CAREPATH methodology for development of computer interpretable, integrated clinical guidelines

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ABSTRACT

The process of developing a computer interpretable, integrated clinical guideline requires multiple considerations and decisions. As part of the CAREPATH project, a holistic approach to comorbidity has been adopted using an integrated clinical guideline for the management of multimorbid patients with mild cognitive impairment or mild dementia. The project's clinical and technical teams would later interpret and implement the integrated clinical guideline into the CAREPATH holistic computer interpretable guideline. Three phases should be completed to accomplish the patient-centered computer interpretable guideline modelling, which include the conceptual modelling, interpretable modelling and localization phases, respectively. This paper describes the methodological viewpoints of this process and the relevant considerations.

CCS CONCEPTS

• **Applied computing → Health informatics**.

KEYWORDS

Decision Support System, Computer Interpretable Guideline, Holistic Patient-Centered Guideline

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1 INTRODUCTION

The development of evidence-based clinical recommendations has been an important mean of improving patient outcome in daily clinical practice [5]. Clinical practice guidelines (CPGs) are intended to enhance the quality of care for patients, improve resource management in the health system and decrease physician-level variability in practice [10]. Yet, efficacy of guidelines can be affected by many factors, including patient multimorbidity conditions [9]. Clinical Practice Guidelines are usually developed for single conditions, and although they may include some decision making related to other morbidities, they do not follow a systematic approach in identifying relationships between guidelines for different conditions [8]. The decision making based on different guidelines may be affected, if guidelines are inconsistent with each other, for example multiple guidelines invoking drug-to-drug interactions. Therefore, it is generally believed that CPGs should be carefully observed in presence of multimorbidity [7]. Such conflicts are usually resolved by the patient discussing their needs with experts for each condition separately, which can be ineffective and inefficient.

Despite the increasing number of clinical guidelines and the evidence supporting their usefulness, the degree of non-compliance has been remarkable [2]. Healthcare providers might not comply because they consider the process difficult and time-consuming in daily clinical practice [6]. In this context, healthcare professionals need clinical decision support services to detect and warn them about guideline conflicts, to select upon the most suitable treatment options in the light of evidence-based guidelines and to schedule and prioritize treatment activities [4]. To facilitate implication of guidelines in daily practice, Clinical Decision Support Systems (CDSSs) have been developed and implemented in different fields of clinical practice to assist in coordinating complex activities [1]. Yet, to achieve high levels of improved patient outcome and clinical adherence, the process of translating CPGs into CDSSs should be pursued with sophisticated methodologic considerations.

CAREPATH is a research project aiming at improving healthcare interventions for the management of conditions of elderly multimorbid patients suffering from mild cognitive impairment or

mild dementia by developing ICT solutions through an integrated patient-centered approach. As part of this project, a holistic approach to multimorbidity has been adopted for the management of multimorbid patients with mild cognitive impairment or mild dementia by the clinical team of the project. The project's clinical and technical teams would later interpret and implement them into the CAREPATH holistic, computer interpretable guidelines. This paper describes the methodological aspect of this process and the relevant considerations.

2 STATE OF THE ART

In recent years, methodologic approaches for improved guideline integration have been proposed in health informatics research. Wilk et al. suggested a first-order logic method for identifying and addressing interactions between different CPGs in multi-morbid patients. This mitigation approach can address concurrent application of multiple CPGs and patient preferences into the decision making process [13].

Other activities have been undertaken in the C3-Cloud project. This ICT infrastructure is designed to support a collaborative care and cure cloud environment for multimorbid patients based on best practice guidelines. The services are provided by a single multimorbidity management plan rather than a digitization of multiple separate guidelines. The consolidated multimorbidity guidelines would later produce personalized rules translated into service processes [3].

In other studies, researchers have proposed an approach to develop an integrated model of multimorbidity and symptom science through a critical integrative review and synthesis process. The proposed method is supposed to provide a model to highlight the multilevel nature of determinants and their expected interactions [11].

In another approach, researchers have proposed a solution for dynamic integration of CPG, in contrast to a-priori design-time static integration. This approach considers the constantly evolving patient health profiles and execution-time events. For the system to cope with comorbidities at execution-time, clinical experts provide CPG integration policies with clearly defined integration semantics, based on Description and Transaction Logics [12].

Overall, it seems that addressing the complex nature of multimorbidity, through clinical guidelines, seems to be a critical issue that should be further investigated through meticulous scientific approaches.

