

Balancing centralised and decentralised EHR approaches to manage standardisation

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Abstract

Balancing regional and national electronic health record (EHR) approaches requires cooperation between clinical and technical experts at different organisational levels. Bridging is necessary to achieve interoperability between regional EHR systems, without neglecting the clinical usefulness. This study has investigated the approaches chosen in modelling the clinical content of EHRs in two out of five regions in Denmark. Based on the knowledge obtained in these studies a 'clinical content format' was developed to facilitate the work of the regions, where the clinical content of EHR systems is modelled. The objective of the clinical content format is to enable share and reuse across organisations, furthermore an objective is to gradually introduce standards. The results of the first iteration of a 'clinical content format' are presented and future adjustments are discussed based on the results.

Keywords:

Computerized Medical Record Systems/standards, Computerized Medical Record Systems/administration and organisation

Introduction

In research communities, semantic interoperability is seen as a key to solving the problem of availability and timeliness of relevant clinical data. Semantic interoperability should make it possible to support shared care seamlessly [1] and reduce repeated data entry [2]. In order to achieve semantic interoperability in health care, several standardisation organisations, such as HL7, CEN, ISO, openEHR and IHTSDO, have formulated standardised information models and reference terminologies.[3] The vision of semantic interoperability, however, can not be achieved without a coordinated implementation of standards in nationwide and local eHealth initiatives.

A coordinated approach faces numerous obstacles. A 2007 EU Commission report was reviewing the eHealth status of eight European countries, Australia, Canada and USA. Here it was pointed out, that in all countries there was limited progress towards full semantic interoperability and a growing realisation that implementation of interoperable eHealth solutions will require years to set up. Also at the organisational level, the report concludes that the different national levels of centralisation and decentralisation should be taken into account. To help

in coordination efforts, all countries have established or are planning to establish eHealth bodies. [4]

As illustrated in Figure 1, a national eHealth body task is the formulation of standards and strategies. The standards and strategies should be generic in order to support nationwide implementation, and should possibly be coordinated internationally. In decentralised eHealth initiatives, commercial applications are purchased and implemented. In the decentralised setup the priority is to keep the initiatives manageable. Thus, there is a contradiction between different organisational levels involved in e-health development.

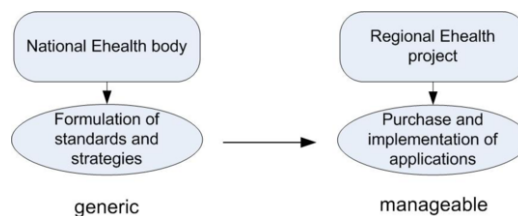


Figure 1 - National eHealth body and regional eHealth projects

In order to further explore the different organisational levels of eHealth, initiatives having both national and regional attention should be studied. Here we have chosen to focus on clinical content modelling in Danish EHR projects, since the scenario presented in Figure 1 is a reality.

National initiatives concerning the structure of EHR content are ongoing in auspices of the Danish eHealth body, Connected Digital Health in Denmark (Connected Health). The initiatives include:

- SNOMED CT has been translated to Danish, which is an important prerequisite in achieving semantic interoperability.
- Several times a year national workshops are held, where regional level actors, who implements the wishes and demands from users in EHR systems, meet. The purpose is to set the framework for exchange of experience early in development.

These are ambitious national initiatives in a small country. However, the initiatives are not trivial to implement since there

is a wide diversity of EHR systems and related IT-systems in the five Danish regions. When the regions implement EHR systems, they prioritise fast solutions that involve users' demands, and the national need to share information across regions becomes secondary. Thus, in the future it will be beneficial to implement standards in regional solutions, but right now specific regional business needs are lacking. Therefore this study addresses how to motivate implementation of national standards such as SNOMED CT in regional EHR projects.

Formalisation of clinical content in EHR projects

Clinical content is defined as the clinical knowledge built into EHR systems, expressed as domain-specific terms, rules and structures.[5]

Clinical content has several objectives:

- To define the interface terminology and relation between interface terminology and a standardised clinical terminology, such as SNOMED CT.
- To define the constraints in the input to EHR systems; e.g., to define a diastolic blood pressure as a number within a certain range.
- To structure the GUI of EHR systems, in order to support a certain clinical workflow.

Clinical content modelling is quite similar to the term 'knowledge level modelling' as described by Beale. Beale describes a two-level modelling approach, where the knowledge level requires its own formalism and structure, and is the level where the numerous, volatile concepts of most domains are expressed.[6] However, clinical content does not have a nationally agreed upon formalism and structure; therefore, and as a result of the decentralisation of EHR implementation, there are variations in the way clinical content is modelled. Thus, it becomes problematic to share and re-use clinical content across organisational borders. This causes each regional unit to commence its own clinical content projects from scratch, a process which is time-consuming and costly. National standardisation could possibly help to solve the problem. This study examines how a structure and formalism for clinical content, called a 'clinical content format', could be developed so as to support standardisation and manageability in a regional context.

