

**KNOWLEDGE MODELING TO DEVELOP A CLINICAL PRACTICE
GUIDELINE ONTOLOGY:
TOWARDS COMPUTERIZATION AND MERGING OF CLINICAL PRACTICE
GUIDELINES**

by

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Submitted in partial fulfillment of the requirements
for the degree of Master of Health Informatics

at

Dalhousie University
Halifax, Nova Scotia
September 2007

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ABSTRACT

Clinical Practice Guidelines (CPGs) are documents based on best evidence and experts' consensus to standardize care, reduce practice variations, and improve quality of care. Computerizing guidelines can facilitate patient-specific decision support at the point and time of care. In this thesis we investigated the clinical and operational pragmatics of CPGs attempting to develop a framework to computerize and execute them for clinical decision support purposes. The research involved knowledge modeling, whereby we applied a knowledge management approach to a body of real-life CPGs—covering a wide spectrum of clinical conditions and specialties—to abstract the underlying concepts, concept relationships, structure and operational constraints within CPGs and develop a unique and comprehensive CPG ontology. We evaluated our CPG ontology by instantiating 5 previously unseen real-life CPGs. This ontology allows (a) computerizing CPGs which offers guideline-mediated decision support, and (b) merging/integrating multiple CPGs along common actions/tasks to support guideline-mediated patient care planning.

CHAPTER 1

INTRODUCTION

1.1. INTRODUCTION

Medical decisions and judgments are highly dependant on the perceptions of individual healthcare providers about concepts such as quality of life, health, and illness. This has caused medicine to be rather a subjective science over the past centuries. Evidence based medicine is an attempt to apply objective criteria and evidence from scientific studies to the medical practice.

Clinical Practice Guidelines (CPGs) are documents based on best evidence and experts' consensus to support decision making process in health care. The application of CPGs have shown that if integrated into the workflow of organizations and applied to the practice of care providers, they can potentially standardize care, reduce practice variations and costs, and improve quality of care [1-3]. However, studies show that they have had poor uptake among practitioners [4]. This may be due to the fact that currently, most CPGs are in textual formats and medical practitioners often find it impractical to use and follow text-based guidelines at the time and point of care, as searching, referring to, and reading the relevant text are time consuming tasks. As text-based documents, clinical practice guidelines have limited applicability at least in the following two aspects:

- (1) Referring to such text-based documents is impractical in today's busy clinical environments that demand fast decision making by practitioners.
- (2) They fail to provide recommendations based on an individual patient's needs and conditions. In other words, they provide the general directions and recommendations with regard to a specific clinical issue and rely on the practitioners to translate these recommendations to patient specific care plans.

Computerizing guidelines has the potential to develop guideline-based decision support systems that can address some of these limitations in terms of the provision of recommendations tailored for individual patients at the point and time of care.

There is a general recognition in the health informatics community that research on developing new methods and knowledge-mediated technologies for informed decision making according to individual patient's profile and the individual requirements of healthcare institution is essential [5]. In [5], Abidi proposes a framework named **CarePlan** based on advanced knowledge management approaches, particularly the Semantic Web, to account for a process-oriented and knowledge-mediated solution for patient-centric healthcare. This framework consists of (1) patient information stored in online records, (2) CPGs, (3) Clinical Pathways, and (4) a semantic web of heterogeneous medical knowledge resources. **CarePlan** intends to develop domain ontologies for its constituent elements to allow a semantic interplay between them. In this research project, we seek to develop a knowledge model for clinical practice guidelines, as one of the consistent elements required for the semantic web framework of **CarePlan**.

1.2. PROBLEM STATEMENT

The research question pursued in this thesis is “how to model the structure and function of Clinical Practice Guidelines at a detailed component level in order to both computerize and execute them”. The research question demands development of a deep understanding of the constituent elements of a CPG and the relationships between them (though not necessarily formally defined).

A key element in guideline-based electronic decision support systems is a representational formalism to represent guideline recommendations in a computer-interpretable format. Only when the knowledge involved in a clinical guideline is represented through such formalism, a decision support system integrated with patient data repositories will be able to interpret and “follow” the recommendations according to the patients' profile and assist practitioners by suggesting “patient-specific” care plans. We refer to the above-mentioned process of following guidelines based on the patients' data as “guideline execution”.