3 METHODOLOGY

For the holistic patient-centered clinical guidelines to be implemented in the modelling phase, the technical and clinical teams need to work together to reach a better understanding of the relevant clinical procedures, as well as a crystal-clear description of clinical pathways and decisions. When such understanding is achieved, the modelling phase can start.

The clinical teams will define the decision making based on their deep understanding of processes, pathways and decisions, supported by further literature review of evidence and guidelines. Then, in collaboration with the technical team, the holistic integrated clinical guideline will be documented as unambiguous rules. This includes the conditions that trigger the rules, the representation of clinical concepts and the algorithm, as well as the outputs. The documentation will be based on structured approaches such as business and logic modelling, used in IT development.

In CAREPATH, we intend to elaborate the holistic, integrated clinical guideline for implementation in Clinical Decision Support (CDS) through a customized Unified Modeling Language (UML)-based approach. The CDS modelling process is an organized, technical methodology with a formal demonstrated model as an output. The technical team performs CDS modelling by means of use case diagrams, activity diagram and flowcharts in conjunction with business processes diagrams.

Three phases should be completed to accomplish the patient-centered computer interpretable guideline (CIG) modelling, which include conceptual modelling phase, interpretable modelling phase and localization phase (Figure 1).

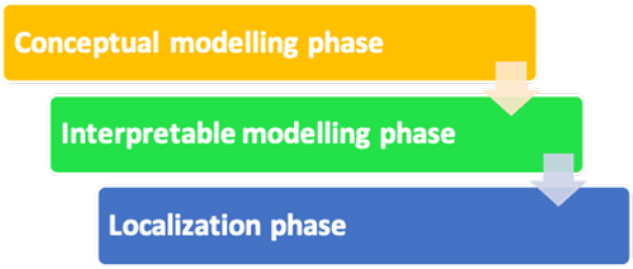

Figure 1: Patient-centered computer interpretable guideline (CIG) modelling phases

3.1 Conceptual modelling phase

Conceptual modelling phase is the first step in this modelling process. We construct a conceptual model and business process based on the holistic clinical guideline developed by the clinicians in the previous steps of the CAREPATH project. In this phase, we intend to establish the consensus guideline as human readable flowcharts and diagrams.

These flowcharts and diagrams are then implemented in the system through human readable decision rules, system and users states and actions. Guidelines in this phase should be prepared for the next steps where they will become both readable by human and transformable to computer interpretable codes. They also need to be appropriate for technical aspects of local adoption by different healthcare sites and institutions throughout the project. Clinicians should provide necessary explanations, evidences and documents to facilitate developing CIGs and validate the final output.

The conceptual model is presented as flowcharts showing all components, including actions, decisions, patient state and execution state in a non-technical format. The inputs to the decision points as patient data should be clearly identified. The output should be later approved by the project's clinical reference group to assure their validity. Details such as patient data elements, clinical actions output format and guideline technical flow are not needed to be addressed at this stage, whereas ontologic and standard term binding should be specified by setting the references to standard terminologies, controlled vocabularies and coding systems including ICD, LOINC and SNOMED.

3.2 Interpretable modelling phase

When the conceptual modelling phase is completed, the technical team will be ready to start implementing the flowcharts and move towards the development of the interpretable model of the CDS.

In the first step of this phase, CDS are implemented through use case models. A use case model describes and formalizes relationships between the software system to be developed and the outside world. It could be easily used to specify the boundaries of the system and the different interactions implemented in the realization of clinical and medical requirements. Use cases are particularly helpful to establish a dialog between clinicians and developers, and helpful as a basic tool used to formalize functional requirements of the system.

We start with our holistic, integrated guideline as our main source of use case scenario. As we formed a consensus flowchart with our clinicians, the best way to form the scenarios is using simple sequence diagram which is compatible with flowchart and conceptual framework previously used. Any new condition or input can result in a series of suggestions based on the integrated guideline which can include medications, further evaluations, lifestyle modifications and patient education among the others. Use case models are made up of two main types of elements: Actors and Use Cases. An actor is defined as an outside entity which is required to have direct interaction with the system. In our model actors are human users (e.g., clinicians, patients, informal caregivers), data sources or software (such as Electronic Health Record, Clinical Assessments), systems and services (including Polypharmacy management service, Patient Empowerment Platform) and devices and sensors (Home monitoring sensors and other similar services). The CDS use case model is developed based on the main actor, who is supposed to be the source for triggering it. Any other actor interacting with the use case are categorized as a secondary actor. Secondary actors, participate in the scenarios but are not the target for the services provided by the CDS. The next element of the use case model is the use case.

