Certification and Quality: the EuroRec Seal Experiences

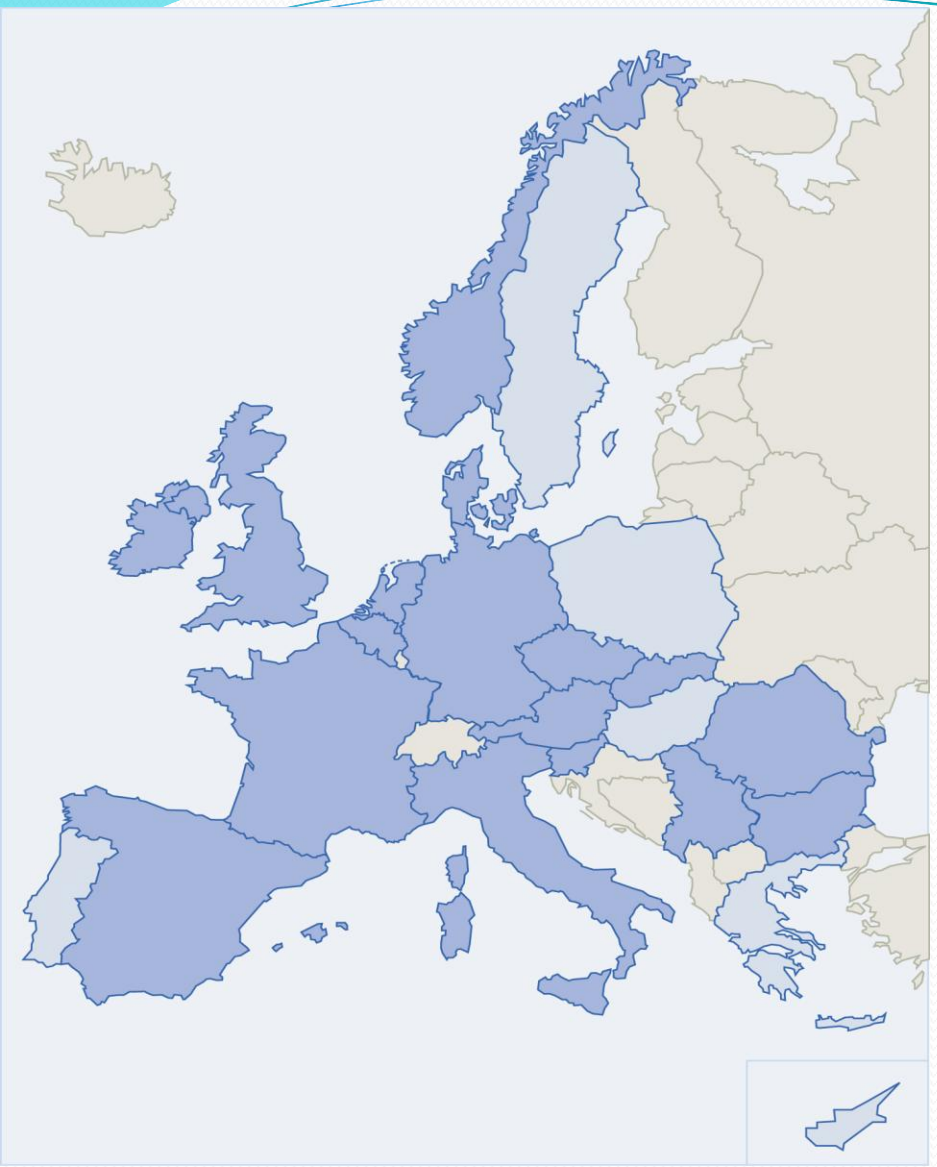
EHR-Q^{TN} Workshop

Lisboa, 25 November 2010

Dr. Jos Devlies

Topics

- The EuroRec Institute
- Definitions and domain limitation
- Importance of Quality Assessment of Health IT products
- EuroRec approach to quality assessment
- Status of the EuroRec Repository of EHR Descriptive Statements
- Roads to certification: role of the stakeholders
- EuroRec Seals: towards cross-border harmonisation
- EHR-Q^{TN} to support the process of certification



The EuroRec Institute

- Not-for-profit organisation
- Federation of National Centres & Associated Centres
- 17 active ProRec Centres
- Active in:
  - Research about EHR systems and their use
  - Product Conformance

Mission Statement

- To promote… and participate in research on development, implementation and use of health records.
- To promote… efficiency, effectiveness, quality and interoperability of health records to improve quality of care.
- To advance and secure acceptance of comprehensive patient centred health records.
- To promote… investment in health records and health informatics.
- To promote European and Global cooperation.

Main activities

- Support National ProRec centres.
- Initiate and Participate in research projects related to the EHR.
- Build a context for EHR Quality Conformance Testing for care and clinical research activities.
- Support authorities in introducing certification of health IT.
- Support EHR industry improving cooperation, benchmarking and procurement of the systems.

Definitions… what are we speaking about?

