Computerized decision support to improve guideline implementation in cardiac rehabilitation: the CARDSS project

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Chapter 2.

A parallel guideline development and formalization strategy to improve the quality of clinical practice guidelines

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Chapter 2. A parallel guideline development and formalization strategy

Abstract

Purpose: Clinical practice guidelines often contain ambiguities, inconsistencies, and logical errors that hamper implementation of these guidelines in practice. As guideline formalization is useful to verify the logical structure, consistency, and completeness of guidelines, several authors have argued that the formalization of guidelines concurrent with their development may improve their quality. However, experiences with such a parallel guideline development and formalization approach have not yet been reported. The goal of this study was to develop such a strategy and evaluate its application in practice.

Methods: Existing methodologies for guideline development and guideline formalization were analyzed and used as a basis to develop a strategy in which guideline formalization is performed concurrently with guideline development. The developed strategy was applied in the development of a clinical practice guideline for cardiac rehabilitation.

Results: A parallel guideline development and formalization strategy was developed that intertwines the processes of guideline development and guideline formalization. Central assets are early involvement of guideline formalization specialists and formalization tools, cooperation between guideline authors and guideline formalization specialists in the development of clinical algorithms, access to domain knowledge when formalization identifies inconsistencies or omissions, and formal verification of the guideline model prior to guideline dissemination. This strategy was applied in the development of a guideline for cardiac rehabilitation and helped to identify several vague and inconsistent recommendations and impracticabilities in the narrative guidelines that could be resolved before publication. In addition, the strategy ensured consistency between the narrative and formalized guideline.

Conclusions: Based on our experience, formalizing a guideline concurrent with its development is feasible in practice and we recommend applying such a strategy as it can be beneficial to the quality of and consistency between the guideline’s narrative and formalized version.
Introduction

In contemporary healthcare, clinical practice guidelines are considered essential instruments to improve the quality of care [1] as they are found to improve patient outcomes, reduce practice variation, and reduce costs [2-4]. However, the compliance to guidelines by care professionals in clinical practice is often low [5]. One important reason for this is that, despite the great efforts put into their development, guidelines often contain ambiguous and vague concepts and recommendations, omissions, inconsistencies, and other errors [6-10]. As these issues hamper the use of guidelines in practice they often do not have the desired quality improvement effect on healthcare [8;10;11].

Guideline formalization is the process of translating the data gathering, decision making and acting described in the guideline in a computer interpretable format. Traditionally, guidelines are formalized to either provide computerized decision support or to exchange guidelines across institutions [12;13]. Increasingly, guideline formalization itself is also found to be a valuable method to verify the logical structure, consistency, and completeness of narrative guidelines [8;10;14-17]. Structuring and summarizing guidelines, and translating them into a formal 'language' has shown to help identify different types of errors that hamper the application of guidelines in practice. In addition, some guideline formalization tools include functionalities to help to identify errors by automatic verification of the logical consistency of the formalized guideline [10;13].

In published accounts, guideline formalization was done after publication of the guideline concerned [7;8;10;14;15-17-19]. In such an approach the errors in narrative guidelines make proper guideline formalization difficult and time consuming without close collaboration with guideline authors. In guideline formalization, it is critical that the formalized guideline closely corresponds to the narrative guideline and reflects the intentions of the guideline authors. Also, to facilitate and reduce the variability in the guideline's interpretation and execution, vague concepts and recommendations in the guideline (e.g., 'low' or 'poor') need to be clearly delineated. The usefulness of identifying problems by formalization is limited when done after guideline publication as the narrative guideline is already published and cannot be changed anymore [8;10]. Resolution of these problems is difficult as it would require the involvement of guideline authors, and if they are resolved this will often compromise the correspondence between the narrative and formalized guideline.

Several authors have suggested to formalize a guideline concurrent with its development [10;15-17]. First, this can be beneficial to the quality of the narrative guideline as this helps to identify problems that can still be resolved prior to publication. Second, close collaboration with the guideline authors is beneficial to the
quality of the formalized guideline and improves the consistency between the narrative and formalized guideline. However despite these potential benefits, such a parallel guideline development and formalization strategy and its application were not yet described in the literature. This paper presents a parallel guideline development and formalization strategy that combines the principles of existing methodologies for guideline development, knowledge engineering and guideline formalization. In addition, we report on our experience with the application of this strategy in the development of a guideline for multidisciplinary cardiac rehabilitation.

