eHealth Standards and Profiles in Action for Europe and Beyond

Deliverable 2.3: Extension of the eEIF #2: Quality Management System for Interoperability Testing

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### Statement of originality

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Abbreviations

CEF: Connecting Europe Facility
(http://ec.europa.eu/digital-agenda/en/connecting-europe-facility)

GA: Grant Agreement

MoU: Memorandum of Understanding

PHC34: PHC-34 projects: eStandards, OpenMedicine, ASSESS CT, VALUeHEALTH

P.O.: Project Officer (E.C.)

SDO: Standard Development Organizations

T/C: Telephone Conference (e.g. GoToMeeting)

TOC: Table of Content

WP: Work Package
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1 Executive Summary

Implementing interoperability is complex and requires special attention to improve the quality development approaches in general as well as quality in the application of the eHealth solutions. This includes interoperability perspective requirements (eq. profiles and standards) and the exchange of information with systems using the same standards. The use of standards can avoid wasting resources reinventing the wheel, whilst offering their users elements of a of common framework and compatibility between vendors. Consider what eHealth systems and interoperability would be like without standards:

- might not work as expected
- exchanged data may be of inferior quality
- may be incompatible with equipment and devices – eHealth systems may not even connect with them
- health organisations would be restricted to one vendor
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Several healthcare authorities have identified quality labelling and certification as an important means to stimulate or enforce the market to comply with national or regional functional and quality requirements as well as to enforce the use of selected standards. In the Antilope project (https://www.antilope-project.eu/), a Quality Management System (QMS) for Interoperability Testing was described and validated. The QMS includes requirements for entities performing Interoperability Testing and the generic description of 9 processes on how to perform Interoperability Testing.

The main objective for this document is to link the (Antilope) Quality Management System for Interoperability Testing to the Refined eHealth European Interoperability Framework (ReEIF).

In this document, the QMS work done for interoperability testing in Antilope is linked into the Refined eHealth EIF layers.

Additionally, this document has identified recommendations for each of the ReEIF layers to ensure efficient and trustworthy interoperability testing:

- **Layer: Legal and regulatory**
  - R01: Catalogue of standards *(what standard can be used and can be tested for interoperability)*
  - R02: Understanding the legal and regulatory framework *(the legal and regulatory aspects which are important in the context of interoperability testing)*

- **Layer: Policy**
  - R03: Measure the use of standards *(also to improve the interoperability testing)*
  - R04: Declare the maturity of standards and interoperability knowledge *(when buying eHealth solutions the vendor and buyer needs to understand the interoperability challenge)*

- **Layer: Care process**
  - R05: Use of realisation scenarios *(what standards can be used for specific ReEIF use*
Layer: Information
  o R06: employ clinical content definitions (there is a need for using formal methods for Clinical Content Definition, including linking to interoperability testing)

Layer: Application
  o R07: apply Quality Management System for Interoperability Testing (deploy the QMS for interoperability testing, developed in Antilope)
  o R08: apply Quality Management System for integration Profiles (based on European best practice)

Layer: IT-infrastructure
  o R09: monitor the maturity of the infrastructure (Use Technology Readiness Levels (TRL) methodology for a qualified dialog between vendors and stakeholders also for interoperability testing).
2 Introduction

2.1 Purpose of this Document

Standards help optimise eHealth systems functionality and compatibility, facilitate interoperability and support consumer safety and public health. Standards form the fundamental building blocks for service and product development by establishing consistent protocols that can be universally understood and adopted. Standards also make it easier to understand and compare competing eHealth systems and it is only with standards that the requirements of interoperability can be assured.

The use of standards can avoid wasting resources reinventing the wheel, whilst offering their users elements of a common framework and compatibility between vendors. Consider what eHealth systems and interoperability would be like without standards:

- eHealth systems might not work as expected
- exchanged data may be of inferior quality
- eHealth systems may be incompatible with equipment and devices – they may not even connect with them
- health organisations would be restricted to one vendor
- vendors would be obliged to invent their own individual solutions to even simplest needs

Today, it is a common requirement that eHealth solutions share seamlessly data (i.e. are interoperable) between products from different vendors and across organisations. Implementing interoperability is complex and requires special attention to improve the quality of development as well as the quality in use of the eHealth solutions.

Several healthcare authorities have identified quality labelling and certification as an important means to stimulate or enforce the market to comply with national or regional functional and quality requirements as well as to enforce the use of selected standards.

One of the assignments for the Antilope project\(^1\) was to deliver a refinement to the first version of the eHealth European Interoperability Framework (see section 4.3). Another assignment for the EC Antilope project was to deliver a Quality Management System for Interoperability Testing.

One purpose of this document is to link the work done in Antilope into the Refined eHealth EIF layers. This will be a relevant input to the roadmap, as we propose that the SDO’s can take ownership for the future maintenance on the Quality Management System for Interoperability Testing.

The document is structured as follows:

- Chapter 3 introduces the concepts for Quality Management System for Interoperability Testing by explaining each of the concepts separately and connected.

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\(^1\) https://www.antilope-project.eu/front/index.html
• Chapter 4 gives a historic overview of the evolution of the eHealth European Interoperability Framework
• Chapter 5 provides an gap analysis for the Refined eHealth European Interoperability Framework focusing on achieving interoperability and interoperability testing
• Chapter 6 describes key areas to be considered in the legal and regulatory layer regarding achieving interoperability and interoperability testing
• Chapter 7 describes key areas to be considered in the policy layer regarding achieving interoperability and interoperability testing
• Chapter 8 describes key areas to be considered in the care process layer regarding achieving interoperability and interoperability testing
• Chapter 9 describes key areas to be considered in the information layer regarding achieving interoperability and interoperability testing
• Chapter 10 describes key areas to be considered in the application layer regarding achieving interoperability and interoperability testing
• Chapter 11 describes key areas to be considered in the infrastructure layer regarding quality in interoperability testing
• Chapter 12 provides a summary of recommendation in the context of the ReEIF to be considered in the eStandards roadmap

2.2 Background: The eStandards Project

eStandards project is based on a community of SDOs, stakeholders and centres of competences and is supported by the eHealth Network, ISO TC215, GS1, IHTSDO, IEEE11073, and IMIA to advance eHealth interoperability and global alignment of standards with seven objectives:

1. Join up with Stakeholders in Europe and globally, to build consensus on eHealth standards, accelerate knowledge sharing, and promote wide adoption of standards.
2. Deliver an evidence-based Roadmap for alignment, iterative consolidation, and broad acceptance of eStandards that is endorsed by SDOs, the eHealth Network, the providers, and the Industry.
3. Contribute to the eHealth Interoperability Framework use cases focusing on clinical content modelling for different paradigms and embed a Quality Management System for interoperability testing and certification of eHealth systems.
4. Collect evidence and provide guidance on the coexistence of competing or overlapping standards in large-scale eHealth deployment nationally and cross-border.
5. Participate in EU/US MoU roadmap actions as the international patient summaries standard.
6. Explore socio-economic aspects of eHealth interoperability, revisiting the language for user-vendor interaction that embodies ‘co-making’ in trust, collaboration and long-term engagement.
7. Align across PHC-34 to nurture innovation, sustainability & growth under CEF and beyond contributing to Key actions of the Digital Agenda 2020.

The proposal’s ambition is to strengthen Europe’s voice and impact, while reinforcing the bridges established with the EU Patient Summary guideline across the Atlantic in Trillium Bridge and among MS with epSOS, eSENS, Antilope, and EXPAND. The eStandards Roadmap and associated evidence
base, a white paper on the need for formal standards, and two guidelines addressing how to work with: (a) clinical content in profiles and (b) competing standards in large-scale eHealth deployments will be pragmatic steps toward alignment and convergence.

**Partners**

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3 Quality Management System for Interoperability Testing

Implementing interoperability is complex and requires special attention to improve the quality management approaches in development in general as well as quality in the implementation and deployment of the eHealth solutions. This includes interoperability requirements (eq. profiles and standards) and the exchange information with systems using the same standards.

This chapter explains the different key concepts in a Quality Management System for Interoperability Testing. The aim is to ensure a common understanding of the concept of Quality, Management, Interoperability and Testing with the focus on adding value to the implementation of eHealth solutions, which can communicate meaningful information.

3.1 Quality

Quality in general can be seen as an accelerator to speed up provision of high quality services and products. However, quality is a complex concept. Definitions are usually inadequate in helping understand the complexity of the concept.

Quality is understood differently by different people. They use the same term, but the concept of quality is difficult to define in a way that is suitable in all contexts. The ISO 8402:1986 standard defines quality as "the totality of features and characteristics of a product or service that bears its ability to satisfy stated or implied needs".

The most accepted general definition is from ISO 9000:2015: – quality – “degree to which a set of inherent characteristics of an object fulfils requirements”. This definition is somewhat wider than from ISO 8402 as requirements include both needs and expectations.

Quality in healthcare is defined in EN 15224:2016 as "degree to which healthcare fulfils requirements related to defined quality aspects". This definition is based on the ISO 9000 definition and relates to eleven defined quality aspects of healthcare identified in the EN 15224 standard. The EN 15224 concretized for healthcare promotes the adoption of a quality process approach and a clinical process approach to enhance customer satisfaction by meeting customer and patient’s requirements.