Four different concepts …

- Conformance testing: related to “standards”
- Compliance testing by an “authority” > Certificate
- Compliance testing by any other “institute” or “organisation” > Label
- Stakeholder ability testing > Accreditation

Different “types” / “domains”

- Functional testing (processing ‘content’)
  - Administrative / Billing Oriented
  - Clinical
- Exchangeability testing (don’t guarantee more than that)
- Usage testing
  - Effective using (measurement issue)
  - Health Care Professional “competence” in “using the tools chosen”
- Health ICT professionals / e-Health Workforce

Importance
of
Quality Assurance
of
Health IT Products

Health IT has a great potential

- To increase efficiency of care by
  - Reducing useless and duplicated tests and interventions;
  - Reducing cost of processing (paper) documents.
- To increase quality of care by
  - Availability of shared interoperable patient data;
  - Monitoring and enabling evidence based disease management;
  - Integrating knowledge based clinical surveillance and decision support.

A big quality issue…

- Quality of the products as such very disparate, sometimes incredibly poor, not always offering what they promise.
- Poor availability of “interoperable” content due to a lack of standards, due to insufficient use of existing standards.
- Poor “usability” of content due to insufficient structuring of that “content”: still too much free text in the absence of efficient tools to interpret that free text.
- Enormous issue of no usage, under-usage, wrong usage of even the best applications.

Quality

- Is never obvious.
- It requires high quality content (correct and precise data).
- It requires correct “interpretation” of that content.
- High quality content can only be obtained:
  - By applications able to produce high quality content
  - By applications able to “manage” that information
  - By users handling those applications properly

Quality requires

- Functionality
- Evolution
- Connectivity & Interoperability
- Reliability & Accountability
- Appropriate use

Functional quality

- The primary administrative and billing related functions (if required) are prerequisites.
- The system needs to provide all the functionality required by its user group: e-prescription, patient safety monitoring, disease and prevention management, data sharing, decision support, care documentation, ….
- The system needs to perform these functions correctly, complying to national or local requirements.
- Implementation has to be “user friendly” and “configurable” within predefined limits.

Evolution

- Requirements are not “eternal”.
- Systems needs to be adaptable to new requirements.
- Authorities (public / private) needs procedures / means to enforce “evolution”.

Connectivity & Interoperability

- To share patient information
- To connect devices and optimise input
- To support and manage clinical processes
- To integrate knowledge

Reliability and Accountability

- Version management: each change is a new version
- Authorship: data entry and content responsibility
- Access traceability
- Audit logs for user / system interaction
- Confidentiality management

Appropriate use

- Very few studies on how systems are used
- Appropriate use requires training and a positive commitment:
  - Education and Training in use of the system and “correct registration”
  - Incentives
- “Meaningful use”:
  - Important and promising initiative
  - Measuring will be an issue

We have a problem…

- To express what we expect an application has to do.
- To document in a reliable way the functions of an application to optimise procurement of applications.
- To translate political and social functional needs into product requirements.
- To verify that these requirements are met…
- To measure the appropriate use of the systems.

We need… a “language”

- To describe functionality.
- To describe requirements.
- To translate those requirements in product specifications.
- To redact test criteria and procedures to validate applications against these specifications.

