Adoption and take up of standards and profiles for e-Health Interoperability
ETSI eHealth workshop on telemedicine
Nice - May, 6-7th 2014
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IHE-Europe
ANTILlope

ANTILope

- Thematic network
- To promote use of standards and profiles for e-Health interoperability and
- To foster their adoptions across EU
The need for interoperability

- **Quality and efficiency** cost savings
- **Sharing and reuse of clinical data**
- **Requires Interoperable systems**
- **Interoperable data exchange services**
- **eEIF** - Interoperability identified by the eHealth European Interoperability Framework as a priority.
Antilope
Background, purpose, outcome

- Digital Agenda and eHealth action plan 2012-2020

- European Projects:
  - 2008-2014 – EpSOS: specifications of the cross border exchange of medical data
  - 2010-2011 - HITCH (Healthcare Interoperability testing and Conformance Harmonisation): eHealth Interoperability roadmap
  - 2011-2012: EHR QTN
  - 2012 - eEIF: eHealth Interoperability Framework
  - 2013 – 2014: Antilope, Thematic Network
  - 2008-2014: eHealth Governance Initiative
<table>
<thead>
<tr>
<th></th>
<th>Recommendations</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Develop an European ecosystem by promoting recognized profiles, test plans and test tools</td>
</tr>
<tr>
<td>2</td>
<td>Define flexible testing processes</td>
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<tr>
<td>3</td>
<td>Provide a European Interoperability Assessment Scheme</td>
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</table>
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 a thematic network:

- Develop documentation and educational materials related to existing standards and profiles for eHealth interoperability mentioned in the eEIF report and:
  - Drive adaption and improve the standard development process
  - Define QA testing guidelines for interoperability
  - Propose a labelling and certification process (EU level and national level)
Antilope Validation Partners

Denmark, Norway, Sweden, Finland, Iceland, Estonia, Lithuania, Latvia
Poland, Czech Republic, Slovakia, Hungary
Ireland, United Kingdom
Belgium, The Netherlands, Luxemburg
France, Switzerland,
Germany, Austria
Slovenia, Croatia, Serbia, Bosnia, FYE Macedonia, Montenegro
Italy, Malta
Portugal, Spain
Romania, Bulgaria, Greece, Cyprus, Turkey

May, 6th 2014 eHealth workshop on telemedicine
Antilope, Background, purpose, outcome

WP1  eIoP Framework: Process driven by use cases (Governance, profiles, standards)
Concrete examples: IoP Framework from countries

WP2  Testing Guidelines (Common approaches and HITCH QMS update)
Concrete examples in countries

WP3  Testing Tools: (Description of the gaps based on EU use cases described in the IoP framework)
Open source community RFP demonstration of test tools during a Workshop

WP4  Certification/labelling process: concept of two levels

WP5  Validation, scalability to EIP and adoption
Workshops

WP6  Communication

WP7  Project Management

EU projects
- eHGI
- HITCH
- Caliope
- EIF study
- EMN-Qu™
- epSOS
- Renewing Health
- ...

Consortia/Standard bodies
- IHE
- Continua
- Eurec
- M403/1
- CEN/CENELEC
- ETSI
- HL7
- GS1
- ...

May, 6th 2014
ETSI eHealth workshop on telemedicine
Purpose of the Summit

• To agree that
  - interoperability is essential for care safety and cost containment
  - interoperability of eHealth systems should never be taken as given.
  - To achieve interoperability use of appropriate standards and profiles supported by appropriate testing is needed.
  - interoperability testing should be based on a Quality Management System using testing tools
  - the eHealth European Interoperability framework is the first step in harmonising interoperability efforts over Europe (at country, region or local level).

• To bring to the point to
  – include in your regulatory framework the concepts of proven and certified functional quality requirements, to reach national as well as cross border interoperability

• To partner towards interoperability
Outcome
Common approach for testing and certification through recommendations for reaching interoperability based on:

- Refined eHealth European Interoperability Framework (reEIF)
- Quality Management System (QMS)
- The test tools inventory
- Quality label and certification processes
Objectives

• Provide a comprehensive set of Use Cases that can be used throughout Europe as a basis for national and regional implementations

• Provide tools and schemas that can assist in shared understanding of interoperability issues
## Antilope Use Cases

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

**Antilope**
Use Cases and Realisation Scenarios
- Medication
- Patient Summaries
- Referral and discharge reports
- Telehome monitoring
- Medical Board Review
- Patient Data Entry
- Laboratory workflow
- Referral and discharge reports
- Medical Board Review
- Patient Data Entry
- Technology workflow
- Laboratory workflow
- Referral and discharge reports
- Medical Board Review
- Patient Data Entry
- Laboratory workflow
- Referral and discharge reports
- Medical Board Review
- Patient Data Entry

Consist of functionalities

Functionalities
- Content
- Document
- Workflow interoperability
- Workflow descriptions
- Access Control
- Terminology
- Patient Identification
- Intra-community
- Communication
- Cross-community Services
- Patient Data Entry
- Referral and discharge reports
- Medical Board Review
- Patient Data Entry
- Laboratory workflow
- Referral and discharge reports
- Medical Board Review
- Patient Data Entry
- Technology workflow
- Laboratory workflow
- Referral and discharge reports
- Medical Board Review
- Patient Data Entry
- Laboratory workflow
- Referral and discharge reports
- Medical Board Review
- Patient Data Entry

can be implemented with Profiles

Profiles
- IHE
- Continua

are based upon standards

Standards
- HL7
- IHTSDO
- LOINC
- ISO
- DICOM
- CEN
- GS1
- ...
A Quality Management System is a set of interrelated or interacting elements that organisations use to direct and control how quality policies are implemented and quality objectives are achieved.

Source: ISO 9000: Quality Management Systems
Quality Manual for Interoperability Testing

Part I
D2.1 Quality Management System

Part II
D2.2 Interoperability Testing Processes

CAB
Requirements for the operation of Conformity Assessment Bodies performing Interoperability Testing

IT-P
- Quality Planning
- Test Plan Definition
- Design Tests
- Develop or Select Test Tools
- Validation
- Prepare Test Session
- Test Plan Execution
- Test Management
- Test Management Update
objectives for Testing Tools

• Identify existing & new testing tools required to cover the selection of Use Cases described in the eHealth European Interoperability Framework (eEIF) and their refinement
• Promote the use of existing testing tools
• Promote the development of required new or improved testing tools
Testing tools gap analysis process

1. eEIF Use Cases
2. ANTILOPE refined Use Cases
3. Selection of Profiles and underlying standards adapted to the Use Cases
4. Existing Testing Tools for Selected Profiles and standards
5. Gaps in existing testing tools
Testing and Certification Objectives

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
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

Delegates based on Scheme

Label/Certification Accreditation Body

Accredits

Conformity Assessment Accreditation Body

Accredits
The Quality Label and Certification processes (1/2)
#### 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

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How to deploy QL & C processes in your organisation, region, or Nation?

4 STEPS