Computerized decision support to improve guideline implementation in cardiac rehabilitation: the CARDSS project
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Computerized Decision Support
to improve Guideline Implementation
in Cardiac Rehabilitation

The CARDSS project

Rick Goud
Computerized Decision Support to improve Guideline Implementation in Cardiac Rehabilitation; the CARDSS Project
PhD thesis, University of Amsterdam, Amsterdam, the Netherlands

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# Table of Contents

**Chapter 1.** General introduction

**Chapter 2.** A parallel guideline development and formalization strategy to improve the quality of clinical practice guidelines  
*Int J Med Inform. 2009; In Press*

**Chapter 3.** Development of a guideline-based decision support system with explanation facilities for outpatient therapy  
*Comput Methods Programs Biomed. 2008 Aug;91(2):145-53*

**Chapter 4.** A pilot study with a computer-based guideline implementation system for cardiac rehabilitation  
*Based on Computers in Cardiology. 2005;32:323−326*

**Chapter 5.** Subjective usability of the CARDSS guideline-based decision support system  
*Stud Health Technol Inform. 2008;136:193-8*

**Chapter 6.** The effect of guideline-based computerised decision support on decision making of multidisciplinary teams: A cluster randomised trial in cardiac rehabilitation  
*British Medical Journal. 2009; In Press*
Chapter 7. Inter-practice variation in assessed patient needs for cardiac rehabilitation
Submitted for publication

Chapter 8. The effect of computerized decision support on barriers to guideline implementation: A qualitative study in outpatient cardiac rehabilitation
Submitted for publication

Chapter 9. General Discussion

Summary

Samenvatting

Dankwoord

Curriculum Vitae
Chapter 1

General Introduction
Chapter 1. General Introduction

The CARDSS project

In 1996, the Netherlands Heart Foundation and the Netherlands Society of Cardiology published the first national clinical practice guidelines for cardiac rehabilitation [1]. Cardiac rehabilitation is a multidisciplinary secondary prevention therapy that is provided to patients after cardiac events (e.g. myocardial infarctions) and cardiac interventions (e.g. heart surgery). The goal of cardiac rehabilitation is to favourably influence the cause of disease, and above all to ensure that patients are in the best possible physical, psychological and social position to return to and maintain their normal place in society [2-6].

In 2001, the Dutch Cardiac Rehabilitation Committee, instituted by Netherlands Heart Foundation and the Netherlands Society of Cardiology, decided to revise and elaborate the cardiac rehabilitation guidelines, because new scientific evidence on, and more experience with, cardiac rehabilitation was available. As measurements in 1999 had shown that the uptake of the 1996 guidelines in clinical practice was poor [7], the cardiac rehabilitation committee decided that, to improve implementation of the new guidelines, a computer program had to be developed that would support professionals in making therapy decisions according to the new guidelines. In 2002, the department of Medical Informatics from the Academic Medical Centre in Amsterdam became involved in the development of this decision support system. This marked the beginning of the CARDSS (Cardiac Rehabilitation Decision Support System) project.

This thesis describes the various scientific studies that were carried out in the CARDSS project during the years 2004-2008. In this chapter we first provide some background information on the most important concepts of this thesis. Subsequently, we describe this thesis’ objective, the various research questions that will be addressed, followed by an outline of this thesis.

Clinical practice guidelines

An important issue in contemporary healthcare is that patients are provided with treatments whose effectiveness are proven by current scientific evidence [8]. Because of technological advancements and increased insights, treatments that were considered effective five years ago might be outdated today. Keeping up to date with the latest scientific advancements is however not easy. Healthcare professionals need to read and assess hundreds of scientific articles a month that are related to their specialism. Just searching in Pubmed [9] for research papers with the keywords ‘cardiovascular disease’ in their title or abstract results in more than 1.4 million related articles of which over 68,000 were published in 2007 alone. Therefore, there is...
a need for effective instruments and strategies that facilitate the delivery of evidence-based care.

One of the instruments considered essential in the delivery of evidence-based care are clinical practice guidelines (CPGs) [8]. CPGs are systematically developed statements, usually developed by a (multidisciplinary) group of expert healthcare professionals, which summarize and describe best practices for specific health conditions [10]. In general, CPGs aim to i) improve the provision of proven-effective care that is tailored to the needs and condition of the individual patient and ii) reduce the variation in the care provided by different healthcare professionals and organizations [10-12]. Healthcare workers are nowadays expected to deliver care according to these CPGs unless they have very good reasons not to. In medical lawsuits adherence to the CPG is increasingly used to judge medical practice [13]. Also for health insurance companies CPG adherence is becoming an important issue [14].