Methods
In published accounts, the development of a guideline and its formalization are two separate and serial processes. However, to make optimal use of the potential benefits of guideline formalization to the quality of narrative guidelines, these separate processes not only need to be conducted concurrently, but moreover need to be intertwined. Subsections 2.1 and 2.2 subsequently describe the processes of guideline development and guideline formalization on which the parallel guideline development and formalization strategy that is presented in this paper is based. The developed strategy was applied in practice during the development of the Dutch guidelines for cardiac rehabilitation. In the final subsection, the domain of cardiac rehabilitation and the guideline development initiative concerned are introduced.

Guideline development
The development of high-quality practice guidelines is laborious and time-consuming, and needs to be organized according to rigorous methods [20;21]. In this paper, we will follow the guideline development procedure described by Shekelle and colleagues [21], which is depicted in Figure 1. The first step of this procedure is setting up a guideline development group to lead the guideline development initiative. Such a group should be composed of a (multidisciplinary) group of experienced and knowledgeable professionals and relevant stakeholders in the guideline’s subject area. Initially, this guideline development group needs to conduct a thorough review of the scientific literature and collect the relevant scientific evidence. Subsequently, the available scientific evidence should be summarized and categorized according to the strength of the evidence. During guideline author meetings, the evidence is interpreted and discussed and recommendations of the guideline are formulated, taking the strength of evidence, resource implications, and feasibility into account. In the following guideline authoring phase, the formulated guideline recommendations and their supporting evidence are crafted into the actual guideline. Finally, a thorough
review is required to ensure the validity, clarity and applicability of the developed guideline.

Guideline development process

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1.</td>
<td>Set up a guideline development team</td>
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<tr>
<td>2.</td>
<td>Identification and assessment of evidence</td>
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<tr>
<td>3.</td>
<td>Interpretation and summarization of evidence</td>
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<td>4.</td>
<td>Deriving guideline recommendations</td>
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<td>5.</td>
<td>Guideline authoring</td>
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<td>6.</td>
<td>Guideline review</td>
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Figure 1. Schematic representation of the general steps of a guideline development initiative, based on the guideline development principles described by Shekelle et al. [21]. Several steps have arrows pointing to their preceding step indicating that their activities might require returning to the previous step.

Guideline formalization

Guideline formalization does not only require that the narrative guideline in question is interpreted and summarized, but it also has to be translated and represented into a computer interpretable format. To this end, guideline formalization is usually a difficult and time-consuming process as it requires both familiarity with the clinical domain concerned as well as experience in knowledge engineering methodologies [15;17;19]. Therefore, both domain experts and informatics specialists ideally need to be involved in a guideline formalization initiative [17].

In the literature, the general process of guideline formalization was not yet fully described. To this end, the process of guideline formalization followed in this paper is based on a combination of the principles of guidelines formalization described in [13;22;23]. Before the actual formalization of guideline, the guideline formalization
team first has to make a decision regarding the approach and the tools to formalize the guideline [13;23]. In the last decades, several approaches to facilitate the formalization and shareability of guidelines have been developed such as the Arden Syntax [24], PROforma [25], GLIF [7], and others [23;26]. Most of these approaches come equipped with knowledge acquisition tools that support guideline formalization in a visual manner [22;27]. The selection of the tools and approach depends, among other requirements, on whether the formalized guideline will provide the basis for computerized decision support, in which case a guideline execution engine should be available [13;22;23].

The first activity in guideline formalization is usually the formal specification of the concepts and relationships in the domain the guideline focuses on, often referred to as a domain ontology [13;22]. To build a domain ontology, it is first needed that the guideline formalization team interprets and summarizes the guideline and forms consensus on the actual definition and meaning of the relevant concepts and recommendations. Once a domain ontology is developed, the guideline’s actual decision logic and control structure needs to be specified accordingly. In most guideline formalization tools the guideline’s control structure is represented in the form of a task-network model [13;22].

The final step in the guideline formalization process is the verification and testing of the formalized guideline [13;23]. Some guideline formalization tools include functionalities to automatically verify the logical consistency of the formalized knowledge base, although these functionalities are still rather limited in most approaches [10;13]. As an additional verification step, the formalized guidelines can be tested in a simulation (e.g., with existing patient records) or clinical (e.g., in a pilot study) environment [13;28;29].