Materials and Methods

Given the growing realisation that interoperability can not be rushed, iteratively improving a clinical content format in terms of standardisation could be part of a solution. The basic idea of the proposed method is that standardisation should be gradually introduced to ensure regional manageability.

Method overview

The method is inspired by Hevner et al., whose approach involves both analysis of business needs and knowledge resulting from research to develop innovative solution in the field of information system research. [7] The method developed is illustrated in Figure 2.

The analysis consists of two activities. The first is that of identifying the 'granulation level' in the current clinical content

projects. Granulation level refers to the granulation of the material currently used to specify Clinical Content e.g. how entry names, formal representation for data-types and setup parameters of the EHR are defined. An analysis of the granulation level should ensure that the clinical content format is recognisable to the users, that it meets their needs and is manageable enough so that it can be used in practice. Granulation level analysis corresponds to Hevner et al.'s analysis of business needs.[7]

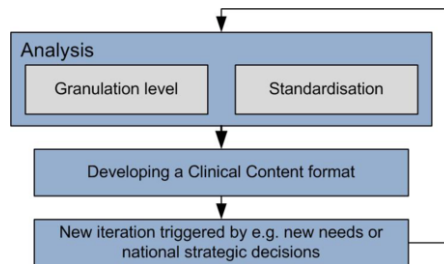


Figure 2 - Method used to develop a clinical content format.

The second activity, Analysis of standardisation, comprises identification of relevant EHR standards and selecting a subset of these based on available strategic decisions and the possibility of articulating clear gains for users. The chosen standardisation approach is integrated into the clinical content format. Analysis of standardisation corresponds to Hevner et al.'s examination of available knowledge resulting from research. [7] Whether standardisation belongs to the research base is an open question, but we regard it as such, since standardisation is widely discussed in the EHR research field. Thus, in the analysis regional needs and national goals of standardisation are balanced.

Based on the analysis, the clinical content format can be developed. Since the field of EHR projects and the standards are constantly changing, the clinical content format should be updated based on results of evaluation, new needs or national strategic decisions. Parallels can be drawn to Hevner et al., who include a number of 'assess' and 'refine' steps to iteratively improve developed solutions.[7]

The method is applied to clinical content modelling in Danish EHR projects as described in the introduction. Details are described in the next section.

Application of method

Granulation level analysis was conducted by examining clinical content projects in two out of the five Danish regions. The analysis included a study of public available information and semi-structured interviews with personnel in the organisations. The Capital Regions clinical content project¹ and the EHR implementation project at Odense University Hospital², were chosen as cases based on years of experience with clinical content modelling. The interviews were conducted according to the

¹ <http://www.regionh.dk/menu/sundhedOghospitaler/SFI/>

² <http://www.epj.dk/wm122413>

method described by Kvale [8]. Three OUH representatives and four Capital Region representatives were interviewed, resulting in 4 hours of recorded data, which was subsequently transcribed.

Relevant EHR standards in a clinical content context were identified by studying research literature (e.g. [3]). The subset to implement in the clinical content format was chosen on the basis of published Danish strategic decisions. Furthermore the possibility of regional adoption of the chosen standards were analysed based on afore mentioned interviews.

After defining the granulation level and the standardisation, the clinical content format was developed using UML class diagrams. The format was visualised in a Mock-Up GUI for developing clinical content, as the Mock-Up GUI provides an intuitive impression of possibilities and limitations of the clinical content format.

The clinical content format was evaluated by means of a presentation for a collection of regional and national actors in the field of clinical content under Connected Health auspices and followed up by an interview with a central Connected Health representative. The application of the method did not include the 'new iteration' step, but the discussion includes ideas about future use of the method as well as the developed clinical content format.

Results

This section consists of the results of the analysis, identifying the clinical content granulation level in the Capital Region and Odense University Hospital (OUH) and the results regarding standardisation. This is followed by a presentation of the developed clinical content format.

Analysis of granulation level

At OUH, the clinical content is modelled in order to enable configuration of the local EHR system, Cambio COSMIC³. The clinical content is modelled through a cooperative arrangement between the hospital departments and a specialised team in the IT-department. The result is visualised in Word-templates. These are used when configuring the EHR system. From the OUH Word-templates, the clinical content granulation level can be deduced. The documentation (input) is most notable at OUH, since overviews of patient data (output) are system-dependent. The hospital departments started using the EHR system in practice as soon as the clinical content was implemented. In the Capital Region, formulation of clinical content is centralised in order to harmonise important documentation and overviews of patient data. The data structure is modelled using an openEHR archetype editor, without modelling real openEHR archetypes, since formal requirements of generic max-datasets are not satisfied. In addition, Mock-Up GUIs are produced in order to visualise both input and output screens. Free text descriptions are also included. These three clinical content information sources are vendor-independent. At present, however, the clinical content is implemented in

Opus ArbejdspladsTM from CSC Scandihealth.⁴ The implemented clinical content is not yet in routine use in any of the 14 hospitals in the Capital Region.