The guideline implementation problem

One of the main challenges in modern healthcare is the dissemination and implementation of CPGs [15]. Despite the fact that working according to CPGs can improve patient outcomes, reduce practice variation, and reduce costs of patient care [10;12;16], several studies have shown that only 60%-70% of the patients are actually treated according to guideline recommendations [17]. This is due to various barriers that professionals may face when they try to incorporate CPGs into care practice [18]. For instance, a professional may not know the details of a particular CPG by heart, or may in certain cases disagree with its recommendations. Barriers can also be related to the CPG themselves (e.g., complexity of rules and recommendations), to the patient (e.g., patients may refuse therapies), to the organization (e.g., insufficient time or resources), or to other environmental factors (e.g., reimbursement policies).

Traditionally, CPGs are disseminated on paper among their target groups (e.g., via publication in a scientific journal). However, it has been found that providing care professionals with paper guidelines is not sufficient to enforce the required change in practice [19]. For this reason, several authors have argued that for effective guideline implementation carefully designed change strategies need to be applied [15;17]. Instruments that are frequently used as part of a change strategy include educational meetings, conferences, audit and feedback, and computerized decision support (CDS).
Chapter 1. General Introduction

Guideline-based computerized decision support

The provision of CDS has been found to be an effective instrument to let healthcare professionals make better decisions [15;17;20;21]. A medical CDS system is a computer program that provides patient-specific reminders, advice, or interpretation of data at the point of care [22]. Although the majority of evaluated CDS systems have proven effective in letting healthcare professionals make better decisions [20;21;23], these systems are still not in widespread use. This is due to technical factors (e.g., usability, flexibility, and stability of the system), human factors (e.g., attitude of professionals towards the use of computers, perceived usefulness of the system), and organizational factors (e.g., lack of incentives or support from the organization) [24]. It is even estimated that about half of all CDS system development projects fail in practice [25]. However, as the use of computers in health care is increasingly accepted the last years, it has become increasingly attractive to use CDS as part of a guideline implementation strategy.

To be able to provide guideline-based CDS, the CPG's recommendations for data gathering, data interpretation, and decision making need to be translated into a computer interpretable format, a process called guideline formalization. A formalized CPG should correspond to the original CPG and reflect the intentions of the guideline authors. However, CPGs often contain ambiguous concepts and recommendations, omissions, inconsistencies, and other errors [14;26-29]. Also, to automatically provide computerized decision support, vague concepts and recommendations in the CPG (e.g., 'low' or 'poor') need to be clearly delineated (e.g., 'low is lower than 3.0'). As CPGs are often formalized after their development, proper guideline formalization is difficult and time consuming without close collaboration with CPG authors due to these errors and vagueness in narrative CPGs [27;28;30-32].

Objective of this thesis

Many studies have evaluated the effect of CDS on decision making behaviour of individual healthcare professionals [20;23]. But although multidisciplinary settings are common in contemporary healthcare, to our knowledge, no studies have investigated the effect of CDS in such a setting. While individual decision making is mainly a cognitive process, decision making in teams is additionally influenced by the social context, such as the interpersonal relationships within the team [33;34]. Therefore, in multidisciplinary settings both CDS systems' requirements and effectiveness might be different.

The objective of the CARDSS project, described in this thesis, was to gain an understanding of aspects the development, deployment, and effectiveness of a
guideline-based computerized decision support system in multidisciplinary outpatient care. To this end, the following research questions were addressed:

Q1: How to develop a computerized decision support system that can assist professionals in working according to the Cardiac Rehabilitation Guidelines 2004?

Q2: Do cardiac rehabilitation professionals consider the developed system usable and useful in practice?

Q3: Does the provided computerized decision support improve implementation of the Cardiac Rehabilitation Guidelines 2004?

Thesis outline

The research questions above were addressed during different studies that were conducted as part of the CARDSS project. The results from these studies are described in the following chapters of this thesis, which are outlined below.

In Chapter 2 and Chapter 3, we describe two studies that were conducted to address research question Q1. In order to provide guideline-based CDS the guideline in question has to be formalized. In Chapter 2, we describe the guideline formalization strategy that was used to formalize the Dutch Cardiac Rehabilitation Guidelines 2004 and report on our experience with this strategy in practice. Chapter 3 describes the results of the requirements analysis and development process of the computer system that provides guideline-based decision support for cardiac rehabilitation: the CARDSS system.

Research question Q2 is addressed in Chapters 4 and 5. Chapter 4 describes results of a pilot study with the CARDSS system in four outpatient clinics to pilot test CARDSS’ usability in practice and verify the quality of the formalized guideline. In Chapter 5 the results of a more rigorous usability study amongst 63 CARDSS users from 27 different centres are described.

