Quality Label and Certification Processes

Karima Bourquard
Director of Interoperability
IHE-Europe
Policy Context

**The challenge**

eHealth Deployment in Europe

**The environment**

- Directive 2002/21/EC  Common Framework on communication networks
- Directive 2007/47/EC on medical devices
- Directive 2011/24/EU on Patients’ rights in Cross Border Healthcare
- MoU on eHealth between EC and US

**Requirement**

Consensus on a common Interoperability Framework
For an harmonized implementation across Europe
To design a European quality label or certification process that supports eHealth interoperability in Europe. These processes shall operate in harmony with country specific quality label or certification processes.

Main benefits:

For Healthcare providers
- A harmonized European market for the eHealth solutions
- Better integration between solutions
- Ability to exchange electronically medical data between Regions and Nations

For Industry
- One recognized quality label or certification process in Europe
- Avoid duplication between the national and regional testing processes
- Factor and mutualize specifications elements and corresponding testing tools
HITCH Roadmap

Get ready 2012-2013

European Strategic Milestones
- Ehealth Interoperability Framework

Testing & Certification Processes
- European-Level QMS V1.0
- Proposed European-Level Testing Process
- Proposed European-Level LabelCert. Process

Testing Tools
- Test Methodology
- Testing Management Platform V1.0
- Test Cases V1.0
- Test Tools V1.0

Operationalize 2013-2014

Evaluation of Testing & LabelCert.
- European-Level Testing Process
- Interop/functional Linkage
- Test Management Platform V2.0
- Test Cases V2.0
- Test Tools V2.0

Support of Project-Level Testing Tools
- Antilope: Advancing eHealth Interoperability

Deploy 2015-20XX

Pilot Testing & LabelCert.
- European Testing & LabelCert. Operational

Support of Project-Level Testing & LabelCert Process
- European Testing & LabelCert. Operational

Antilope

Support of Project-Level Testing & LabelCert Process

European-Level LabelCert Process

Antilope

Support of Project-Level Testing Tools

Test Management Platform V2.0
- Test Cases V2.0
- Test Tools V2.0
Key Recommendations

Stimulate the creation of European market based on the evolving European eHealth Interoperability Framework associated with a modular European Conformance Assessment Program

Harmonize the quality label and certification processes in Europe and among countries and regions

Propose a European interoperability quality label and certification process that allows for flexible national or regional approaches
Recommendations from previous projects

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HITCH

(Healthcare Interoperability Testing and Conformance Harmonisation)

EHR-Q\textsuperscript{TN}

(EHR Quality Labelling)
HITCH Project Recommendations

1. Develop an European ecosystem by promoting recognized profiles, test plans and test tools
2. Define flexible testing processes
3. Provide a European Interoperability Assessment Scheme
1. Apply generic criteria of quality to the initiatives
   (independence, openness, impartiality, transparency and confidentiality)

2. Involve stakeholders to the definition of the priorities in defining feasible goals

3. Structure the Quality label and Certification processes in line with ISO standards
ANTILOPE Methodology
Definition of an Interoperability testing strategy in Europe

Key points to be taken into account:

- Comprehensive test plan, test cases, tools and test data
- Definition of exhaustive/mandatory/realistic Use cases/test cases
- Risk assessments
- End-users actively involved
Testing, Quality labelling and certification processes

Functional Model
**QL & C processes**

- Requirements, activities and tasks to support an entity in organizing high quality interoperability assurance or certification

**Conformity assessment**

- Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (ISO/IEC 17000)
A certification or quality label process requires:

- **A Certification/Label Scheme Owner**: a party that sets the Certification or a quality label program or system;

- **A label/Certification Body**: a party that issues the quality label or certificate on the basis of the conformity assessment performed by a conformity assessment body;

- **A Conformity Assessment Body**: a party that assesses the conformity of products, services and/or suppliers (often called a testing laboratory)
Quality label and Certification Functional Model

Label/Certification Scheme Owner

Delegates based on Scheme

Label/Certification Body

Test Report

Conformity Assessment Body

Submit Product for conformity assessment

Product Developer

Certificate/Label Issued

Accredits

Label/Certification Accreditation Body

Delegates based on Scheme

Accredits

Conformity Assessment Accreditation Body
Implementation: Model 1
Labeling by eHealth project using accredited testing lab(s)
Implementation: Model 2

Labeling & testing by eHealth project (no third party accreditation)
Case Studies
Case study-1 : DMP in France

• **Objective :**
  – DMP is the national PHR/EHR in France
  – The process called “homologation” is described in detail in the annex II. The goal of the « homologation » is to validate that the healthcare software connected to the DMP (French National PHR) are conform with the DMP specifications.