EuroRec approach to quality assessment

EuroRec Repository

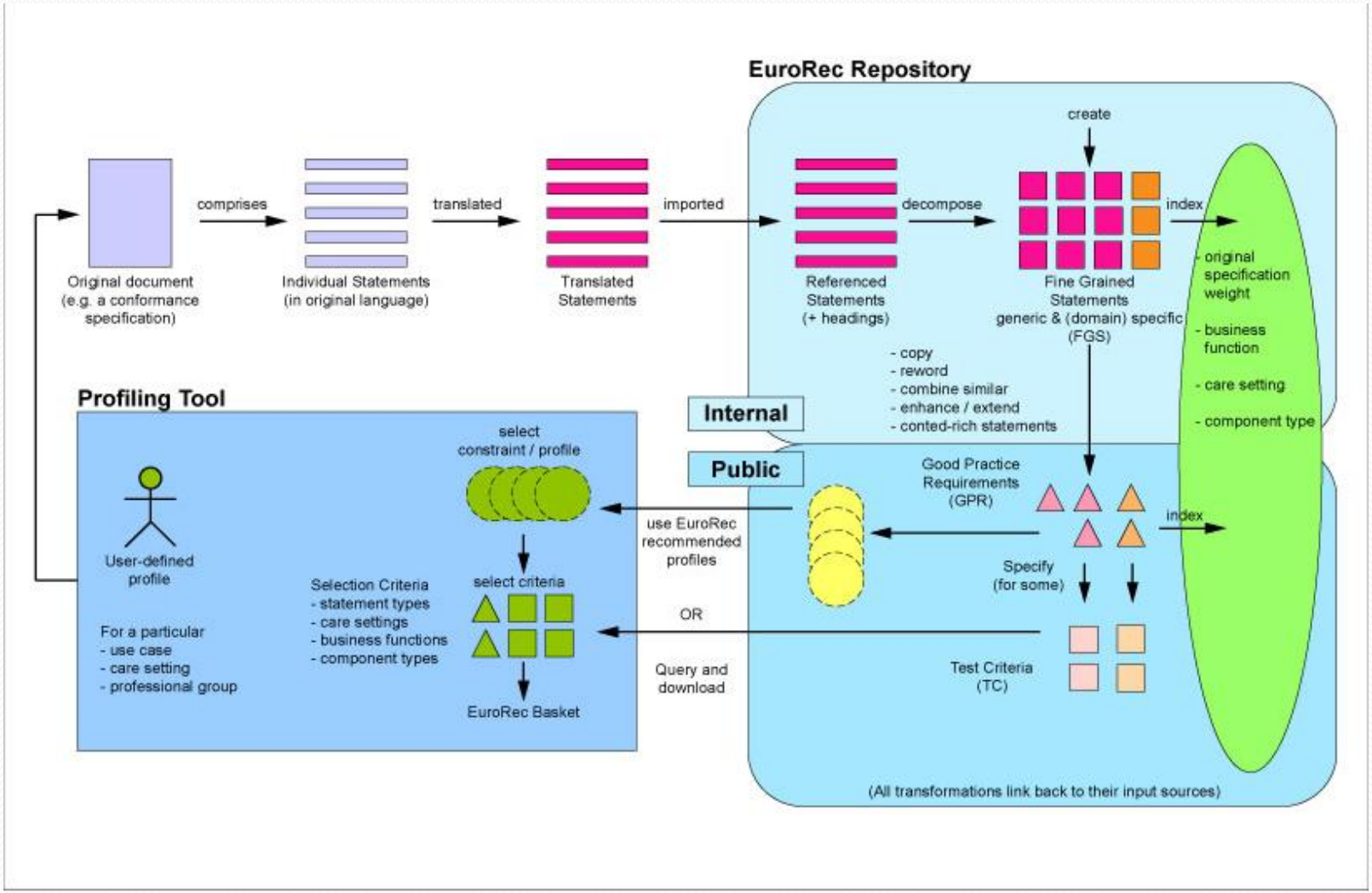
EuroRec created

- A repository of functional “descriptive statements”
  - Over 1.700 statements
  - A subset translated in 19 languages
  - Generic statements as well as statements addressing “specialised” areas as e.g. “requirements for EHR systems as source for clinical trials data”
- EuroRec does not define what’s required
  - *Suggesting* “professional profiles”.
  - Leaving it to *the authorities to decide* what’s important… slightly different in each country (healthcare still national competence).
  - Also “less than best” practice needs to be described.

EuroRec created

- Tools to use these statements
  - As test criteria for quality labelling
  - For Product procurement
  - For Product documentation
- A set of services to assist interested parties
- A validation service against "cross-border subsets" of quality requirements (EuroRec Seal)

