EHR systems
Quality Labelling and Certification
… and other trends

Prof. Dr. Georges De Moor
EuroRec President

European Institute for Health Records (EuroRec)
The EuroRec Institute (EuroRec) is a European independent not-for-profit organisation, whose main purpose is **promoting the use of high quality** Electronic Health Record systems (EHRs) in Europe.

EuroRec is overarching a **permanent network** of National ProRec centres and provides services to industry (developers and vendors), healthcare systems and providers (buyers), policy makers and patients.

EuroRec produced and maintains a substantial resource with ± **1700 functional quality criteria for EHR-systems**, each categorised and translated in several European languages. The EuroRec Use Tools help users to handle this resource.
EHRs certification: why?

- **Care Providers**: assurance and **trust** in quality and functionality of **EHRs** and other eHealth solutions

- **Vendors**: de-fragment market and improve market access

- **Health Care Authorities**: promote use of **high quality systems** and make sure that the anticipated benefits are realised (e.g. **inter-operability** important in the context of a continued care model)

- **Patients**: quality of care, safety, privacy...
EHR Quality Labelling & Certification

Current status (1)

**US:** ARRA and HITECH act and *Meaningful use of Certified EHR technology approach.* The current 6 Authorised Testing and Certification bodies have certified (dd. 1 November 2011) 1200 EHR products/modules.

**Europe:** national certification schemes in place in 10 member states and starting *harmonisation of certification* through the EuroRec “Seals 1 and 2” now in 27 countries (cf. the EHR-Q-TN project).

Remark: there is an 80-90 % **commonality** between the functional certification criteria of Europe and of the US... but regulations differ!
Current status (2)

- The launch of the permanent program for Certification of Electronic Health Records will be **delayed in the US until mid-2012**, in order to coincide with the anticipated final rule for Stage 2 of meaningful use and standards and certification criteria.

- **US:** The final rule is expected to require **new** and revised standards, **specifications for** establishing the standards and **certification criteria** to qualify for the Medicare and Medicaid EHR incentive program.
Current status (3)

• At present, the EuroRec Repository contains +/- 1700 Criteria/ Fine Grained Statements with + 15000 index links. The majority of the Fine Grained Statements are referencing one or more Source Statements (at the moment +/- 4000 links exist) and can be grouped into Good Practice Requirements. The current database contains +/- 200 of these Good Practice Requirements.

• A large number of these criteria have been translated into 18 European languages (Bulgarian, Croatian, Czech, Danish, Dutch, Estonian, French, German, Greek, Hungarian, Italian, Polish, Portuguese, Romanian, Serbian, Slovakian, Slovenian and Spanish).

EuroRec Seals 1 and 2
The EuroRec Repository

Profiling Tool

- User-defined profile
- For a particular:
  - use case
  - care setting
  - professional group

Selection Criteria
- statement types
- care settings
- business functions
- component types

Procurement Spec or a Test Plan

Saved, exported, translated

Internal

- Q-REC Good Practice Requirements (GPR)
- Q-REC Test Criteria (QTC)

Public

- Q-REC
- Specify (for some)

Create

- decompose
- import
- source statements (+ headings)

Fine Grained Statements
- generic & (domain) specific

Index

- original specification weight
- business function
- care setting
- component type

(all transformations link back to their input sources)
The EuroRec Use Tools

The EuroRec Use Tools™ suite enables the licensee to prepare and to manage certification, documentation and procurement of Health IT products in general, actually mostly focused on Electronic Health Record systems.

The EuroRec Use Tools™ are designed for professionals, using the EuroRec Repository, within the limits of the license agreement.

The EuroRec Institute, owner of The EuroRec Use Tools™ and the EuroRec Repository, offers on request consultancy services for starting certification of Health IT products as well as training services for The EuroRec Use Tools™.

For more information contact: services@eurorec.org
In December 2009 EuroRec has released a profile identifying the functionalities required of an EHR system in order to be considered as a **reliable source of data for regulated clinical trials**.

Details of the profile, including information designed to support use, are accessible from the EuroRec website. A sister profile has been endorsed by Health Level Seven® (HL7®).

As both the EuroRec and HL7 profiles draw upon the same standard requirements for clinical trials, ”conforming to one” will mean, in principle conformance to both.

