A method for specification of structured clinical content in electronic health records

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Abstract: The Copenhagen County is using clinical guidelines in the electronic health record development to provide documentation support, process support and decision support for the healthcare professionals. The electronic health record development is based on three main components: The first component is a national information model. The second component is a common classification system (SNOMED). The third key component is the so-called "clinical content". This paper describes the structured "clinical content", how it is linked to the clinical process, and how it is used to create clinical guidelines in the form of standard care plans. The Copenhagen County and MEDIQ has developed a methodology for identifying and specifying structured "clinical content" to be used in electronic health records. The method combines analyses of national clinical guidelines with local experience and practices and it heavily involves healthcare professionals. The method includes four main steps: Analyses of background material, analyses of clinical process-flow, mapping to standards (the national information model and the common classification system), and specification of the structured clinical content itself. Three secondary steps may be added to specify the clinical content in more detail: Workflow analyses, analyses of quality indicators, and decision analyses. This paper reports the experiences using the method and stresses the demand for a common exchange format and IT-tools for documenting clinical content in a formalised way.

Keywords: Documentation, clinical guidelines, clinical content, documentation support, process support, decision support, methodology

1. Introduction

One of the main goals of the current Danish IT strategy [1] for healthcare, is the dissemination of electronic health records (EHR) in hospitals. The Counties and the Central Health Authorities have agreed, that that electronic health records based on common standards is to be implemented in all Danish hospitals by 2008. The National Board of Health has developed a common standard, the so-called “Basic Structure for Electronic Health Records” [2]. This is a process-model, based on a problem-oriented way of documenting the activities, using structured data from all professional groups. Furthermore, The National Board of Health is proposing that the national classification system should be substituted with the SNOMED CT terminology [3]. SNOMED CT is currently translated into Danish.

However, experience from the past two-three years in implementing the EHR at a large scale shows that the model and the terminology are not sufficient for...
dissemination and user acceptance of the EHR. A third element is required – the so-called "clinical content" [4]. The clinical content includes standard plans, standard activities, standard goals, and standard results, as well as the related decision points. The specification of clinical content results in a representation of clinical guidelines, as well as context-related information, and templates for data entry/presentation.

The clinical content can be extracted from international/national/regional/local guidelines, care plans, indicators in quality databases, textbooks, and knowledge of clinical practice. This paper presents a method for systematic collection and assessment of the clinical content, mapping to relevant process models and terminologies, and a specification of clinical content that can be used directly in the EHR systems. This will focus the EHR development on clinical process support, documentation support, and decision support, which is expected to be key points for the EHR acceptance by the clinical user. Furthermore, it has been shown that conforming to guidelines is a good way to improve the quality of medical care [5].

Extensive work has been made internationally regarding access to guideline resources [6, 7], models and languages for formal representing guidelines [8,9] as well as proposals for exchange formats for these guidelines [10, 11]. The concept of archetypes has been proposed for representing information similar to what we include in the clinical content specifications [12]. The archetype concept has been elaborated by the openEHR Foundation with the Archetype Object Model [13] and the Archetype Definition Language [14]. Furthermore the part of the clinical content related to presentation of data could be represented in the openEHR templates [15] which currently also being included in the CEN standard for EHR communication [16].

It should be noted that the method reported here is focused on how healthcare professionals and informaticians can cooperate specifying structured clinical content. The resulting clinical content should be expressed in a formal language in order to be processed and exchanged. Most of the clinical content probably could be represented with Archetype Definition Language or similar formalisms. However, the method does not imply the use of a specific formal language. In Denmark, national decisions regarding standardisation of clinical content representation and exchange formats have not yet been made.

2. Materials and methods

In connection with the EHR development and implementation in the Copenhagen County, a need for structured specification of the clinical content was acknowledged. This was based on the first trials using the Basic Structure for Electronic Health Records in EHRs in a clinical setting [17].

Two projects were initiated with the purpose of developing a method for specification of formalised clinical content in EHR. Both projects had heavily involvement from clinical users representing all clinical professions. The group included some experts in the selected clinical domain and some other clinicians involved in the EHR development in the county.

The first project was validating an EHR prototype focusing on converting national text-based guidelines to structured standard care plans, use of SNOMED CT as a basis for the terminology, and user acceptance of the user interface. The project was organised as nine workshops with 25 participants. The clinical topic was Acute
Coronary Syndrome, and the first version of operational standard plans was produced for this area. The first version of the methodology was also proposed.

The second project aimed at refining the proposed methodology by applying it on three areas. The work on Acute Coronary Syndrome was continued and treatment of Acute Abdominal Aorta Aneurism and Schizophrenia were selected as the other areas. The projects was organised with up to six workshops with 25 participants [18, 19]. Apart from (incomplete) specifications of the clinical content in the selected areas, a complete method was now proposed [20].

This method is reported in the following sections.

3. Results

The proposed method is divided in two parts – the overview and the refinement (see Figure 1). The method is iterative, in the sense that the clinical content resulting from the overview phase, can be detailed and improved by running through the refining phase one or several times. This strategy is aimed at creating useful results with a small workload, and then improving the specifications in accordance with available resources in those areas where clinical knowledge is accessible.

3.1. Step 1 – Identification of background material

The background material consist of guidelines, care plans, data descriptions of quality databases, textbooks etc. This is used as the reference for the clinical evidence and is the main knowledge basis for specification of the clinical content.