On the basis of an analysis of the Clinical Content in OUH and the Capitol Region the granulation level of the Clinical Content appears compatible. In short, the result can be expressed in following statements, defining the clinical content format:

- Input is described with setup parameters; e.g., a numeric field has the setup parameter 'unit'.
- Output is described with setup parameters; e.g., a description of the data source.
- The structure of a GUI using the clinical content is defined by an ordering of input and output fields.

Based on these observations the clinical content format can define a delimited and ordered collection of input and output fields with intended use in a specified clinical context. This granulation level limits the possible amount of information provided by the clinical content format since advanced functionality such as decision support cannot be implemented in this simple model. The simplicity reflects the current needs and support manageability, since the details that are defined are limited to those that are currently needed.

Analysis of standardisation

Standardisation of EHR system models and terminology is identified as prerequisites to obtain semantic interoperability.[9]

In Denmark, a strategic decision has been made to use SNOMED CT as common terminology. It is likely that users of the clinical content format could be convinced to map to SNOMED CT to avoid that each organisation is inventing its own terminology, for the GUIs for example. Regardless of whether standardised EHR system models are implemented in the future or message-based interoperability is continued, a prerequisite for sharing data is that the terminology is unambiguous. For the clinical content format, we analysed, that it would be manageable to use SNOMED CT for classification and indexing purposes. Indexing refers to labelling an input or output field with a SNOMED CT code, while classification refers to the selection of one code from a SNOMED CT subset. This simple implementation of the terminology will not facilitate all the possible applications of SNOMED CT. For example, free text is not translated into SNOMED CT concepts. As for the analysis of granulation level, this means that defined details are limited to those that are currently needed

When identifying standardised EHR system models, our conclusion was that since HL7 v. 3 and openEHR/ CEN16303 standards included a dual modelling approach[3], these could be feasible in the definition of clinical content. The clear gains for users of the Clinical Content format, however, remain unclear, since the EHR systems in use are based upon proprietary information models. In Denmark, no strategic decisions are made regarding use of any of these international standards.

³ <http://www.cambiosys.com/>

⁴ <http://www.scandihealth.dk/>

Therefore, the use of these standards is not explored in this first iteration on a clinical content format.

Clinical content format

The clinical content format, suggested based on the two cases, is illustrated in a simplified model in Figure 3. The *Specification* class contains the ID of a clinical content specification, e.g., the purpose, such as nutrition screening and the organisation, for example OUH. A *Specification* contains a *Structure Element* for each input and output field. The *hierarchy* attribute defines the placement of the field on the GUI. A *Structure Element* can be either an *Input* or an *Output* field, with added *setup* parameters. A *Structure Element* also contains *Terminology* that allows each field to be indexed using SNOMED CT. A specialisation of the *Input* class is *List*. The list allows the user to choose between several alternatives, when connected to the *Terminology* class. This allows for the use of SNOMED CT for classification purposes.

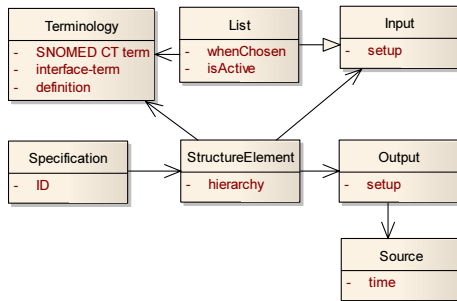


Figure 3 - Simplified clinical content format.

A detailed definition of the format is formulated but not described in this paper. The format is visualised by a Mock-Up GUI for developing clinical content. This is presented in Figure 4. The general idea is that input and output elements from the right side of the GUI can be brought into a hierarchy denoted by 1 and 2. Here interface terminology, SNOMED CT codes and field definition can be added.

When presenting this clinical content development tool, for potential users under Connected Health auspices, it was found that the overall objective of both meeting user’s needs and introducing standardisation was considered complex and unexplored. The complexity is discussed in the next section.

Discussion

This study illustrates how a national clinical content format can be developed that balances both regional needs and national goals of standardisation. Hence, the developed approach can be used to facilitate share and re-use of clinical content. As described in the section on Method, future development and iterations of the clinical content format are intended to gradually introduce standardisation to enable a higher degree of interoperability. The complexity of this task, however, should not be

underestimated, since factors other than clinical content modelling should be taken into account.

