), extra information can be is needed regarding contra-indications and relevant laboratory testing results. The list of current medication can consist of the following medication information:</p> <ul style="list-style-type: none"> • Prescriptions • Dispenses • Administrations <p>These lists can be shown separately, or in an integrated view</p>
Information	List of current medications

Participants	<ul style="list-style-type: none"> • Healthcare professional (HCP) • Pharmacist • Patient
Functional process steps	<ol style="list-style-type: none"> 1. Patient visits HCP 2. HCP requests the current medication list 3. HCP views the list of current medications from his EHR

Realisation Scenario description:

Title	e-Prescription and e-Dispensing on a national/regional scale with a national medication register
Related Use Case	e-Prescription and e-Dispensing on a National/regional scale
Scenario context	There is a central (national/regional) location where the current medication is monitored and updated.
Actors	<ul style="list-style-type: none"> • HCP EHR System (HealthCare Provider) • Medication List Source
Transactions	<ul style="list-style-type: none"> • (HCP login) • lookup of patient • request current medication list from another system • Download medication list
Technical process steps	<ol style="list-style-type: none"> 1. Patient visits HCP 2. HCP EHR System selects the patient 3. HCP EHR System requests the current medication (from the Medication List Source, which is an external system) 4. HCP EHR System imports the list of current medications into the HCP EHR System 5. HCP views the generated list of current medications from his / her own HCP EHR System
Associated profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: CMPD • Information: PRE, DIS • IT Infrastructure: XCA, ATNA, CT • Access control: BPPC, XUA(++)
Possible issues	<ul style="list-style-type: none"> • When medication information is stored centrally, where should the information about contra-indications be stored? • When medication is stored in federated systems, locally or inter-organisationally, a standardised definition of the data elements and the data formatting of medication information is needed, as information from different sources have to be brought together. • Often, the alerts (interactions, contra-indications and allergies) information is not a part of the prescription system – in that case, the information will have to be distributed separately, or the software that creates the medication list will have to extract this information from other systems (such as an EHR)
Implementation examples	<ul style="list-style-type: none"> • ...

5.1.3 Use Case 1c: e-Prescription and e-Dispensing on a patient-level scale

This Use Case describes the viewing of a patient / citizen of his /her own current medication list. The implementation will depend strongly on the national / regional architecture.

Use Case description:

Title	e-Prescription and e-Dispensing on a patient-level scale
Purpose	Access for the patient to his current medication list.
Relevance	The patient wants to view his/her own current medication list. The patient may wish to print the list, show it to a healthcare provider, or get information about side-effects, dosage et cetera
Domain	Medication
Scale	Patient at home and on the move
Context	The patient must have access to the internet. Some form of patient identification must be in place
Information	The current medication list, existing of prescription and / or dispensation information about the current medication of the patient.
Participants	<ul style="list-style-type: none"> • Patient
Functional process steps	<ul style="list-style-type: none"> • Patient opens a website • Patient logs in on the website (his PHR, or a pharmacy) • Patient navigates to the page with the current medication • Patient views the medication list • Patient prints the medication list

Realisation Scenario description:

Title	Patient views and prints his/her current medication list
Related Use Case	e-Prescription and e-Dispensing on a patient-level scale
Scenario context	Availability of a website / app with functionality to view the current medication list
Actors	<ul style="list-style-type: none"> • Identity Checker • Personal Health Record System
Transactions	<ul style="list-style-type: none"> • Patient Login • Current Medication View • Current Medication Print • (Transaction logging)
Technical process steps	<ol style="list-style-type: none"> 1. Patient opens a website (for example, his Personal Health Record System) 2. Patient logs in 3. Patient navigates to the page with the current medication 4. Patient views and then prints the current medication list
Associated profiles	<ul style="list-style-type: none"> • Policy : -- • Care process : -- • Information: PRE, DIS • Infrastructure: CT, ATNA • Security : --
Possible issues	<ul style="list-style-type: none"> • In a PHR (personal health record), the interpretation of the findings

	and observations made by healthcare professionals, can be accompanied by additional explanatory information
Implementation examples	<ul style="list-style-type: none"> • ...

5.2 Use Case 2: Request and results sharing workflow for radiology

Imaging information-sharing supports the secured sharing of imaging studies and reports (including their publishing, finding and retrieval) across a group of hospitals and practices within a nation or region. This use case provides ambulatory providers with secure yet easy online access to patients' imaging results, as well as to any prior diagnostic examinations from imaging departments (which can be used either for comparison or to avoid duplicating imaging procedures). Also, the workflow, from request to results viewing, is subject of this Use Case. This Use case is divided into two separate Use Cases, mainly because of the current situation, where the workflow and architecture within a hospital differs greatly from the exchange of information between healthcare institutes.

5.2.1 Use Case 2a: Requests and Results sharing workflow for radiology on a National/regional scale

Use Case description:

Title	Request and results sharing workflow for radiology on a National/regional scale
Purpose	Sharing the results of radiological diagnostic studies, both images and reports, and insight in the workflow, between healthcare institutions.
Relevance	This use case supports the secured sharing of reports (including their publishing, finding and retrieval) and imaging studies across a group of hospitals and practices within a region or nation. It provides ambulatory healthcare professionals with secure yet easy online access to patients' imaging results, as well as to any prior diagnostic examinations from imaging departments (which can be used either for comparison or to avoid duplicating imaging procedures). In this Use Case, the tracking of the diagnostic study workflow is also described.
Domain	Radiology
Scale	National/regional, inter-organisational
Context	This Use Case has the objective of sharing imaging information beyond the boundaries of a typical, single hospital organisation. It can be used to make the information available to practitioners in different organisational entities. It builds on the "request and results sharing workflow for laboratory" use case which is described immediately below.
Information	<ul style="list-style-type: none"> • Diagnostic Study Request • Radiology Study Images • Radiology Report
Participants	<ul style="list-style-type: none"> • Specialist – requests the diagnostic study

	<ul style="list-style-type: none"> • Radiologist – performs the diagnostic study, and writes the radiology report • HCP – general practitioner or specialist – receiver(s) of the results of the diagnostic study
Functional process steps	A patient is suffering from lung cancer and has received surgical treatment in a hospital. After discharge from the hospital, imaging information – such as results from computer tomography – is made available to the patient’s primary care physician as well as to an office-based medical oncological specialist for follow-up treatment.

Realisation Scenario description:

Title	Cross-enterprise requesting and viewing of radiology study
Related Use Case	Use Case 2: Request and results sharing workflow for radiology
Scenario context	In this scenario, the <u>requesting</u> and <u>performing</u> of the diagnostic study is done within a healthcare institute, and the <u>viewing</u> of the results is done from outside the healthcare institute.
Actors	Study Requestor Study Performer Study Consumer
Transactions	Request Diagnostic Study Perform Diagnostic Study Report Diagnostic Study
Technical process steps	<ol style="list-style-type: none"> 1. The Study Requestor request a study from the Study Performer 2. The Study Performer stores the images 3. The Study Performer stores the Study Report 4. The Study Consumer shows the study images and report
Associated Profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: XDW, XbeR-WD, PAM, XCPD • Information: -- • IT Infrastructure: XDS, XDS-i, XCA, XCA-i, ATNA, CT • Access control: BPPC, XUA(++), PIX/PDQ
Possible issues	This Use Case is described for a National/regional level. However, it could also be used as a basis for a cross-border realisation.
Implementation examples	...

5.2.2 Use Case 2b: Requests and Results sharing workflow for radiology on an intra-organisational scale

Use Case description:

Title	Request and results distribution workflow for radiology within a hospital
Purpose	This use case supports the workflow related to imaging diagnostic tests performed inside a healthcare institution, for both identified orders and unknown orders, with regard to both identified patients and unidentified or misidentified patients.