Finally, to answer research question Q3, a multi-centre cluster randomized trial with CARDSS was conducted. In this trial, multidisciplinary teams from 31 participating outpatient clinics were randomized to receive either of two versions of CARDSS: the full version providing CDS on guideline-recommended therapies, or a version that does not provide these therapy recommendations. This trial and the effect of the CDS on multidisciplinary team concordance to guideline recommended therapy decisions are described in Chapter 6. In Chapter 7 we determine the variation between centres in assessed patient needs for cardiac rehabilitation, and identify the influence of different measurement instruments on assessed needs. Chapter 8 describes a
Chapter 1. General Introduction

qualitative study amongst professionals in 21 centres that implemented CARDSS to understand the circumstances that influenced CDS' effectiveness.

This thesis concludes with Chapter 9, in which the results from the various studies described in this thesis are synthesized and discussed, and recommendations for further research are provided.

Reference List


Chapter 1. General Introduction


Chapter 2.

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

*Int J Med Inform. 2009; In Press*

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Arie Hasman
Anne-Margreet Strijbis
Niels Peek
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
A review is required to ensure the validity, clarity and applicability of the developed guideline.

<table>
<thead>
<tr>
<th>Guideline development process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set up a guideline development team</td>
</tr>
<tr>
<td>Identification and assessment of evidence</td>
</tr>
<tr>
<td>Interpretation and summarization of evidence</td>
</tr>
<tr>
<td>Deriving guideline recommendations</td>
</tr>
<tr>
<td>Guideline authoring</td>
</tr>
<tr>
<td>Guideline review</td>
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</tbody>
</table>

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
Chapter 2. A parallel guideline development and formalization strategy

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.

![Figure 3. Initial version of the flowchart summarizing the needs assessment procedure described in the national cardiac rehabilitation guidelines. Initial versions created by guideline authors often contained text-based decision logic.](image)

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
Chapter 2. A parallel guideline development and formalization strategy

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.

Reference List


Chapter 2. A parallel guideline development and formalization strategy


Chapter 3

Development of a guideline-based decision support system with explanation facilities for outpatient therapy

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Abstract
For effective guideline implementation it is recommended to develop and apply carefully designed implementation strategies and instruments. Computerized decision support systems (CDSSs) are such instruments as they can improve guideline adherence by providing advice at the point of care. To improve the implementation of the Dutch cardiac rehabilitation guidelines a CDSS, named CARDSS, was developed. CARDSS actively provides care professionals with patient-specific, guideline-based treatment recommendations at the onset of a patient’s rehabilitation trajectory. To maximize the chances of acceptance, CARDSS also provides explanation facilities and other additional information management services, and takes the working procedures specific to multidisciplinary outpatient care into account. CARDSS is currently used in over 40 Dutch cardiac rehabilitation outpatient clinics. This paper describes the development of the CARDSS system. In particular, technical issues are discussed concerning the delivery of active decision support, and the provision of advice rationales to users while taking account of dynamic clinical contexts and changing guidelines.
Introduction

Although clinical practice guidelines propagate best practices for specific healthcare conditions [1], adherence to guidelines in clinical practice is often low [2]. Apparently, it is not sufficient to provide care professionals with paper guidelines to enforce the required change in practice. For this reason, several authors have argued that effective guideline implementation requires that a carefully designed implementation strategy be followed [3;4]. One such strategy that has been advocated in the literature is the deployment of a computerized decision support system (CDSS) that provides advice to care professionals based on the guideline’s recommendations. Systematic reviews have shown that these CDSSs can improve guideline adherence [5;6].

The scientific literature discusses various aspects of guideline-based CDSS development. First, the paper guideline has to be translated into a computer-interpretable format in order to provide computerized guideline-based decision support [7], a process called guideline formalization. Second, design aspects of the CDSS should be carefully considered as several CDSS characteristics have shown to significantly contribute to their success [5;8]. These include providing decision support to professionals automatically, integration of the CDSS with other information systems, and provision of advice at the time and location of decision making. In addition, CDSS developers should consider letting the CDSS provide additional information management services, including providing professionals with the recommendation rationales and scientific foundations [8;9]. Finally, CDSSs should be optimally integrated into the existing working procedures of healthcare professionals which requires considering domain and application specific issues [9].

Many studies have focussed on the effects of guideline-based CDSSs on guideline adherence and patient outcomes [5]. However, success factors of CDSSs are still poorly understood [5;8-10], partly because descriptions of these systems are scarce. The literature has therefore called for a better reporting of design and development aspects of CDSSs [8].

