Quality Labelling and Certification of Electronic Health Record Systems

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Abstract:
The Danish Health IT strategy 2003-2007 demands implementation of Electronic Health Records (EHR) in all Hospitals based on common standards. The aim is to achieve integration and semantic interoperability between different EHR systems in order to support a better communication and coherence between the health care parties. The National Board of Health has developed a common model, which is a prerequisite for the development and implementation of interoperable EHR systems. The adoption of the common EHR model has been promoted and validated through a number of pilot projects in different Hospitals. The Danish EHR Observatory, which has been monitoring the development of EHR in Denmark since 1998, has developed a methodology for Quality labelling and certification of EHR systems. The methodology for certification of EHR systems has been used to validate EHR systems from different vendors to document to which extent the systems are based on the national requirements for EHR.

Keywords:
Electronic Health Record; Standards; Assessment; Quality labelling; Certification; Methodology; Interoperability.

1. Introduction
The Danish Electronic Health Record Observatory was launched in 1998 by the Danish Ministry of Health. The purpose of the EHR Observatory is to support the realisation of the National Health IT strategy by monitoring and assessing the dissemination and implementation of EHR applications in the Hospitals. The EHR Observatory is disseminating national and international experience and best practice to the EHR actors. The Danish EHR Observatory is funded by the Ministry of Interior and Health, the Association of Danish Regions and the Copenhagen Hospital Corporation.

The Danish Health Care system can in brief be characterised by:
- The National Health Service covers all 5.3 million citizens
- 3.500 GPs have 90% of all patient contacts
- More than 90% of GPs use EHR for clinical documentation
- GPs are largely publicly funded
- 65 hospitals are owned by 14 counties and the Copenhagen Hospital Corporation
- 4.6 million outpatient visits per year
- 22.000 hospital beds of which less than 100 are in private hospitals
• 1.3 million annual discharges
• 22 % of hospital beds are served by EHR (by mid-2004)

In 2003 the Ministry of Interior and Health approved a new national IT strategy for the Danish Health Care Service [1] for the period 2003 to 2007. The purpose of the National IT Strategy for the Danish Health Care Service is to establish a common framework for the full digitization of the health care service during the period 2003–2007. The fiscal agreement for 2003 between the government and the counties (i.e. the hospital owners) states as a common goal that electronic health records based on shared standards is to be implemented in all Danish hospitals by the end of 2005.

The aim of the shared standards and common concepts for health records and IT systems is that data can be shared and that they can efficiently support interdisciplinary high quality care. The purpose is also to enable communication of data between EHRs and other IT systems without forcing the involved parties in the health care service to utilize systems from the same vendor. In this way standards will support a free market as well as the desired degree of specialised applications.

Figure 1 – EHR coverage 2001-2004

The ambitious goal that all hospitals must have EHR by the end of 2005 is a driving force for the EHR implementation in Denmark; however this rigorous schedule is now being eased. The dissemination of EHR is monitored and surveyed by the EHR Observatory using the number of beds covered by EHR as an indicator for the national coverage. In June 2004 the national average coverage was 22% [5][8], varying from 0% to 70% among the regions. The coverage in the previous years and the estimates for the next years are shown on figure 1.

A particularly important initiative of standardization is the national project “Basic Structure for Electronic Health Records” (BEHR)[2]. Based on standards elaborated by the National Board of Health, this project creates the foundation for a coordinated formation of concepts in EHRs in the hospital sector.

The “Basic Structure for Electronic Health Records” is a generic information model for clinical information systems published by the National Board of Health. This model sets the national standard for EHRs. It is characterized by using the clinical problem solving process as the structural backbone for all clinical information and it is designed to directly support continuity of multiprofessional health care across all environments of the entire health care service.

The Clinical Process is a specialization of the general method for problem solving and in the health care domain the BEHR model includes at a generic level: ‘Diagnostic Consideration’ leading to a set of ‘Diagnosis’, ‘Planning’ leading to a set of ‘Interventions’,

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‘Execution’ of ‘Interventions’ leading to ‘Outcome’ and ‘Evaluation’ of ‘Outcome’ validated by ‘Goal’.

Figure 2 - Basic Structure for Electronic Health Records

1. Diagnostic Consideration
Diagnostic Consideration is a process of collecting and analysing facts in order to understand the patient condition and determine the problems faced. This process implies that the health professionals, describes the problems that are in focus. The documentation of the problems is expressed primarily as structured diagnoses by all kind of health professionals (doctors, nurses, physiotherapists). ‘Diagnosis’ is a clinical judgment where an actual or potential patient condition is in focus. Within the context of the conceptual model this professional judgment is defined in a much broader sense than a solely medical view.

2. Planning
Planning is a process during which interventions to be performed are outlined according to expected or desired outcomes. This process implies that health professionals add a number of concrete interventions for diagnostics, treatment, prevention, care, rehabilitation etc. The BEHR model requires that one or more diagnosis should be indicated for each intervention.

3. Execution
The interventions are executed and the outcome is documented. In this context, outcome is seen broadly as information about the patient's condition, i.e. results of examinations as well as different kinds of treatments and preventive actions e.g. medication, nursing, surgery, rehabilitation programmes etc.

4. Goal and evaluation
A goal in BEHR has to be operational and is the documentation of what is expected or desired outcome of intervention. If the expected outcome does not meet the expected goal, the health care professionals have to continue a new cycle in the BEHR model.