Relevance	Results from a radiological examination that has been requested should be made available to medical staff members who are working in multiple medical departments within the hospital organisation. This use case ensures the availability of timely, complete and consistent patient information as well as avoidance of potential duplicate testing within the hospital organisation.
Domain	Radiology
Scale	Intra-organisational
Context	<p>In a hospital setting, a physician from a medical department in charge of patient treatment may typically request some form of imaging diagnostics for the specific patient. Ideally, the radiological department receives all the relevant information about the patient's identity, relevant medical information, and the reason for requesting this examination.</p> <p>The Digital Imaging and Communications in Medicine (DICOM) standard has gained broad acceptance in the field: it is a data standard for transmitting medical imaging information as well as complementary clinical information. The degree of complexity implicit in medical imaging has contributed over time to vendor-specific implementations of image archiving technologies in picture archiving and communications (PACS) systems based on the DICOM standard. Therefore, the term of “vendor neutral (image) archives” (VNA) has emerged. These vendor-neutral solutions provide a single, enterprise-wide repository for patient-centric medical images.</p> <p>Although this specific market trend focuses on the technical aspects of data storage and data management, it also demonstrates the need to support the interoperability of the distribution of imaging information within hospital organisations.</p>
Information	<ul style="list-style-type: none"> • Diagnostic Study Request • Radiology Study Images • Radiology Report
Participants	<ul style="list-style-type: none"> • Specialist – requests the diagnostic study • Radiologist – performs the diagnostic study, and writes the radiology report • GP – general practitioner – receives of requests the results of the diagnostic study
Functional process steps	<ul style="list-style-type: none"> • A surgeon requests an X-thorax • The radiologist receives the request and accepts it; an appointment is made • The patient visits the radiology department, and the radiology assistant takes the X-ray image(s). These are stored in the radiology system (PACS) • The radiologist examines the radiology images and writes / dictates his findings in a report • The radiology report is sent to the requestor (the surgeon) • The surgeon looks at the radiology images and the radiology report

Realisation Scenario description:

Title	Intra-organisational requesting and viewing workflow of radiology study
Related Use Case	Request and results sharing workflow for radiology
Scenario context	In this scenario, the requesting of the diagnostic study is performed within the healthcare institute. The cross-enterprise aspect lies in the requesting/viewing of the results from outside the hospital.
Actors	<ul style="list-style-type: none"> • Study Requestor • Study Performer
Transactions	<ul style="list-style-type: none"> • Request Diagnostic Study • Perform Diagnostic Study • View Study Results
Technical process steps	<ol style="list-style-type: none"> 1. The Study Requestor request a study from the Study Performer 2. The Study Performer stores the images 3. The Study Performer stores the Study Report 4. The Study Consumer views the study images and report
Associated Profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: SWF (describes workflow within a radiology department), RWF (reporting workflow) • Information: REM • IT Infrastructure: XDS, XDS-i, ATNA, CT • Access control: BPPC, XUA(++), PIX/PDQ
Possible issues	This Use Case is focused on the National/regional level. However, it could also be used as a basis for a cross-border or a intra-organisational realisation.
Implementation examples	...

5.3 Use Case 3: Requests and Results sharing workflow for laboratory

Laboratory testing results are relevant information to all healthcare professionals involved in the healthcare episode of the patient. Therefore, they should be available to all. The sharing of this sensitive information ought to be enabled across organisational, regional and even national boundaries.

Two Use cases describe the high level workflow of requesting, performing, reporting and sharing of laboratory tests.

Use Case 3a focuses on the national or regional availability of laboratory test results for authorised healthcare professionals who are involved in the treatment of the patient.

Use Case 3b describes the workflow within a hospital, and highlights the requesting and order management aspects.

5.3.1 Use Case 3a: Results sharing workflow for laboratory on a National/regional scale

This use case supports the secure sharing of laboratory reports (such as their publishing, finding and retrieval) and test results across a group of hospitals and practices within a

region or nation. It provides ambulatory providers easy and secure online access to new laboratory test results, as well as earlier test results for comparison.

Use Case description:

Title	Request and results sharing workflow for laboratory on a National/regional scale
Purpose	The secure sharing of laboratory reports (such as their publishing, finding and retrieval) and test results across a group of hospitals and practices within a region or nation. This use case provides ambulatory providers with secure yet easy online access to new laboratory test results for their patients, as well as earlier test results for comparison.
Relevance	<p>Today, about 60-70% of all diagnoses are based on clinical laboratory testing. The spectrum of testing ranges from highly standardised cost efficient commodity testing, such as blood counts or clinical chemistry, to innovative, personalised testing procedures for analysis of human genetics.</p> <p>All healthcare professionals involved in the healthcare episode of a patient should have access to the relevant laboratory results for their role in the healthcare process. Laboratory results information often comes from different sources. For the end-users, a transparent, source-independent, combined viewing of these results provides them with the necessary background for their decision-making. The patient should also have access to these laboratory results.</p>
Domain	Laboratory
Scale	National/regional
Context	<ul style="list-style-type: none"> • Current “state-of-the-art” order processes for “external” users such as GPs still involves a lot of paper work. This leads to manual work, errors in patient and order demographics and is considered to be very time consuming. Moreover, this procedure is notoriously error prone. • There is a huge interest among laboratories and primary care professionals in electronic ordering systems. However, there is a risk that this may lead to non-standardised solutions that may solve the electronic ordering process from the perspective of a single laboratory, but do not reduce the workload for a general practitioner working with different laboratories. • There is a demand for on-line access to lab test results, both from healthcare professionals and as part of an on-line electronic patient record. Today’s solutions mainly involve dedicated point-to-point communication between laboratory and GP’s information systems. The GP typically only has access to lab results of tests ordered by him / herself. It is nearly impossible to find out what other lab results are available for a patient.
Information	<ul style="list-style-type: none"> • Laboratory request information • Laboratory results
Participants	<ul style="list-style-type: none"> • Specialist • Laboratory assistant • Laboratory analyst
Functional process steps	<ul style="list-style-type: none"> • A patient visits his general practitioner with complaints of fatigue • The doctor orders a blood screening by filling in a paper order

	<p>form. He asks the patient to go to a phlebotomy (blood drawing) facility of choice, to get blood drawn.</p> <ul style="list-style-type: none"> • The patient shows up at the phlebotomy station and shows the paper form. Blood is drawn and the samples are marked • The phlebotomy station sends the test tubes to the laboratory • The laboratory performs the tests • The laboratory sends the test results to the requester of the tests
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Realisation Scenario description:

Title	Cross-enterprise sharing of laboratory results
Related Use Case	Request and results sharing workflow for laboratory on a National/regional scale
Scenario context	This use case describes a simple process of request and results, but not a “closed loop system”. Also, there is no
Actors	<ul style="list-style-type: none"> • Lab Results Source • Results Viewer
Transactions	<ul style="list-style-type: none"> • Request Laboratory results • Retrieve Laboratory results • Show Laboratory results
Technical process steps	<ol style="list-style-type: none"> 1. Physician logs in and requests laboratory results of a patient 2. Results are gathered from the different laboratory result documents that are available of the patient in the XDS registry 3. Results are shown in a viewing format as instructed in the “View” option of the XD-LAB IHE profile. This profile collects the different result documents and shows the combined information in a format that is recognised by the requesting physician.
Associated Profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: -- • Information: XD-LAB • IT Infrastructure: PIX/PDQ, XDS, CT, ATNA, BPPC, XUA(++) • IT Infrastructure, cross-regional: XCA, XCA-i , XCPD
Possible issues	<ul style="list-style-type: none"> • This Realisation Scenario assumes the availability of laboratory results in a document-based format (usually, a CDA document). Rules for the combination of information from different documents must be agreed upon for a shared, uniform viewing format.
Implementation examples	...

5.3.2 Use Case 3b: Request and results distribution workflow for laboratory within a hospital

Use Case description:

Title	Request and results distribution workflow for laboratory within a hospital
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Purpose	Laboratory requesting and results viewing within a hospital organisation
Relevance	Test results from clinical laboratory services may be requested and should be made available to medical caregivers who work in multiple medical departments within the hospital organisation on a need-to-know basis. This use case should ensure the availability of timely, complete and consistent patient information as well as avoidance of potential duplicate testing within the hospital organisation.
Domain	Laboratory
Scale	Intra-organisational
Context	<ul style="list-style-type: none"> The differences between intra- and cross-enterprise information exchange are becoming smaller, as laboratories and hospitals can also be seen as separate systems, whether they are located within a hospital, or in another location. A standardisation of the laboratory result report would make that distinction even smaller, because in that case, results from both intra-organisational and external laboratory tests can be viewed with the same “tools”, eliminating the need for proprietary infrastructural connections between the laboratory information system and healthcare information systems. Traditionally, there is a direct connection between the Laboratory Information System (LIS) and the Hospital Information System (HIS). However, more and more information comes from other sources, from specialised or commercial laboratories, from primary care, and from other hospitals. A viewing system that can show all this information requires a standardised format for the exchange of laboratory results. The following Use Cases describe a scenario where laboratory results are formatted in such standardised documents. IHE has a Profile called LTW (Laboratory Testing Workflow) which deals with the complete workflow <u>within</u> a laboratory.
Information	<ul style="list-style-type: none"> Laboratory request information Laboratory results
Participants	<ul style="list-style-type: none"> Specialist Laboratory assistant Laboratory analyst
Functional process steps	<ol style="list-style-type: none"> Physician requests laboratory tests through electronic ordering Laboratory assistant takes a blood sample from the patient Sample is brought to the laboratory Results are reported in the Laboratory Information System Results are copied to the Hospital Information System Physician views the laboratory results from his/her EHR system

Realisation Scenario description:

Title	
Related Use Case	Request and results distribution workflow for laboratory within a hospital
Scenario context	The hospital has deployed the IHE LTW Profile
Actors	<ul style="list-style-type: none"> Order placer Order filler Order Result Tracker

	<ul style="list-style-type: none"> • HCP EHR System
Transactions	<ul style="list-style-type: none"> • Request laboratory tests • Send laboratory results (from LIS to HIS)
Technical process steps	<ol style="list-style-type: none"> 1. Order placer requests laboratory tests through electronic testing and adds relevant medical information 2. (Laboratory assistant takes a blood sample from the patient, and brings it to the laboratory) 3. (Blood sample is analyzed in the Laboratory Information System) 4. Results are stored in the Laboratory Information System 5. Results are copied to the Hospital Information System (internal link) 6. HCP views the laboratory results in the HCP EHR system
Associated profiles	Policy: -- Workflow: LTW Information: XD-LAB, LSCD, SVS Infrastructure: CT, ATNA Access control: PAM, PIX/PDQ
Possible issues	The difference between intra-organisational and cross-enterprise information viewing of laboratory results is becoming less obvious, as more and more laboratory results are generated outside the confines of the healthcare organisation itself. Standardised formatting of laboratory results enables vendor- and organisational-independent exchange and viewing of laboratory results coming from different sources. However, agreements around quality assurance are needed before information coming from different sources can be “mixed”.
Implementation examples	...

5.4 Introduction to Use Cases 4 and 5

The next two Use Cases focus on the transferral of patient-related information, in the form of patient summaries. As has been described by IHE, patient summaries can be classified in three categories: collaborative, episodic, and permanent⁶:

- **Permanent:** Permanent patient summaries “summarize the entirety of a patient's medical history and therefore cover a broader range of patient problems”. A permanent patient summary is often referred to in the context of a longitudinal medical record. It summarizes the medical history of the patient, and provides information about the current health status, including the actual discharge summary. This type of summary is defined as a Patient Summary, and is the subject of Use Case 4a, 4b and 4c.
- **Collaborative:** A collaborative summary is defined as serving the interests of a specific provider by “providing the most relevant information about the patient”. A referral letter may serve as an example of this type of patient summary. This type of summary is the subject of Use Case 5a.
- **Episode:** “Episodic summaries have the primary purpose of highlighting the most relevant details of focused periods of time in a patient history. Examples include discharge summaries”. A discharge summary is a concise summary of the recent

⁶ [http://wiki.ihe.net/index.php?title=PCC_TF-1/XDS-MS - Cross-Enterprise Sharing of Medical Summaries .28XDS-MS.29 Integration Profile](http://wiki.ihe.net/index.php?title=PCC_TF-1/XDS-MS_-_Cross-Enterprise_Sharing_of_Medical_Summaries_.28XDS-MS.29_Integration_Profile)

episode, and highlights the diagnosis, therapy and recommendations for further treatment at the end of a healthcare episode. It is a transfer of information, often to the primary healthcare professional the referred the patient to the specialist. This type of summary is the subject of Use Case 5b.

All types of Summary contain information such as:

- Demographic information about the patient (e.g., name, birth date, gender)
- A medical summary consisting of the most important clinical patient data (e.g. medical history, past surgical procedures, allergies, current medical problems, medical implants)
- A list of the current medication. There is much debate as to what constitutes a “current medication list”. Generally, it consists of prescription- and dispensing information. Information about the patient summary itself (e.g., author, date of generation of the patient summary was generated).

5.4.1 Use Case 4: Patient Summary sharing

A Patient Summary is meant as a general overview of the patient’s health history and current situation. It is a concise clinical document that provides an electronic patient health data set that is applicable both for unexpected as well as expected healthcare contact. The content of the patient summary is defined, at a high level, as the non-exhaustive data set of information needed for health care coordination and continuity of care. The purpose of a Patient Summary, as defined by IHE, is Permanent.

5.4.2 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

	<p>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 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	<ul style="list-style-type: none"> • Patient Summary (in patient’s language and country B language) • Patient consent
Participants	<ul style="list-style-type: none"> • Patient • HCP in country of origin • HCP in another country
Functional process steps	<ul style="list-style-type: none"> • (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)
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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	<ul style="list-style-type: none"> • Identity Checker • Authorisation Checker • HCP EHR System • HCPO (Health Care Provider Organization) • National Contact Point • Semantic Services • Transaction Logger
Transactions	<ul style="list-style-type: none"> • 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	<ol style="list-style-type: none"> 1. Patient visits a HCP in Country B (not country of origin) 2. HCP has to be authenticated and authorised for this patient by his local system 3. Patient has to be authenticated 4. Patient consent has to be validated 5. PS (Patient Summary) requested at NCP country A 6. PS translated by semantic services 7. PS sent to NCP country B 8. Patient summary has to be retrieved
Associated profiles	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	...

5.4.3 Use Case 4b: Patient Summary sharing on an inter-organisational scale

Initiatives for a “generic” Patient Summary are being undertaken in several countries such as Austria (ELGA), the Netherlands (*Registratie aan de Bron*, “Registration at the Source”), Belgium and others.

Use Case description:

Title	Patient summary sharing on a national scale
Purpose	Sharing information about the medical background and history of a patient by a healthcare professional within a country or region
Relevance	For the exchange of medical information about a patient, a Patient Summary provides the participants in a healthcare pathway with the

	<p>basic medical background information. In collaborative healthcare, in the transfer of a patient to another hospital, and in a multidisciplinary board review, the Patient Summary functions as the standardised information set of medical information. The structuring of basic information such as current medication, allergies, advance directives, diagnoses and therapies allows the different healthcare information systems to absorb the information from any other healthcare information system. The treatment of patients without proper medical background information is hazardous and should be avoided. This Use Case proposes a way towards solving this problem.</p>
Domain	Patient Summary
Scale	National/regional, inter-organisational
Context	<p>The growing number of chronic healthcare conditions, together with a more multidisciplinary approach to chronic disease management, have increased the need for the exchange of medical information between healthcare organisations and individuals. Since this involves the exchange of information between different healthcare information <i>systems</i>, a standardised patient summary containing the basic medical background information of the patient, in a uniform and structured manner, is seen as an important step towards healthcare integration.</p> <p>Several countries in Europe are working towards a national set of structured and standardised data, to be used as starting point for a national Patient Summary.</p> <p>There are challenges, though. The selection of data elements, the level of granularity, the terminologies and coding system, and the formatting of the message or document, depends on national principles and requirements, on legislation, architecture vision and on choices made in the past. It requires a lot of effort, and a lot of consensus, to get a broadly accepted (and implemented) Patient Summary. Everyone sees the advantages, but the devil is (as usual) in the details.</p> <p>In a number of countries, initiatives have been taken towards the definition of a national dataset for the exchange of health information. Typically, they start with the core pieces of medical information that are relevant to all healthcare professionals.</p> <p>The exact content and format of the different national Patient Summaries will be interesting study material for (later) comparison and harmonisation. Although there are existing templates for the composition of a Patient Summary, such as CCD (Continuity of Care Documents), XDS-MS (also called IHE Medical Summary) and others, in practice these are often used as starting points only. This may also have to do with the fact that some of these “templates” were written from a national rather than an international point of view. Also, the amount of detail, data elements specific for a country, et cetera, will also lead to different specifications; a Patient Summary is the result of negotiations between different stakeholders. This comparison is outside of scope for the Antilope project, but this Use Case could be used as a reference for any such initiatives.</p> <p>Here is a short overview of the current initiatives of the different national initiatives towards defining a standardised Patient Summary:</p> <p>In the Netherlands, all academic hospitals, together with Nictiz, are</p>

	currently working towards the definition and implementation of such a national Patient Summary, the “Registratie aan de Bron” (“Registration at the Source”). They are defined as the basic set of information that is going to be used in the transfer of a patient (currently, the scope is hospital to hospital). The information is defined in the CDA document format, and uses elements of CCD, LOINC, SNOMED-CT and other international and national standards, besides some proprietary elements.
Information	<ul style="list-style-type: none"> • Patient Summary • Other information (referral note, specialism-related information, diagnostic studies, diagnostic study reports, etc.)
Participants	<ul style="list-style-type: none"> • Patient • Physician in a healthcare organisation A • Physician in healthcare organisation B
Functional process steps	<ul style="list-style-type: none"> • The patient consults a health professional in a hospital • The HCP decides that the patient needs to receive surgical intervention in another healthcare organisation (healthcare organisation B) • The patient gives consent to the HCP for the sharing of the medical information with a HCP or specialism (role) in healthcare organisation B • The HCP refers the patient to a HCP in healthcare organisation B • An appointment is made in healthcare organisation B, and the patient consults the HCP there • The health professional retrieves the Patient Summary and uses it for the consultation. In the following two Realisation Scenarios, different methods are described, which can be briefly described as “push” and “pull”. These are actually simplified depictions of the actual workflow and technology involved in the exchange, but they illustrate the fact that the same Use Case can be realised in different ways.