The EuroRec Repository

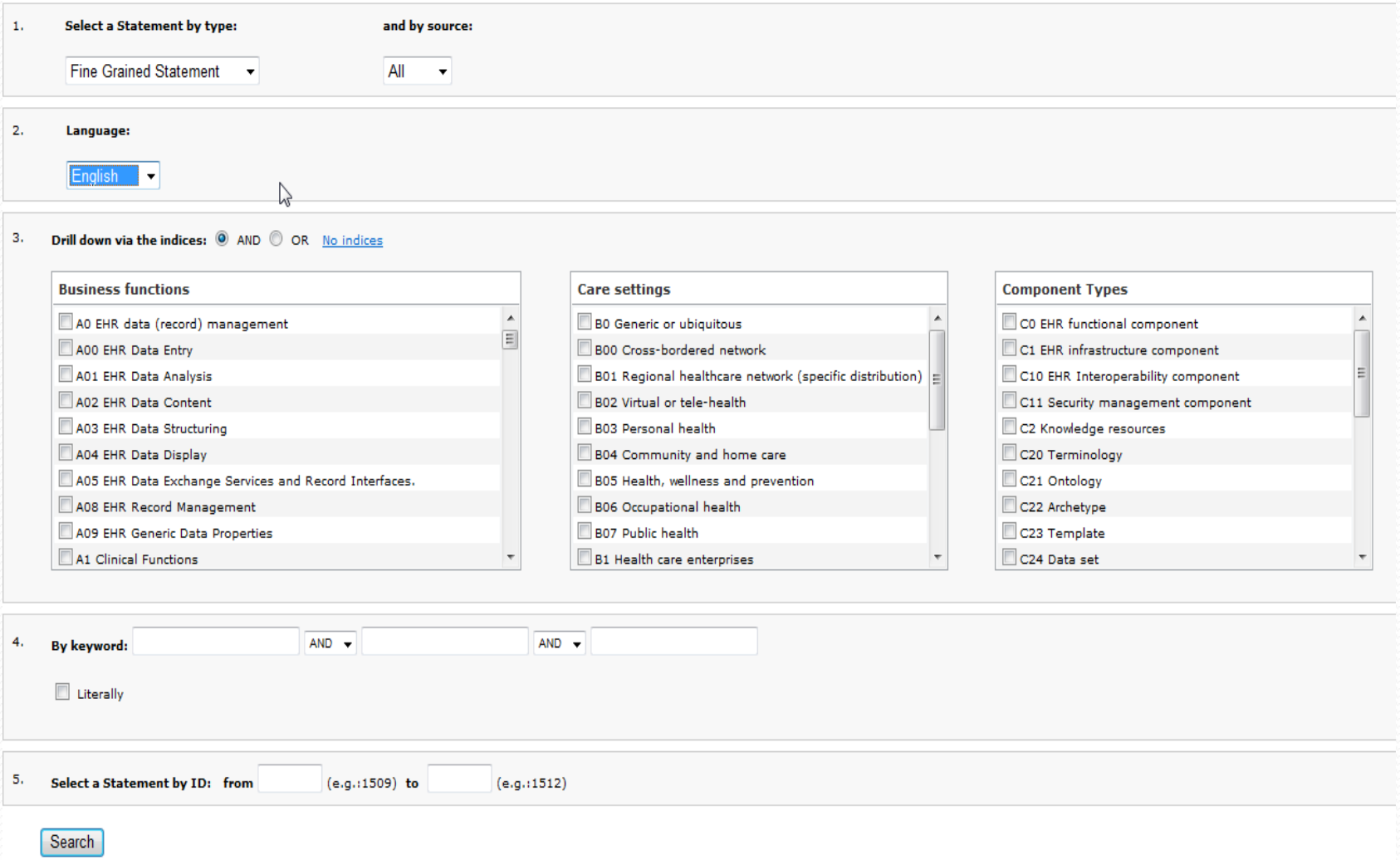


Sources…

- Belgium (1999-2006-2010)
- CCHIT (USA)
- Alberta (Canada)
- Ireland (GP-IT)
- France (LAP)
- Denmark
- Meaningful use (USA)
- Clinical research (eClinical Forum)
- Austria (Lab functions)

http://www.eurorec.org

Indexing and Search Interface



Medication related decision support…

GS001672.02	The system has provisions for updating the coded list of medicinal products.	1	1
GS001677.03	The system alerts the user for an inappropriate daily dose for a given patient considering age, weight and gender.	4	1
GS001690.03	The system offers a dose calculator for patient-specific dosing based on age, weight, length and/or renal function.	3	1
GS001691.02	The system recommends automatically the patient specific dosing based on weight, age and gender.	3	1
GS001692.02	The system recommends automatically the patient specific dosing based on renal function.	2	1
GS001693.03	The system connects with a medicinal product database enabling patient specific dosing recommendations.	2	1
GS001700.03	The system enables to update the medicinal product database by updating its content.	1	1
GS001701.03	The system enables to update the medicinal product database by replacing the current version with a recent one.	1	1
GS001702.03	The system alerts the user if the medicinal product database is outdated.	1	1
GS001708.04	The system enables the creation of a "local" medication formulary of the most commonly prescribed medicinal products.	3	1
GS001709.02	The system is linked to a database with information on necessary follow up tests on prescribed medicinal products.	1	1

HL 7 criteria

DC.2.3.1.2	F	**Support for Patient Specific Dosing and Warnings**	**Statement**: Identify and present appropriate dose recommendations based on known patient- conditions and characteristics at the time of medication ordering **Description**: The clinician is alerted to drug-condition interactions and patient specific contraindications and warnings e.g. pregnancy, breast-feeding or occupational risks, hepatic or renal insufficiency. The preferences of the patient may also be presented e.g. reluctance to use an antibiotic. Additional patient parameters, such as age, gestation, Ht, Wt, BSA, shall also be incorporated	E	1. The system **SHALL** provide the ability to identify an appropriate drug dosage range, specific for each known patient condition and parameter at the time of medication ordering. 2. The system **SHALL** provide the ability to automatically alert the provider if contraindications to the ordered dosage range are identified. 3. The system **SHALL** provide the ability for the provider to override a drug dosage warning. 4. The system **SHOULD** provide the ability to document reasons for overriding a drug alert or warning at the time of ordering. 5. The system **MAY** transmit documented reasons for overriding a drug alert to the pharmacy to enable communication between the clinician and the pharmacist. 6. IF the maximum daily doses are known THEN the system **SHALL** apply the maximum dose per day in dosing decision support. 7. The system **SHOULD** compute drug doses, based on appropriate dosage ranges, using the patient's body weight.

Main difference: functionality and "regulation" in one statement

Problem:

-quite some criteria does (not/only) apply in a given environment / domain of application

-regional / national differences depending on legal / cultural context or on local priorities

Nevertheless: addressing the same issues

EuroRec

Fine Grained Statement:

ID:GS001677. 03
Source: QREC **ID:**
Statement type: Fine Grained Statement

Statement:
The system alerts the user for an inappropriate daily dose for a given patient considering age, weight and gender.