Guideline execution can become complicated by different issues arising when two or more guidelines are to be executed for a single patient concurrently. When a patient suffers from different co-morbidities, his/her conditions may require several guidelines to be executed in parallel. Therefore, a comprehensive guideline formalism should support concurrent execution of multiple guidelines and allow “*merging*” common parts of the guidelines if the guidelines allow to do so.

In this thesis, we seek to address the above-mentioned issues and aim to reach the following goals and objectives:

1.3. GOALS AND OBJECTIVES

Our main goal is *to develop a knowledge model for clinical practice guidelines and to instantiate them using our model*. We aim to develop an ontology-based guideline formalism that can represent CPGs at a detailed component level and semantically differentiate between CPG knowledge elements so that an execution engine can follow the guidelines for individual patients and generate patient-specific recommendations. Further, as explained earlier, patient conditions may demand execution of several guidelines in parallel. Therefore, we plan to consider the possibility of “merging guidelines” if the guidelines knowledge and patient conditions allow to do so. Modeling medical activities at a detailed specialized level will facilitate distinguishing common elements between concurrent guidelines which is essential for guideline merging.

We anticipate that this ontology will be used by the **CarePlan** framework to adapt personalized care plans from the standard plans recommended by CPGs. **CarePlan** intends to develop domain ontologies for its constituent elements to allow a semantic interplay between them. The knowledge management approach employed by its framework demands a knowledge-centric formalism for representing clinical guidelines [5].

1.4. RESEARCH CHALLENGES

As explained above, the main goal of this thesis is to abstract the representation of knowledge within a CPG in terms of a model—the model should identify the structural, conceptual and functional aspects of a CPG. In reaching this goal, we identified the following research challenges:

- 1. Knowledge modeling:** In order to create our knowledge model, we must discover the inherent structure of clinical practice guidelines. Guideline authors do not organize guidelines based on a knowledge model. In fact, different people use different structures for writing a guideline, yet they inadvertently use a set of constructs (such as actions, decisions, recommendations, etc) that are embedded in a CPG. The presence of these constructs and their systematic (though unconscious) arrangement implies the presence of a high-level model for CPGs; this model is typically tacit and resides in the mind of the CPG authors. However, to develop decision support systems, based on CPG, one needs to abstract this model to systematically represent the knowledge contained within a CPG. There are two ways of abstracting a CPG model: (a) acquiring it from domain experts through long and tedious interviews; or (b) studying the knowledge artifact—i.e. the CPG—to identify its constituent elements and their relationships. For knowledge modeling purposes, we have chosen to take the latter approach. To reach our goal, we had to decompose clinical guidelines into their constituent parts at conceptual and pragmatic levels and then develop a model to represent CPG in terms of these constituent parts while maintaining the (semantic) relations between these parts. We argue that our CPG model needs to be comprehensive enough to represent guideline knowledge elements at a detailed level in order to allow semantic recognition of each element by **CarePlan** reasoning engines.
- 2. Explicating tacit knowledge involved in CPGs:** Clinical guidelines are usually developed by a group of domain experts for other healthcare providers and clinicians. This leads to implicit indication of some parts of the guideline as the authors have the assumption that their audience has enough clinical knowledge to

understand the involved tacit knowledge. Explicating this tacit knowledge, which is needed for both modeling and instantiation phases, can be challenging as it requires appreciation of the domain knowledge, identification of the parts of the guideline where tacit knowledge is involved, understanding the tacit knowledge, and interpreting this knowledge to explicit statements.

- 3. Integration with patient data:** Clinical guidelines provide the needed clinical knowledge for practitioners to guide them in managing patients having different conditions. However, to provide patient-specific CPG based recommendations, a computerized guideline-based decision support system requires patient data/information to be integrated with guideline knowledge. This integration is challenging because it needs mapping of guideline concepts to the patient's data/information stored in external repositories and EHR systems. Since different EHR systems utilize different data structures, this mapping should be mediated by a standard patient data concept structure, such as HL7.
- 4. Multiple CPG Merging/Integration:** In practice, clinical conditions of a patient who suffers from different co-morbidities may make him/her eligible for several guidelines to be executed in parallel. The fact that these guidelines may have similar recommendations implies the need for considering the possibility of merging or integrating guidelines at their common parts. Merging two (or more) CPG guidelines in a dynamic manner whilst maintaining clinical pragmatics will allow for the use of CPG for patients with co-morbidities. Merging guidelines can be challenging because the recommendations of their common parts do not necessarily take place at the same time. Concurrent execution of guidelines can even be more complex when guidelines contradict each other (for example a guideline recommends a drug whereas another guideline recommends stopping that drug), or when recommendations of different guidelines can have potential adverse effects if administered together.