In manufacturing, quality is a measure used to document that a service or a product is free from defects and significant variations. Any deviation from fulfilment of the requirements implies a non-conformance to the level of quality of the service or product.

The perception of quality is partly subjective and may be understood differently by different people. Consumers may focus on fulfilling their expectations and vendors on conforming to specifications.

The ISO 9001:2015 specifies requirements for a quality management system when an organization:

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2 ISO 8402:1994 Quality management and quality assurance - Vocabulary
3 EN 15224:2016 Health care services. Quality management systems.
a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
b) aims to enhance customer satisfaction through the effective application of the quality system including processes for improving the system and assuring conformity to customer and applicable statutory and regulatory requirements.

All the requirements of ISO 9001:2015 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

The standards themselves do NOT define the actual quality of a product or service.

In the context of interoperability testing, the quality can be judged as:

- “fitness for use”\(^5\)
- “conformance to requirements”\(^6\)

### 3.2 Quality Management

Quality Management aims to ensure that an organization, product or service is consistently fulfilling requirements\(^7\). It has four main components:

- quality planning
- quality provision assurance
- quality control
- quality improvement

Quality management is focused not only on product and service quality, but also on the means to achieve it. Quality management, therefore, uses quality assurance and process control to achieve consistent results.

Every organisation is dynamic and always in a state of change that includes changes to policies, objectives and procedures from time to time. Versioned documents (revisions) will reflect the changes. Revisions should have an effective date and, of course should be distributed in advance to ensure changes are well known and ready for use.

The implementation of Quality Management is a continuous cycle consisting of the following actions “Plan, Do, Check, Act” (PDCA\(^8\)), which are described below. The Quality Cycle is an iterative four-step management method for the control and continuous improvement of processes and results (services and products) shown in Figure 1.

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\(^5\) according to Joseph Juran (https://totalqualitymanagement.wordpress.com/2009/06/07/dr-joseph-juran/)
\(^6\) according to Philip Crosby (https://en.wikipedia.org/wiki/Philip_B._Crosby)
\(^7\) Quality Management. https://en.wikipedia.org/wiki/Quality_management#cite_note-1
\(^8\) https://en.wikipedia.org/wiki/PDCA
Figure 1: The PDCA cycle

- **Plan** – establish objectives and make plans (analyse organisation's situation, establish overall objectives and set interim targets, and develop plans to achieve them).
- **Do** – implement plan, execute the process
- **Check** – measure results (measure/monitor how far actual achievements meet the planned objectives).
- **Act** – correct and improve plans. Learn from mistakes done during practical planned implementation in order to achieve better results next time.

The PDCA cycle is also known as the Deming wheel\(^9\).

### 3.3 Quality Management System

A Quality Management System (QMS) is a collection of applied business approaches focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction.

Application of QMS in an organisation allows to:

- say what it does and do what it says
- document what it does, and do what it documents
- maintain consistency and transparency
- create a quality culture by applying “PDCA” cycle (Plan, Do, Check, Act)
- establish a clear basis from which continuous improvement can be achieved.

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The International Standard for Quality management (ISO 9001:2015) and the European concretization for healthcare EN 15224:2016 adopts a number of management principles identified in ISO 9000:2015 that can be used by top management to guide their organizations towards improved performance:

- **Customer focus**
  - The primary focus is to meet customer requirements and to strive to exceed customer expectations

- **Leadership**
  - Leaders shall establish direction and create the conditions to achieve the quality objectives.

- **Engagement of people**
  - Competent, empowered and engaged people are essential to create and deliver value.

- **Process approach**
  - Manage interrelated processes as a coherent system to deliver consistent results

- **Improvement**
  - Ongoing improvement of the quality objectives to support organizational success

- **Evidence-based decision making**
  - Decisions based on analysis of information leveraging theory and practice are more likely to produce the desired results.

- **Relation management**
  - For sustained success, an organization manages its relationships with interested parties and stakeholders.

### 3.4 Interoperability

Sharing of healthcare information is vital and the key to ensure and improve the patient healthcare provision as a part of the clinical process. The concept for meaningful sharing of healthcare information is interoperability. Interoperability can be expressed as shared understanding of data representations and concepts between different systems. Making interoperability operational can achieved by using high quality standards for sharing of healthcare information.

A widely used definition for interoperability comes from IEEE “the ability of two or more systems or components to exchange information and to use the information that has been exchanged”\(^{10}\). This definition has two parts. The first part “the ability of two or more systems to exchange information” is about standardisation of data formats and communication protocols to connect systems for the purpose of information exchange. The second part “the ability to use the information that has been exchanged” is addressing the challenge of developing systems where data can be used by both humans and machines, to achieve correct and meaningful utilisation of the exchanged data.

3.5 Testing

Testing is an investigation conducted to provide stakeholders with information about the quality of the product or service under test\(^\text{11}\). Test techniques include the process of errors or other defects, and verifying that the product is fit for use.

Testing will evaluate the extent to which the system under test (SUT):

- meets the requirements
- responds correctly to kinds of inputs
- performs its functions within an acceptable time
- is sufficiently usable
- can be installed and run in its intended environments
- achieves the general result its stakeholders desire

Testing can provide objective, independent information about the quality of the system software under test and the risk of its failure to users.

3.6 Interoperability Testing

The risks often seen in integration and poor interoperability are:

- Loss of data: As data is passed between applications, there is a risk the data can be lost or misdirected.
- Incorrect operation: As data and control are passed between applications, are the results correct? Does the application operate as the users expect?

These risks can also be seen as the driver for proactive strategy, which includes sufficient testing. To test the risk of loss of data involve communicating data across defined interfaces and then using the data in other eHealth solutions.

Interoperability testing involves testing whether a given software program or technology is compatible with others. Interoperability testing an eHealth solution encompasses testing with other eHealth solutions that have met compliance by using the same standards. Interoperability testing will assess and document the IEEE definition: “the ability of two or more systems or components to exchange information and to use the information that has been exchanged”. This interaction is always between 2 or more different systems or 2 or more different applications all together and demonstrates that implementation of standards provide end-to-end functionality as described or implied by a specification.

Many times interoperability testing is confused with conformance testing.

Conformance testing\(^\text{12}\) concentrates on specific components in a system often related to a single standard (or a set of related standards). It is unit testing rather than system testing. Conformance testing applies to open interfaces and checks for conformance of the unit under test to the

\(^{11}\) Exploratory Testing, Cem Kaner, November 17, 2006 (http://www.kaner.com/pdfs/ETatQAI.pdf)

\(^{12}\) HITCH project. D1.1 Definition of the QMS requirements. April 2010.
requirements defined in a base specification or profile (standard). Conformance tests are executed under controlled conditions using a dedicated test system. One of the strong points of conformance testing is that the tester has a very high degree of control and observability. This means, for example, that error behavior can explicitly be tested by provoking abnormal scenarios. In this sense, a good conformance test suite will include aspects of robustness, something which interoperability testing (commonly known as IOT) cannot (explicitly) do.

Interoperability Testing (IOT) concentrates on a complete system testing rather than unit testing. It shows, from the user’s viewpoint, that functionality is accomplished (but not how). Because tests are usually run over whatever (human user) interfaces are available, there is far less observability and control than with conformance testing. In this sense, IOT is less thorough than conformance testing, but wider in scope. Interoperability testing gives high-level of confidence that systems will interoperate with other systems against which it has been tested, but it does not prove conformity (interoperating systems may not be conformant), neither does it guarantee interoperability with other systems not included in the testing process.

Conformance testing and interoperability testing are complementary techniques. Many certification schemes require, for example, conformance testing as a prerequisite to interoperability testing.

### 3.7 Quality Management System for Interoperability Testing

Most everyone agrees that interoperability would improve patient care and reduce costs. However, unfortunately many solutions are not tested and implemented as specified and agreed before. This costs a lot of extra resources as many failures are only discovered once they are in daily operation. Unexpected failures leave customers and end-users with negative experience in using eHealth solutions in their daily practice and may seriously affect a patient’s treatment and safety.

The purpose of a Quality Management System for interoperability testing is to ensure the ability to provide high quality services and products by continuously enforcing quality policies and objectives for interoperability testing within the organization and across its borders. The implementation of the QMS for interoperability is a continuous cycle consisting of the actions “Plan, Do, Check, Act”.

4 The eHealth European Interoperability Framework

4.1 HITCH project (2010-2011)

The Healthcare Interoperability Testing and Conformance Harmonisation (HITCH) project\(^\text{13}\) developed in 2010-2011 a vision of how interoperability and conformance testing of eHealth systems should be organized in Europe and beyond. This ranges from the analysis of eHealth testing tools, over quality management in interoperability testing, to complete certification and quality labelling scenarios.

The HITCH project also contributed to the European Commission’s roadmap on eHealth interoperability testing and provided recommendations to institutions and authorities interested in establishing cross-vendor interoperability testing events but also to vendors that like to implement an in-house interoperability testing Quality Management System. Additionally, HITCH provided a vision on how a future eHealth quality labelling or certification could look like in Europe. The quality of the roadmap was quality assessed by HITCH partners that are already deeply involved in those topics.