Realisation Scenario 1 description:

Title	Patient Summary sharing with “push” of the information
Related Use Case	Patient summary sharing on a National/regional scale
Scenario context	In this Realisation Scenario, the Patient Summary (along with other necessary documents and/or images) is sent by information system A in healthcare organisation A to the information system in healthcare organisation B. This is sometimes being referred to as “push”. Usually, this will be the scenario, especially if the sender of the information knows exactly to which HCP and hospital the patient is referred.
Actors	<ul style="list-style-type: none"> • Document Source • Document Consumer
Transactions	<ul style="list-style-type: none"> • Record patient consent • Notification of document availability • Sending of documents
Information	<ul style="list-style-type: none"> • Patient Consent • Referral Note • Patient Summary • Other relevant documents

Data flow	<ul style="list-style-type: none"> • Storing of patient consent to repository • Sending selected documents to remote location • Viewing these documents from an external location
Technical process steps	<ol style="list-style-type: none"> 1. Healthcare information system A (HIS A) stores the patient consent 2. After selection of the relevant documents by the HCP, HIS A sends the relevant documents to HIS B through a secure electronic connection 3. HIS B receives the documents, and stores them. It shows a notification for the HCP in healthcare organisation B.
Associated profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: -- • Information: XDS-MS (or other Patient Summary) • IT Infrastructure: XDR • Access control: BPPC
Possible issues	Governance of the data definition of the national Patient Summary
Implementation examples	...

Realisation Scenario 2 description:

Title	Patient Summary sharing with “pull” of the information
Related Use Case	Patient summary sharing on a National/regional scale
Scenario context	In this Realisation Scenario, the Patient Summary (along with other necessary documents and/or images) is retrieved by information system B in healthcare organisation B from the information system in healthcare organisation A. This is sometimes being referred to as “pull”. In the case of an emergency intake of a patient, available information is drawn from another system. At the time of arrival of the patient in the A&E department, no information about the patient is available.
Actors	<ul style="list-style-type: none"> • Document Consumer • Document Registry • Document Repository
Transactions	<ul style="list-style-type: none"> • Record patient consent • Requesting Patient Summary • Retrieval of Patient Summary
Information	<ul style="list-style-type: none"> • Patient Consent • Patient Summary
Data flow	<ul style="list-style-type: none"> • Store Patient Consent • Request information from another healthcare organisation, including the patient consent • Retrieve Patient Summary
Technical process steps	<ol style="list-style-type: none"> 1. Healthcare information system A (HIS A) stores the patient consent 2. After selection of the relevant documents by the HCP, HIS A sends the relevant documents to HIS B through a secure electronic connection 3. HIS B receives the documents, and stores them. It shows a notification for the HCP in healthcare organisation B.
Associated profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: -- • Information: XDS-MS (or other Patient Summary)

	<ul style="list-style-type: none"> • IT Infrastructure: XDS, CT, ATNA, PIX/PDQ • Cross-domain: XUA, XCPD • Access control: BPPC
Possible issues	Governance, versioning of the Patient Summary.
Implementation examples	...

5.4.4 Use Case 4c: Patient Summary sharing on a patient-level scale

It was an important design decision that the epSOS project decided to support a patient's access to his/her personal patient summary⁷. This is a service that adds value to the existing national patient access services. Therefore, the implementations of relevant requirements for patient identification, authentication and authorisation have been delegated to either regional or national access services.

Note: In the following Use Case description, some epSOS abbreviations are used:

- **NCP** stands for “National Contact Point”, which is the connection point for the information exchange between countries in the epSOS architecture.
- epSPA - epSOS Patient Access Service. In the original Use Case work, the epSOS Patient Access Service was abbreviated to **epSPA**. Later, when elaborating the Use Cases into Service Specifications (Deliverable D1.4.3_EED SERVICES including Specification for all services, the abbreviations **PAC (Patient Access)** is used for the same concept. In the project glossary, only the final abbreviation appears.

Use Case description:

Title	Patient Summary sharing on a patient-level scale
Purpose	Patient viewing of his or her own Patient Summary
Relevance	<p>This use case provides the patient with flexibility to make use of his/her personal patient summary. On the one hand, the service provides a translation of data into the suitable medical terms of the home country of the patient (for instance, when the patient is not fluent in the language of country A and needs to access his/her own clinical documents in their native language).</p> <p>On the other hand, it offers the patient the freedom to make the translation available to a healthcare practitioner who is not participating actively in the epSOS project.</p>
Domain	Patient Summary
Scale	Patients at home and on the move / Cross-border

⁷ A patient's access to his/her personal patient summary is limited to the information created for the cross-border care. It is not about the access to the full patient summary in his/her home country.

Context	During the epSOS project, participants agreed that the patients involved in the large-scale pilot should be informed that they are involved in the collection of personal patient data that is collected in the patient summary. They should also receive access to their personal data. In addition a patient should be supported by other value added services, in particular with an adequately translated version of his/her patient summary which s/he may in turn want to make available to medical services providers of his/her personal choice. The patient is in the case of epSOS only able to view his/her Patient Summary, not to add or record any data.
Information	Patient Summary
Participants	<ul style="list-style-type: none"> • Patient at home or on the move
Functional process steps	<ul style="list-style-type: none"> • The health professional in the country of the patient's origin updates/produces the medical information used in the patient summary on the basis of an encounter • The patient requests his or her patient summary from the national patient access service (through the secure web service of the NCP in country A). The national patient access service (including patient identification, authentication and role authorisation) verifies that the patient access rights to the information, including his or her age, is sufficient to allow access to the data • Patient requests list of available Patient Summaries • The national patient access service provides the requested document/list of existing PSs for the identified patient • Patient selects the Patient Summary to consult through NCP from country A • The epSPA/PAC service (see above) is invoked to produce a translation of the coded content of the document into the language of the country that is being visited. The PAC service uses the MTC (Master Translation / Transcoding Catalogue) for the language of the country visited, produced by that country⁸ • NCP A requests data set of the Patient Summary to the NCP of the country that holds selected Patient Summary. • The patient receives the translated document • The patient reads, copies, uses and distributes the document as he or she considers appropriate.

Realisation Scenario description:

Title	Sharing a Patient Summary with a healthcare provider
Related Use Case	Patient Summary sharing on a patient-level scale
Scenario context	One possible way in which the patient may want to distribute the information is to give it to a new health professional on the occasion of a new medical encounter, whether this intervention is scheduled or

⁸ This workflow is only valid for ePrescription and the patient summary. In Use Case Patient Access, the document will be translated into the language of the home country of a patient. For example, an Austrian patient will receive ePrescription and the patient summary always in German.

	<p>unscheduled. This step is relevant only if the health professional does not, for some reason, have access to the patient summary⁹.</p> <p>NOTE from epSOS: “It is important to note that the patient access service is a national prerogative. As such, neither functionality nor requirements thereto are regulated by epSOS”. (quote from D4.E.1)</p>
Actors	<ul style="list-style-type: none"> • PHR System • NCP-A (National Contact Point A, own country) • NCP-B (National Contact Point B, other country) • Translation Service
Transactions	<ul style="list-style-type: none"> • Patient identification • Patient Summary retrieval
Technical process steps	<ol style="list-style-type: none"> 1. Patient requests information about Patient Summaries via NCP-B using (for example) his/her PHR System 2. Patient is authenticated by the NCP-B 3. Patient requests Patient Summary from country A 4. NCP presents selected Patient Summary 5. Translation of selected Patient Summary in country A is made available by a Translation Service
Associated profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: -- • Information: XPHR, RTM (translation) • Infrastructure: XDS (Consumer), ATNA, CT, XCA • Access control: BPPC, XUA(++)
Possible issues	<ul style="list-style-type: none"> • Document management: when the HCP makes a copy of the Patient Summary, is the provenance of that document safeguarded? • How to determine that the patient is who he says he is (authentication) • Does patient’s authentication provides same level of trust and security of HCP’s authentication <p>For more issues/disadvantages of patient access please see D3.2.2. of epSOS</p>
Implementation examples	...

5.5 Use Case 5: Cross-enterprise Referral and Discharge Reporting

There are different types of summaries, for different purposes. In general, a distinction can be made between the following types of summary.

A Patient Summary contains generic information about the medical history of the patient, but it also focuses on the current medical problem.

⁹ Suitable mechanisms that meet organisational information security policies would need to be agreed.

A Collaborative Medical Summary also contains information about current complaints, reason for referral, findings from anamnesis and physical examination, and results of diagnostic studies.