Created by Dequae Miet **on** 04/12/2007
Last Updated by Devlies Jos **on** 18/02/2010

Referenced statements:

SS000312. 01 - BE-99 - 196-4 - The system detects wrong or unusual posologies in function of gender, age an weight of the patient.
SS000633. 01 - CCHIT-06 - 99 - The system shall check for daily dose outside of recommended range for patient age (e.g., off-label dosing).
SS004179. 01 - IE07 - DC.1.7.1.16. - The system should provide the ability to create prescriptions in which the weight-specific dose is suggested.
SS004349. 01 - IE07 - DC.2.3.1.2.7. - The system should compute drug doses, based on appropriate dosage ranges, using the patient's body weight.

Good Practice Requirements:

EU003328.04 - The system recommends automatically the patient specific dosage (daily dose) based on weight, age, gender, renal function and/or liver function. The system offers a default dosage (adult of 75 kg) in case no patient specific dosage can be recommended. The system connects therefore to a specific database. The system alerts for an inappropriate daily dose for a given patient.

Indices:

Business Functions:
A01 EHR Data Analysis
A04 EHR Data Display
A10 Medication Management
A10.2 Decision support & medication care quality surveillance
A15 Clinical Decision Support: alerts, reminders,...
A35 Pharmacy services
Care settings:
B10 Long-term care (institution)

Multilingual content

Repository Statistics

Fine Grained statements	
Total FGS:	1688
Total links Business Functional Indices:	6135
Total links Care setting Indices:	5233
Total links Type of Statement Indices:	2897
Total links Indices:	14265
Total links SS FGS:	3759
Unconnected FGS:	230

Translations

- Bulgarian: 350
- Croatian: 179
- Czech: 57
- Danish: 151
- Dutch: 565
- Estonian: 399
- French: 422
- German: 288
- Greek: 203
- Hungarian: 295
- Italian: 346
- Polish: 116
- Portugese: 109
- Romanian: 481
- Serbian: 352
- Slovakian: 1571
- Slovenian: 205
- Spanish: 1132