This paper describes the development of an electronic patient information system with a CDSS for cardiac rehabilitation, named CARDSS (CArdiac Rehabilitation Decision Support System). Cardiac rehabilitation is a multidisciplinary outpatient therapy for patients that suffered a cardiac incident (e.g., myocardial infarction or cardiac surgery). The therapy aims to favourably influence the cause of disease, and to ensure that patients are in the best possible physical, psychological and social position to return to their normal place in society [11]. CARDSS was developed concurrently with a revision of the Dutch national guidelines for cardiac rehabilitation [12], with the aim to improve the implementation of these guidelines in clinical practice. It comprises a guideline-based CDSS that automatically provides guideline-based
Chapter 3. Development of CARDSS

Treatment recommendations to professionals at the onset of a patient’s cardiac rehabilitation trajectory. Specific attention is spent to the design and realization of explanation facilities, needed to support the decision making during weekly multidisciplinary team meetings. CARDSS can provide its users with advice rationales that remain consistent when clinical data or guidelines have changed.

This paper is organized as follows. The next section provides a review of the literature on the development, architecture and success factors of guideline-based CDSSs. Section 3 discusses the principle design considerations for CARDSS, while section 4 provides a description of its architecture and functionalities. The current status of CARDSS’ implementation is described in section 5, followed by a discussion of the lessons learned from this project. Finally our plans for further research are described.

Background

Guideline formalization

One particular challenge in contemporary medical informatics is to foster adherence to practice guidelines by providing guideline-based computerized decision support at the point of care. To this end, the guideline in question must be translated into a computer-interpretable format that can serve as the knowledge base of a CDSS [7;13]. Also an associated guideline execution engine that is able to execute and reason with this formalized knowledge, must be deployed [7].

In the last decade, several research groups have developed various guideline-formalization languages such as the Arden Syntax [14], ASBRU [15], GLIF [16], and others [17]. Although all guideline-formalization languages have their own specialties and features, most build on a hierarchy of guidelines and guideline steps (e.g., decisions and actions) that unfold over time, using concepts defined in domain-specific ontologies [18].

Several guideline-formalization languages come equipped with software tools to support the design, realization, and deployment of CDSSs. Examples are the Protégé editor to encode guidelines in GLIF [19] and the GLIF3 execution engine [20]. Moreover, several CDSS-development frameworks exist to support the entire engineering life-cycle of these systems, such as the PROforma [21], SAGE [22], and GASTON [23] frameworks.

Prior to the development of a guideline-based CDSS it should be decided which guideline-formalization language and tools will be used. Developers can develop some components themselves, use a separate guideline-formalization language, guideline modelling tool, and guideline execution engine, or use an existing CDSS-development framework.
Architecture of CDSSs

Generally speaking, if medical CDSSs are introduced in an existing application architecture, they must communicate with a host system and one or more (patient) databases [24;25]. The host system is the front-end application used by healthcare professionals in daily practice, which uses the services the CDSS provides (e.g., a computerized physician order entry (CPOE) system). When introduced in such architecture, the CDSS can operate in several ways. One possible mechanism is that the CDSS is triggered by the host system whenever a user's action requires verification or advice from the CDSS. This does require that the host system is functionally designed to support interaction with an (external) CDSS when necessary. However, there currently exist no communication or interface standards for this purpose and most host systems do not support such interaction [26]. Therefore triggering of the CDSS usually requires the deployment of an event monitor component, which actively monitors one or more clinical databases for the availability of new information that is relevant to the CDSS. However, this solution is inefficient as it leads to unnecessary network and database service utilization.

After the CDSS has been triggered, its recommendations or warnings should be communicated to the appropriate decision makers (e.g., in the case of a drug prescription, the prescribing doctor or pharmacotherapist). One possibility is to let the host system communicate these recommendations or warnings directly to its users. Again, this requires that the host system is functionally designed to accept messages from (external) systems such as a CDSS. However, also standardization on this issue is lacking and this type of functionality is therefore rarely supported by existing host systems. In these situations, the use of a notification server is required, which handles the communication of CDSS recommendations to the decision makers through, for example, e-mail, pop-ups, or pager.

CDSS success factors

During the last two decades, a large number of studies have addressed the effects of CDSSs on clinical practice. Systematic reviews found that active CDSSs, which provide unsolicited advice during the end-user's routine working procedures (e.g., while electronically ordering medication), are significantly more effective in improving practitioner performance than passive systems, which require end-users to recognize that consulting the CDSS would be useful [5;8]. In the systematic review by Kawamoto et al. [8], also system function turned out to contribute to effectiveness: therapy recommendations have more clinical impact than diagnostic advice. Also, the provision of decision support at the time and location of decision making, and CDSS
integration into the clinicians' workflow, have been found to contribute to the success of CDSSs [8;9;13].