**Development of the Dutch cardiac rehabilitation guidelines**

Outpatient cardiac rehabilitation is a multidisciplinary rehabilitation and secondary prevention therapy provided to patients after hospitalization for cardiac events (e.g., myocardial infarctions) and cardiac interventions (e.g., heart surgery). Cardiac rehabilitation is critical to ensure both that patients are in the best possible physical and psychosocial condition to return to and maintain their normal place in society, and that their future cardiovascular risk is reduced [30-32]. However, despite its proven cost-effectiveness [32], cardiac rehabilitation practice is poorly standardized and does not follow the available evidence in many Western countries [32-34].

To stimulate the provision of evidence-based cardiac rehabilitation, the Netherlands Heart Foundation and the Netherlands Society for Cardiology, a patient interest and
professional organization respectively, decided to develop a new national guideline in 2002. Early in the guideline development process, these organizations decided to develop a computerized decision support system to improve guideline implementation and assigned this task to the Department of Medical Informatics of the Academic Medical Center in Amsterdam. To improve the quality of the narrative guideline and to ensure the consistency between the narrative and formalized guideline, it was decided to apply a parallel guideline development and formalization strategy.

In this project it was decided to use the GASTON toolset [27] to formalize the cardiac rehabilitation guideline. GASTON is a state-of-the-art toolset to formalize clinical practice guidelines and consists of an ontology-based guideline representation language and a guideline modeling tool. The guideline modeling tool has a user interface that enables guideline authors to develop guidelines represented as a flowchart and is comparable to other guideline modeling tools such as Protégé [35] and PROforma’s Tallis [36]. In addition, it also contains a guideline execution engine that can be used to build a computerized decision support system.

**Results**

**The parallel guideline development and formalization strategy**

The proposed parallel guideline development and formalization strategy is schematically depicted in Figure 2. The strategy combines the processes of guideline development and guideline formalization as follows. The parallel guideline development and formalization strategy starts with setting up a guideline development team. However, concurrently a team of specialists in guideline formalization (e.g., medical informaticians) is formed to lead the formalization process. In a serial formalization strategy it is important to invite domain experts in the guideline formalization team to correctly interpret and formalize the guideline [8;17]. In a parallel guideline development and formalization strategy this is no longer needed as the guideline formalization team closely collaborates with the guideline authors during the guideline formalization process.

In the initial steps of the guideline development process, the guideline development team and guideline formalization team focus on separate activities. The guideline development team initially focuses on the identification, assessment, interpretation, and summarization of relevant scientific evidence, while the guideline formalization team selects the approach and tools that will be used to formalize the guideline. If a computerized decision support system is to be developed, its technical and functional
requirements can be determined by the guideline formalization team at this stage by consulting guideline authors and other field workers.

The actual collaboration between the guideline authors and the guideline formalization team starts during the derivation of the recommendations of the guideline. In this phase, one or more members of the guideline formalization team participate in guideline author meetings to get familiarized with the domain, concepts, and recommendations of the guideline. Concurrently, the guideline formalization team can start to specify a domain ontology based on the initial guideline recommendations. At this point, specifying a domain ontology can already help to identify vague or incomplete concepts and recommendations that can be discussed with guideline authors.

A central asset of the parallel guideline development and formalization strategy is that guideline authors and the guideline formalization team jointly develop a flowchart or clinical algorithm that summarizes the process of data gathering, decision making and acting described in the narrative guideline. Increasingly, guidelines are augmented with such an algorithm or flowchart, but these summaries often lack explicit domain knowledge that hamper both their interpretation and formalization in case they are developed by guideline authors alone [8]. The collaboration between guideline authors and (medical) informaticians in this process, each bringing relevant expertise to the table, has been shown to improve the logical consistency and completeness of these clinical algorithms or flowcharts [8]. In the parallel guideline development and formalization strategy, the resulting clinical algorithm or flowchart can be used as the basis for guideline formalization while the guideline development team crafts and authors the actual narrative guideline. Any problems encountered or errors identified during guideline formalization can be directly discussed with and, if necessary, resolved by guideline authors.

During the regular guideline development process [21], the narrative guideline is reviewed by its authors, external reviewers, and future users to assure its validity, clarity and applicability. In the parallel formalization strategy additional forms of guideline verification can be applied. First, formal verification of consistency of the formalized guideline can help to identify additional inconsistencies and logical errors [10;14;15]. Second, if the guideline model is incorporated into a computerized decision support system, the guideline can be evaluated using a set of test case patients or during a field study [13;28;29]. These verification steps can reveal additional guideline flaws which can be addressed prior to publication. In addition, a field test can reveal impracticabilities in the guideline.
Figure 2. Schematic representation of the parallel guideline development and formalization strategy. The horizontal lines between activities indicate that the guideline authors and the guideline formalization team collaborate in these steps. Several steps also have arrows pointing to their preceding step indicating that their activities might require returning to the previous step.

