EHR Certification Experience from Denmark

Knut Bernstein
MEDIQ
kb@mediq.dk

Agenda

- The certification guideline
- Examples from the certification
- The vendor's view
- Lessons learned

Objective for the guideline

- To introduce a uniform and transparent methodology for the certification of EHR in Denmark (and in Europe)
- It is mandatory to follow the guideline, i.e.
  - Result and documentation of different certifications can be compared
  - Improving reproducibility

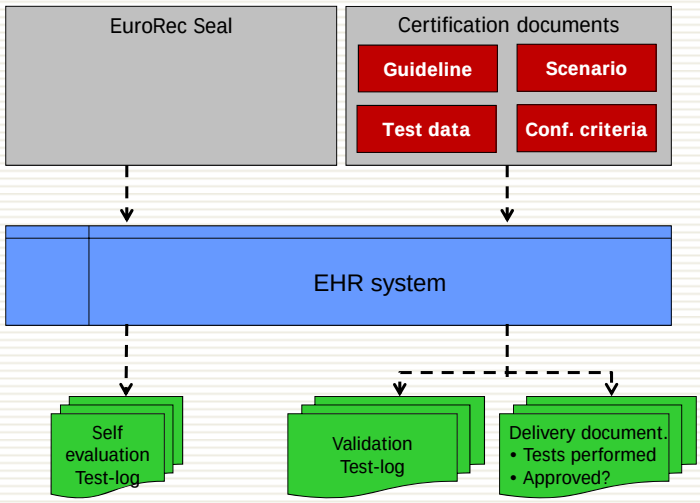
MEDIQ

Compliance and conformance

- The certification documents to what extent the software product is compliant with the conformance criteria being tested
- The certification, does not ensure:
  - Stress testing: system performs with expected volumes
  - Execution testing: system achieves desired level of proficiency
  - Recovery testing: system can be returned to an operational status after a failure
  - Operations testing: system can be executed in a normal operational status
  - Security testing: system is protected in accordance with importance to organisation

MEDIQ

Certification methodology



MEDIQ

EuroRec Seal Statements

Each version of a health item has a date and time of registration.
Each version of a health item has a user responsible for the effective data entry identified.
Each update of a health item results in a new version of that health item.
Each version of a health item has a status of activity, e.g. active or current, inactive, history or past, completed, discontinued, archived.
Deletion of a health item results in a new version of that health item with a status "deleted".
Each version of a health item has a person responsible for the content of that version. The person responsible for the content can be a user or a third party.
A complete history of the versions of a health item can be presented.
Each version of a health item has a date of validity.
The system enables the user to designate individual health items as confidential.
Each health item is uniquely and persistently associated with an identified patient.
Each version of a health item is uniquely and persistently identified.
Each user is uniquely and persistently identified.
The system enables to assign different access rights to a health item (read, write,...) considering the degree of confidentiality.
All patient data can be accessed directly from the patient record.
Each patient and its EHR is uniquely and persistently identified within the system.
The system takes the access rights into account when granting access to health items, considering the role of the care provider towards the patient.
The system offers to all the users nationally approved coding lists to assist the structured and coded registration of health items.
The pick lists and reference tables offered by the system are the same for all the users of the same application.
The system does not display deleted health items, audit logs excepted.
The system does not include deleted health items in clinical documentation or export, for audit purposes excepted.

MEDIQ

Test scenario

- The objective is to describe the context and to ensure that the business process are tested from start to end
- The scenario list a number of steps, where each step gives precise instruction on what to do
- In average a test of a EuroRec Seal statement will include 3-4 steps.