In their systematic review on guideline-implementation CDSSs, Shiffman et al. [9] conclude that many factors influence their success or failure, and it is yet unclear which factors are decisive. They however state that, to increase the probability of success, users should be given something of value to compensate for the time required to learn and use the system. To maximize the usefulness of guideline-implementation CDSSs, Shiffman et al. recommend considering the implementation of various information management services [27], including explaining the rationale for guideline topics and recommendations via for example literature citations.

**Design Considerations**

To determine the requirements of CARDSS, one of the authors (RG) visited six cardiac rehabilitation outpatient clinics and participated in all meetings of the cardiac rehabilitation guidelines development committee in which requirements for the system were regularly discussed. The information management services described by Shiffman et al. [27] formed the starting point to determine the functional requirements of CARDSS.

As described in §2.3, a CDSS should interact with a front-end application (host system) and patient databases in order to provide patient-specific recommendations to the appropriate decision makers. However, the requirements analysis showed that no information system or database specific to cardiac rehabilitation yet existed in the Netherlands; most centres relied on paper-based or simple electronic (e.g. spreadsheet-based) patient records/registries. This circumstance required that, to implement a CDSS, also a host system a database had to be developed as a part of CARDSS.

Based on the requirements analysis it was decided that, to maximize the chances of acceptance, CARDSS was to support the entire process of cardiac rehabilitation. However, the focus of CARDSS was to support the process of assessing patients' needs for rehabilitation therapy and to improve adherence to the guidelines at this point. The guidelines describe a needs assessment and therapy indication procedure during which 15 to 40 patient items are assessed, which should be conducted for all cardiac patients two weeks after discharge from the hospital [12]. The needs assessment procedure is either conducted multidisciplinary, or by a single multidisciplinary team member (e.g., rehabilitation nurse, physiotherapist, rehabilitation specialist, dietician, psychologist, and social worker). During the needs assessment procedure, a preliminary therapy plan is formulated. The actual therapy decisions are made during
a weekly multidisciplinary meeting, after which patients start their rehabilitation programme, generally lasting six to sixteen weeks. The effect of therapy on patient recovery is individually assessed at the end of the rehabilitation programme.

Principal CDSS requirements

To foster adherence to the needs assessment procedure as described in the guidelines, it was decided to let CARDSS actively guide its users in conducting this procedure through a structured dialogue, prompting the user to enter the required patient information. Before making a decision on a patient’s rehabilitation programme, the CDSS should automatically show the rehabilitation therapies proposed by the guidelines (‘consulting model’, [28]).

It was also decided that, to support multidisciplinary needs assessment, it should be possible to start, interrupt, and continue the CDSS consultation at any time, and by different users. This requires that the status of the needs assessment process of individual patients can be reconstructed by the system. Multidisciplinary CDSS consultation also requires that data is stored on a central database server that is accessible to multiple client systems. However, simultaneous CDSS consultation for the same patient should never lead to inconsistent CDSS recommendations or database inconsistencies.

Explanation of relevance

The requirements analysis also pointed out the need to provide users access to relevant guideline sections and literature references during decision making: professionals indicated they are sometimes unaware of the relevance of certain needs assessment tasks, or of how these tasks should be interpreted. Scientific studies have shown that clinical users rarely consult clinical knowledge sources, even though they often have clinical information needs during patient encounters [29]. The reason is that it takes too much time to find the answers. By providing links to context-relevant resources, integrated into clinical information systems (infobuttons), clinical performance can be improved [29;30]. However, the literature on infobuttons mainly focuses on their integration with clinical information systems [29], and does not discuss how such functionalities should be implemented in a guideline-based CDSS.

The implementation of infobuttons in CARDSS first required that the cardiac rehabilitation guidelines were converted to an electronic, linkable, format. Second, links to relevant guideline sections for individual guideline steps needed to be included into the CDSS's knowledge base. Most guideline-formalization approaches allow for doing so, although this issue has received little attention in the literature
Third, the CDSS should be able to communicate the links, relevant to a specific needs assessment topic, to the host-system, which should provide this information to its users upon request. Therefore, a close coupling of the CDSS and the host-system is necessary.

**Explanation of rationale**

The actual decision making on a patient's therapy plan is made during the multidisciplinary meeting, based on the needs assessment conducted several days before. If the CDSS is to support this multidisciplinary decision making, it should also provide insight into the reasons for recommending particular therapies (i.e. answering the 'how'-question in traditional expert systems). Although it is recognized in the literature that providing such explanation facilities is important for CDSS adoption and guideline implementation [8;31], mechanisms to implement such functionalities are not discussed in the literature. To provide insight into the rationale for a recommendation, the 'chain of guideline steps' resulting in that recommendation needs to be reconstructed. As multiple paths in the guideline can lead to the same recommendation, this is not a trivial matter.