4.2 eEIF (2012-2013)

In 2012, the European Commission developed an eHealth European Interoperability Framework (eEIF) in the context of the generic European Interoperability Framework (EIF). In 2013 Deloitte conducted a study report for the European Commission. The study, defines a vision of a European eHealth Interoperability Framework with four levels: technical, semantic, organisational and legal. It also assessed technical specifications from the epSOS\(^\text{14}\) interoperability framework and from two consortia, IHE\(^\text{15}\) and Continua Health Alliance\(^\text{16}\), against the identification criteria of the annex II of the Regulation on European Standardization\(^\text{17}\).

The roadmap on eHealth interoperability testing was included in the study.

The study consists of four parts\(^\text{18}\):

1. Study report
   - aims to provide a reading guide to the study by illustrating the background and rationale of the study
2. Vision on eHealth EIF
   - aims to build a consensus on the vision of the eHealth EIF
3. Assessment framework

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\(^{13}\) HITCH project. [http://www.hitch-project.eu/](http://www.hitch-project.eu/)

\(^{14}\) epSOS project. [http://epsos.eu/](http://epsos.eu/)

\(^{15}\) IHE Integration the Healthcare Enterprise. [https://ihe.net/](https://ihe.net/)

\(^{16}\) Continua Health Alliance (new name: Personal Health Alliance). [http://www.pchalliance.org/](http://www.pchalliance.org/)


- aims to provide a working tool to assess profile development organisations and their profiles

4. First proposal technical layer
- aims to create a preliminary, non-exhaustive version of the technical part of the eHealth EIF. Its scope is determined by a list of ten prioritised use cases and their corresponding profiles

The eHealth EIF is positioned as an operational tool kit for implementers and purchasers to deploy eHealth systems. The aim is to serve as a reference guide in calls for proposals and tenders, but possibly also for deployment at the national and regional levels. By offering such a toolkit, the eHealth Interoperability Framework will promote convergence on the use of interoperability standards and technical specifications and contribute to increasing the interoperability of deployed eHealth Systems.

As the intention of the study was to apply the generic EIF to the domain of eHealth, the structure of the generic EIF acted as a basis for the structure of the eHealth EIF.

A completeness check for all the different concepts used in the eHealth domain made it clear, that the notion of eHealth services, or more generally, high-level use cases, should be included in the eHealth EIF. A Member State analysis confirmed the importance of principles, organisational interoperability, semantic interoperability, and technical interoperability.

The eHealth EIF structure is shown on Figure 2 below.

![Figure 2. eHealth EIF structure](image)

It shall be noted that the four interoperability levels specified in the generic EIF are also used in the eHealth EIF for ease of comparison with that documentation. This was despite the fact that there were discussions and debate about the various levels of interoperability.
4.3 Antilope project

The ambition of the EC funded project Antilope was to drive eHealth interoperability in Europe and beyond. Between 2013 and 2015, key national and international organisations were working together to promote and drive adoption of testing guidelines as well as testing tools on a European and national level. They created, validated, and disseminated a common approach for testing and certification of eHealth solutions and services in Europe.

Antilope supported the dissemination and adoption of the European Interoperability Framework and roadmaps, National/Regional and local Interoperability projects building on these recommendations. In particular, with relation to the eStandards project, Antilope delivered:

- A refined eHealth European Interoperability Framework (ReEIF)
- Defined and validated testing guidelines and common approaches on Interoperability Labelling and Certification processes at European and at National/Regional level.

The two deliverables are further described below.

4.4 Refined eHealth European Interoperability Framework

One of the assignments for the EC Antilope project was to deliver a refinement to the first version of the eHealth European Interoperability Framework.

Interoperability involves many different aspects that have to be taken into account. Aspects such as legislation and guidelines, contracts and agreements between exchanging parties, governance and maintenance, shareable workflows, standardised data elements, semantic and syntactic choices, applications, technical infrastructure, and safety and privacy issues, all play a part. Only when all these aspects have been taken into account, and when all stakeholders are involved in the process, implementation can be successful.

The refined eHealth EIF model is an extension of the original EIF model, which comprises of four main layers as shown on Figure 3.
Figure 3. The original eHealth EIF has four main layers.

The refined model splits two of the original layers into two, and expands to six layers as shown on Figure 4.

Figure 4. Refining the eHealth EIF from four to six main layers.
Since 2012 the eHealth Network (eHN\textsuperscript{19}) has been in place as the formal meeting point on eHealth of the ministries of health of the EU Member States, mandated by article 14 of the Directive on Patients’ Rights in Cross Border Health Care. The European Commission (DG Santé) is co-chairing this network with one of the member states.

The eHN endorsed the Refined eHealth EIF (ReEIF\textsuperscript{20}) on the 8\textsuperscript{th} meeting in November 2015. The ReEIF is expected to be of great structuring value for the communication and decision-making processes on projects and solutions for eHealth. It offers a framework of terms and methodologies for reaching a common language, a common starting point, for the analysis of problems and the description of eHealth solutions throughout Europe.

## 4.5 Quality Management System for Interoperability Testing

Another assignment for the EC Antilope project was to deliver a Quality Management System for Interoperability Testing.

The deliverable was a Quality Manual for Interoperability, consisting two parts:

- Part I: Quality Management System (QMS) for Interoperability Testing
- Part II: Interoperability Testing Processes.

The Quality Manual is a customisable description and a set of templates that allow a Testing Entity to create its own, specific Interoperability Testing guideline in the form of a single Quality Manual for Interoperability Testing. Authorities and end users may also use the Quality Manual for Interoperability Testing to confirming or recognising the quality and competencies for the entity performing the interoperability testing.


Part I of the Quality Manual describes a generic Quality Management System and requirements for the operation of Conformity Assessment Bodies (CAB) performing Interoperability Testing. The implementation of the QMS for interoperability is a continuous cycle consisting of the actions “Plan, Do, Check, Act” based on the main principles in ISO 9000.

Part II of the Quality Manual describes the Interoperability Testing Processes. The Interoperability Testing Processes is a set of interconnected “guidelines” that describes how to run a test session from start to end. Each process has defined input and output and can be maintained and improved in isolation and by different people with the required experience and skills.

The Interoperability Testing Processes are based on IEEE 829:2008\textsuperscript{21} and European Best practice and describes processes for:

- Quality Planning
- Test Plan Definition
- Design Tests
- Develop or Select Test Tools
- Validation
- Prepare Test Session
- Test Plan Execution

\textsuperscript{21} IEEE 829:2008 Standard for Software Test Documentation
- Project Management
- Process Management Update

Each of the nine interconnected Interoperability Testing Processes is described by using a generic template and a checklist on how each process can be adjusted to specific and/or local use.
5 High level mapping of the QMS for IOT to the ReEIF

The main objective for this document is to link the (Antilope) Quality Management System for Interoperability Testing to the Refined eHealth European Interoperability Framework (ReEIF).

In the following Table 1, the six interoperability levels are explained in more detail.

Table 1. The six ReEIF levels explained.

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal and regulatory</td>
<td>On this level, compatible legislation and regulatory guidelines define the boundaries for interoperability across borders, but also within a country or region.</td>
</tr>
<tr>
<td>Policy</td>
<td>On this level, contracts and agreements between organisations have to be made. The purpose and value of the collaboration must be set. Trust and responsibilities between the organisations are formalised on the Policy level. In governance documents, the governance of collaboration is anchored.</td>
</tr>
<tr>
<td>Care Process</td>
<td>After the organisations have agreed to work together, specific care processes are analysed and aligned, resulting in integrated care pathways and shared workflows. This level handles the tracking and management of the workflow processes. The shared workflow prescribes which information is needed in order to deliver the integrated care.</td>
</tr>
<tr>
<td>Information</td>
<td>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.</td>
</tr>
<tr>
<td>Applications</td>
<td>On this level, agreements are made about the way import and export of medical information are handled by the healthcare information systems. The technical specification of how information is transported is at this level (communication standards). The information systems must be able to export and import using these communication standards. Another aspect in this level is the integration and processing of exchanged information in user-friendly applications.</td>
</tr>
<tr>
<td>IT Infrastructure</td>
<td>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.</td>
</tr>
</tbody>
</table>
For each of the ReELF layers a number of key areas have been identified to be taken into consideration for achieving interoperability and interoperability testing. However, some of the key areas are not to be considered directly for interoperability testing activities, but as a prerequisite or necessary for efficient interoperability testing.

**Figure 6. Key areas for achieving interoperability through efficient interoperability testing.**
6 Layer: 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.

Using technology to improve eHealth services including sharing of essential data for the individual patient, can potential save a significant amount of money and can allow citizens easier access to their own data and facilitate their participation in prevention and treatment. However, all too often, such progress is hindered by difficulties connected to implementation.

The legal and regulatory aspects are not always updated for communication technology solutions. They miss essential elements for delivering the eHealth interoperability building blocks necessary for health care services and for involving patients and citizens.

Interoperability also involves international cooperation. Agreement on cross-border interoperability can help to create the robust and resilient infrastructures necessary to exchange health data information.

The EU Commission highlights the importance of interoperability as a core element of its Digital Single Market Strategy. A Digital Single Market is one in which the free movement of goods, persons, services and capital is ensured and where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence. Achieving a Digital Single Market will ensure that Europe maintains its position as a world leader in the digital economy, helping European companies to grow globally.\(^{22}\)

One of the major challenges in making eHealth systems interoperable is that the rules that apply to these transactions can be complex, unclear, and may differ between Member States.

