EuroRec, HITCH: Zertifizierung von Funktion und Interoperabilität für ELGA

Stefan Sauermann
22.4.2010, HL7 Jahrestagung
Where am I?

- Electronics Engineer
- 15 yrs Med. University of Vienna, research
- Biosignal work
- Then standards, medical informatics

Acting program director Biomedical Engineering Sciences (Master)
Chairman of national CEN and ISO mirror, founding member of IHE Austria
Consulting the national EHR project (CDA documents harmonisation)

www.technikum-wien.at
Hats on

- **Research**
  - [www.healthy-interoperability.at](http://www.healthy-interoperability.at)
  - Objective assessment of the fusion frequency in functional electrical stimulation using the fast Fourier transform.
  - Kinematic evaluation in Parkinson's disease using a hand-held position transducer and computerized signal analysis.
  - Computer aided adjustment of the phrenic pacemaker: automatic functions, documentation, and quality control.

- **Teaching**
  - Acting program director, Biomedical Engineering Sciences (Master)
  - Lecturer: Electronics, Informatics, eHealth

- **Consulting**
  - national Austrian EHR project ELGA, CDA documents harmonisation
Not for profit hats

- **Austrian Standards Committee ON-K 238, chairman**
  » http://www.on-norm.at/publish/medinfo.html
  - national CEN and ISO mirror
  - Head of delegation to CEN TC 251 and ISO TC 215

- **eHealth Initiative,**
  » http://ehi.adv.at/
  - moderator of WG 2 – interoperability and standards
  - Strategy recommendations for eHealth implementations in AT

- **IHE Austria, founding member**
  » www.ihe-austria.at
  - Program coordinator for the Connectathon Workshops 2009

- **ProRec Austria, Vice president**
  » www.prorec.at

- **HL7 Austria**
About the layout…

- Should this be HL7, IHE, EuroRec, …?
- Let some of the praise go to Technikum Wien!
- My home is my castle.
Program

- Certification
  - Cure of all evil?
  - The devil itself?

- Available work
  - EuroRec repository
  - The European project HITCH: IHE joins forces with Eurorec

- Challenges, ways to navigate them
  - What do we „certify“ and why?
  - How do we do it without pain?

- Next steps
  - HIS vendors, resident doctors software vendors, ELGA, … ?
The age pyramid
Why the age pyramid?

- As we get older, we may change our attitudes towards certification:
  - Some of us start to hate it (even more)
    - It hinders access to market
    - It costs money and time
    - It is misused
  - Some begin to love it (at least a bit)
    - We buy a certified medical device and we are sure that it works
    - Some of us live on it (or because of it)
    - It makes a market
    - The law is beginning to ask for it („Medical Device Directive“ and „Software“, 2009ff)
What exactly is EuroRec

- The « European Institute for Health Records »
- A European not-for-profit organisation (April 16, 2003)
- Mission: the promotion of high quality Electronic Health Record systems (EHRs) in Europe
- Federation of National ProRec Centres (incl. all types of stakeholders)

Source: Georges De Moor, MD, PhD, Gent University, Gent, Belgium, EuroRec President, Presentation Prague, 19 February 2009: Extending “Certification of Electronic Health Records” at a Pan-European Level. Available at www.eurorec.org
EuroRec: History of EC Projects

- MediRec (1994-95), Medical Records and Quality
- ProRec (1996-98), Promotion Strategy for EHRs in Europe
- Widenet (2000-03), Establishing EuroRec’s Network
- RIDE (2008-10), Semantic Interoperability (partner)
- EHR-Implement (2008-10), Political, Social and Economical aspects when implementing national EHRs systems
- QREC (2006-08), Quality Labeling and Certification of EHRs in Europe
- EHR-Q-TN (2009-2011), Thematic Network
- .....
EuroRec’s Workflow

Diagram showing the workflow process:

1. Original document (e.g., a conformance specification)
2. Individual Statements (in original language)
3. Translated Statements
4. EuroRec Repository
   - Create
   - Decompose
   - Index
5. EuroRec Basket
   - Use EuroRec recommended profiles
   - Query and download
6. Good Practice Requirements (GPR)
7. Specify (for some)
8. Test Criteria (TC)

Processes include:
- Select constraint/profile
- Select criteria
- For a particular case: use case, care setting, professional group
- Selection Criteria: statement types, care settings, business functions, component types

All transformations link back to their input sources.
EuroRec Use Tools

*The EuroRec Composer™*
To compose user defined, re-usable and exchangeable baskets of Fine Grained Statements.

*The EuroRec Certifier™*
To format a EuroRec Basket content to obtain the basic layer for the certification of EHR systems. This is done by adding structure and attributes to the selected Fine Grained Statements (e.g. mandatory, optional...)

*The EuroRec Scripter™*
To produce and link Test Scenarios to EuroRec Baskets for Certification, Documentation and/or Procurement purposes.

*The EuroRec Documenter™*
To document EHR systems and their functions, enhancing their understanding and comparability by using the EuroRec statements.