2. Materials and methods
An important aspect of the EHR implementation is that the EHR vendors use the common concept model in their solutions and that they participate in testing and the further development of BEHR. One of the tools to ensure a high degree of coherence when
implementing BEHR has been addressed in the IT strategy by a specific action. The Danish National Board of Health launched in June 2003 a National BEHR project [6][7], with the objective to establish a number of reference implementation of the BEHR model in the Danish Hospitals. An important outcome of the project was to assess the actual use of BEHR and the clinical impact of using the BEHR model. The Danish EHR Observatory [3] has assessed the project within 3 areas:

- Certification: validate to what extend the EHR prototypes are based on the national BEHR model
- Exchange of information between EHR systems
- Assessment of the clinical impact by using BEHR.

The validation (certification) of to what extend the EHR prototypes was based on the BEHR model, was an important milestone in the project, to ensure that that the EHR system was compliant with the BEHR model when assessing the clinical impact of the systems.

This paper is only reporting the certification, where the prerequisite for the EHR prototypes in the project was:

- The EHR system has implemented the BEHR model, including the central use cases, the Reference Information Model (RIM) and the business rules.
- The EHR system is designed as a multi user system.
- The EHR system is user friendly and has an acceptable performance
- The EHR system is stable and includes all aspects of security

The BEHR model is specified in a number of documents and includes use-cases, business rules, RIM model, data descriptions and XML-schemas. The specifications include also a data set and data scenarios to validate if an EHR system is compliant with BEHR specifications. The data for validation is extensive and includes approximately 500 individual tests.

The EHR Observatory developed a methodology [4] to be used to validate to what extend an EHR system is compliant with the specifications as shown on Figure 3.

The test of an EHR system is done in two phases. In the first phase the test is done by the vendor of the system (self assessment). When the vendor finds, that the system is mature to pass the test, a new test is performed together with individuals from the EHR Observatory.

The purpose of the self-assessment phase is to allow the vendor to try out the methodology and ensure that the expected result of the assessment can be fulfilled. When the start for the self-evaluation is agreed with the EHR Observatory, the vendor has maximum 2 weeks to perform the self-assessment. During the self-assessment, the vendor documents the result of each individual test in a test protocol and a test log. In case the test protocol documents a result above an agreed threshold, the vendor requests the EHR Observatory to perform the final assessment.

The purpose of the assessment phase is to examine to what extent the EHR system is compliant with the BEHR specifications. The assessment process is fully documented and allows that parts of the test, which fails can be re-assessed later. The time for the assessment is scheduled to maximum 2 days and the EHR Observatory records the results of the individual tests in a test protocol. By the end of the assessment a report, which concludes the overall result of the test is prepared. The report is concluding whether the EHR system passed the assessment (Yes or No). If the EHR system did not pass the test it can be conditional approved which means that the vendor has to correct some minor errors. In case the result reveals considerable deviation from the BEHR specifications or that important elements are not implemented accurately, a new assessment is required. The assessment phase is finalised by the EHR Observatory and the vendor is signing the report.
A prerequisite for running the assessment phase is that the vendor documents that the EHR installation and execution environment correspond to a real operational environment. This implies that the installation includes all necessary components and resources to avoid that the tests is not influenced by irrelevant causes.

Before the assessment phases are started, a set of criteria for passing the test has to be agreed upon. The criteria for the National BEHR project were stipulated by the National Board of Health:

- Minimum 90% of the test set can be demonstrated without any errors
- All use cases in the BEHR specifications can be demonstrated by the EHR system
- The 10% errors, which can be accepted, may not occur by excluding one or more use cases.

3. Results

In the National BEHR project the model was implemented in two main pilot projects, in Amager Hospital and in Aarhus County.

The first assessment took place in Amager Hospital the 24 and 25. February 2005. Before the assessment, the vendor had performed a self-evaluation, which documented that they had not performed all the required tests. By the EHR Observatory assessment, 50% of the 500 individual tests were tested and out of these, 50% was accepted. The result of the assessment was summarised in a report, which concluded that a new assessment should take place.

The 23. and 24. March 2004 a new assessment was performed. The starting point was to test the areas, which failed at the first assessment and continue with the individual tests which were not performed.

By the two assessments 90% of all tests were done and out of these test 55% was accepted.

Due to lack of resources in the pilot project the vendor had decided not to implement use cases for the tasks: “Manage relatives”, “Monitor documentation” and “Error handling”. If the test of these three use cases was excluded from the test protocol, the final result increased to 80%.

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An analysis of the tests which was accepted showed that the EHR prototype had all the core parts of the BEHR model implemented and the EHR prototype was therefore approved as a basis for the clinical evaluation.

The second assessment took place in Aarhus the 12. and 13. April 2004. Before assessment the vendor had performed a self-evaluation, but the documentation was not forwarded to the EHR Observatory. At the EHR Observatory assessment, 100% of the 500 individual tests were performed and out of these 65% was accepted. In this pilot project the vendor had decided not to implement use cases for “Manage relatives”, “Monitor documentation” and “Error handling”. If the test of these 3 use cases was excluded from the test protocol the final result was increased to 85%. An analysis of the accepted tests showed that the EHR prototype had all the core parts of the BEHR model implemented and the EHR prototype was therefore approved as a basis for the clinical evaluation.

4. Discussion and conclusion

The assessment of the two EHR prototypes (Amager Hospital and Aarhus County) was performed in test environments, which, due to security reasons, was disconnected from the real operational environment. A prerequisite for the assessment was that the EHR installation and execution environment correspond to a real operational environment and that the installation had all necessary components and resources.

By the assessment of the two EHR prototypes a sufficient environment was established and the effort was concentrated on the task to assess to what extend the EHR prototypes had implemented the BEHR model.

As the assessment found a lot of errors in the EHR systems, which was not identified during self-assessment, the external assessment methodology can be used by the vendor to improve the quality of the system.

The same methodology can be used by the end-user as a part of the acceptance test when buying a new system.

Based on the result of the assessment, it can be concluded that the used methodology together with the BEHR specification is a systematic way to test to what extent an EHR system have implemented the BEHR model.

5. References


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