The output for the activity is a library (preferably in electronic form), with all relevant documents. This is accompanied with a directory of the documents with classification of type, evidence level, priority in the specification etc.

![Figure 1 – The seven steps of specification of clinical content. The iteration between overview and the refinement phase is shown.](image-url)
3.2. Step 2 – Working out clinical process flow diagrams
In this step the background material is analysed and combined with the participant’s knowledge on clinical process flow and procedures. The result is a graphical representation of the clinical process, using symbols for start- and end-points, process, decision points, data etc.

The diagrams are worked out in several versions with increasing richness and details. The diagrams are important tools for keeping the overview and creating transparency in the development.

3.3. Step 3 – Mapping to standards
In order to re-use the data in the EHR and communicate the clinical content it is necessary to relate the information to standards. This step includes three consecutive activities: An analysis of the data representing the clinical process, a mapping to the concept model (in this case the Danish Basic Structure for Electronic Health Records), and a mapping to the terminology system (in this case SNOMED CT).

It should be noted that the two last activities should be performed by informaticians and standard experts. The clinicians should be kept in a review role.

3.4. Step 4 – Working out the clinical content
The goal with this step is to specify the clinical content in a systematic and structured way. The output from this step should be used directly to configure an EHR system. The description of the clinical content should be in accordance with clinical and management goals, and should reflect the clinical evidence identified in the previous steps.

The result of the step is specification of standard (care) plans, containing activities, containing results, as well as the related decision points. The specified clinical content will in the first place be documented in dedicated forms, which contain the information necessary to configure an EHR. Secondly the clinical content will be documented in a formal language, i.e. as archetypes using the archetype description language.

3.5. Step 5, 6, 7 – Detailing the clinical content
While it is recommended that step 1-4 is performed sequentially, the workflow analyses, quality indicator analyses and decision analyses can be performed in any sequence. Each of these analyses will refine and qualify the first version of the clinical content specifications.

These analyses are contributing with additional information from different focal points. The workflow analyses take into account which professional group performs the activities identified in the process-flow diagram. These analyses give the opportunity to change the workflow and enhance the cross-professional cooperation.

The quality indicator analyses aim at ensuring that the necessary data for the selected indicators actually is present in the EHR. This analysis can give an input to the data analyses and an update of the clinical content specifications.

The decision analyses make explicit the decision criteria and the selection possibilities in the clinical process flow. When feeding this in the EPR, the system can provide decision support and advanced reminders in relation to the standard plans. The intention is not to mimic the diagnostic decisions.
4. Discussion

The proposed method was developed and used within different medical areas, both within emergency/internal medicine, surgery, and psychiatry. Physicians, nurses and other clinical professions participated in the development.

Substantial education was needed in the first series of workshops. The participants were introduced to the complete method at the first workshops. Before the participants were performing a specific step, the information about that step was repeated. The participants were introduced to basic informatics concepts like information models, terminologies, structuring of processes and information. However, the education in these concepts was carefully adjusted to the medical area in question.

The clinicians felt comfortable using the method, and the use of flow diagrams was clearly a useful vehicle for structuring the guidelines and discussing professional differences (step 2). The diagrams typically underwent three iterations to reach the agreement on granularity and content.

The clinicians expressed that the mapping of the clinical content towards the process model was the most difficult part (step 3). However, after the mapping actually had been made, the next step (step 4) became very easy, because the specification of standard plans, their relation to the relevant diagnoses and to the standard results were laid out by the mapping activity.

During the quality indicator analyses (step 6), the clinicians teased out the specific clinical indicators, taking into account recommendation from the Danish Secretariat for Clinical Guidelines \[21\] and the indicators already selected by the National Indicator Project \[22\]. This analysis typically revealed the need for updating flow diagrams (from step 2) or the data list (from step 3).

The method also proposes forms for how the resulting structured clinical content should be documented. This documentation is to be used for configuration of the EHR system. Since the EHR-tool for entering the clinical content is not finalised, the electronic version of the clinical content has not yet been tested by the clinicians. The validation of the format of the clinical content has therefore not taken place. It is likely that the forms will need to be updated in order to get a better match with the requirements arising from the EHR-implementation.

5. Conclusion

The specification of structured clinical content is proposed as a prerequisite to enable EHR systems to present clinical guidelines dynamically at the user interface. This is expected to support the practice of evidence-based medicine.

The method presented has shown useful for transforming text-based international/national/regional/local guidelines, care plans etc. into structured specifications of clinical content. This is expressed as standard care plans or set of procedures linked to specific diagnoses. Templates for documentation of results related to the procedures are also outcomes of the specification process.

However, is not tested how the specified clinical content will work when implemented in the EHR, since the development has not yet reached this stage.

It is evident that development of the clinical content within many medical areas is a huge task. Therefore, the work has to be shared between different stakeholders in Denmark. It is also crucial to enable re-use of international guideline work.
Furthermore, it is necessary that the Danish concepts are adjusted to the international standardisation work in openEHR, CEN and HL7 [15], and that we continue the search for useful IT-tools for documentation of the structured clinical content.

Consequently, it is essential that some decisions are made at a national level – based on international experiences:

- A standard for the structure of the clinical content, i.e. an information model
- A standard for an exchange format based on that model

Furthermore, there is a need for the following system development adjusted to the Danish context:

- An IT-tool for specifying the clinical content in the agreed structure
- EHR-systems that can import the agreed format
- EHR systems that can handle the formalised clinical content in the user dialog

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References

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