Next step: endorsement by ISO (TC/215) as a standard.

The EHR4CR Project (see further).
Accreditation schemes for research units (in EHR4CR by ECRIN) and certification of EHR vendor software for the re-use of data in research (in EHR4CR by EuroRec) go hand in hand.

Together they will accelerate the adoption of a more harmonised approach throughout Europe and serve as a powerful means for ensuring reliability and trustworthiness of the research partners (i.e. data providers) towards the pharmaceutical industry. Both the vendors of certified products and the data sources that will be accredited will get a competitive advantage.
EHRs: Trends...

- **Patient-centered** (gatekeeper?) and longitudinal (life-long) records
- Multi-disciplinary / **multi-professional**
- Transmural, distributed and **virtual**
- **Structured and coded** (cf. semantic interoperability)
- More **metadata** and coding in EHRs at granular level!
- **Intelligent** (cf. decision support), clinical pathways...
- **Predictive** (e.g. genetic data)
- More **sensitive** content (!privacy protection)
- **Personalised**
- **Integrative**
Towards Integrated Health

- Biosensors
- Environmental Data
- Genomic data

Integrated Health Records

Phenomic data
The adoption, use and interoperability of Electronic Health Records has become a major focus of European and US eHealth policies, strategies and investments.

Drivers for Integrated EHRs and Semantic Interoperability are:

- Manage increasingly complex clinical (multi professional) care
- Let interact multiple locations of care delivery
- Deliver evidence based health care
- Need for intelligent decision support in medicine
- Improve safety and cost effectiveness of health care
- Enrich population health management and prevention
- Better exploit biomedical research
- Empower and involve citizens
Semantic Interoperability (ctd)

S.I. requires widespread and dependable access to published and maintained collections of coherent and quality assured semantic resources: “the detailed clinical models or clinical archetypes”.

Hence the need of archetypes and templates mapped to EHR-interoperability standards and bound to well specified multi-lingual value sets, indexed and associated with each other via ontologies and referenced from modular care pathway components.

(Multilingual not only to support cross-border care but also to enable cross-border aggregation of research data!)
New generation **personalised medicine** underpinned by ‘**omics** sciences’ and translational research needs to integrate data from multiple EHR systems with data from fundamental biomedical research, clinical and public health research and clinical trials.

Clinical **data** that are shared, exchanged and linked to new knowledge need to be formally represented to become **machine procesable**. This is more than just adopting existing standards or profiles, it is “mapping clinical content to a commonly understood meaning”.
Longer term:

In the longer term a governance organisation needs to be nominated

• to support, oversee and quality manage the future development of semantic interoperability resources (clinical models) for health

• and to develop an action plan for future research and educational investments.

= A UNIQUE ROLE for EuroRec
Significant changes to be anticipated

• Everything driven by “**BIG**” data (genomics, proteomics, metabolomics...): processes in healthcare are **data intensive**!

• In 2008: 1bn PCs (today: shift also from personal to **personalised computing**!)

• In 2020: 10 bn **mobile connected devices** ...Mobile computing encourages people to use web services more often (in Q2 2011: already more than 1 million Apps within the group of bigger stores)

• The rise of the Cloud will create an explosion of consumer focused web services (**cloud based Personal Health Records** to be directly adopted by consumers? )
Cloud computing is no longer a buzz term but a reality ...

With the opportunity for **on-demand Software-as-a-Service**, migrating IT services to the clouds is an opportunity that is hard to ignore...
PHRs, EHRs and the Re-use of EHR data

Patient

TRUST

Clinician

PHR

EHR (EMR, EPR…)

Privacy Enhancing Techniques

Clinical Trials & Research

Safety and Adverse Event Registers

Knowledge Mgmt Platforms

Decision Support Systems

Healthcare Management

Marketing

Billing

Clinical Trials

Safety and Adverse Event Registers

Knowledge Management Platforms

Decision Support Systems

Healthcare Management

Marketing

Billing
Including:

- Foreword by Herman Van Rompuy - E.Council President

- Memorandum of Understanding signed by:
  - Neelie Kroes - E.Commission Vice-President
  - Kathleen Sebelius – Secretary of HHS
## Past Projects