MEDIQ

Test data

- The aim is to provide data which have been specifically identified for testing the EHR against the EuroRec Seal Criteria
- Data is typically used to verify that a given set of input to a given function produces a specified result
- It is mandatory to use the specified test data, unless it is clearly stated the test data only serve as examples

MEDIQ

Conformance criteria

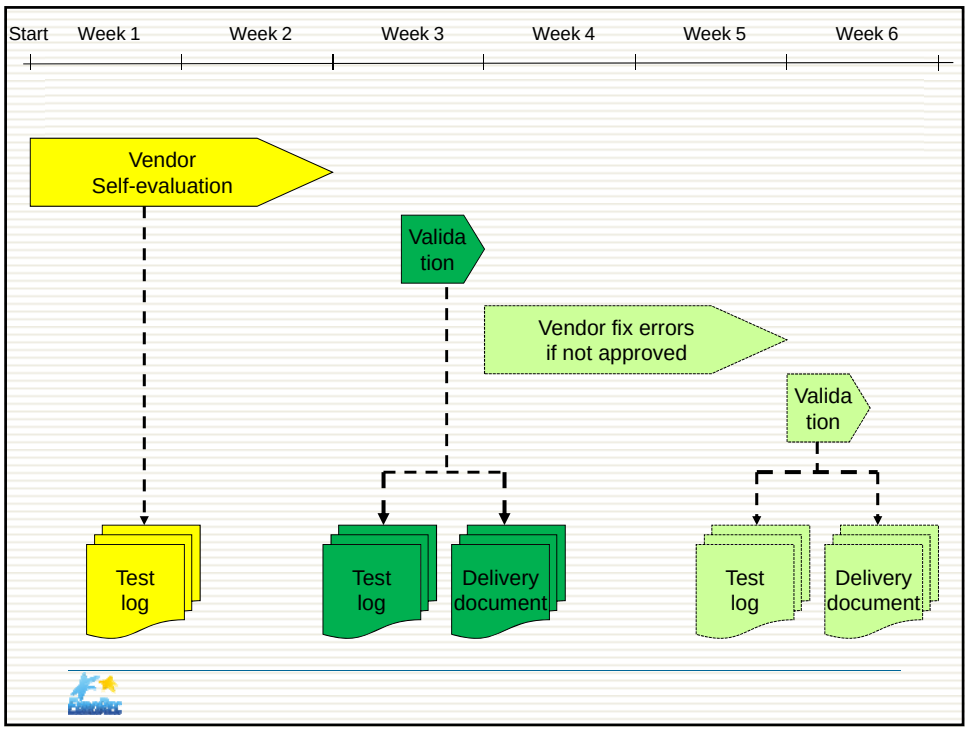
- The aim is to explicitly state the conditions for passing the test
- Based on a functional testing with the emphasis on testing the externally observed functionality against the EuroRec Seal (black-box testing)

MEDIQ

Health Item – date and time

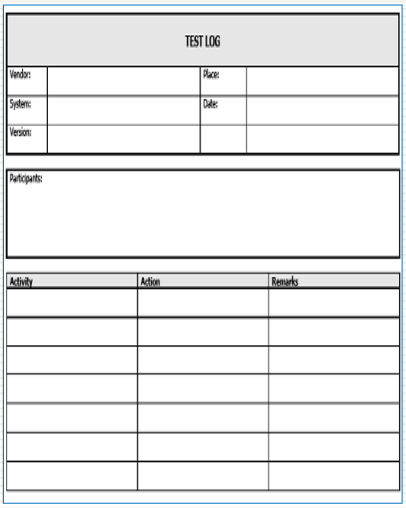
Quoted Statement	Each version of a health item has a date and time of registration.
Test scenario	1. Search for patient 2. Add a health item, eq. a diagnose 3. Add a health item, eq. an intervention 4. Add a health item, eq. a consultation note
Test data	1. Patient #1 2. Diagnose: Chronic Heart Failure 3. Intervention: Electrocardiogram 4. Consultation note: Congestive heart failure with severe LV systolic dysfunction
Conformance criteria	Check that the date and time for the diagnose, the intervention and the consultation note are the same as the date and time for the registration.