6.1 What standards to be used

Standards play a key role in achieving interoperability and enable products to work together. They also lead to improved service quality and a competitive market with a diversity of vendors and new technological development.

The value of interoperability depends on the relevance and comprehensiveness of the data communicated that concern clinical relevance and clinical context. Standards applied to support high level of interoperability need to include both these aspects – clinical relevance and context and this means that the relation to defined clinical processes and the main type of health problems for patient treatment need to be unambiguously defined.

An open standard is usually contrasted with proprietary standard or a standard that is owned and controlled by an individual or a corporation.

Achieving interoperability through standards usually entails adopting a set of standards and
guidelines that specify the preferred way that health organisations, vendors, citizens and other
partners interact with each other.

The aim is to agree on a set of standards (catalogue of standards), which forms the requirements for
eHealth solutions. The catalogue of standards will provide important information for procurers,
vendors and the owners on standards, which are mandatory to use. The catalogue of standards may
not only list agreed standards but also list emerging new standards, which are monitored but not yet
mandated to use. The catalogue may also list the maturity level of individual standards and examples
of their use. The standards catalogue should have basis in the eHealth legislation.

The agreed set of standards will take into account the standards development lifecycle23 as shown on
Figure 7.

![Figure 7. Standards Development lifecycle. Source: eStandards D3.1.](image)

Each standard in the standards catalogue shall be provided with sufficient information, for example:

- The name and version of the standard
- Description of the standard
- Link to the standard
- Who are the owner of the standard
- The degree of recommendation for the standard
- The purpose/use of the standard
- Who shall use the standard
- How to respect the standard
- Date for use of the standard

23eStandards D3.1 The case for formal standardization in large-scale eHealth deployment.
http://www.estandards-project.eu/index.cfm/published-deliverables/#collapse3
• Type of the standard

Based on the requirements for an eHealth solution and the standard catalogue, the vendor and buyer decide the set of standards to be implemented.

Many years’ experiences show the benefit and needs to test and certify if a vendor have implemented a standard correctly.

A natural consequence of the catalogue of standards is that all eHealth systems can be tested and certified for the standards implemented. Only standards, which are in the catalogue of standards can be tested and certified.

6.2 Reference architectures

Reference architectures describe the main logical structures and concepts for a specific area, which can form the basis for the selection of standards to be used. They act as framework for the development of interoperable eHealth solutions. Reference architectures draw point of orientation and principles for the development of the specific area and provide the health care partners and vendors with a common conceptual ground for the development. To create coherence, it is important that development of standards and profiles is connected to data and architecture. This accordance can be achieved by describing in the reference architecture the context of use for the standards.

6.3 Access to data

In health care, informed consent refers to the process whereby the patients and the health care practitioners engage in dialogue about the nature of a proposed medical treatment, the consequences, the harms, the benefits, the risks, and the alternatives. Informed consent is a fundamental principle of health care. In the context of interoperability testing, it is important to have a good understanding of the legal framework. The rules vary from country to country and the use and requirements about standards and interoperability testing is often very abstractly described.

Informed consent is also about the patient’s right to deny access his/her health data. For example in a certain country, patients may have the right to deny that a specific health care professional have access to his/her health data as shown on Error! Reference source not found..
Looking further at this example will raise a number of questions. For example, what happens to data, which previously have been communicated.

Common interpretation of the legal and regulatory framework will ensue that data communicated between systems is only accessible to authorised users. For example, when an electronic prescription is transmitted from a primary care system to a pharmacy system, only the users authorised to prescribe, dispense or administer the prescription can access the information.

Health information interoperability standards are developed by a wide variety of stakeholder organisations including regulators, vendors, consultants and healthcare providers. Most often, the development of interoperability standards involves technical committees that define methods and groups representing communities of interest.

Concerning interoperability testing it will be useful to have guidelines and examples on how standards shall be implemented taking into account the legal and regulatory framework. The guidelines and examples will need input from the standardisation organisations and the authorities in charge of the legal and regulatory framework. This would allow interoperability testing to be attuned to specific jurisdictions, using testing scenarios that abide to the local rules.

### 6.4 Benefits and costs of interoperability

A Digital Single Market is one in which the free movement of goods, persons, services and capital is ensured and where individuals and businesses can seamlessly access and exercise online activities under conditions of fair competition, and a high level of consumer and personal data protection, irrespective of their nationality or place of residence. Achieving a Digital Single Market will ensure that Europe maintains its position as a world leader in the digital economy,
helping European companies to grow globally\textsuperscript{24}.

In more than 20 years a lot efforts were invested into the development of standards for health information representation, communication and interoperability testing. The optimal degree of interoperability is context-specific and depends on technological solutions, use of standards, and the economic conditions in a market. Interoperability is not an aim in itself and there are both benefits and costs of interoperability to consider.

There is a need to balance the demand for interoperability and still achieve optimum benefits. Consequently, the business drivers for a sustainable health system are those that reduce the demand and enhance the provision of quality care in a timely manner. To meet these requirements stakeholders need to invest in the establishment of the necessary eHealth infrastructure components, based on standards. This investment will also include the operation of the infrastructure including test and certification of vendor system to ensure they have implemented the agreed standards as agreed and specified.

The benefits and cost of achieving interoperability is an open question, which still requires more research. We have attempted to answer this question in part in eStandards D6.3 and D4.2r2, but there is need for more systematic work. As shown on Error! Reference source not found. there is a desired range for the degree of interoperability by comparing the economic benefits and the related cost.

For example interoperability can be achieved by sharing free text. This will be useful in many situations to get the needed information to continue a treatment. But, if all information which are shared, information based in free text will grow and in many other situations it will be chaotic to get an overview of historic data and use the information in a specific treatment. If the same (free text) information is communicated highly structured and coded, it may in some cases be difficult to implement, because the many different systems have to update their internal structure to retrieve and process the information correctly. Some areas will even be so complex that the project for achieving interoperability fails.
7 Layer: Policy

On this level, contracts and agreements between organisations have to be made. The purpose and value of the collaboration must be set. Trust and responsibilities between the organisations are formalised on the Policy level. The governance underpinning collaboration is anchored in governance documents.

The Re EIF policy layer describes the process with which a group takes decision to direct the development of interoperability and the quality of interoperability testing. eHealth policies are affected by the country’s organisational structure from the state, to the government and down to the citizen.

7.1 Measuring the use of standards

Many countries have Health information technology or eHealth strategies supporting that development of health information and communication technologies (ICT) contribute significantly to improving the health system. Such development requires successful coordination, integration, and sharing of information in a context of changing work processes and a continuously changing political environment.

Best practice eHealth strategies include a well-defined vision, strong national leadership with participation from all stakeholder groups engaging people with Health Informatics expertise and identifying actions to guide the development and implementation eHealth solutions. Such strategies need to include the establishment and maintenance of the necessary national eHealth infrastructure based on standards.

Selecting a standard is a strategic choice and an important requirement is if that standard is fit for purpose. The most important criteria for assessing if a standard is fit for purpose is the extent of current use, which includes:

- for what purpose (Re EIF use case)
- status and duration for the use (trial, daily operation)
- where are the standard used (countries, regions, local)
- vendors/system (how many vendors have implemented the standard and in what systems)

Detailed information on the use of specific standards is in general limited and moreover, is not monitored and published by the standardisation organisations. In the past years, there have been many EC funded project with the aim of collecting and assessing the use of eHealth and to a lesser degree use of interoperability standards.

For example, in 2011, an eHealth Strategies study\(^\text{25}\) published progress achieved with respect to national and regional eHealth solutions in EU and EEA. The study report gives no concrete information on what eHealth standards are used.

\(^{25}\) eHealth Strategies. European countries on their journey towards national eHealth infrastructures. Karl A. Stroetmann, Jörg Artmann, Veli N. Stroetmann, January 2011
The global internet population grew 18,5% from 2013-2015 and represents now 2,3 billion people. Figure 10 shows the number of “transactions” which happens every minute for some of the popular services on the internet:

- Skype calls (110.040)
- Facebook user likes (4.166.667)
- Twitter tweets (347.222)
- Snapchat snaps (284.722)

![Figure 10. The global internet population is 3.2 billion people (Source: Doug Fridsma)](image)

Those figures cannot and shall not be compared to eHealth communication. However, the monitoring of numbers can be used as common means to measure eHealth strategies with regards to interoperability achieved.

Strategic initiatives can be extended with information on potential “transactions” and milestones for achieving an agreed number of transactions. In the context of interoperability and interoperability testing, there is need to discuss this topic with the standardisation organisations to agree on how use of standards can be monitored.

### 7.2 Declaring maturity for knowledge to standards and interoperability

The need to refer to standards to ensure interoperability of eHealth solutions has become obvious to all levels of administration where purchasers are aware of their responsibility in this area.
For some eHealth solutions, the related standards, the technical implementations, and the clinical content to be communicated are general knowledge. In such a case, procurement is straightforward.