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<th>FP</th>
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<td>MediRec</td>
<td>FP3</td>
<td>1994-1995</td>
<td>Declaration (Recom. 9)</td>
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<td>ProRec</td>
<td>FP4</td>
<td>1996-1998</td>
<td>Creation of first ProRec centres</td>
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<td>Widenet</td>
<td>FP5</td>
<td>2000-2003</td>
<td>Creation of EuroRec</td>
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<td>Q-Rec</td>
<td>FP6</td>
<td>2005-2008</td>
<td>Creation of Repository &amp; Tools</td>
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<td>RIDE</td>
<td>FP6</td>
<td>2006-2007</td>
<td>Roadmap for Interoperability</td>
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<tr>
<td>EHR-Implement</td>
<td>FP6</td>
<td>2007-2010</td>
<td>National Policies for EHR Implementation in the European area: social and organisational issues</td>
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### Other Projects

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<tr>
<td>EHR-Q^TN</td>
<td>FP7</td>
<td>2009-2012</td>
<td>Thematic Network on Quality Labelling and Certification of EHR Systems</td>
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<tr>
<td>ARGOS</td>
<td>FP7</td>
<td>2010-2011</td>
<td>Transatlantic Observatory for Meeting Global Health Policy Challenges through ICT-Enabled Solutions</td>
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<td>HITCH</td>
<td>FP7</td>
<td>2010-2011</td>
<td>Healthcare Interoperability Testing and Conformance Harmonisation</td>
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<td>EHR4CR</td>
<td>IMI call 2</td>
<td>2011-2015</td>
<td>Electronic Health Records for Clinical Research</td>
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<td>INBIOMEDvision</td>
<td>FP7</td>
<td>2011-2013</td>
<td>Promoting and Monitoring Biomedical Informatics in Europe</td>
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<td>eHealth Innovation</td>
<td>FP7</td>
<td>2011-2013</td>
<td>eHealth Innovation – Scaling up eHealth facilitated personalized health services: Developing a European roadmap for sustained eHealth Innovation</td>
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Starting Projects

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<td>EURECA</td>
<td>FP7</td>
<td>Enabling information re-use by linking clinical research and care</td>
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<tr>
<td>SALUS</td>
<td>FP7</td>
<td>Scalable, standard based interoperability framework for sustainable proactive post market safety studies</td>
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<tr>
<td>SemanticHealthNet</td>
<td>FP7</td>
<td>Network of Excellence on semantic interoperability and European health infostructure</td>
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Prospects (5 in the pipeline):

...EUCLID, GEE ALLIANCE, PORTRAITS, RDECODE, a next NOE...
Past, ongoing and future EU efforts

- **Deployment of certification** at Pan-European level (*EHR-Q-TN and next Thematic Network project*)

- Strengthening **collaboration** with others (*HITCH and RDECODE, PORTRAITS*)

- **Continued international cooperation** with e.g. the US (*ARGOS and GEE Alliance...*)

- Further development of the certification criteria for the **re-use of EHR data** for clinical research (*EHR4CR, EURECA, and EUCLID...*)

- Personalised Medicine and mobile device issues: **integration of biomedical data**, **PHRs** and other issues (*INBIOMEDvision and eHealth Innovation*)

- More focus on **semantics**, more clinicians’ involvement and more EHR-content-related criteria (*SemanticHealthNet, SALUS*)
The Future

• EuroRec will continue to raise awareness at pan European level, in particular towards Healthcare Authorities and Policy Makers (cf. the BELGRADE DECLARATION and other initiatives...)

• EuroRec will strengthen its network via further EC funded projects (and by involving its ProRec centers through new mechanisms) (cf. also EuroRec’s complete market inventory and roadmap)

• Eurorec believes in new technologies and new paradigms (existing legacy systems are often a handicap)

• Europe needs to organise in the longer run structural funding for EHR and eHealth related Certification activities (EuroRec should play for the medical software a role analogous to the one played by the European Medicines Agency (EMA) for new medicines (cf. safety etc.)
THANK YOU!

Prof. Dr. Georges J.E. De Moor
- georges.demoor@ugent.be
- http://www.eurorec.org

the Future is also in...