MEDIQ



Test log

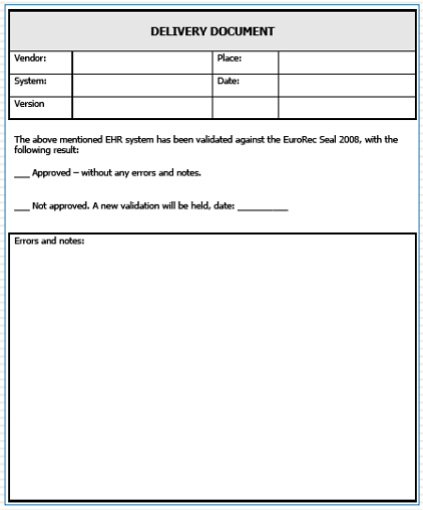
- A template used to document the actions and results of the test
- It is mandatory to use at the self-evaluation and the validation
- If an error is detected, it shall be documented exhaustively



MEDIQ

Delivery document

- To document if the EHR system has passed the test or not
- After the validation, the certifier will fill in the delivery document
- The delivery document is signed by the representative from the vendor and from ProRec



DELIVERY DOCUMENT

Vendor:		Place:	
System:		Date:	
Version			

The above mentioned EHR system has been validated against the EuroRec Seal 2008, with the following result:

___ Approved – without any errors and notes.

___ Not approved. A new validation will be held, date: _____

Errors and notes:

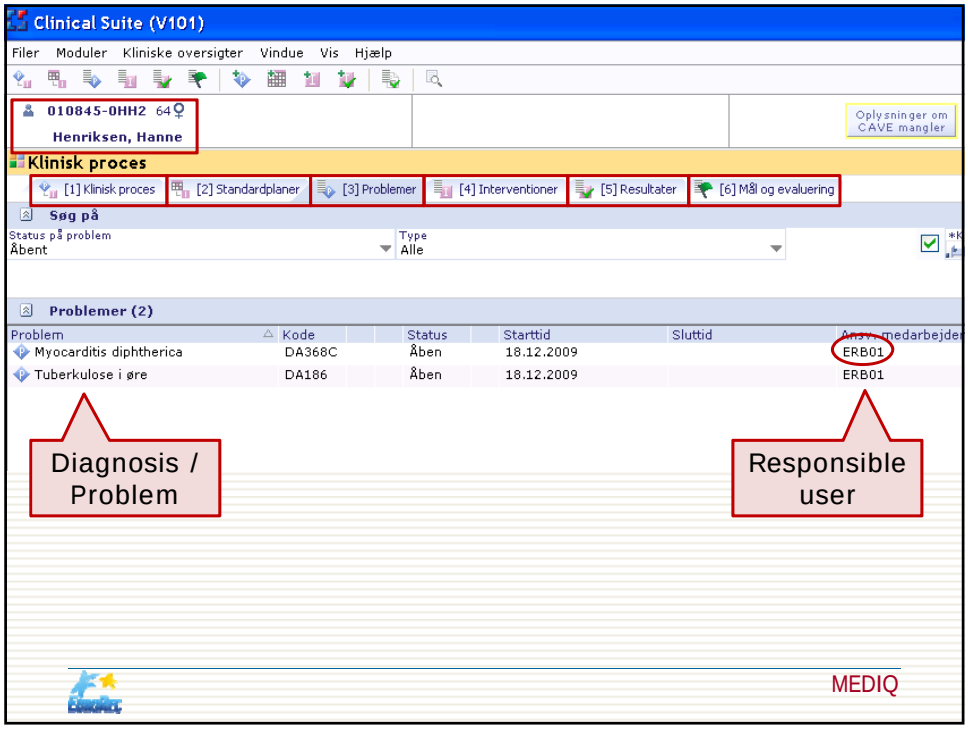
The specified test environment

- Minimum two networked computers with printers etc.
  - All necessary components and resources for running the test shall be available (PCs, laptops, printers, servers etc.)
- The system shall be preloaded with necessary test data before the test
  - Number of patients and data descriptions are specified in the guideline
- The EHR system shall be configured as a “live” system running in daily operation