However, in general, purchasing an eHealth solution involving standards is complex and requires close co-operation between the end-user organisations and the vendors of the solution. Existing means of public procurement through mandatory reference to standards is in general not effective due to a technical and educational gap between the standards and the end-users of the eHealth solutions. Unfortunately, many eHealth solutions are not tested and implemented as specified and agreed or requirements are not specific enough. This costs a lot extra resources as frequently failure is first detected when the eHealth solution is in daily operation. Unexpected failures leave customers and end-users with negative experience in using eHealth solutions in their daily practice and may seriously affect patient’s treatment and safety.

A policy for disclosing skills and knowledge of the buyers and sellers concerning standards, interoperability and interoperability testing may accommodate this challenge. It is already common and well known how to make demands in the tender documents for the vendors’ knowledge and maturity in supporting the fundamental processes for achieving interoperability.

In the tender documents, it is likewise important to declare the maturity of the buyer’s knowledge of processes with achieving interoperability. The vendors’ maturity can enter into the evaluation criteria for selecting the best offer. But most important is to compare the vendors’ and the buyers’ maturity for processes for achieving interoperability. The objective is to detect any missing expertise and agree how this can be allocated to the project. For example, vendors have sufficient knowledge regarding implementing the technical standards, but limited experience in the configuring clinical processes and specifying the clinical content. Alternatively, the buyers may have the expertise in the clinical processes but limited knowledge or hospital use of standards. It this example, it is important to include extra resources and knowledge to assist the work on identifying what data from the hospital treatment are necessary to share with other health organisations.

The maturity declaration for the buyer is primarily focussed on whether they are prepared to support the development and implementation of the new eHealth solution. For the co-operation to be successful, it is important to be open and honest about the available resources, the expertise, and knowledge that can be invested in the project.

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8 Layer: Care Process

After the organisations have agreed to work together, specific care processes are analysed and aligned, resulting in integrated care pathways and shared workflows. This level handles the tracking and management of the workflow processes. The shared workflow prescribes which information is needed in order to deliver integrated care.

Interoperability is important as data needs to be accessible and sharable across organisations and providers. However, the interoperability challenge is often discussed purely from a data and eHealth solution perspective. When we need to recognise that interoperability is more than integrating data across various different eHealth systems. Interoperability needs to support workflow and processes and needs to be implemented with specific objectives such as efficiency and care pathways in mind. Just because two eHealth solutions are interoperable it does not mean that clinical pathway across eHealth solutions is well supported. It is important that health processes also interoperate and that people involved share common understanding to enable an eHealth solution in one organisation work seamlessly with an eHealth solution in another organisation.

8.1 Access to data in handover situations

Clinical pathways shall be well-documented in handover situations, where the responsibility for the treatment of the patient is transferred to another organisation and shall be agreed across specialities and organisations. This work is also important for achieving interoperability and testing the overarching eHealth system for interoperability, even if defining the clinical pathways is not within the scope for this document.

However, the handover situations are exactly the key point for achieving interoperability. When a patient during a visit to his General Practitioner is referred to a highly specialised service in a Hospital, some data is vital to continue the treatment efficient. In this example, it is obvious that the data shall be communicated by using a referral standard. In many other situations, however, it will be very useful that the clinical pathway descriptions are supported by data sharing agreements, which describe the standards to be used and the minimum data sets, which can be shared in specific situations. These data sharing agreements will be employed in the interoperability testing of eHealth solutions.

It can be considered that the standards also should include information on where in the clinical pathways they can be used perhaps by adding examples on existing use of the standards related to use cases, which are in daily operation.

8.2 More use case realisation scenarios

In the eHealth Interoperability Framework (eEIF), launched by DG Connect of the European Commission, eight use cases were identified. The Antilope project refined the eEIF (ReEIF) and added templates for use case descriptions as well as realization scenarios.

eStandards D2.1 Extension of the eEIF added two new use cases. The resulting ten use cases are
shown in Table 2.

Table 2. ReEIF use cases

<table>
<thead>
<tr>
<th>№</th>
<th>Medical domain</th>
<th>Use case title</th>
<th>Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medication</td>
<td>e-Prescription and e-Dispensing</td>
<td>eEIF, ReEIF (Antilope)</td>
</tr>
<tr>
<td>2</td>
<td>Radiology</td>
<td>Request and results sharing workflow for radiology</td>
<td>eEIF, ReEIF (Antilope)</td>
</tr>
<tr>
<td>3</td>
<td>Laboratory</td>
<td>Request and Results sharing workflow for laboratory</td>
<td>eEIF, ReEIF (Antilope)</td>
</tr>
<tr>
<td>4</td>
<td>Patient Summary</td>
<td>Patient Summary Sharing</td>
<td>eEIF, ReEIF (Antilope)</td>
</tr>
<tr>
<td>5</td>
<td>Referral- and Discharge reporting</td>
<td>Cross-enterprise Referral and Discharge Reporting</td>
<td>eEIF, ReEIF (Antilope)</td>
</tr>
<tr>
<td>6</td>
<td>Participatory healthcare</td>
<td>Involvement of chronic patients in electronics documentation of healthcare information</td>
<td>eEIF, ReEIF (Antilope)</td>
</tr>
<tr>
<td>7</td>
<td>Tele monitoring</td>
<td>Remote monitoring and care of people at home or on the move using sensor devices</td>
<td>eEIF, ReEIF (Antilope)</td>
</tr>
<tr>
<td>8</td>
<td>Multidisciplinary consultation</td>
<td>Medical Board Review</td>
<td>eEIF, ReEIF (Antilope)</td>
</tr>
<tr>
<td>9</td>
<td>Antenatal care</td>
<td>Integrated antenatal care</td>
<td>eStandards (D2.1)</td>
</tr>
<tr>
<td>10</td>
<td>Public Health</td>
<td>Immunization use case</td>
<td>eStandards (D2.1)</td>
</tr>
</tbody>
</table>

Figure 11 explains the relation between Use Case, Realisation Scenario, and an actual (national) project. A Use Case is an implementation-independent description that can be adopted by all European 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, eHealth projects can decide which Realisation Scenario best suits the national/regional or local requirements.

Figure 11. Projects select a certain Realisation Scenario that fits their needs (source Antilope project)
eStandards D2.1 included the development of a use case database and the related realization scenarios.

In practice, there are several potential realization scenarios for each use case, but the use cases in the repository include only one or few realization scenarios for each use case. Hopefully, standardization organizations and eHealth projects will add more realization scenarios in the future, showing how a use case can be implemented using different IT architectures and families of standards.

27 The ReEIF use case repository can be accessed at: http://usecase-repository.ihe-europe.net
9 Layer: 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.

Healthcare is information-intensive, generating huge volumes of data every day. The cost for handling information take up a large part of the total health budget and encompasses collecting information, storing information and searching for information. It is therefore essential that information is managed in the most effective way possible in order to ensure a high quality and safe health care service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. In order to deliver these benefits health information standards must not only cover the syntax (structure) but also the semantics (meaning) of the data exchanged. For example, when giving a patient a drug, a nurse needs to be sure that the prescribed dose of the correct drug are administering to the right patient and that the patient is swallowing the drug. Lack of up-to-date information can lead to the unnecessary duplication of tests and delays in treatment. In addition, health information has a key role to play in healthcare decisions, introduction of new treatments and decisions on best value for money in health and social care provision.

Information and communications technology (ICT) has an important role to play in ensuring that information to drive quality and safety in health and social care settings is available when and where it is required. For example, it can support a much faster, more reliable and safer information flow between the many health care organisations, such as general practitioners and hospitals.

During the past years, many successful ICT solutions have been implemented. However, it is still common that patients are asked the same questions due to lack of a coherent and integrated approach to health information. There are several reasons, not only technical reasons, but also organisational, legal and medical. A analyse of why clinical information is not reused is shown in Table 3.

Table 3. Reasons why clinical information is not reused. (Source: Gert Galster. MIE 2012).

<table>
<thead>
<tr>
<th>Missing availability to data</th>
<th>Why</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>The information is not when or where it is needed</td>
<td>The health record is being, so I have to ask the patient about the same questions as my colleague</td>
<td>Organisational</td>
</tr>
<tr>
<td>The information is present, but usage of the existing source is prohibited</td>
<td>The patient has not consented that I can see the health record</td>
<td>Legal</td>
</tr>
</tbody>
</table>
The information is present but not routinely used in its available form for quality

The information does exist in the nationwide registry, but the overall quality is not sufficient for clinical use

Organisational

The information is apparently present, but in the specific situation it is considered inadequate due to inadequate relevance

Clinical information has a shelf life. The temperature from yesterday cannot be used today

Medical

Achieving human interoperability is still a research and clinical challenge, especially when the healthcare information is re-used cross sector involving different health specialities, different vocabularies and classification systems. The optimal division between sharing free text and/or highly structured information is also challenging. Free text is often very useful to understand the actual problem for a patient. If the actual problem instead is structured it may be more difficult to achieve human interoperability.

In other words, interoperability can be achieved via a set of precisely defined terms that are shared among a set of well-known participants. The disadvantage is that these terms usually have different meanings for other communities.

### 9.1 Clinical Content Definition

Health care is fragmented. Treatment is across sectors with many specialities. The health professionals have different educations and use different sets of concepts (classifications). Ogden and Richards\(^\text{28}\) meaning triangle on Figure 12, shows the challenges in sharing the same understanding of concept.