**Accounting for changing clinical data**

A relatively easy mechanism to reconstruct a recommendation's rationale is to let the CDSS re-execute the guideline, using the patient data available in the database. However, this may lead to inconsistencies if the clinical data underlying the recommendation have changed. In many clinical domains, it is a natural phenomenon that clinical data change over time as most clinical observations and measurements are inherently temporal. To avoid such inconsistencies, it is necessary to store some characteristics of recommendations.

One possibility is to store a recommendation together with its time of generation in a database, which makes it possible to use the original clinical data, underlying the recommendation, to re-execute the guideline and reconstruct the path of the guideline steps. This solution requires little additional data to be stored, but does involve, and places an additional load on, the CDSS' execution engine.

A second possible method to provide a recommendation's rationale is to simply store the recommendation and all the guideline steps that led to it. This solution does not require any involvement of the execution engine, and is therefore not affected by dynamic clinical data. However, for this solution more information needs to be stored in the database.
Accounting for changes in guideline content

Another important issue in the development of CDSSs is dealing with changes in guideline content [32]. As evidence from clinical studies accumulates, clinical practice guidelines often need revision in order to ensure that they still reflect the prevailing clinical opinion. When this happens, also the knowledge base of an associated guideline-based CDSS needs to be revised accordingly. Again, by simply re-executing the guideline, such changes in the system may lead to inconsistencies when the rationale of a past recommendation is requested, and the guideline steps on which the recommendation was based have changed. Dealing with this issue also requires that information concerning recommendations is stored.

One solution is to store each recommendation made by the system and the associated guideline version number in a database. Then, when a past recommendation’s rationale is requested by a user, the CDSSs can put the proper version of the formalized guideline into operation and re-execute it. This solution does need to be complemented with a mechanism that accounts for the problem of changing clinical data described in the previous subsection, and also requires that the CDSS’ execution engine is able to manage and reason with different guideline versions.

However, it is also possible to use the second mechanism to provide robust explanation facilities that was proposed in the previous subsection. When we store all recommendations inclusive of their underlying guideline steps in a database, the list of guideline steps underlying a specific recommendation can always be reconstructed, irrespective of whether the formalized guideline was updated: Updating the content of the guideline in the CDSS does not affect the information of the previously generated recommendations stored in the database. Again, this solution does require that more information is stored, but does not require any involvement of the CDSS’ execution engine to reconstruct the recommendation’s rationale.

Although both solutions are equally valid, in CARDSS we decided to implement a mechanism that did not require guideline re-execution, as the tools used to build CARDSS were unable to put different guideline versions concurrently into operation. The implemented mechanism is further explained in section 4.2.4.

Additional information management services

The requirements analysis pointed out that also documentation, registration, and presentation facilities [27] had to be incorporated in CARDSS to increase the chances of a successful adoption of the system by its users. To be able to evaluate progress in patients’ conditions during their rehabilitation programme, longitudinal assessment of patient data needed to be supported as well. Also, cardiac rehabilitation outpatient
clinics should be allowed to locally extend the standard data model with additional clinical or administrative data items, to make CARDSS usable as an electronic patient record. Finally, CARDSS had to support the analysis of group-based statistics related to demographic, cardiac rehabilitation, and guideline adherence information.

**System Description**

**The CARDSS Architecture**

To provide all the required functionalities, CARDSS consists of three different components, namely a CDSS, a host system, and a database. We will refer to the host system as Patient Information Management System (PIMS). The system architecture is shown in Figure 1. The concurrent development of the CDSS, the host system and database, made the development of separate (inefficient) clinical event monitor and notification server components unnecessary. These components would have been required if the CDSS were to communicate with existing host systems and databases in different outpatient clinics.

**CDSS development**

To facilitate the development, maintenance, and implementation of the CDSS, the GASTON CDSS-development framework [23;24] was used. GASTON is a state-of-the-art framework for building decision support systems, and consists of (i) an ontology-based guideline representation language, (ii) a guideline modelling tool that enables guideline authors to formally describe and easily modify practice guidelines visually, and (iii) a guideline execution engine. The designers of the GASTON framework were willing to provide personal assistance in the development of CARDSS.