*The EuroRec Procurer™*
To list and describe, for purchase purposes, required functionalities and product characteristics using EuroRec statements.
<table>
<thead>
<tr>
<th>Q-REC ID</th>
<th>Statement</th>
<th>RS</th>
<th>GPR</th>
<th>Indices/Comment/View Translation / Modify</th>
</tr>
</thead>
<tbody>
<tr>
<td>GS001549.03</td>
<td>The system enables to enter medication items.</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>GS001553.01</td>
<td>The identity of the prescriber is linked to each (version of each) medication item.</td>
<td>1</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001554.01</td>
<td>The system stores the dates of the prescriptions linked to the appropriate medication item.</td>
<td>2</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001555.01</td>
<td>Each medication item has a start date.</td>
<td>3</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001556.01</td>
<td>Each medication item may have a date of last modification.</td>
<td>3</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001557.03</td>
<td>Each medication item may have one or more dates of renewal.</td>
<td>1</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001558.01</td>
<td>Each medication item can have an end date.</td>
<td>2</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001560.01</td>
<td>A medication item can be entered by an authorised user other than the prescriber.</td>
<td>1</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001561.02</td>
<td>A medication item can be a prescription as well as a non-prescription medication.</td>
<td>1</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001562.01</td>
<td>A medication item can be an over the counter product or a complementary medicinal product.</td>
<td>2</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001565.01</td>
<td>The system stores when appropriate for each medication item the dose strength.</td>
<td>2</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001566.01</td>
<td>The system stores when appropriate for each medication item the route of administration.</td>
<td>2</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001567.01</td>
<td>The system stores when appropriate for each medication item the number of medicinal product units per take and the number of takes per day.</td>
<td>3</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001568.01</td>
<td>The system stores when appropriate for each medication item the frequency of applying the day regimen of administration.</td>
<td>3</td>
<td>1</td>
<td>A10.0</td>
</tr>
<tr>
<td>GS001569.01</td>
<td>The system stores when appropriate for each medication item the duration of applying the day regimen of administration.</td>
<td>3</td>
<td>1</td>
<td>A10.0</td>
</tr>
</tbody>
</table>
Does this look familiar? It is „you“!!

- The system SHALL provide the ability to capture nonprescription medications including over the counter and complementary medications such as vitamins, herbs and supplements.
  - Source: HL7 EHR TC, Electronic Health Record – System Functional Model, Release 1, February 2007, Chapter Three: Direct Care Functions

- The system should provide the ability to capture non prescription medications including over the counter and complementary medications such as vitamins, herbs and supplements.
  - EuroRec SS003926.01 “Referenced statement”

- A medication item can be an over the counter product or a complementary medicinal product.
  - EuroRec GS001562.01 “Fine grained statement”
Details out of the repository

**View Statement**

<table>
<thead>
<tr>
<th>Referenced Statement:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ID:</strong> SS003926.01</td>
</tr>
<tr>
<td><strong>Source:</strong> IE07 ID: DC.1.4.2.6</td>
</tr>
<tr>
<td><strong>Statement type:</strong> Referenced Statement</td>
</tr>
</tbody>
</table>

**Statement:**

The system should provide the ability to capture non prescription medications including over the counter and complementary medications such as vitamins, herbs and supplements.

**Created by** Vannevel Martine **on** 05/09/2007

**"First attempt" Heading:** Manage Medication List

**Derived fine grained statements:**

1. GS001562.01 A medication item can be an over the counter product or a complementary medicinal product.

2. GS001561.02 A medication item can be a prescription as well as a non-prescription medication.

**All Comments/Interpretations:**

No comments/interpretations added yet.
EU Project HITCH: Healthcare Interoperability Testing and Conformance Harmonization

- Provide the European Commission with a Roadmap towards the interoperability conformance testing of information systems in the field of Healthcare.

- Organise the role of the commission in the development of testing tools.

- Partners: INRIA, MEDCOM, IHE, ETSI, EUROREC
  - IHE Austria / formally UAS Technikum Wien

- Thanks to Karima Bourquard, Director Interoperability IHE-Europe, IN-SYSTEM, for her slideset from Bordeaux 12-16 April 2010
HITCH Overall Concept

**Requirements**
- EU Projects
  - I 2010, M403
  - Calliope, epSOS
- SDOs
  - HL7
  - Dicom, CEN, CENELEC, ETSI
- Health Organisations
  - EAHIP, ECR
  - ESR, EuroRec, IHE-Europe, PGEU...
- International
  - CCHIT
  - Infoway
  - IHE-Int.

**Issues**

**Top-down**

**Solutions**

**HITCH Roadmap on issues and solutions for interoperability**

**Tools and Processes**

**Bottom up**

- National, Regional and Local projects
- Market Industry, SMEs

**Real interoperable world**
Deliverables

- Description of the state of the art (T4.1)
  - Overview of quality labelling in Europe and outside Europe.

- Vision Statement (T1.3)
  - Vision for a European interoperability testing quality management system (QMS). Organisation, roles and responsibility of competent partners.