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What can be easily understood in one organisation can be misinterpreted or difficult to understand in other organisations. Clinical documentation as free text is well understood across organisations but is not preferred when the need arises to get a quick overview of the patient’s conditions or to carry out more complex analysis.

Medical informatics professionals have for many years worked on defining concepts for structured data. Today we know that too much structure leads to difficulties in understanding the data communicated and imposes extra workload in data entry. The balance between free text and structured data is still a major challenge for the quality of the clinical content to be shared.

From the early use of Information and communications technology (ICT) in the health care sector, the many different vendor applications have most often been established by an autonomous data design approach. This is a critical factor that has hindered meaningful sharing of data across different clinical scenarios. Messaging standards, e.g. UN/EDIFACT and HL7 v2.x, have been widely implemented for many years and have supported well many use cases where a paper-flow was substituted by a digital solution (discharge letter, referral, prescription, lab result).

The requirement for today’s digital eHealth solutions is often based on a set of standards from different standardisation organisations.

Clinical content is the definition, in fine-grained detail, of what we mean by the concepts we want to
record, share and process in eHealth systems. Defining clinical content is a massive task and the work is growing with the rise of genomics and personalised medicine. Maintaining the clinical content is also a big task even for the largest healthcare vendors or government programmes.

Substantial effort across projects and initiatives has been invested on defining clinical content for eHealth systems. Despite some progress, the area is still huge and complex and requires more research and development.

It is important to understand that the challenge is a clinical one, where the work must be clinically led and not led by IT-specialists or terminology specialists, who are typically distant from daily clinical practice. This distinction is as important as recognizing that clinical knowledge combined with information technology and terminology expertise is needed.

One approach for defining clinical content and clinical context is presented in the revision of EN-ISO 13606-3:2009. The approach is based on the system of concepts defined in ISO 13940/Contsys. Another approach is based on SNOMED CT expressions or CIMI detailed clinical models. Recently, a lot of work is also carried out outside standards organizations such as the work of clinical building blocks in NICTIZ (NL) and the work of Professional Record Standards Body (PRSB, UK), outlined in deliverable D2.2.

A generally accepted and tested best practice guideline or methodology for defining clinical content is not present today. However, two different approaches have been identified:

- Clinical content derived from a standard as a reference model with stepwise specialization
- Clinical content defined by use cases with a formal stepwise methodology for generalization

The two approaches are described below as examples.

**9.1.1 Clinical content derived from use case**

Many eHealth implementations, which include sharing of data, are use case driven. Often the implementation of sharing of data is based on one specific standard or profile. For example the Consolidated CDA (C-CDA) implementation guide contains a library of CDA templates for the US realm, incorporating and harmonizing previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). The C-CDA is to be used for implementing the following CDA documents and header constraints for clinical notes: Care Plan including Home Health Plan of Care (HHPoC), Consultation Note, Continuity of Care Document (CCD), Diagnostic Imaging Reports (DIR), Discharge Summary, History and Physical (H&P), Operative Note, Procedure Note, Progress Note, Referral Note, Transfer Summary, Unstructured Document, Patient Generated Document.

CDA-templates specify clinical content, which can be included in an HL7 CDA documents used to implement the specific use case. These templates need to be localized or constrained to fit national and local needs and legal requirements. This can be achieved with local profiles or implementation guides.

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An often-used work approach for preparing this profile is setting up a group of people with expertise in standard development, clinical work, eHealth development and terminology. Sometimes it is also needed to bring in other competencies to ensure that that the clinical content and the requested exchange of data functionality are compliant with the applicable legal and regulatory framework.

The difficulties for the group are not to understand the standard, but to agree and harmonise what data to be used in the profile to achieve interoperability. This also includes quality criteria for conformance testing.

There is high demand for guidelines on how to profile a specific standard or template including conformance testing criteria. Access to similar work done considered as best practice would no doubt improve the adoption of standards and ease the implementation. However, several of these implementation guides are created by competence centers sometimes in their local language. We recommend that Standards organisations in cooperation with local stakeholders should be encouraged to collect and disseminate such best practices in creating profiles or implementation guides through concrete examples.

9.1.2 Clinical content defined by a formal stepwise methodology

Contributions by clinicians, patients and on occasion by other disciplines to the development of standardized clinical content models will play a major role in provision of quality care for their patients in the eHealth future.

eStandards deliverable D2.2 Guideline: How to harmonize & establish selected clinical content for eIF use case, presents a generic guideline for the way in which the requirements and specification of clinical content for interoperability assets should be developed in a process largely driven by domain experts in response to a well specified interoperability need. It also indicates how the clinical content that might be contained within multiple existing standards profiles, and/or specifications might be aligned, again largely through domain experts.)

Interoperability Testing of clinical content is a part of the application layer described in chapter 11 below. The information layer provides the examples and conformance statements that will be used in interoperability testing.

eStandards D2.2 Guideline: How to harmonise & establish selected Clinical content for eIF use cases, include a chapter, describing a test scenario (using heart failure as an example).

Although these approaches appear to be distinct, in the long term alignment is essential as it will facilitate developing an infrastructure for pursuing quality in semantic interoperability one use case or domain at a time.

An example reflecting this alignment approach is illustrated with patient summary for emergency or unplanned care use case in eStandards D3.4.

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30 Guideline: How to harmonise & establish selected clinical content for eIF use cases. eStandards project. October 2016.
31 http://www.estandards-project.eu/index.cfm/deliverables/
10 Layer: Applications

On this level, agreements are made about the way import and export of medical information by the healthcare information systems. The technical specification of how information is transported is addressed at this level (communication standards). The information systems must be able to export and import data using these communication standards or application programming interfaces (APIs).

Another aspect in this level is the integration, processing, visualizing of exchanged information in user-friendly applications.

10.1 Quality Management System

As described in section 4.3, part 1 of the (Antilope) Quality Manual for Interoperability Testing, the Quality Management System (QMS) is based on ISO 9001.

Often during the preparation of the QMS and when presenting the QMS, people ask if other QMS standards have been considered. It is not clear why they ask, but it is true that there are many different QMS standards. The degree to which these standards are linked to interoperability testing varies. Some of the most often mentioned are shown in the table below.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN ISO 9001:2015</td>
<td>Quality Management Systems – requirements</td>
</tr>
<tr>
<td>EN 15224:2015</td>
<td>Quality Management System in Healthcare</td>
</tr>
<tr>
<td>EN ISO 17011:2004</td>
<td>Conformity assessment- General requirements for accreditation bodies accreditting conformity assessment</td>
</tr>
<tr>
<td>EN ISO 17020:2012</td>
<td>Conformity assessment – Requirement for the operation of various types of bodies performing inspection</td>
</tr>
<tr>
<td>EN ISO 17025:2005</td>
<td>General requirements for the competence of testing and calibration laboratories</td>
</tr>
<tr>
<td>EN ISO 13485</td>
<td>Medical devices. Quality management systems. Requirements for regulatory purposes</td>
</tr>
<tr>
<td>NEN-EN-ISO 14971</td>
<td>Medical devices – Application of risk management to medical devices</td>
</tr>
<tr>
<td>ISO-IEC 62304</td>
<td>Medical device software – Software life cycle processes</td>
</tr>
<tr>
<td>PAS 277:2015</td>
<td>Health and wellness apps – Quality criteria across the life cycle – Code of practice</td>
</tr>
</tbody>
</table>

In order to obtain a better understanding the content and usability of these standards for interoperability testing, ISO 9001:2015, EN 15224:2016 and ISO 17025:2005 was compared. The aim was to compare the text in within similar topics. For the two first standards, it was easy as ISO standards from 2015 have the same structure in 10 chapters. For ISO 17025:2005 some extra work was needed to find and compare similar topics. It shall be mentioned that not all parts of the three standards was compared and analysed. The objective was “limited” to get a better understanding of the content and if some of the other standards are a better choice than ISO 9001, which was selected in Antilope as the standard for the Quality Management System for Interoperability Testing.

The result of the comparison of the standards can be summaries as:

- They all establish a quality management framework for how a business manages its key
processes,
- They all express generic, high level requirements to the quality management (personal, documentation, follow up on errors, improve customers satisfaction, etc) – which is important.
- None of the standards includes any hints or practical guidance on how to perform interoperability testing.

Additional standards for medical devices (NEB-EN-ISO 14971, ISO-IEC 62304 and PAS 277:2015) were analysed to check if they included specific information on testing or interoperability testing. For software testing, such as ISO/IEC 25023:2016(en) Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Measurement of system and software product quality could provide the necessary link to software quality depending on the specific requirements of the eHealth system.

The conclusion, in this project, is that ISO 9001:2015 is still a good choice for the QMS for interoperability testing in the context of large scale eHealth deployment. It should also be noted that after finalising the Antilope project, the competence center for the Danish Health Care Network (MedCom) decided to implement a QMS for Interoperability Testing, based on the Antilope specifications. MedCom was ISO 9001 certified in May 2017.

It shall be mentioned that the Quality Management System to be selected shall always be the system used for the entire organisation. However, it is evident that using a Quality Management System for Interoperability testing is still emerging and only few organisations, which perform interoperability testing have formalised procedures for the work to be done.

10.2 Interoperability Testing

As mentioned in the above section the Danish Health Care Network (MedCom) has implemented a QMS for Interoperability Testing.