To facilitate and improve guideline formalization, a medical informatics specialist (RG) participated in all meetings of the cardiac rehabilitation guidelines development committee, and co-authored the flowchart summarizing the needs assessment procedure, that accompanies the guidelines. Concept versions of the guidelines and the flowchart were used to build a domain-ontology in GASTON’s ontology editor. The summary flowchart was used as a basis for the formalization of the needs assessment procedure in GASTON’s knowledge acquisition tool, complemented with information from the written guidelines. Inconsistencies, omissions, or vague concepts that hampered proper formalization of the guidelines were discussed and adjusted during meetings with guideline authors. The resulting knowledge base was implemented in GASTON’s execution engine which together operated as a CDSS.
Figure 1. Architecture of the CARDSS software system. CARDSS consists of a CDSS, the PIMS (Patient Information Management System) host system, and the CARDSS database. The PIMS consists of a user-interface component, a business logic component, a database communication layer, and a CDSS communication layer that manages the communication between the PIMS and the CDSS.

**PIMS development**
The PIMS operates as front-end application that cardiac rehabilitation professionals use to conduct the needs assessment procedure and decide on cardiac rehabilitation therapies for their patients. To let CARDSS support professionals with conducting the needs assessment procedure via a structured dialogue, a direct communication interface between the PIMS and the CDSS was developed in cooperation with the vendor of the GASTON framework.

**CARDSS database development**
In CARDSS, the functionalities of the PIMS and CDSS are tightly interrelated, as it provides decision support to professionals through a structured dialogue. Therefore, we decided to store both clinical and CDSS-related information into a single database. This database consists of 26 tables and needs to be installed on each clinic's main server machine where CARDSS is used.

**The functionalities of CARDSS**
Figure 2 provides an overview of CARDSS' functionalities. On the left-hand side of the figure we find the four main functionalities, each of which is decomposed into several
sub-functionalities. CARDSS supports the work of cardiac rehabilitation professionals as follows. At the onset of a patient’s needs assessment procedure, the professional involved launches the CARDSS system and creates a new patient record in the PIMS by entering the patient’s demographic information. Subsequently the professional conducts the needs assessment procedure just like he or she used to, except that all relevant information is now recorded in CARDSS instead of onto paper. Several clinical assessment instruments, such as a quality of life questionnaire, are electronically available in CARDSS. The system automatically calculates and interprets their results. After the needs assessment procedure has been completed, the professional discusses the results with the patient, and records a preliminary rehabilitation plan in CARDSS. A paper report of the needs assessment can be printed. In the weekly multidisciplinary meeting, the preliminary rehabilitation plan is discussed and a joint decision regarding the plan is made. During these meetings CARDSS can be consulted. The final rehabilitation plan, including the starting dates of the rehabilitation therapies, is subsequently recorded into CARDSS.

During and after the rehabilitation programme, professionals can use CARDSS to evaluate the progress in the patient’s health condition in various ways: by re-assessing his or her quality of life, by assessing the progress with respect to the patient’s rehabilitation goals, and by re-assessing other items added to CARDSS’ standard data model (e.g., heart rate in rest). The results can be visualized in tables and in several types of charts.

Finally, professionals can generate population statistics for a given period, using either self-defined queries or queries defined by an SQL expert, of which the results can be visualized in tables and charts.

**Decision support during the needs assessment procedure**

Assisting professionals in collecting all patient information relevant to the needs assessment procedure is implemented in CARDSS as follows. When a user initiates (or continues) a needs assessment procedure, the PIMS activates the CDSS. Subsequently the CDSS executes the first (next) guideline step for which patient information is required, and queries the PIMS for the necessary patient information. If the requested information is available in the database (hence it was already entered earlier in the needs assessment procedure) it is returned to the CDSS. If not available, the PIMS prompts the user to enter the necessary information. Based on the information provided by the CDSS to the PIMS, the PIMS dynamically builds up each screen of the needs assessment dialogue. After the user has entered the necessary information, the PIMS sends this information back the CDSS, which then evaluates the next relevant
guideline step. This process continues until the needs assessment procedure is completed or interrupted.

Figure 2. Visual representation of the functionalities of CARDSS. Boxes represent functionalities. Arrows show how functionalities decompose into sub-functionalities. The ellipse represents a feature, part of the functionality it is attached to. Italics font indicates that the functionality or feature is CDSS related. CR = cardiac rehabilitation.

**Explanation of relevance**

To provide professionals with context-relevant guideline information during the needs assessment procedure, the guidelines were first converted into HTML. Second, in GASTON’s knowledge acquisition tool, links to relevant sections of the guidelines were added to the properties of individual guideline steps. These properties are communicated by the CDSS to the PIMS, which processes them and, when appropriate, shows the user that explanatory information is available by showing an infobutton next to the requested patient information. If the infobutton is pressed, relevant guideline information is shown to the user.