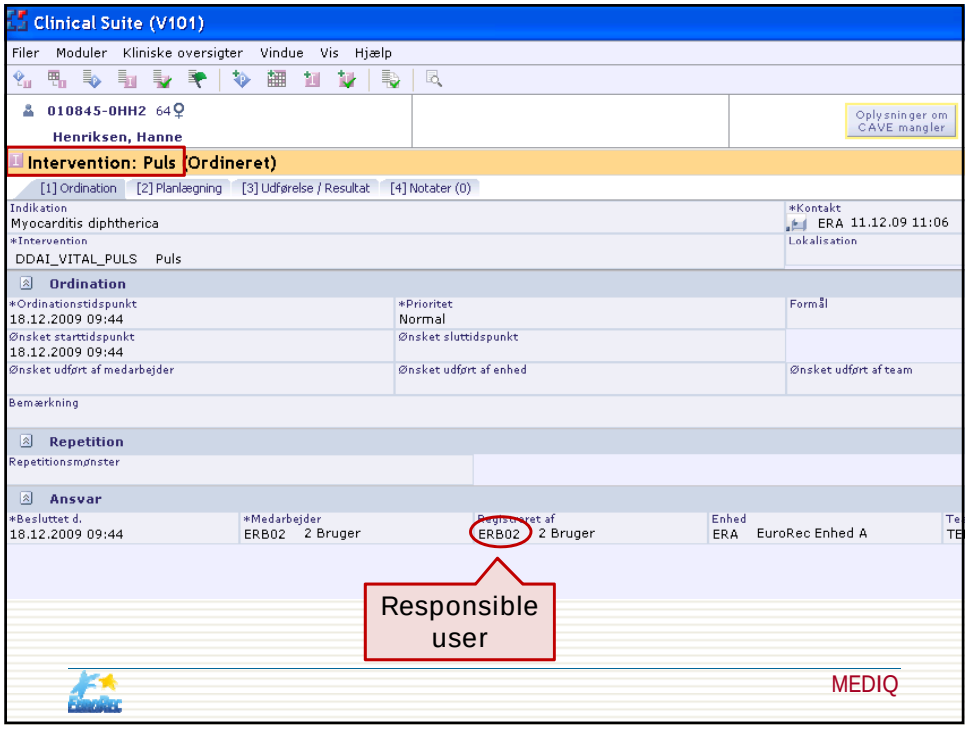
Responsible user

Quoted Statement	Each version of a health item has a user responsible for the effective data entry identified.
Test scenario	1. Login 2. Search for patient 3. Add a health item, eq. a diagnose 4. Login (different user) 5. Search for patient 6. Add a health item, eq. an intervention
Test data	1. User #1 2. Patient #1 3. Diagnose: Myocarditis Diphterica 4. User #2 5. Patient #1 6. Intervention: Measure heart rate (puls)
Conformance criteria	Check that user #1 is responsible for the diagnose and user #2 is responsible for the intervention.