A use case represents the interaction between the main or secondary actors and the CDS system. It is described by a set of scenarios to meet a fundamental goal in the system. Every use case must be linked to at least one actor and cover at least one scenario with an added value in the target health management process. By the means of Use case model and its elements, the users are able to demonstrate categorized system pathways, triggers (e.g., adding a new patient, prescribing a drug, ordering a laboratory test, or entering a new problem on the problem list etc.), inputs (e.g., patient demographics, patient test results, drugs lists, states), interventions and outputs.

In the second step of interpretable modelling phase, business process models are developed, which are defined as a sequence of actions carried out by different actors working together to deliver a tangible result and achieve the expected added value. Generally, in UML-based approaches, business processes are routinely represented using activity diagrams. However, in CAREPATH, we prefer to use Business Process Modelling Notation (BPMN), which is considered to be easier to grips with. In the CAREPATH project methodology, we use business processes in combination with guideline flowcharts to extract more details about what has been determined from use cases. These may include but are not limited to decision tree pathway identification, the trigger event in any decision node, switching and changing in states and actors and the expected results or targeted objectives. The input and output parameters of CDSs will be conceptualized based on the guidance of CDS Hooks specification.

The third step is about extracting rules and actions definition and implementation tables. Considering the fact that use case models and business process models generally describe the business and not the IT system, there is a need to translate any nodes and pathways into rules and action records format. It would be preferable to present them in preformatted table templates. In this step, three consecutive outputs are to be achieved.

The first output is the variable-driven table. For each variable, title, definition, type, range, production source, availability source and role should be defined. Variables from other systems that are expected to get integrated in the final CDSS should also be included at this stage. When all variables are defined, conflict management should be performed both at decision points and action points by clinical reference group. While completing this task, we might identify some necessary data that has not been addressed before. Such data should be either accessed from other sources, substituted by or computed from other existing data.

The second output is the decision/rule table that is somehow the most important output which is going to be formed based on data gathered through previous stages and is supposed to be used for CDS module formation. The table has records showing decision nodes and their relations with explanatory fields as demonstrated in Table 1.

The third output in this list is a set of output cards. These are outputs formed based on CDS hooks card template and include actions such as sending a message to a clinician, showing a detailed suggestion from an evidence-based guideline, offering a choice of care plan activity suggestions (such as appointments, referrals, medication requests, patient activities as diet or exercise regimens) or simply documenting an event. Each of these cards has card code, summary, description, source, calling node/rule ID(s) and suggestion (e.g., activity, appointment, request).

3.3 Localization phase

At this phase models are ready to be implemented and customized based on the clinicians' opinion for different settings. This should be done in collaboration with the technical team and with considering legislative and ethical issues. When adaptation is completed, the pilot implementation can begin, and the system will be tested by simulated scenarios and data.

Localization consists of adaptation of inputs and outputs of CDS module and contents in accordance with the language, cultural and other specifications of the intended target settings.

4 CONCLUSION

The process of developing a computer interpretable integrated clinical guideline requires many considerations and decisions. Strong collaboration between clinical and technical team and reciprocal activities are needed to complete the task in an appropriate way. Differences in standards used by target systems, variability of local

Table 1: Node/Rule table explanatory fields

Node/Rule Item Name	Node/Rule Item Description
ID	Node Identification Number.
Trigger	The events that cause a decision support rule to be invoked. when the rules should be triggered.
Associated rule (Clause)	Description of the CDS rule/algorithm in the format of "if…then…else" statement.
Purpose type	Purpose of the CDS rule, e.g., for treatment suggestions, poly-pharmacy detection, risk assessment, lifestyle.
Description of the purpose	It explains the problem to be addressed: what, who (responsible actor), where (location/setting), when (timeline), etc.
Input(s)	The data elements used by the rule to make inferences, e.g., patient age, gender, blood pressure, medication list, etc.
Output(s) description	Description of possible actions or offered choices of the CDS module, e.g., alert, reminder, medication suggestion, care plan goal/activity, risk report, showing a guideline, etc.
Output(s) card ID	Associated CDS hooks cards ID.
Reference	Source of information, When the original guidelines flowcharts do not provide all information needed, we made some assumptions based on related guidelines or consensus.
Context	Clinical context, such as target disease combination, stages in clinical process, relevant clinical activity, decision making point, etc

rules and standards, inconsistency between guidelines and definition, need for unprecedented data and heterogeneity of the stakeholders are all issues that contribute to the complexity of this step.

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