**Application of the parallel guideline development and formalization strategy**

The above described parallel guideline development and formalization strategy was applied in the development of a clinical practice guideline for cardiac rehabilitation. Initially, a guideline development group was formed by the Netherlands Heart Foundation and the Netherlands Society of Cardiology by recruiting a large number of field experts and experienced cardiac rehabilitation providers. Concurrently, the department of Medical Informatics of the Academic Medical Centre in Amsterdam formed a team of medical informaticians and computer scientists to lead the guideline formalization process. One of the authors (RG), a medical informatician, was assigned to lead this process. To become familiar with the domain and the content of the
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guideline, he participated in all guideline authors’ meetings and visited several cardiac rehabilitation outpatient clinics.

Similar to international guidelines [30-32], the Dutch national cardiac rehabilitation guideline proclaims that patients should be offered an individualized rehabilitation program according to their needs. To this end, the guideline describes an information-gathering and therapy indication procedure which requires assessing 15 to 40 data items concerning the patient's medical, physical, and psychosocial condition and lifestyle, finally leading to a recommendation for each of four therapies: exercise training, education therapy (education about the consequences of the patient's disease), lifestyle change therapy (risk-related behavior correction), and relaxation and stress management training. A flowchart summarizing this needs assessment procedure was developed that could be augmented to the guideline to help professionals in putting this needs assessment procedure into operation, and that could be used as a basis to formalize the guideline. The guideline authors and guideline formalization team actively collaborated in the development of this flowchart. The guideline authors incrementally defined and discussed the flowchart's clinical content and structure. Concurrently the guideline formalization team used the flowchart as a basis to formalize the guideline in GASTON. During the development of the summary flowchart, both the structure and the content of different parts of the flowchart were adjusted or extended according to recommendations of the guideline formalization team. In initial versions of the flowchart, created by guideline authors, many decision procedures were still cast in writing; an example is shown in Figure 3. However, these textual procedures often left room for multiple interpretations due to incomplete information (e.g., what should be provided to patients that smoked prior to, but stopped after their cardiac incident and think they need help to continue not smoking?). Because the process of guideline formalization forces one to specify complete and unambiguous decision procedures, it was not possible to create a formalized version of these flowcharts that would precisely correspond to the paper flowchart. It was therefore chosen to replace such written descriptions with structured, graphical descriptions that could be more easily mimicked during guideline formalization.

Initial versions of the narrative guideline and the flowchart also contained several inconsistent and incomplete recommendations that hampered its applicability and hampered proper formalization. For example, the guideline recommended caregivers to offer their patients counseling if their emotional or social quality of life (QoL) was too low. The guideline advised to use a dedicated QoL questionnaire for heart disease patients [37] to assess quality of life, but did not specify the threshold values needed to determine if a patient’s QoL score was to be considered too low. Similarly, the
guidelines stated that patients should be offered exercise therapy if their scores on either a bicycle test or a Shuttle Walk Test were 'too low', again without providing the relevant threshold values. Such threshold values are however indispensable to enable automated reasoning with the formalized guideline and their absence therefore hampered the formalization process. Also, vague terms such as 'too low' could result in (unwanted) variation in the interpretation of this recommendation by professionals. The guideline formalization team discussed these issues with the guideline authors, and it was decided to include the relevant threshold values into the guideline.

Automated verification of the guideline’s logical consistency was not carried out as this was not supported by the GASTON toolset at the time. Instead, we conducted a field test with the formalized guideline in addition to the guideline’s ‘normal’ review process. To this end the formalized guidelines were incorporated into a computerized decision support system [38] that was used to conduct the field test. Four Dutch outpatient clinics were asked to assess each patient’s needs for cardiac rehabilitation using the computerized decision support system, critically review its patient-specific recommendations, and finally record the final therapy decisions into the system. All patient information entered in and recommendations generated by the system were stored. After the pilot study all participants filled in a questionnaire and were interviewed to assess their opinion on the guidelines. In addition, the quantitative data collected were analyzed. During two months the four outpatient clinics used the computerized decision support system for 134 patients' needs assessment procedures [39]. The field test pointed out two additional issues in the guideline that were not identified during the review phase of the narrative guideline. First, the pilot study showed that some hospitals lacked the facilities to carry out either of the two recommended exercise tests to objectively assess patients’ physical condition. Second, an additional inconsistency in the guideline was discovered: a contra-indication for a specific rehabilitation therapy assessed in one part of the flowchart was not taken into account in another part which incidentally resulted in the specific therapy being recommended although a contra-indication existed. This inconsistency was previously
overlooked because of the complexity of the flowchart. These issues were discussed with the guideline authors and were resolved in the final version of the guideline: a third possible exercise test was introduced that could be performed by all hospitals and the erroneous recommendation was adjusted. The new national cardiac rehabilitation guidelines [40] were published in January 2004.