An Episodic Medical Summary also contains information about reason for referral, findings from anamnesis and physical examination, results of (more) diagnostic studies, diagnosis, therapy and medication, discharge information, and possibly a prognosis and/or a care plan for the further treatment and medication after discharge.

An example of a Collaborative Summary is the referral letter, from primary care to secondary care, for instance, from a GP (General Practitioner) to a cardiologist). This is the subject of Use Case 5a.

Use Case 5b focuses on the end of a healthcare episode, where a healthcare provider produces a discharge report (also called a discharge letter) that is a summary of the episode. The discharge letter is meant for the requestor of the healthcare episode (this is often the referring GP, but other specialist may also receive a copy), but is often also used for internal use, as a concise summary of the episode, and for future reference.

5.5.1 Use Case 5a: Referral of patient from primary to secondary care

A collaborative patient summary is defined as serving the interests of a specific provider by “providing the most relevant information about the patient”. A referral letter may serve as an example of this type of patient summary. This type of summary is the subject of Use Case 5a.

If a patient is to be referred from primary to secondary care, the IHE profile defines the respective Use Case as an “Ambulatory Specialist Referral”. In this instance, a primary care physician makes use of the collaborative patient summary, consolidates the respective medical information from an electronic medical record, and transfers the relevant data securely to a medical specialist.

Use Case description:

Title	Referral of patient from primary to secondary care
Purpose	Requesting of specialist care, including the transferral of relevant medical information
Relevance	For the referral of a patient, all relevant medical information should be accessible by the healthcare professional who will be responsible for further treatment.
Domain	Referral- and Discharge reporting
Scale	National/regional
Context	The electronic referral of a patient from a GP to a specialist often consists of a referral letter, containing the reason for referral, some information on the complaints and findings, and additional information such as medical history and current medication. Often, there is no electronic sending of this letter: it is given to the patient, who brings it with him if he or she visits the specialist. A workflow where the entire referral process can be tracked and managed would create a more efficient process, and a better transfer of medical information (i.e., electronic and structured data). This Use Case describes such an improved workflow.

Information	<ul style="list-style-type: none"> • Referral letter • Patient Summary
Participants	<ul style="list-style-type: none"> • Patient • HCP in primary care (GP) • HCP in secondary care (specialist)
Functional process steps	<ol style="list-style-type: none"> 1. Patient visits his GP. The GP decides to refer the patient to a specialist 2. The patient signs a patient consent 3. The GP generates a referral letter through his Primary Care Information System that automatically selects data from the system, and creates a patient summary. It also generates a template of a referral letter. The GP adds the reason for referral, and other relevant information that is not in the automatically generated patient summary. 4. The GP opens a web-based program, logs in, and selects a specialist. 5. The GP sends the referral to the specialist via a secure connection

Realisation Scenario description:

Title	Referral of patient from primary to secondary care using push technology
Related Use Case	Referral of patient from primary to secondary care
Scenario context	In this Realisation Scenario, the GP knows to which specialist he is going to refer the patient. He/she sends a request for further treatment, the reason for referral, and a patient summary to the selected specialist through a secure point to point connection
Actors	<ul style="list-style-type: none"> • Authorisation Manager • Primary Care EHR System (general physician) • Secondary Care EHR System (specialist) • HealthCare Provider Selector
Transactions	<ul style="list-style-type: none"> • Authorisation Manager generates Patient Consent • Primary Care EHR System generates an automated referral letter (GP edits the letter) • Primary Care EHR System stores the edited and finalised referral letter • Primary Care EHR System selects the target specialist from a list of available HCPs • Send referral to specialist
Technical process steps	<ol style="list-style-type: none"> 1. (Patient visits GP. The GP decides to refer the patient to a specialist) 2. The GP selects the patient in his / her Primary Care EHR System 3. The GP selects the generation of a referral letter. The Primary Care EHR System automatically selects data from the system, and creates the referral letter. The referral letter is shown in an editable form, the GP can add the reason for referral, and other relevant information that is not in the automatically generated letter

	<ol style="list-style-type: none"> 4. The GP selects a specialist from a HealthCare Provider Selector 5. The referral letter is sent to the receiving specialist
Associated profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: -- • Information: MS (also called XDS-MS), HPD • Infrastructure: XDR, CT, ATNA • Access control: BPPC, XUA(++), PIX/PDQ
Possible issues	<ul style="list-style-type: none"> • in Poland, patients choose a particular specialist themselves due to long waiting time and the fact that GPs do not always have agreements with specialists or even up-to-date knowledge about available specialists (the National Health Fund provides such information on their website). Use Case 4b describes two Realisation Scenarios, one with a “push”, and one with a “pull”-scenario. This Use Case describes a “push” scenario, but a comparable Realisation Scenario as in Use Case 4b may be applied.
Implementation examples	...

5.5.2 Use Case 5b: Discharge report from secondary care

Use case 5b describes the reporting of an episode of care a summary of referral from specialised care (specifically, acute care discharge) to primary care (ambulatory care). It thus makes use of the same definition of terms that can be found in the IHE profile XDS-MS described above in use case 5a

Use Case description:

Title	Discharge report from secondary care
Purpose	Summary of an episode of care to a GP or other specialist, including the transferral of relevant medical information
Relevance	For the referral of a patient, all relevant medical information should be accessible by the healthcare professional who will be responsible for further treatment.
Domain	Referral- and Discharge reporting
Scale	National/regional
Context	After having received specialised treatment in a hospital setting, the patient is released. Episode-based patient summary information (with a focus on the treatment of the specific disease) is prepared by the attending physician in the hospital. If appropriate, the information is transferred to the primary care physician and medical specialists.
Information	Referral letter
Participants	Patient HCP in secondary care (specialist) HCP in primary care (GP)
Functional process steps	<ol style="list-style-type: none"> 1. Specialist creates an automatic discharge letter in his EHR, in editable form

	<ol style="list-style-type: none"> 2. Specialist edits the text treats the patient and patient visits GP. The GP decides to refer the patient to a specialist 3. The GP selects the patient in his / her healthcare information system (HIS) 4. The GP writes a referral letter. 5. The GP selects a specialist and sends the referral letter to the specialist
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Realisation Scenario description:

Title	Referral of patient from primary to secondary care using push technology
Related Use Case	Referral of patient from primary to secondary care
Scenario context	In this Realisation Scenario, the GP knows to which specialist he is going to refer the patient. He/she sends a request for further treatment, the reason for referral, and a patient summary to the selected specialist through a secure point to point connection
Actors	<ul style="list-style-type: none"> • Secondary Care EHR System (specialist) • Primary Care EHR System (general physician)
Transactions	<ul style="list-style-type: none"> • Generate Summary (discharge letter) • Send Document
Technical process steps	<ol style="list-style-type: none"> 1. Secondary Care EHR System generates a discharge letter and shows this in editable form to the specialist 2. Specialist edits the automatically generated document 3. Specialist saves the Referral letter 4. The Secondary Care EHR System sends the discharge letter to the Primary Care EHR System of the referring GP
Associated profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: -- • Information: MS (also called XDS-MS) • Infrastructure: XDR, CT, ATNA • Access control: BPPC, PIX/PDQ
Possible issues	The automatically generated content of the referral letter may contain structured and coded elements that are defined on the national/regional level.
Implementation examples	...

5.6 Use Case 6: Involvement of chronic patients in electronic documentation of healthcare information

Introduction

The relative importance of chronic diseases such as diabetes, cardiac disease, chronic obstructive pulmonary disease (COPD) and hypertension is constantly growing issue worldwide, with specific relevance to Western Europe. It is broadly accepted that about 20 per cent of patients within healthcare systems incur 80 per cent of the overall costs of healthcare delivery for Europe and the US. For the well-being of this extremely relevant patient segment, an appropriate treatment concept should consider both medical therapies

and close monitoring of disease-specific clinical parameters so as to provide a continuous stimulus for healthy living.

There is a group of use cases that support the concept of “for ever-present care”. They aim at involving a patient actively in the documentation of his/her specific chronic condition (or conditions), and making this physiological information available to medical staff either at a hospital or another medical service provider to assist in the diagnosis and/or monitoring of the patient's treatment.

One option to encourage patient interaction and compliance with an appropriate treatment regimen involves the use of PC-based, web-based, or mobile applications, that enable new ways of involving the patient in his/her own healthcare process. In general, these applications may consist of several functionalities that are described below.

1. Patient generated data

The data may include quantitative information such as weight or blood pressure, as well as qualitative information about personal health. These *patient generated data* facilitate a more continuous monitoring of the patient's health status that can be used to generate warning signs before complications of these chronic conditions occur.

2. Patient empowerment

The applications also may offer functionalities for informing, reassuring and supporting the patient, helping him/her to adhere to the set health improvement goals.