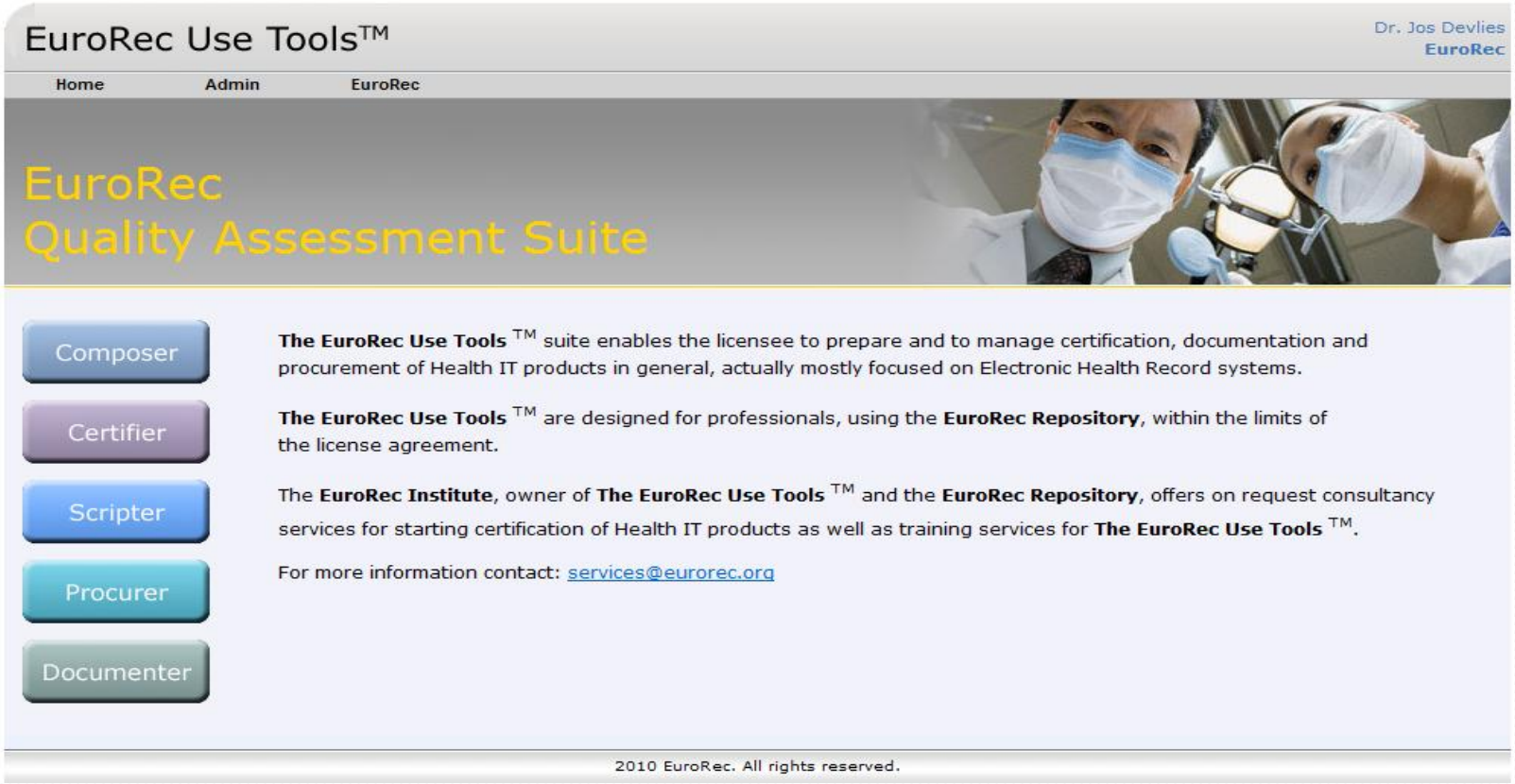
EN - Each change of status of a health issue results in a new version of that health issue.
BG - Всяка смяна на статуса на здравен проблем е нова версия на този здравен проблем.
CS - Každá změna stavu zdravotní položky vede k nové verzi zdravotní položky.
DE - Jede Änderung des Status eines Gesundheitsproblems ergibt eine neue Version dieses Gesundheitsproblems.
DK - Enhver ændring i et dataelement relateret til patientens helbred, resulterer i en new version af dataelementet.
EL - Κάθε αλλαγή της κατάστασης ενός ζητήματος υγείας οδηγεί σε νέα έκδοση του ζητήματος υγείας.
ES - Cada cambio en el status de un item sanitario provoca una nueva versión de ese item sanitario.
ET - Iga kord, kui terviseteema olekut muudetakse, luuakse selle terviseteema uus versioon.
FR - Chaque modification de l'état d'activité d'une donnée donne lieu à une nouvelle version de cette donnée.
HR - Svaka promjena statusa zdravstvenog problema rezultira novom inačicom tog zdravstvenog problema.
HU - Az egészségügyi adatelem minden változásának eredménye egy új verziója ennek az egészségügyi adatelemnek.
IT - Ogni cambiamento di stato di una problematica sanitaria genera una nuova versione di quel problema sanitario.
NL - Elke wijziging van de status van een zorgelement heeft een nieuwe versie van dat zorgelement tot resultaat.
PL - Każda zmiana statusu elementu rekordu medycznego powoduje utworzenie nowej wersji tego elementu.
PT - Cada mudança de estatuto de um tópico de saúde resulta numa nova versão desse tópico.
RO - Fiecare modificare a statusului a unei probleme de sănătate va conduce la o nouă versiune a acelei probleme de sănătate.
SB - Svaka izmena statusa zdravstvenog stanja ima za rezultat novu verziju tog zdravstvenog stanja.
SK - Každá zmena stavu zdravotného údaju má za následok novú verziu tohto zdravotného údaju.
SL - Vsaka sprememba statusa zdravstvenega podatka povzroči nastanek nove različice tega podatka.