MEDIQ

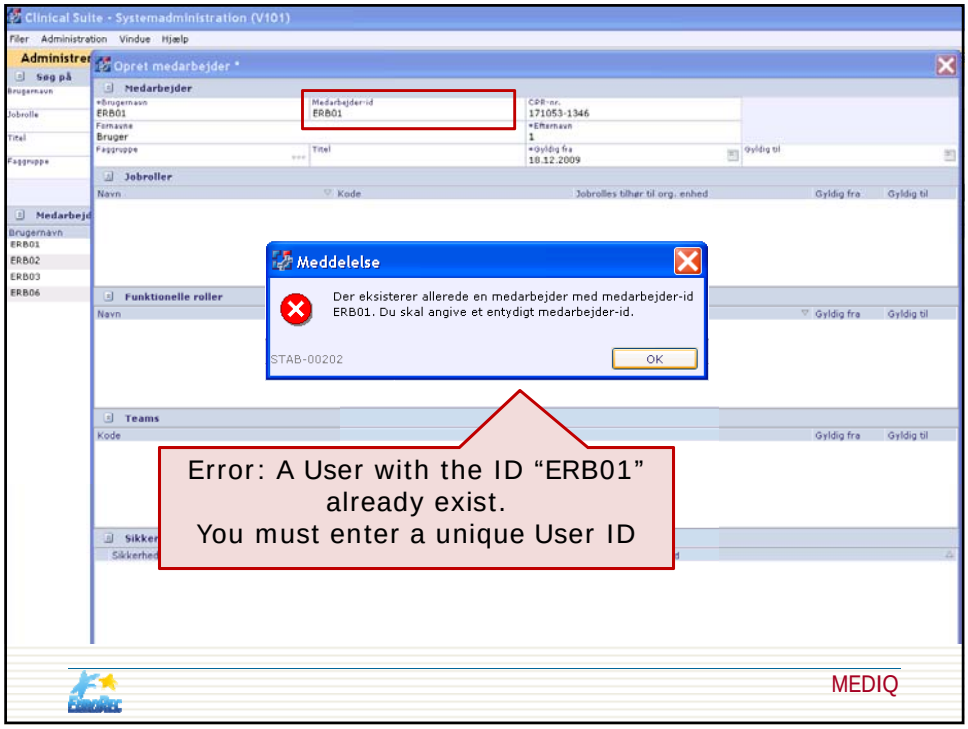


MEDIQ

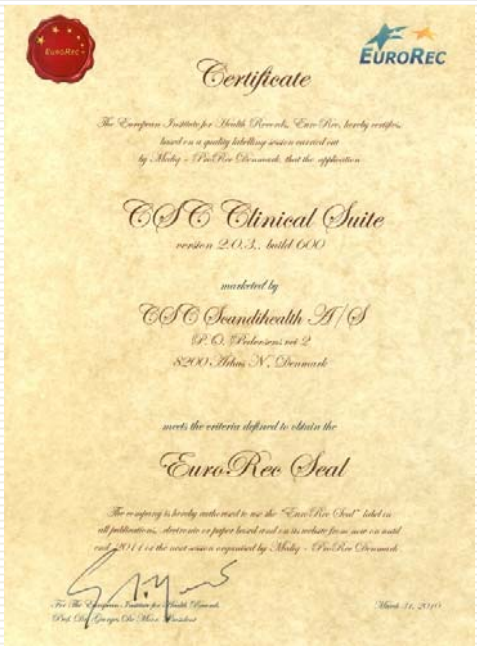


Unique user ID

Quoted Statement	Each user is uniquely and persistently identified.
Test scenario	1. Search for an existing user and display 2. Create a new user with the same attribute 3. Create a new user 4. Delete the new user
Test data	1. Print the attributes for the existing user 2. Use same attribute as the existing user 3. Construct data for a new test user 4. The new test user
Conformance criteria	Check that it is not possible to crete a new user, whith the same id (uniqely). Check that an existing user can't be deleted.



MEDIQ



- CSC announces the achievement of the EuroRec certificate world-wide

MEDIQ

Lessons learned

- Statements in the seal must be verifiable by a functional test
  - Eq. no test of databases structure and content
- A coherent vocabulary for the certification and statements is needed
- Scenario and test data
  - will improve the clarity and precision of a statement
  - should be developed together with the statement
  - different scenario and test data is recommended for different domains (hospital, primary care..)
- There is room for improvement, but...

Conclusion

- The seal is available
- The methodology for testing and docum-entation is available
- The seal granting procedure is in place
- The vendors welcome a clear and transparent procedure...