The Antilope Quality Manual, part II: Interoperability Testing processes, is the work to be done. The nine generic procedures, in part II, need to be further detailed described and understood by all the persons working with interoperability testing. The detailed description of the processes can also be used by the customers (vendors and users of eHealth solutions) to gain insights into how the interoperability testing processes are operated from the start to the end.

The work necessary to localise the nine interoperability testing processes may not be underestimated. It took one year, and 1-2 meetings with the test group every month. The challenge was to understand each working process and harmonise the workflows for performing interoperability testing.

With conclusion of this work, the nine interoperability-testing processes were supplied by 20 Standard Operational Procedures (SOP) and 25 templates for documenting a specific test session.

After Quality the Manual was prepared, it took another 6 months to implement the system before an accredited body did the ISO 9001 certification.
The above story confirms the usability of QMS for interoperability testing.

### 10.3 Syntax and communication rules

When writing a standard, preparing a profile or writing a test protocol for interoperability testing, it is important to assess the optionality for each data element. Some data elements are mandatory and other is optional. Some standards use more classifications for optionality.

Unfortunately, different standards use different classifications for optionality.

In a multi-vendor and multi-standard environment, this is confusing and can lead to errors in the implementation and unnecessary delays due to discussions during interoperability testing.

For example, it often happens that vendors have different interpretations of the meaning of a data element being optional.

Sender systems normally can agree that they may communicate the data item, but not necessarily. However, when testing interoperability it is important to be more precise. If a data item is optional and the sender system has no functional use of this data element, it is accepted not to verify if the data element can be communicated. If however, the sender system has the necessary functionality, it shall demonstrate that it can export and communicate the data element.

For receiving systems, there can often be greater disagreements. Does an optional data element mean that the receiving system shall be able to read and process the data element or just leave it? The right answer is that a receiving system shall be able to read any optional data element and use the data element in the eHealth system.

The above examples demonstrate a need to harmonise and agree on the definition for optionality across standards organisations. It is obvious, that different perceptions of communication rules and optionality lead to errors and low quality in interoperability testing. An organisation may communicate an optional data element assuming that the information will be taken into account by the receiving organisation. In case this data element is processed, it may not appear to the end user and may compromise patient safety.

There is also need that entities, which perform interoperability testing are specifying communication and syntax rules, which will be used for the interoperability testing. Such syntax and communication rules will also be helpful for the vendors when they implement different standards.

Postel’s law, a general design guideline for robustness in software, but also in quality for developing test protocols for interoperability testing: Be conservative in what you send, be liberal in what you accept.

### 10.4 Quality Management System for profiling

Standards are specifications, which are broad in scope and can include more content than needed for
Before standards can be used for implementation, they need to be profiled to make sure they conform to local policies. Profiling is called different names. For example, HL7 CDA uses the term implementation guidelines or templates.

IHE Profiles\(^{32}\) 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.

The Consolidated CDA\(^{33}\) (C-CDA) implementation guide contains a library of CDA templates, incorporating and harmonizing previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP).

Both IHE profiles and HL7 C-CDA templates need to be profiled i.e. localized before they can be used in a specific implementation as mentioned above. The “final” profiling before implementation is more and more done by national eHealth competence centers like NICTIZ in Netherlands and MedCom in Denmark, which have local knowledge of laws and regulations. The profiling organizations are also having the main contact and dialog with the SDO’s.

Profiling is rather complex and not limited to ensuring that the relevant clinical content can be communicated. For example the work also include taking into account national laws and regulations and existing agreed classification to be used. Therefore, there is a close link between the Quality Management System for Interoperability Testing and the profiles. For example, some errors, which are detected in an Interoperability Test session, are due to the insufficient quality of the standard and/or profile. The error is captured and can be sent to the team who are responsible for improving the standard and/or profile.

**Error! Reference source not found.** shows the development and implementation costs linked to the risk of interoperability errors. Interoperability can be achieved incrementally as part of a continuous process that needs to be maintained. The individual standards over time will be more stable but the profiles may change more often in accordance with changes in European and national law and regulations to reinforce cross border eHealth interoperability.

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\(^{32}\) [http://ihe.net/Profiles/](http://ihe.net/Profiles/)

Figure 13. Development and implementation costs are linked to the risk for errors in interoperability

As shown on the figure if there are no coordination and common concepts the risk for interoperability errors is high. In the past 20-25 years, common rules, principles, and concepts have been defined. The SDO’s have developed standards, which have been profiled and implemented with sufficient clinical content. The national competence centres, IHE, HL7 and others have developed mechanism to perform interoperability testing.

Based on the past 20-25 years’ experience, we know that profiling is difficult and today there is a demand for generic description on how to profile a standard and that too needs to be subject to quality management very much like standards themselves.

The work is similar to the work done in the Antelope project by preparing the Quality Management System for Interoperability. We need a similar work for a Quality Management System for profiling. The adoption of standards will benefit of having a generic description of the profiling processes, based on European best practice.
11 Layer: 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.

In the context of achieving quality in interoperability, this chapter describes key infrastructure and architecture elements to consider when performing interoperability testing.

11.1 Infrastructure architecture

Although interoperability requires technical conformance among eHealth solutions, it does not require that each organization implement exactly the same technology. Stakeholders will strive for baseline interoperability across the eHealth IT infrastructure, while encouraging innovation that improves usability and enriches functionality.

The architecture of the health data infrastructure must be robust with regard to scale and to the actual needs for access to data and allow variety among specific implementations. In short, the architecture must be flexible enough to incorporate any particular technology, and specific enough to ensure adherence to system-wide principles for the exchange of health information.

Today’s eHealth infrastructure architecture can be classified in three areas:

- Messaging
- Central repositories
- Indexing

The test procedures for interoperability testing often depend on the actual design and implementation of the infrastructure. For example, HL7 CDA can specify the technical specification and clinical content, but the actual clinical documents in HL7 CDA can be shared using messaging, central repositories or indexing.

The three variants for the eHealth infrastructure are described below.

11.1.1 Messaging

In eHealth, messaging is the exchange of messages (specially formatted data describing events, requests, and replies) to a messaging server, which acts as a message exchange switchboard for client programs. Messaging may also follow a point-to-point model, with a sender and a receiver (or more receivers). Other actors than the sender and receiver are not able to access the data. See Figure 14.

Messaging allows programs to share selected data, to isolate resources and interdependencies, and easily handle an increase in message volume. Messaging also makes it easier for eHealth solutions to communicate across different programming environments (languages, compilers, and operating systems), since each environment needs to understand only the common messaging format and protocol.
eHealth messaging is widely used for referrals, discharge summaries, prescriptions, lab requests and associated results, booking, billing and clinical notes. Often messaging is also used to substitute an ordinary large volume paperflow.

![Diagram of messaging system](image)

**Figure 14. Messaging is used for point to point communication**

The HL7 version 2.x messaging standards, are perhaps the most widely implemented standards for health care in the world that allows for the simple exchange of clinical data between systems. It defines both the transport and messaging standards to convey information. For more than 25 years the nordic countries have been using the UN/EDIFACT standards for sending messages between organisations.

Interoperability testing of the implementation of messaging standards are a mature discipline and follows text protocols for each standard.

### 11.1.2 Central repositories

A central repository is a consolidated database with shareable data as shown on Figure 15.

A repository is typically domain specific. As an example, consider that the central repository can be a national laboratory repository that allows all laboratory test results in the country to be searched and viewed. The implication is that all laboratories in the country shall store a copy of all test results in the national repository.
11.1.3 Indexing

A third variant of eHealth infrastructure for sharing data among different eHealth solutions is indexing.
The concept for indexing is that metadata for all data to shared are registered (stored) in an index with a pointer to where the data can be looked-up.

Indexing has become very popular in the past few years because it supports sharing of any kind of “files” independently of content or structure.

When an indexing infrastructure is established, it is easy to add new files (CDA, images, pdf-files) to be shared.

With the rise of the data economy, central repositories and indexing seem to become more attractive than messaging, since they simplify running predictive analytics.

11.2 Maturity of the infrastructure

A key in achieving interoperability is to establish a well-developed and -managed health data infrastructure, which can share data efficiently and securely between healthcare organizations, providers and patients. In this context, content models that are stable and mature are essential.

However, interoperability testing of the infrastructure is also needed. For example, the index variant of the infrastructure may in certain jurisdictions comply with IHE XDS specifications. However, this test is not adequate to assess whether the infrastructure is robust and mature to be used in daily operation. As eStandard deliverables notes, the metadata of XDS need to be harmonized for large scale eHealth deployment.

Technology readiness levels (TRL) is a method of estimating technology maturity of Critical Technology Elements (CTE). TRL are based on a scale from 1 to 9 with 9 being the most mature.
technology. The use of TRLs enables consistent, uniform discussions of technical maturity across different types of technology. A comprehensive discussion about TRLs was published by the European Association of Research and Technology Organizations (EARTO)\(^{34}\).

Different definitions are used for the TRL scale. The table below shows the European Commission definition of the TRL levels.