3. Shared decision making

Especially in chronic healthcare conditions, there is a trend towards a shared decision making regarding treatment, prevention, and life quality. Applications can offer many tools to support this possibility including teleconferencing, and discussion threads.

Use Case: chronic heart failure

Monitoring patients with chronic heart failure is one example of how monitoring the healthcare status at home can help improve the quality of life for chronic patients. These patients are often treated with a combination of medicine, exercises, and dietary advice. Medication is given to improve the cardiac output of the patient, but sometimes the dosage needs to be adjusted. A non-optimal dosage may lead to lower heart output rate, which leads to oedema, and an increase in body weight. Thus the function of the heart can be monitored by a daily measurement of the body weight.

Use Case 6 describes the remote monitoring of a patient with chronic heart failure. The patient enters his/her body weight, along with some other data, in a smartphone/tablet app. This app sends the data to a Monitoring Service, where the data is stored. The software of the Medical Triage centre creates periodic summaries of the measured values at intervals and can create an alert whenever the measured values are outside the pre-set constraints for the patient. This information is viewed and monitored by a Medical Triage Service. If needed, this service can contact the patient and assess the situation. In case the situation does not improve after some measurements (for instance, a dosage change), the healthcare professionals that are involved in the treatment of the patient are alerted, and an appointment with the medical facility can be made. The whole “mechanism” allows a quicker response to changes in the health status of the patient, and at the same time avoids unnecessary in- or outpatient visits. The schema below illustrates the different workflow steps for this Use Case.

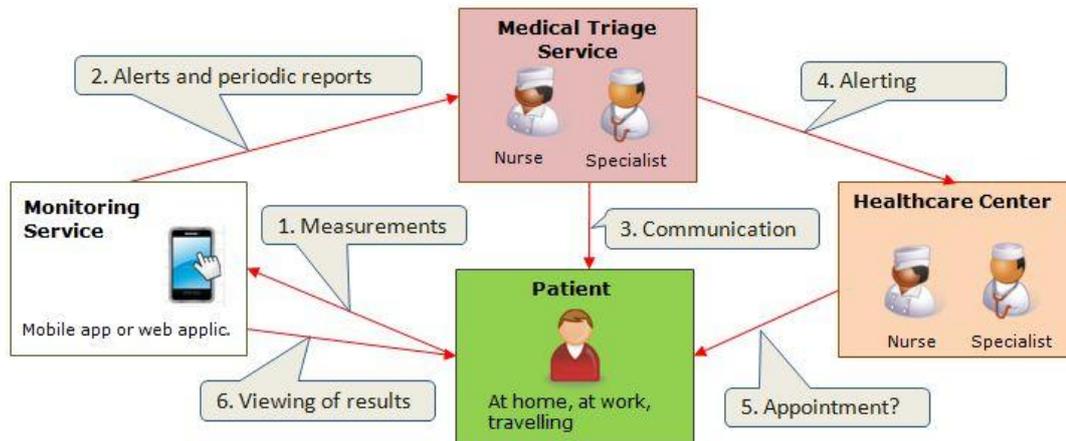


Figure 7: integration of self-measurements in the medical realm

Use Case description:

Title	Involvement of chronic patients in electronic documentation of healthcare information
Purpose	Registration and monitoring of patient-generated health parameters for quick and adequate response to warning signals
Relevance	<p>The concept of “for ever-present care” which takes place outside conventional care facilities provides numerous benefits for patients, providers, payer organisations and health care systems. These benefits include:</p> <ul style="list-style-type: none"> • Patients benefit from a closer monitoring of their health status that is based on a large number of data points gathered more often. As a consequence, medication typically fits the patient’s individual context better and unplanned hospitalisation can often be avoided. On average, the patient leads a healthier lifestyle and benefits psychologically from the awareness of participating in a well-organised treatment concept. • Providers underline the positive aspects that result from of a better knowledge of recent patient health status as well as a longer patient history. This enables more solid decision-making about further therapeutic action. • Studies on disease management initiatives in multiple countries have proven that, on average, patients benefit from a better health status at a lower treatment cost. This is a major driver for payer organisations and/or for the public health care system which have a high interest in efficient and effective health care provision.
Domain	Participatory healthcare
Scale	Citizens at home and on the move
Context	Worldwide: 860 million individuals with chronic conditions. In Europe, more than 65% of healthcare spending is on chronic condition management.
Information	<ul style="list-style-type: none"> • Daily upload of patient generated data • Alert report (in case of exacerbation)

	<ul style="list-style-type: none"> • Periodic status report
Participants	<ul style="list-style-type: none"> • Patient • Monitoring Service - data collecting and monitoring software • Medical Triage Service - healthcare professional(s) • Healthcare Centre
Functional process steps	<ol style="list-style-type: none"> 1. Patient weighs herself, and measures his/her blood pressure 2. Patient enters the data in a mobile app 3. The Monitoring Service monitors the data (from many patients) 4. The Monitoring Service creates an alert for the patient, and sends it to a Medical Triage Centre 5. The Medical Triage Centre contacts the patient and adjusts the medication dosage (if necessary) 6. The Medical Triage Centre sends a report of the intervention to the Healthcare Centre (that connects to the healthcare professional who is responsible for the patient) 7. A few days later, the health parameters have not shown the expected improvement, and the Healthcare Centre is alerted 8. The Healthcare Centre makes an appointment with the patient.

Realisation Scenario description:

Title	Telemonitoring of patients with chronic heart failure
Related Use Case	Involvement of chronic patients in electronic documentation of healthcare information
Scenario context	The patient has internet access, and can be expected to enter the measured data
Actors	<ul style="list-style-type: none"> • Monitoring Service - data collecting and monitoring software • Medical Triage Service - healthcare professional(s) • Healthcare Centre
Transactions	<ul style="list-style-type: none"> • Send Measurements • Send Alert
Technical process steps	<ol style="list-style-type: none"> 1. (no software action)– 2. Patient enters weight and blood pressure in a smartphone/tablet/pc application. The information is sent to and saved in the Monitoring Service software 3. Information is monitored and checked against the min-max values that have been set for this patient, and against sudden changes compared to previous measurements 4. Sudden rises or drops in the measured values trigger an alert message to the Medical Triage Centre 5. The Medical Triage Centre contacts the patient (by phone, out of scope for this Use Case) 6. The patient's medication dosage is changed (out of scope for this Use Case) 7. The Medical Triage Centre sends an alert to the Healthcare Centre 8. The Healthcare Centre makes an appointment with the patient (out of scope for this Use Case)
Associated profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: --

	<ul style="list-style-type: none"> Information: MS (also called XDS-MS) Infrastructure: PIX/PDQ, XDS/ XDR/ XDM, CT, ATNA Infrastructure, Patient Care Device: HRN, WAN+, DEC*/RTM*, LAN+ or PAN+,(MHD, DEC) Access control: BPPC, XUA(++)
Possible issues	XDR enables sending a “push” alert to another party. This may be realised with XDR (which is a web service-based solution), or, within an XDS affinity domain, with either DSUB or NAV.
Implementation examples	...

5.7 Use Case 7: Remote monitoring and care of people at home or on the move using sensor devices

This Use Case focuses on the remote monitoring and care of people outside the environment of care facilities, involving sensors that transmit information such as activity, heart rhythm, blood pressure, glucose level, weight and so forth.

In this Use Case, the blood pressure measurements that have been gathered by a device are sent electronically to an application, which in turn sends the data via the internet to a central location where these data are collected and monitored. This location may relay the information to other networks and services.

This use case describes the first step, where information is sent from a device to a mobile application.

Title	Remote monitoring and care of people at home or on the move using sensor devices
Purpose	Wireless communication between measuring devices and a mobile application
Relevance	A more continuous monitoring of relevant healthcare parameters can increase the quality of life of a patient, because it can provide early indicators of deteriorating health. Earlier intervention decreases complications. Also, these warning signs can be monitored by software algorithms that can identify trends, and send alerts to healthcare professionals when a measurement that exceeds the preset upper or lower values. Using graphs to show the measurements over a period can help motivate the patient to adhere to dietary or exercise regimes: the patient becomes more conscious of the positive effects of these efforts. Also, patients who use these devices may feel more secure about their health status, knowing that it is being tracked and checked.
Domain	Telemonitoring
Scale	Citizens at home and on the move
Context	Consider a middle-aged patient with chronic heart failure who needs to measure his/her blood pressure on a daily basis. The blood pressure device can send the measurement results to a mobile application through a wireless connection. These results can then be sent from the mobile device to a chronic care management centre or to a responsible healthcare professional. The information is

	monitored both by rules-based logic implemented as part of the application, and by qualified nurses on an on-going basis. If needed, a physician is informed about any relevant degradation in the patient's health status, so that preventive measures can be taken at an early stage. As a result, patients' complications can be detected early, and the patient is less likely to return to the hospital.
Information	Blood pressure values
Participants	<ul style="list-style-type: none"> • Patient • Healthcare professional
Functional process steps	<ol style="list-style-type: none"> 1. Patient measures his/her blood pressure with an electronic blood pressure meter 2. The blood pressure meter sends the measured data to a smart phone , tablet or PC 3. The mobile application shows the latest measurement.