Discussion

In this paper we have presented a parallel guideline development and formalization strategy that intertwines the processes of guideline development and guideline formalization. Central assets are the early involvement of guideline formalization specialists and formalization tools, the cooperation between guideline authors and guideline formalization specialists in the development of a summary flowchart or clinical algorithm, easy access of guideline formalization specialists to guideline authors in case of questions or errors, and verification of the formalized guideline prior to guideline dissemination. This strategy was successfully applied in the development of a guideline for multidisciplinary outpatient cardiac rehabilitation. In this project, guideline formalization helped to identify ambiguities, incomplete and inconsistent recommendations, and impracticabilities in the narrative guideline. As formalization was done during the development of the guideline these problems could be resolved before publication of the guideline. In addition, the apprehended strategy ensured a close correspondence between the content of narrative and formalized guideline, and guideline authors could be immediately consulted upon doubt, vagueness or errors.

Although several authors have hypothesized that the formalization of a guideline concurrent with its development is beneficial to the quality of narrative guidelines [8;10;15;17], such a parallel guideline development and formalization strategy was not yet described and no experience with its application was yet reported in the literature. We are the first to describe such a strategy and report on our experience with it. Biondich et al. [16] have described two initiatives in which guideline authors and medical informaticians collaborate in guideline development. However, they do not describe a structured procedure as was done in this paper, and provide no results of the collaboration.

It is unclear to which extent our findings will generalize to other initiatives as the parallel guideline development and formalization strategy was applied in only one project. Also, the strategy was not directly compared to a serial guideline development and formalization approach as such a comparison is not possible within a single guideline development initiative. However, we believe that most issues that were
found to hamper the narrative guideline’s applicability and formalization would still be present if no parallel guideline development and formalization strategy was applied.

Application of the parallel guideline development and formalization strategy might delay guideline development and publication, as concurrent guideline formalization can identify problems that require guideline authors to further elaborate or adjust the guidelines. To limit this possible delay in development, it is important that guideline developers realize in an early stage of, or even before starting guideline development that guideline formalization can be of value to the guideline’s quality and that (medical) informatics specialists should be involved in this process.

In this project we used the GASTON toolset [41], which contained both a guideline modeling tool and a guideline execution engine that can be used to build a computerized decision support system. There exist a number of other toolsets similar to GASTON, such as Proforma’s Tallis [36], Protégé [35], and SAGE [42], and others [23;26]. Since the differences between these toolsets are small we believe that each of these toolsets is equally suitable for application within the parallel formalization strategy. However, as do most of the other toolsets [10;13], the version of GASTON that we used had limited functionalities to automatically verify the consistency of the formal guideline. As these functionalities are useful to identify guideline flaws [10], we recommend the developers of these toolsets to include or improve such functionalities.

Usually, guidelines are formalized to provide professionals with computerized decision support. It is expected that issues concerning the legal liability for the quality of the knowledge bases and recommendations of computerized decision support systems will become important in the near future as there is an increased focus on quality and safety in healthcare [43;44]. As the formalization of guidelines has proven to often lead to errors and difficulties [7;8;18;19], these issues will pose an interesting challenge to the field of medical informatics. However, we believe that the parallel guideline development and formalization strategy can provide a possible solution to this issue. The application of this strategy ensures that the formalized guideline corresponds to the narrative guideline and is consistent with the opinion of the guideline developers. This makes it possible that the guideline authors take full responsibility for the content of the knowledge base of guideline-based computerized decision support system.

The results from our project show that a parallel development and formalization strategy can be successfully applied in practice. Based on our experience, we recommend that guideline authors consider formalizing a guideline concurrent with its development as the parallel development and formalization of a guideline helps to
improve the quality of the narrative guideline by helping to identify errors in the
guideline before publication. Also, the strategy ensures a close correspondence
between the narrative and formalized guideline which is important if formalized
guidelines are shared among institution or used to provide computerized decision
support.

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