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRL 1</td>
<td>Basic principles observed</td>
</tr>
<tr>
<td>TRL 2</td>
<td>Technology concept formulated</td>
</tr>
<tr>
<td>TRL 3</td>
<td>Experimental proof of concept</td>
</tr>
<tr>
<td>TRL 4</td>
<td>Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)</td>
</tr>
<tr>
<td>TRL 5</td>
<td>Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)</td>
</tr>
<tr>
<td>TRL 6</td>
<td>Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)</td>
</tr>
<tr>
<td>TRL 7</td>
<td>System prototype demonstration in operational environment</td>
</tr>
<tr>
<td>TRL 8</td>
<td>System complete and qualified</td>
</tr>
<tr>
<td>TRL 9</td>
<td>Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)</td>
</tr>
</tbody>
</table>

These high-level definitions of TRL levels can be further refined and used to communicate the maturity of the eHealth infrastructure. Figure 17 shows an example on how the TRL methods have been used for maturing a Telemedicine Infrastructure based on XDS and HL7 CDA in Denmark\(^{35}\).

\(^{34}\) http://www.earto.eu/fileadmin/content/03_Publications/The_TRL_Scale_as_a_R_I_Policy_Tool_-_EARTO_Recommendations_-_Final.pdf

Figure 17. TRL methodology can be used to assess the maturity of infrastructure

By extension, TRL levels can be used to characterize standards-based large-scale eHealth projects and best practices in the use of standards and profiles across Europe and globally.

The FHIR maturity model\(^{36}\) offers an alternative viewpoint to maturity with five levels of maturity for FHIR resources. This model can be extended to other standards and profiles used in the context of a large scale eHealth infrastructure. It's based on the Capability Maturity Model framework, and the intention is to give implementers a sense of how mature a resource is based on the level and types of review it has been subject to, and the extend to which it has been implemented.

12 Refined eHealth European Interoperability Framework

12.1 The new European Interoperability Framework

The first version of the EIF was adopted in 2010. As the field of information technology is developing by fast speed and existing EU policies evolve and new EU policies emerge, the EIF needs an overall revision after six years of existence. The framework had to better react on emerging technological trends like open data and cloud computing. It also needs to be fully aligned with the most recent EU policy developments concerning the new EIF.

The new European Interoperability Framework\(^{37}\) (EIF) is part of the Communication (COM(2017)134) from the European Commission adopted on 23 March 2017. The framework gives specific guidance on how to set up interoperable digital public services. The new EIF is undertaken in the context of the Commission priority to create a Digital Single Market in Europe.

![Figure 18. The new EIF conceptual model.](https://ec.europa.eu/isa2/eif_en)

In 2012, the European eHealth Commission developed the eHealth European Interoperability Framework (eEIF) in the context of the generic European Interoperability Framework (EIF).

The Refined eEIF (ReEIF) was delivered by the Antilope project in 2014 and the ReEIF is further strengthening by the eStandard project by adding two new use cases (eStandard D2.1).

12.2 Recommendation for a new eHealth European Interoperability Framework

The aim of this deliverable is to link the Quality Management System for Interoperability Testing the ReEIF layers. Additionally, this document has identified recommendations for each of the ReEIF layers to ensure efficient and trustworthy interoperability testing.

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\(^{37}\) [https://ec.europa.eu/isa2/eif_en](https://ec.europa.eu/isa2/eif_en)
Below is recommendation for each of the ReEIF layers (chapter 6-11) to be considered when updating the eHealth EIF. All recommendations below will support quality management of interoperability testing through:

- Alignment with policy development
- Alignment with emerging technological trends
- More focus on EIF implementation

The eStandards project supports the “Antilope” ReEIF, and still recommends six layers in the eHealth EIF. These six layers are important to ensure that relevant topics are addressed at the right layer and discussed by the right stakeholders. However, it is important to analyse in more details the implications of not using the same four layers as a conceptual model for discussing and achieving interoperability for all public digital services.

<table>
<thead>
<tr>
<th>Layer: Legal and regulatory</th>
<th>Stakeholders: Regulators and advisors, Directors, Lawyers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation 01: Catalogue of standards</td>
<td>Agreement on what standards to be used will lead to improved quality and a competitive market with a diversity of vendors and new technology development. Member states shall be encouraged to maintain and publish a catalogue of standards. Protocols for interoperability testing shall be published and on a longer run aligned across Europe.</td>
</tr>
<tr>
<td>Recommendation 02: Understanding the legal and regulatory framework</td>
<td>In the context of interoperability testing, it is important to have a good understanding of the legal framework. The rules vary from country to country and the use and requirements with concerning standards and interoperability testing is often superficially described. Common interpretation of the legal and regulatory framework will ensue that data communicated between systems is only accessible to authorised users. Concerning interoperability testing it will be useful to have guidelines and examples on how standards shall be implemented taking into account the legal and regulatory framework. The guidelines and examples will need input from the standards organisations and the authorities in charge of the legal and regulatory framework.</td>
</tr>
<tr>
<td>Layer:</td>
<td>Stakeholders:</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Policy</td>
<td>Policy makers</td>
</tr>
<tr>
<td></td>
<td>Healthcare Managers</td>
</tr>
<tr>
<td></td>
<td>Healthcare Professionals</td>
</tr>
</tbody>
</table>

Recommendation 03: Measure the use of standards
Information on the use of specific standards is in general lacking and is also not monitored and published by the standards organisations. The eEIF should encourage or require that the use of standards is monitored and published. This will help vendors and users to get better information on how specific standards work and gain insights on the volume of data shared. Regarding interoperability testing this information can be used to set the right requirements for testing.

Recommendation 04: Declaring maturity for knowledge to standards and interoperability
In general, purchasing an eHealth solution involving standards is complex and requires close co-operation between the end-user organisation and the vendor of the solution. Existing means of public procurements through mandatory reference to standards is in general not effective, due to the technical and educational gaps between the standards and the end-users or managers of the eHealth solutions.
A policy for declaring the skills and knowledge of standards, conformance, and interoperability testing expected for buyers and sellers, may accommodate this challenge.

<table>
<thead>
<tr>
<th>Layer:</th>
<th>Stakeholders:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care Process</td>
<td>Policy makers</td>
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<tr>
<td></td>
<td>Business and Information architects</td>
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<tr>
<td></td>
<td>Information analyst, terminologist</td>
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<tr>
<td></td>
<td>Healthcare Managers</td>
</tr>
<tr>
<td></td>
<td>Patients</td>
</tr>
</tbody>
</table>
Layer: Care Process  
Stakeholders:  
Policy makers  
Business and Information architects  
Information analyst, terminologist  
Healthcare Managers  
Patients

**Recommendation 05:** Create more use case realisation scenarios  
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 specific standards and profiles. The actual implementation of these Use Cases can be based upon the adoption of a Use Case and a Realisation Scenario. In practice, there are several potential realization scenarios for each use case, but today there are limited few realization scenarios for each use case. The standards organizations and eHealth projects are encouraged to add more realization scenarios in the future, showing how a use can be implemented using different IT architectures and standards and profiles.

Layer: Information  
Stakeholders:  
Business and Information architects  
Information analyst, terminologist  
Software engineers  
Patients  
Healthcare Professionals  
Patients

**Recommendation 06:** Clinical Content Definition  
Defining clinical content is a massive task and the work is growing because of genomics and personalised medicine. Maintaining the clinical content is also a big task even for the largest healthcare vendors or government programmes. There is a need for formalised methods for Clinical Content Definition, which also includes a solid link to interoperability testing.

Layer: Application  
Stakeholders:  
System architects  
Software engineers  
System engineers  
System managers
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<th>Layer: Application</th>
<th>Stakeholders: System architects, Software engineers, System engineers, System managers</th>
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<td><strong>Recommendation 07:</strong> Quality Management System for Interoperability Testing</td>
<td>Organisations who are performing interoperability testing are encouraged to use the Quality Management System for Interoperability testing developed in the Antilope project. The QMS is implemented by IHE Europe and MedCom in Denmark. The QMS system in MedCom was ISO 9001 certified in May 2017.</td>
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<td><strong>Recommendation 08:</strong> Quality Management System for Profiling</td>
<td>Before standards typically need to be localized for implementation, they need to be profiled creating an implementation guide. The profiling is rather complex and not limited to ensuring that the relevant clinical content can be communicated. For example, this work also includes taking into account national laws and regulations and the classification agreed to be used. There is a close link between the Quality Management System for Interoperability Testing and the profiles. For example, some errors detected in an Interoperability Test session are due to insufficient quality of the standards and/or profiles in use. The errors captured should be sent to the team who are responsible for standard and/or profile as part of a standard operating procedure. There is a need to develop a Quality Management System for Profiling. This will promote European collaboration on the use of standards and profiles.</td>
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<td>Layer: It-infrastructure</td>
<td>Stakeholders: System architects, Software engineers, System engineers, System managers</td>
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| It-infrastructure | System architects  
| | Software engineers  
| | System engineers  
| | System managers  |

**Recommendation 09:**
Maturity of the infrastructure

A key in achieving interoperability is to establish a well-developed and -managed health data infrastructure, which can share data efficiently and securely between healthcare organizations, providers and patients. Interoperability testing of the infrastructure is also needed. Technology Readiness Levels (TRL) offer a useful tool methodology to facilitate qualified dialog between stakeholders and vendors. It is an advantage if all projects in Europe use the same methodology for this dialog, which would also support the cross border dialog regarding interoperability testing.