Realisation Scenario description:

Title	Sending a device measurement to a mobile app using Bluetooth® or Zigbee®
Related Use Case	Remote monitoring and care of people at home or on the move using sensor devices
Scenario context	With the constant innovations in mobile apps and wearable devices, healthcare parameters can be easily obtained and sent to mobile or pc-based applications, using wireless technologies such as Bluetooth®, Zigbee®, Wi-Fi etc. The Continua Health Alliance has created design guidelines for the exchange of medical information on the basis of existing and accepted standards. The patient has internet access, and a blood pressure meter that can send its data using Bluetooth® or Zigbee®.
Actors	<ul style="list-style-type: none"> • Blood pressure meter • Mobile app
Transactions	<ul style="list-style-type: none"> • The blood pressure meter sends the measured data via Bluetooth to a nearby mobile phone, tablet or pc • The Mobile app receives the measurements, and shows them through its user interface.
Technical process steps	<ul style="list-style-type: none"> • Patient uses an electronic blood pressure meter to measure his/her blood pressure • The information is sent to the mobile application • The patient is informed that the information has been received
Associated profiles	<ul style="list-style-type: none"> • Policy: -- • Care process: -- • Information: -- • Infrastructure: Patient Care Device: PAN, LAN/WAN, (MHD, DEC) • Access control: --
Possible issues	Data encryption may be needed to send the information over Bluetooth or Zigbee.
Implementation examples	...

5.8 Use Case 8: Medical Board Review

Use Case description:

Title	Medical Board Review
Purpose	Workflow support and sharing of relevant medical information for a multidisciplinary medical board review. The purpose of a medical board review is to formulate a recommendation for the further treatment of a patient. Medical board reviews are often arranged for the discussion of a number of patients with a specific disease, such as cancer, heart failure or COPD.
Relevance	Medical Board Reviews are meetings where a team of medical professionals of different professions, and often from different hospitals, get together (physically or by remote conference) to assess the cases of patients (using medical images and other relevant medical information), discuss the cases, and advise on the further treatment of the patient. In many countries, the Medical Board Review is an important phase in the multidisciplinary care pathway
Domain	Medical Board Review
Scale	National/regional, inter-organisational
Context	<p>In the Netherlands, most Tumour Board Review (TBR) meetings are held for specific Tumour types, such as oesophageal cancer, colon cancer, lung cancer, et cetera. They are held after the diagnostic studies have been completed (pre-therapeutic TBR), and often also after the treatment of the patient (post-therapeutic). At a typical Tumour Board Review, which usually takes 1 hour, between 5 and 15 patients are being reviewed. On average, between 5 and 20 different Tumour Board meetings are held each week per hospital.</p> <p>The main output of a Tumour Board Review is a report containing the collective findings, conclusions and recommendations for the further treatment of the patient.</p> <p>This may also include the recommendation to include a patient in a clinical research trial.</p> <p>Tumour Board Review meetings also serve as a platform for sharing the latest guidelines, developments and insights in the diagnosis and treatment of the specific cancer type. The sharing of knowledge is seen as a valuable asset.</p>
Information	<ul style="list-style-type: none"> • Request for the medical board review including a concise summary of relevant information • Radiological images and report • Pathology slides and report • Laboratory results
Participants	<p>The composition of participants varies with the subject of the medical board review. As an example, the following healthcare professionals partake in the medical board review process:</p> <ul style="list-style-type: none"> • Requesting specialist (depending on the location of the tumour) • Radiologist • Pathologist • Oncologist • Radiotherapist

	<ul style="list-style-type: none"> • Surgeon • Oncological nurse, case manager
Functional process steps	<ol style="list-style-type: none"> 1. A specialist (requester) requests a medical board review for a patient. He/she sends the request (with the reason for request, a patient summary and all the relevant images and pathology reports) to the organiser 2. The organiser of the medical board review checks if the patient meets the inclusion criteria of the board 3. The organiser sends the affirmation to the requester 4. All participants can prepare for the medical board review by viewing and examining all the relevant medical information 5. At the medical board review meeting, all participants discuss the case. 6. A scribe writes down the recommendations of the board 7. The medical board review report is authorised by all, and sent to the requester (and possibly to other involved healthcare professionals).

Realisation Scenario description:

Title	Cross-enterprise Medical Board Review
Related Use Case	Medical Board Review
Scenario context	The participants to the Medical Board Review are located in different hospitals. Optionally, a video conferencing tool enables the participants to have live contact.
Actors	<ul style="list-style-type: none"> • MBR Requestor • MBR Scheduler • MBR Preparer • MBR Scribe • MBR Chairperson
Transactions	<ul style="list-style-type: none"> • Request MBR (Medical Board review) • Schedule MBR • Prepare MBR • MBR meeting and reporting • Finalize MBR
Technical process steps	<ol style="list-style-type: none"> 1. A specialist (MBR requester) requests a medical board review for a patient to the MBR Scheduler. He/she sends the request (with the additional information to the MBR Scheduler. 2. The MBR Scheduler checks if the patient meets the inclusion criteria of the board, and looks for a timeslot for the MBR for that patient 3. The organiser sends the affirmation to the requester 4. All participants can prepare for the medical board review by viewing and examining all the relevant medical information 5. At the medical board review meeting, all participants discuss the case. 6. A scribe writes down the recommendations of the board <p>The medical board review report is authorised by all, and sent to the requester (and possibly to other involved healthcare professionals).</p>
Associated	<ul style="list-style-type: none"> • Policy: --

Profiles	<ul style="list-style-type: none"> • Care process: XDW, XTB-WD, PIX/PDQ • Information: (any documents, depends on implementation) • Infrastructure: XDS/ XDR/ XDM, ATNA, CT • Access control: BPPC, XUA(++)
Possible issues	<p>Information is stored in different ways in different systems. Agreements on using structured data exchange have to be made in order to facilitate a “cross-organisational” view on the information. For this, content profiles can be used, but different types of Medical Board Reviews require different content profiles.</p>
Implementation examples	...

6. Conclusions

6.1 Key messages of Work Package 1

The three key messages of Work Package 1 are:

Use cases provide a shared understanding of interoperability issues	The Antilope use cases can be used as practical starting points for eHealth projects.
Using international standards and profiles improves interoperability	Selecting and tuning/refining these use cases and their associated realisation scenarios for a particular project offers access to proven and widely used standards and profiles, and also to the associated testing and certification methodologies and tools.
Definition of terms, uniform models for interoperability, and uniform description of use cases are necessary for the improvement of interoperability	Antilope offers clear definitions of interoperability terms, and proposes a model for a uniform description of healthcare interoperability use cases and realisation scenarios.

6.2 Roadmap recommendations

[This chapter will be filled in after the international summits have been held, and will give recommendations for the governance and maintenance of the results of the Antilope project]

Sections of this chapter will be:

- Maintenance
- Inclusion of new Use Cases
- Inclusion of new standards and profiles

7. Appendices

7.1 Appendix A: Abbreviations of Organisations and Standards

EIP AHA	European Innovation Partnership on active and Healthy Ageing
ASIP Santé	Agence des Systèmes d'Information Partagés Santé
<u>ASTM</u>	American Society for Testing and Materials International
CAB	Conformance Assessment Body
<u>CALLIOPE</u>	CALL for InterOPERability
<u>CDA</u>	Clinical Document Architecture
<u>CEN</u>	European Committee for Standardization
<u>CHA</u>	Continua Health Alliance
<u>DICOM</u>	Digital Imaging and Communications in Medicine
DMP	Dossier Médical Personnel /Partagé
EA	European Accreditation
<u>eHGI</u>	eHealth Governance Initiative
<u>EHTEL</u>	European Health Telematics Association
EHR QTN	Thematic Network on Quality of Electronic Health record systems
<u>EIF</u>	European Interoperability Framework
<u>eEIF</u>	eHealth European Interoperability Framework
<u>ETSI</u>	European Telecommunications Standards Institute
<u>GS1</u>	Global Standards 1
HITCH	Healthcare Interoperability Testing and Conformance Harmonisation
<u>HL7</u>	Health Level 7
IAF	International Accreditation Forum
<u>IEEE</u>	Institute of Electrical and Electronics Engineers
IEEE	
<u>IETF</u>	Internet Engineering Task Force