1.5. RESEARCH SOLUTION APPROACH

In this thesis, we define and follow a methodology to solve the problem stated above and to achieve our goals and objectives. This methodology comprises the following steps:

- 1. CPG Categorization:** Clinical practice guidelines are available for different medical disciplines and settings. We categorized CPGs along six axes including: Acute vs. Chronic, Primary vs. Secondary, Specialty Group (Medical vs. Surgical), Setting (Inpatient vs. Outpatient), Age Group, and Orientation (Problem Oriented vs. Task Oriented).
- 2. CPG Selection:** Our methodology includes taking 20 sample guidelines from different categories and analyzing/abstracting them in order to develop our CPG knowledge model. This selection was done along the above-mentioned categories and based on the researcher's medical knowledge and perception so that the number of selected guidelines from each category reflects the approximate number of available guidelines and relative importance of each category.
- 3. CPG Knowledge Modeling:** We analyzed the sample guidelines in order to discover the inherent structure of CPGs and to extract the CPG knowledge elements which would help us develop a representational model of a CPG. This step can be described as reverse engineering in which we took a number of the knowledge artifacts (i.e. sample guidelines) and analyzed them to develop a knowledge model.
- 4. CPG Ontology Engineering:** Based on the model developed in the previous step, we created classes, attributes, and relationships which formed our CPG ontology. We used Protégé Frames for this purpose.
- 5. CPG Ontology Evaluation:** After completion of our CPG ontology, we chose five previously unseen guidelines along the same categorization schema defined in step 1 and instantiated them to assess the ability of our ontology to model them.

1.6. CONTRIBUTIONS

In this research project, we make the following contributions toward the knowledge of CPGs and their computerizing:

1. Development of an **ontology based knowledge model to represent clinical guidelines**. We aim to model clinical activities at a detailed specialized level which would allow an execution engine to semantically distinguish between different activities. We have also analyzed the possibility of **merging guidelines** at three levels including encoding level, execution level, and guideline knowledge level and intend to address this issue at encoding and execution levels. In fact, modeling clinical activities at a detailed specialized level will allow the execution engine to distinguish common parts between concurrent guidelines and merge them if possible.
2. Defining six **guideline categorization axes** to classify different clinical guidelines. These axes include: Acute vs. Chronic, Primary vs. Secondary, Specialty Group (Medical vs. Surgical), Setting (Inpatient vs. Outpatient), Age Group, and Orientation (Problem Oriented vs. Task Oriented).
3. Proposing a **methodology** to extract guideline knowledge elements and develop an ontology as a mode to represent them. This methodology, as explained earlier, has a reverse engineering approach that involves analyzing a number of clinical guidelines (as knowledge artifacts) in order to identify the knowledge elements, discover the inherent structure of guidelines, and develop a CPG ontology accordingly.
4. **Encoding (instantiating) a set of clinical guidelines** using the above-mentioned ontology. This task not only helped evaluate our CPG ontology in terms of its ability to instantiate new guidelines, but also can collaborate toward a computerized guideline repository which we anticipate to be used by **CarePlan** framework in a healthcare environment.

1.7. THESIS ORGANIZATION

This thesis document is organized as the following chapters:

In **Chapter 2**, we will review some literature providing a background for our research project. We will define clinical practice guidelines and then present evidence from the literature that supports computerization of clinical practice guidelines and suggest that a guideline-based decision support system can be beneficial. We will then discuss about ontologies and ontology development and present three guideline formalism ontologies that are close to our intended work.

Chapter 3 presents our research methodology. We will clearly define our goals and objectives and analyze the problem of merging guidelines. We will then discuss our rationale for developing a CPG ontology and finally outline our ontology development methodology followed by our intended methodology to evaluate our ontology.

In **Chapter 4** is dedicated to the methods used to develop our ontology. We will discuss the conceptual structure of clinical guidelines and present the main concepts of our ontology in detail, reviewing their classes, attributes and relationships. A detailed discussion about our solution for guideline merging issues will be provided at the end of this chapter.

In **Chapter 5** we will evaluate our ontology based on its ability in modeling clinical practice guidelines, its ability to address merging issues, and based on guideline formalism comparison dimensions introduced by Peleg et al [6].

Finally, **Chapter 6** outlines our research achievements, limitations, and suggestions for future directions.