- Gap analysis. (T2.3)
  - Strategy in terms of research and tools to reach the objectives of vision

- Action plan (T4.3)
  - Evaluation of possible labelling scenarios and impacts.
    - self certification
    - third party certification
    - other types of certifications.
  - A scenario will be proposed as the best one and a deployment timeline proposed.
HITCH Task 4.2: Relationship between functional and interoperability criteria (editor EuroRec)

- Linkages between:
  - functional: EuroRec
  - Interoperability: IHE

- How to achieve the two goals in the same certification/ labelling testing

- Certification vs labelling (definitions)

- Which requirements are in overlap
Positions in HITCH (anecdotal evidence)

- “IHE and EuroRec finally have started formal cooperation.”
  - “Good! We like each other.”
  - “IHE has testing experience and real life impact.”
  - “EuroRec has certification methodology.”

- “The EU Commission is ordering this”
  - “They may then put it into use.”
  - “It mentions epSOS.”

- “Let’s get this done well!”
  - „Let’s make it useful“
Now how does this affect us here …

Image: Cardone Record Services, Mount Prospect, IL, USA, available online http://www.cardonerecords.com/about.htm

... on our way to here?

- The moment of „Plug-In“ is on the horizon!!

- Documents travel widely
  - Receivers do not know document authors
  - Hundreds of IT systems will meet for the first time

- Pain on the receiving end
  - „The interface does not work!“
  - „The codeset is wrong!“
  - „This is YOUR fault!!“
  - „Definitely NOT!!“
Humble requirements: correct data travels safely

- The right data needs to arrive at the right system at the right time.
- It definitely needs to be correct!!
- How do we make sure it is?
Austrian EHR: ELGA

- **Build it**
  - ELGA task

- **Connect to it**
  - Software vendors all over the place

- **Fill it**
  - Doctors all over the place
  - IT support

- **Built intelligent applications on it**
  - All of them

Image: ELGA Folder, 12.2008. ELGA GesmbH, Schiffamtsgasse 15, 1020 Wien, Austria
www.elga.gov.at
The semantic part

- **Healthcare decides**
  - workflow
  - content
    - define
    - Structure
  - use

- **IT implements**
  - Information models
  - nomenclature
  - Transport methods

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Unit</th>
<th>Reference range</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>182</td>
<td>mg/dL</td>
<td>74-109</td>
<td>+</td>
</tr>
<tr>
<td>HbA1c</td>
<td>5.7</td>
<td>%</td>
<td>4.0-6.0</td>
<td></td>
</tr>
<tr>
<td>Insulin</td>
<td>70.7</td>
<td>mU/L</td>
<td>2.6-24.9</td>
<td>+</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>157</td>
<td>mg/dL</td>
<td>120-200</td>
<td></td>
</tr>
</tbody>
</table>

- „Semantic“
- „Interoperability“
Engineering below

- **WHAT**
  - `<code code="2093-3" codeSystem="2.16.840.1.113883.6.1", codeSystemName="LOINC" displayName="Cholesterin"/>

- **WHEN**
  - `<effectiveTime value="20081201075606+0100"/>

- **UNIT, VALUE**
  - `<value unit="mg/dL" value="157" xsi:type="PQ"/>

- **REFERENCE RANGE**
  - `<low value="120" unit="mg/dL"/>
  - `<high value="200" unit="mg/dL"/>
  - `<interpretationCode code="N" displayName="Normal"/>
The challenge

- Survive „P Day“
- when IT all plugs together
EuroRec / HITCH Status in Austria

- EuroRec Workshops 2009
  - Resulting suggestion out of UBIT
    - “Use EuroRec to clearly define:
      - ELGA functions
      - Healthcare provider software functions”
    - “Let's meet again!” (Open)

- Informal contacts, 2010
  - “This might be interesting to do as we connect a number of resident practitioners to our hospital group.”

- HITCH formal connection established, late 2009
IHE on the planet (as of 2010)


Pin Colours:
Planned: Red
In Pilot: Yellow
Production: Green
Austrians have „densely populated“ the planet!
Best of both

- Following years of blood, sweat, toil and tears, Austria has a miraculous success story image.
  - eCard
  - IHE implementations
  - ELGA, Standards, CDA, …
  - Many positive contributions big and small

- The world listens if we talk.
  - (It may not always act immediately, but at the end, who does?)

- Let us do another useful thing here and show them.
  - Use the channels that we have.
A possible way forward in Eurorec / HITCH

- Bring functional interoperability criteria into EuroRec?
  - Only has pure function today
  - To be added:
    - Example: „The system needs to transmit a medical report over a standardised interface.“

- Then use this in „Baskets“ and in „EuroRec Scripter ™“ ??
No risk no fun

- In practice we need
  - Cooperation of the „doers“
    - Felt benefit for all
    - Work done
    - International harmony
  - …

- We need to defuse the bombs
- Lets use the energy to make things sparkle
Other risks

- Get run over sleeping
- Burn out overdoing it

Images:
- University Services (Sleep lab), Philadelphia, USA, Making Sleep Work For You, http://www.makingsleepworkforyou.com/
Thanks for the attention

Off for coffee!!!

- www.ihe-austria.at
- www.euorec.org
- www.prorec.at
- http://www.euorec.org/RD/HITCH.cfm
- http://www.hl7.at/
- .......

- sauermann@technikum-wien.at