<u>IHE</u>	Integrating the Healthcare Enterprise
<u>ISO</u>	International Standards Organisation
<u>IHTSDO</u>	International Health Terminology Standards Development Organisation
<u>MLA</u>	Mutual Recognition Arrangement
<u>M403</u>	Mandate 403 (eHealth Interop)
<u>NIST</u>	National Institute of Standards and Technology (U.S.A.)
<u>OASIS</u>	Oasis
<u>QLorC</u>	Quality Label or Certification
<u>QMS</u>	Quality Measuring System
<u>RENEWING HEALTH</u>	REgioNs of Europe WorkINg toGether for HEALTH
<u>RUP</u>	Rational Unified Process
<u>SNOMED-CT</u>	Systematized Nomenclature of Medicine - Clinical Terms
<u>UML</u>	Unified Modelling Language
<u>XDS</u>	Cross-enterprise Document Sharing (IHE)

7.2 Appendix B: Glossary of 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://itc1sc36.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	Generic EIF

	accorded proper legal weight”	
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	<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)	“An organisation developing profiles is called a Profile Development Organisation (PDO).”	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> 	Generic EIF <i>(italic: addition of study team)</i>

	<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

7.3 Appendix C: Overview of the identified IHE and Continua Profiles

Below is an alphabetic list of the Profiles that are mentioned in the Antelope Use Cases and Realisation Scenarios:

ATNA	Audit Trail and Node Authentication	basic security through (a) functional access controls, (b) defined security audit logging and (c) secure network communications
BPPC	Basic Patient Privacy Consents	method for recording a patient's privacy consent acknowledgement to be used for enforcing basic privacy appropriate to the use
CPMD	Community Medication Prescription and Dispense	integrates prescription, validation and dispensation of medication in the ambulatory sector.
CT	Consistent Time	enables system clocks and time stamps of computers in a network to be synchronized
DEC	Device Enterprise Communication	transmits information from medical devices at the point of care to enterprise applications
DIS	Pharmacy Dispense Document	records the dispense of medication to a patient
HPD	Healthcare Provider Directory	Provides a shared list of healthcare providers
LCSD	Laboratory Code Sets Distribution	distributes managed sets of clinical laboratory codes (battery, test and observation codes)
LTW	Laboratory Testing Workflow	integrates ordering and performance of in-vitro diagnostic tests by a clinical laboratory inside a healthcare institution
PAM	Patient Administration Management	establishes the continuity and integrity of patient data in and across acute care settings, as well as among ambulatory caregivers
PDQ	Patient Demographics Query	lets applications query by patient demographics for patient identity from a central patient information server
PIX	Patient Identifier Cross Referencing	lets applications query for patient identity cross-references between hospitals, sites, health information exchange networks, etc.
PRE	Pharmacy Prescription Document	records a prescription
RID	Retrieve Information for Display	simple and rapid read-only access to patient-centric clinical information that is located outside the user's current application
RTM	Rosetta Terminology Mapping	harmonizes the use of existing nomenclature terms defined by the

		ISO/IEEE 11073-10101 nomenclature standard
SVS	Sharing Value Sets	distributes centrally managed common, uniform nomenclatures
SWF	Scheduled Workflow	integrates ordering, scheduling, imaging acquisition, storage and viewing for Radiology exams
XCA	Cross-Community Access	allows to query and retrieve patient electronic health records held by other communities
XCPD	Cross-Community Patient Discovery	supports locating communities with patient electronic health records and the translation of patient identifiers across communities.
XD-LAB	Sharing Laboratory Reports	content (human and machine readable) of an electronic clinical laboratory report
XDR	Cross-enterprise Document Reliable Interchange	exchanges health documents between health enterprises using a web-service based point-to-point push network communication
XDS	Cross Enterprise Document Sharing	share and discover electronic health record documents between healthcare enterprises, physician offices, clinics, acute care in-patient facilities and personal health records
XDS-I	Cross-enterprise Document Sharing for Imaging	Update extends XDS to share images, diagnostic reports and related information across a group of care sites.
XDW	Cross Enterprise Document Workflow	coordinates human and applications mediated workflows across multiple organizations
XPHR	Exchange of Personal Health Record	content and format of summary information extracted from a PHR system for import into an EHR system, and visa versa
XUA(++)	Cross-Enterprise User Assertion	communicates claims about the identity of an authenticated principal (user, application, system...) across enterprise boundaries - Federated Identity. The “++” is an extension of the Profile attributes

In the schema below, an overview of these different Profiles is given. The Profiles are divided into overall functionality groups.

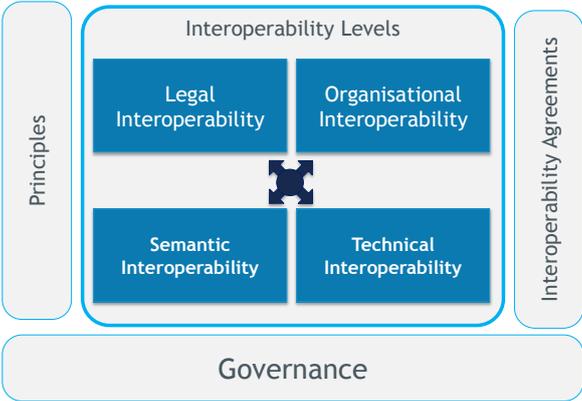


Figure 8: IHE and Continua Profiles referred in this document

7.4 Appendix D: Refinement of the eHealth EIF model

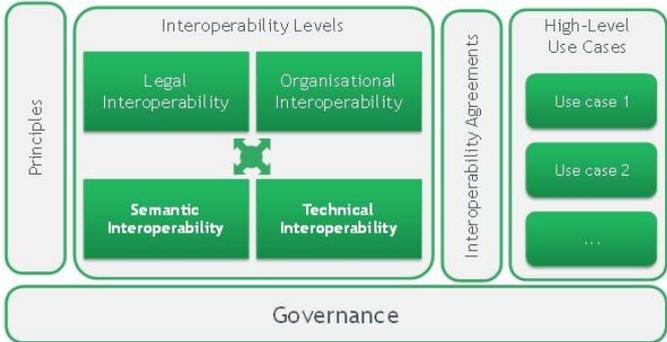
From EIF model to the eHealth EIF model.

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.

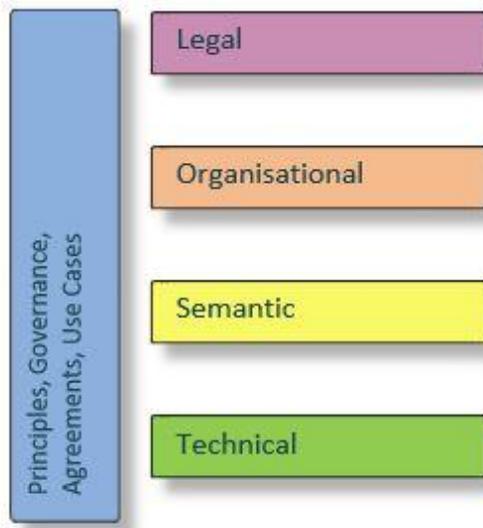
Inventory of current interoperability models

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.

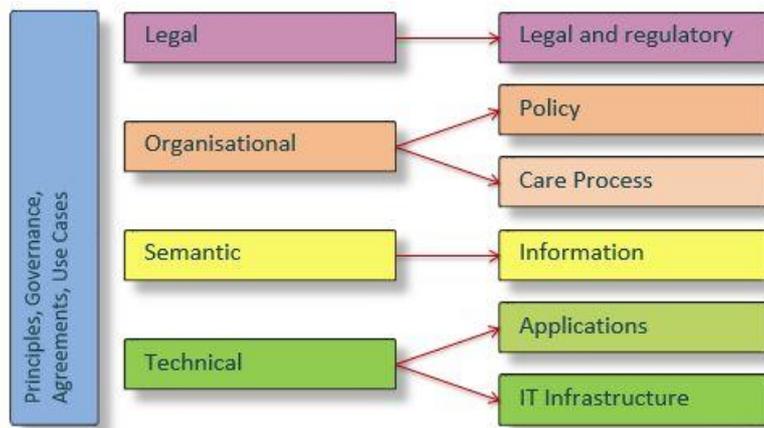
These refinements are described below.

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	Here, a distinction has been made between interoperability between healthcare ICT systems (which often need proprietary connections and

	IT Infrastructure	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
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Here is the visual representation of the second step:



In the third step, the “cross-level” aspects are divided into two vertical bars that represent aspects that are relevant to all the horizontal bars:



The first vertical bar points to the importance of using (open and international) standards and profiles in all the interoperability layers, and that these can be tested and labelled / certificated. The second vertical bar highlights the need for addressing security and privacy in all the layers.

Note: the vertical bars can be left out or in, depending on the purpose of the model. This is also the case for the grey sidebars. On a national level, the upper bar (legal and regulatory) is sometimes left out also, because within one region / country, the legislation is the same for everyone.

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