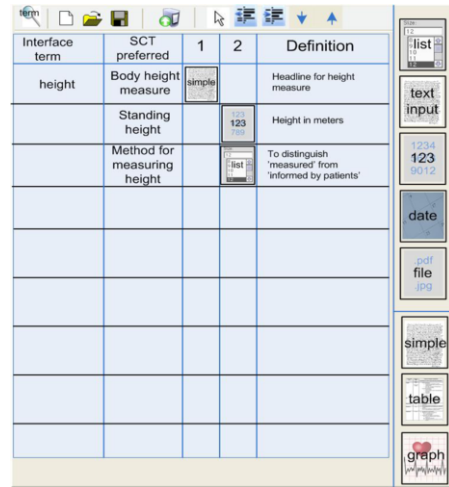


Figure 4- GUI presenting the possibilities of the clinical content format

In Figure 5, clinical content is bridging the technologically-oriented and clinically-oriented aspects. Clinical content should reflect clinical practice; for example, it should support the workflows and support clinical documentation. The long-term goal, however, is clinical standardisation. The purpose of clinical standardisation is to support evidence-based guidelines, to have standardised terminology and practice across organisational boundaries and to be able to document the clinical quality. Another aspect to be taken into account is the status of the currently available models and systems. The existing models and systems impose limits on the kind of clinical content that can be configured and the potential degree of interoperability. The long-term goal is to implement international EHR standards including reference terminologies, hereby enabling fully semantic interoperability. To improve health care delivery, cooperation is needed and multiple aspects should be taken into account; this is illustrated in the following example.

‘At hospital A, they have improved the diabetes care by reviewing the clinical guidelines and incorporating them into their practice. While doing this, clinical content modelling was included. A national clinical content format was used as well as the proprietary format of the local EHR system. Expression of the clinical content in the national format enables hospital B to start a similar diabetes care. Thus, A and B carry out the same treatment and collect the same data; therefore they could compare the quality of their respective care or conduct clinical research. However, their vendors should make exchange of relevant data possible which is solved by introducing technical standardisation. After a while A and B decide, that they want to improve the structure of their documentation in order to enhance the documented quality of care. This leads to another

cycle of implementing clinical content, further refinement and improvement of the technical standardisation and so on.'

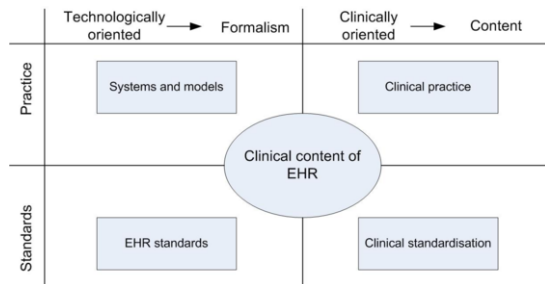


Figure 5- Factors contributing to the complexity of modelling clinical content of EHR systems.

The need for integration of the clinical and technical fields, as described in the above example, is a challenge that has also been identified in the international literature. In some studies, the focus has been on sharing experiences of how to manage EHR systems so that they support clinical practice. In [10], the modelling is done by a proprietary and simple XML-based model, without following a specific standard. This means that, in order to make the model clinically useful, technical standardisation is under-prioritised. In other studies, focus is on using an international EHR standard to model a clinical setting. In [2], openEHR archetypes were modeled, but they were not considered comprehensive and general enough to represent the maximum dataset because they were tailored to local needs. Since maximum datasets are a prerequisite for something to be considered an openEHR archetype, the newly modeled archetypes could not be fed back to the openEHR organisation directly. This means that experience regarding clinical aspects may be lost or delayed because the selected standard is not completely followed.

The method that we have introduced, inspired by Hevner et al., could be a tool to bridge standardisation and user needs in contrast to the above examples, where either technical standardisation or clinical usefulness is chosen. However, the method needs to be evaluated more thoroughly and to include more empirical work in order to ensure cooperation between relevant regional and national organisations. These organisations would include not only regional EHR projects and national eHealth bodies, but also clinical personnel, medical societies, EHR standardisation organisations and vendors of EHR systems so as to reflect the complexity of balancing regional and national approaches and achieving interoperability.

Conclusion

Coordination of regional EHR projects and national or international standardisation approaches is a prerequisite for achieving semantic interoperability. In this study, a method is proposed that makes standardisation manageable in a regional context. However, the complexity of balancing regional and

national approaches and achieving interoperability should not be underestimated. Cooperation is needed between regional EHR projects, national eHealth bodies, clinical personnel, medical societies, EHR standardisation organisations and vendors of EHR systems in order to fully accomplish the task. Future work will include studying the feasibility of a clinical content format, by implementing a tool to develop and share clinical content in a specific Danish region and systematically acquire results in a longer time span.

Acknowledgements

We would like to thank the clinical content organisations in the Capital Region and Odense University Hospital for interview. Connected Digital Health in Denmark has also been most helpful in completing the study.

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