A set in Portuguese

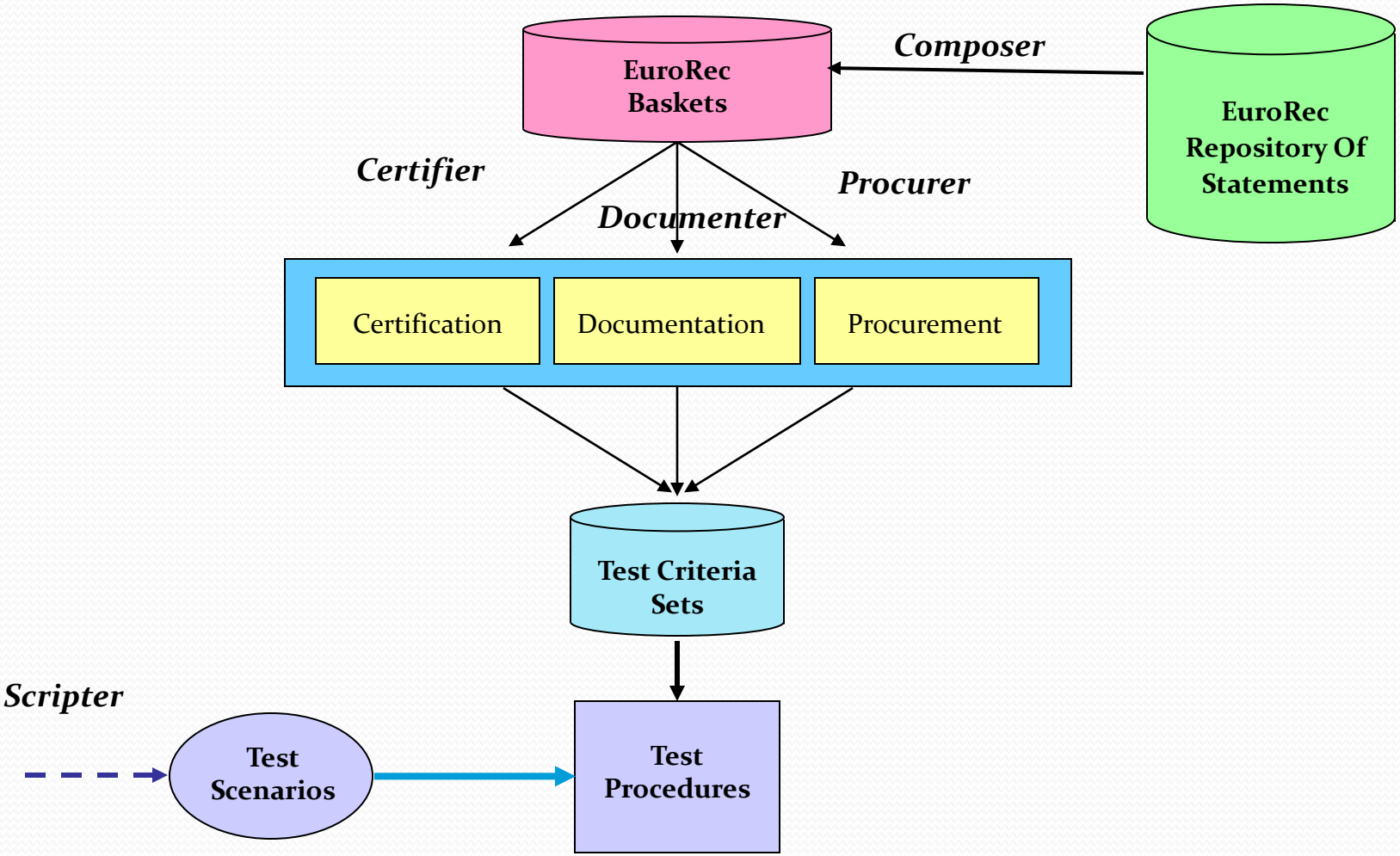
GS001537.03	Cada versão de um tópico de saúde tem uma data e uma hora de registo.
GS001538.02	Cada versão de um tópico de saúde tem um utilizador responsável pela identificação da introdução efectiva dos dados.
GS001539.02	Cada actualização de um tópico de saúde resulta numa nova versão do mesmo.
GS001579.02	Cada versão de um tópico de saúde tem um estatuto de actividade, por exemplo, activa ou corrente, inactiva, histórica ou passada, completa, descontinuada, arquivada.
GS001593.02	A anulação de um tópico de saúde resulta numa nova versão desse tópico de saúde com o estatuto de "anulado".
GS001594.02	Cada versão de um tópico de saúde tem uma pessoa responsável pelo conteúdo dessa versão. A pessoa responsável pelo conteúdo pode ser um utilizador ou uma terceira pessoa.
GS001595.01	Cada mudança de estatuto de um tópico de saúde resulta numa nova versão desse tópico.
GS001598.02	Pode ser apresentado o histórico das versões de um tópico de saúde.
GS001901.02	Cada versão de um tópico de saúde tem uma data de validade.
GS001945.01	O sistema permite ao utilizador identificar tópicos de saúde individuais como confidenciais.
GS001945.01	O sistema permite ao utilizador identificar tópicos de saúde individuais como confidenciais.
GS002127.01	O sistema permite identificar documentos de forma única.

How to use the EuroRec Repository?

EuroRec Use Tools



EuroRec Repository Use Flow



EuroRec Use Tools

Quality Assessment
and
Certification

Importance of “Labelling”

- The only way to be sure that a system:
  - behaves as documented and expected by the (future) user, accelerating adoption of EHR;
  - can be used in order to meat content related quality;
  - complies with regulatory requirements regarding
    - Functionality.
    - Security.
    - Interoperability.

Who wins from certification?

- Patient: quite obviously: safer/better care
- Health authorities:
  - Enabling / guaranteeing that better care
  - Possible to enforce a strategy: how do you otherwise get a "wish" on the market / available at the point of care
- Care Professionals as users:
  - Guarantee that a system fulfils it's "promises"
- Suppliers / industry:
  - Unambiguous specification of market – national requirements
  - Market clearing possible on "quality issues"

Does labelling guarantee quality?

- Having good systems is a first step.

  This includes the function of sharing / exchanging patient information.

- Getting them used properly is another issue
  - Enforced regulation does not work => sub-optimal use
  - Let the market do his job… takes an eternity
  - Incentives….for using those systems => meaningful use in the USA, EHR bonus for the users
- Education and training are essential… 25 years after the first PCs still…

EuroRec

Routes
to
Functional Certification

Road to functional certification

- An authority issues a tender or contract to an organisation to
  - Define the test environment
  - Write test scenarios
  - To perform the tests
  - To validate applications against those criteria
- The authority grants the “labels”:
  - certificate in case of an authority
  - conformance label in case of an organisation.

“Public” Certification

- An organisation (professional organisation) or an authority decides to issue functional and quality requirements for EHR systems.
- Translate interactively with users and providers these requirements into a “basket” of descriptive functional statements.
- Document – where needed – the selected statements.
- Expect the systems to be quality labelled: mandatory or incentivated.