• **Specifications defined by ASIP Santé (national agency) based on IHE profiles, HL7 and DICOM**
  – Access to the DMP
  – INS (National Identification of the Patient)
  – Creation and management of the DMP
  – Registration of medical documents in the DMP
  – Consultation of the DMP
  – Other services

• **Label/Certification scheme defined by ASIP Santé**
Case study – 1 : DMP in France

Step 1
Registration of the Vendor to the process (ASIP Santé)
Registration and published candidates for DMP compatibility

Step 2
Access to the test environment
Access to the support
Pre-Homologation: upload files and validation of the tests

Step 3
Homologation and testing validation
Update and bugs resolution
Final decision by the committee and publication of the results

Label (Homologation) Process

Mapping Services/Standards and Profiles
Objective: epSOS is an European Project that the goal is to demonstrate cross-border interoperability between eHealth record systems in Europe by exchanging Patient Summary and ePrescription documents for a patient travelling in Europe.
Case study – 2 : epSOS project

**eEIF**

UC1, UC2a, UC2b

<table>
<thead>
<tr>
<th>Nr</th>
<th>Level</th>
<th>Use case</th>
<th>Profiles</th>
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| 1  | Cross-border | epSOS project - e-Prescription and e-Dispensation for cross-border information sharing for citizens travelling in Europe | IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*  
Pharmacy: PRE*, DIS* |
| 2a | Cross-border | epSOS project - patient summaries for cross-border information sharing for citizens travelling in Europe | IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*  
Patient Care Coordination: XPHR* |
| 2b | Cross-border | epSOS project - patient having access to his or her patient summary | IT Infrastructure: XCPD*, XCA*, CT*, ATNA*, BPPC*, XUA*  
Patient Care Coordination: XPHR* |

**epSOS Specifications**

**IHE Profiles**

**epSOS Testing Process**

- New PN
- New NCP

- Improvement of an existing service
- Newly added service
- PN who achieved a PAT, and then switched its NCP

**Test Plans**

**Testing Tools**
Harmonisation of the quality label or certification processes in Europe
The Quality Label and Certification processes (1/2)

International profiles, guidelines, standards, test tools

International → Selection →
- Use cases
  - Recognized Profiles and standards
  - eELF, other

Testing Methodology
  - Test Plans
  - Test Tools

Testing schemes
- Certification by an accredited (e.g. ISO 17065) third party
- Certification by a non-accredited third party testing by an accredited (e.g. ISO 17025) test laboratory
- Quality assurance
- Other
In Europe: Three key steps

1. Define the Interoperability Conformance Assessment Scheme closely related with the eEIF
2. Promote creation of accredited Conformance Assessment Bodies in Europe
3. Develop Suitable Organisation for the QL&C process
At the National and Regional levels

1. National and Regional Project leverage profiles recognized by eEIF and use flexibility with needed national extensions

2. Ensure that the European level certification may be used as an entry criteria at the national level

3. Organise acceptance and the recognition of profiles candidates in the eEIF based on local use cases
European eHealth Governance Group

(Stakeholders: Authorities, Competence Centers, User and Vendor Associations)

Interop. Framework Governance (eEIF)

Interop. Quality Label or Certification Governance

IOP Framework Coordination

QL&C Coordination

Conformance Body Assessment

SDOs and Profiling Organisations

EU Terminology Value Set Mgt Body

Cross-Border projects (e.g. epSOS specifications)

National or Regional eHealth

National or Regional eHealth

Cross-Border projects

Projectathon Connectathon

Other

IHE

Antilope
• European eHealth Governance group
  – All categories of stakeholders
  – Take decision and validates Interoperability framework and Conformance Assessment Program Scheme

• Interoperability Framework coordination
  – Refines, selects Use cases and profiles and maintains the eEIF
  – Analyses and prepares all the items in order to reach the consensus before validation by the eHealth Governance Group

• Conformance Assessment Scheme coordination
  – Specifies the Conformance Assessment Program scheme
  – Delegates the testing validation to the CABs
Guidelines and recommendations
How to deploy QL & C processes
In your organisation, region, or Nation?

Step 1: Define your needs on Quality Label or Certification
- **Input**
  - National/regional project using use cases, standards and profiles described in the eEuropean Interoperability framework (eEIF - Antilope WP1) or other needs
  - List of existing Test tools and test plans (Antilope WP3)
- **Activities**
  - Analyse the gaps between the eEIF and the needs
  - Specify the needs of QL or C regarding the specifications and requirements
  - Specify the Conformance Assessment Program scheme for the project
- **Output**
  - Conformance Assessment Program scheme (CAPS)
  - Specifications of the tooling needs

Step 2 Setting up the QL or C context
- **Input**
  - step 1 output
- **Activities**
  - Select existing test tools and test plans and describe what are missing
  - Specify the tender for the development of the new test tools by following the recommendations of Antilope WP3 (open source recommended)
  - Define the organisation: Is scheme owner QL or C body the same organisation or two organisations and what are their level of recognition?
  - Specify the testing process and procedures (WP2 QMS, ISO standards)
  - Select the Conformance Assessment Bodies and their QL or C level
- **Output**
  - Organisation in place
  - Selection of CABs
  - Selection of organisations or companies that will develop new test tools and test plan

Step 3: Execute and Report
- **Input** from the previous steps
- **Activities**
  - Recruit candidates for the QL or C
  - Check whether the candidates have their EU label or certificate
  - Execute the test process
  - Validate and report the results
  - Publish the results
- **Output**
  - Validation report, passed candidates

Step 4: Assess and Communicate
- **Input** from all the previous steps
- **Activities**
  - Evaluate the entire process (including the selection of specific profiles, test tools and test plan that can be shared at the European or International level)
  - Communicate on the existence of new use cases, profiles, test plans and test tools and add them in the inventory database.
  - Communicate on the results of the QL or C process
- **Output**
  - Communication plan
  - Assessment Report
  - Interoperability Framework to be communicated
Roadmap

Key messages
Stimulate the creation of European market based on the evolving European eHealth Interoperability Framework associated with a modular European Conformance Assessment Program

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For more information, please refer to document D4.1. available on the Antilope website:

http://www.antilope-project.eu/
Any questions?