“Individual” Certification

- A predefined set of criteria defined by an organisation issuing a “quality label”
- Indicated for “cross border” labels
- Supplier submit his products freely
- Some buyers may require such a label

Certificate >< Label

- Label:
  - An organisation tests a product on its conformance to a set of predefined requirements.
  - Requirements based on an "agreement".
- Certificate:
  - Conformance label issued by an accredited organisation, entitled to do so on the basis of legal / regulatory rules

Product Certificate / Label >< Usage Certificate / Label

- Product certificate confirms that a product is able to perform a given functionality in a defined way in a given context.
- Usage certificate confirms that a user uses a “certified product” appropriately (correctly and sufficiently) in order to meet an expected usage level.

EuroRec Seal

a cross border conformance label

EuroRec Seals

- How do you realise cross-border "harmonisation" of applications, able to produce "similar" quality?
- EuroRec approach: stepwise, based on more "generic" functional requirements.
- EuroRec issued two "Seals"
  - Seal Level 1 : 20 mainly generic statements
  - Seal Level 2 : 50 criteria also addressing security and confidentiality management.
- http://www.eurorec.org/consortium_intern/seal/index.cfm
- Available in all the languages

http://www.eurorec.org/usetools/tools/documenter/document.cfm?ID=44&view=2&CFID=247395&CFTOKEN=96200482

Composition of the seal

Number	Index	Index Title
12	A00	EHR Data Entry related
9	A02	EHR Content related
8	A03	EHR Structuring Data
22	A04	EHR Display
1	A05	EHR Data Exchange Services and Record Interfaces
14	A09	EHR Generic Data Properties
7	A10	Medication Management
3	A11	Clinical Statements Management
3	A14	Shared Care
2	A15	Clinical Decision Support: alerts, reminders
7	A22	Demographic Services
1	A32	Laboratory Services
4	A6	Health Information System management
23	A7	Privacy and Accountability Services
6	A8	Technical Security Services

Getting a Seal

- At the request of an application supplier.
- Tested by a local partner, considering local / national requirements.
  - Alternative: linked to a national certification session
- Comprehensive test documentation.
- Seal granted at European Level.
- Evolution: certification of modules.
- A possible way to progress: an authority requires a Seal for any public tender.

Different initiatives and approaches in Europe

Actual Situation 'National' Product Labelling

- Administrative and billing related conformance testing:
  - Reporting to National /Regional Health Authorities and Insurance
  - Very common for hospitals, pharmacies, etc…
  - Some countries also in ambulatory care: DE, AT, NL, IT…
- Clinical functionality
  - Limited (Be, IE, …)
  - Sometimes complementary to billing software : DE
- Tender based product validation: UK

Data exchange - Interoperability

- Mainly related to data exchange
- Public or Official testing: NO, DK, NL: different formats
- Industry Initiative: IHE – Integrate the Healthcare Enterprise
  - Yearly Connectathons
  - Europe and USA
  - Based on "industry standards" : XDS and CDA (Clinical Document Architecture – HL7)

Future

- Cross – Border / Global Certification?
- Quality Assessment should be mandatory:
  - In Public Tenders
  - For any reuse of clinical data
  - To participate in National Projects
  - To participate in EU funded research

EHR-Q^{TN} Project

28 partners
24 countries

EHR-Q^{TN}

- Thematic Network project
- To promote quality labelling and certification
- Main actions:
  - > 70 workshop
  - Development and Translation of Repository
  - EHR Market Overview
  - Roadmap to Certification

Belgian experiences and lessons

… takes time

- Started in 1998: definition of basic functionality of the EHR
- Request to three main vendors in 1999 to define a set of “functional requirements” to enable an optimal functionality.
- Consensus selection of a initial set to be validated (2000-2001)
- Agreeing on “incentives” in order to promote the use of quality assessed applications
- First quality labelling (done by health ministry): 2002.
- New criteria for 2004 and 2006..
- Meanwhile also for physiotherapists, dental medicine and home nursing.
- Some opposition from hospitals
- Then it stocked

New start…

- 2008: Law related to the e-Health platform
- 2009: setting up a working group to define / select priorities for label …2009
- 2010: issuing a “call for tender” to “test the applications for GPs”…
- Concrete steps from acceptance of the offer to effective testing:
  - Detailed description of the criteria
  - Define test patient data (to be added to the data of an existing practice considering privacy issues)
  - Define and document test scenarios / scripts
  - Effective testing (started today !!!)
  - Evaluation and reporting to the authorities

Impact on the products & market

- Number of suppliers: + 50 => 17 products / 13 suppliers
- Functional improvement of all the remaining systems
  - Unified prevention management
  - Patient Summary (Sumehr)
  - Migration between applications guaranteed
  - Links know knowledge bases
  - Standardised data exchange
- Quality improvement
  - Traceability
  - Trustworthiness
  - Version management…
  - Increasing usage performance

Conclusions

- Health IT has enormous potentiality but at the same time a quality problem
- Authorities should take their responsibility
  - Quality of Health IT application should be an issue
  - Research budgets should be limited to quality labelled EHR applications
  - Effective use of quality labelled products should be stimulated (and measured): incentives
- Industry and Users should be involved in the process.

Thank you!