**Decision support in selecting cardiac rehabilitation therapy**

During the conduction of the needs assessment procedure, the CDSS regularly provides the PIMS with guideline-recommendations based on the information entered
Chapter 3. Development of CARDSS

by the users. This PIMS collects and manages these recommendations. If needs assessment data changes or additional information is added, for example by another user, recommendations are dynamically updated by the CDSS and processed by the PIMS.

Figure 3. Screen in which the rehabilitation programme is formulated based on therapy recommendations by the guidelines. The user can ask the system to provide the line of reasoning that has led to a particular recommendation by pressing the green ‘?’ button next. In this case the rationale behind the recommendation to give ‘Exercise therapy’ is shown.

When the needs assessment procedure has been completed, professionals must decide upon the therapies that the patient in question will follow during the rehabilitation programme. At this point, the PIMS automatically shows the rehabilitation therapies that are recommended by the guidelines. A sample screenshot is shown in Figure 3. Professionals may always choose to deviate from the guidelines’ recommendations – for instance based on patient preferences, or availability of therapy facilities.
Figure 4. Entity-relation diagram of the PIMS data model to provide guideline recommendations’ rationales, with entity attributes omitted for convenience. The data model implements a singly linked list with backpointers designed to store all recommendations made by the system, including the underlying chains of reasoning. The weak entity ‘Patient_GuidelineStep’ is an intersection table to implement a many-to-many relationship between the ‘Patient’ and ‘GuidelineStep’ entities. The same goes for the weak entity ‘Patient_Recommendation’. Both the ‘Patient_Recommendation’ and ‘Patient_GuidelineStep’ entities hold an attribute that references to their preceding ‘Patient_GuidelineStep’.

Explanation of recommendations’ rationale

When deciding upon the rehabilitation therapies that a patient will follow, users can request insight into the rationale of each individual recommendation, as shown in Figure 3. The functionalities to do so are implemented in the PIMS as they could not be provided by the version of GASTON that was available during the development of CARDSS. We recall from Section 3.3 that it was decided to store all recommendations provided by the system in a local database, including the chains of reasoning that led to those recommendations. This was done because the available version of GASTON was unable to put different guideline versions concurrently into operation.

In the cardiac rehabilitation guideline, it is always a list of consecutive guideline steps that underlies, and justifies, a recommendation. Because the number and type of guideline steps required to reach a recommendation varies from patient to patient, we cannot store this type of information in a flat table. Therefore a relational data model was designed for this purpose; the corresponding entity-relation is shown in Figure 4. As appears from the figure, all guideline steps that are assessed, and recommendations that are generated during a patient’s needs assessment procedure,
are stored in the database. In addition, with each stored item a reference to its
preceding (parent) guideline step is included. Therefore, this data model is actually an
implementation of a singly linked list with backpointers. The model data supports
chains of reasoning with variable length and supports the reconstruction of a
recommendation’s rationale irrespective of changed clinical data and updated
guideline content.

**Status report**

**Pilot study**

A prototype version of CARDSS was tested during a two month pilot study in four
different outpatient clinics in 2003 [33]. The number of patients enrolled in the pilot
study was 134. During this pilot study the system was quickly accepted by its users
and could be easily integrated into the clinical working procedures. From the pilot
study several adjustments and additional functionalities to the system were
formulated, including improvements in generating aggregated statistics, but also
adding a message-board to improve the communication between the different
healthcare providers and disciplines.

**Implementation**

In January 2004 the prototype version of CARDSS was presented concurrently with
the release of the guidelines at a national conference. During workshops, the system
was demonstrated to representatives of 62 different Dutch outpatient clinics. In July
2004 all 101 Dutch outpatient clinics were probed for their interest in using CARDSS
for the organization of their cardiac rehabilitation. Hospitals could buy the system for
€100,- or could participate in a cluster randomized trial to evaluate the effect of the
decision support on guideline adherence. CARDSS was released in January 2005 and is
currently being used in over 40 Dutch outpatient clinics.

**Lessons learned**

There exist a number of frameworks for implementing clinical practice guidelines in a
computer-interpretable and executable format, such as PROforma/Arezzo [21], SAGE
[22], and GASTON [23]. From a scientific point of view, the differences between these
frameworks are small, and they would probably have been equally suitable for the
development of CARDSS. In this project we decided to use the GASTON framework
[23] as its developers were able to provide personal support during the development
of CARDSS.
We have experienced that the tools from the GASTON framework can be successfully used to build a complete CDSS from guideline formalization to guideline execution. Its domain ontology editor and guideline modelling tools provide an easy and intuitive user-interface to formalize guideline knowledge. However, we had to involve the designers of the GASTON framework to build a custom communication interface that met our requirements to effectively integrate the decision support services provided by the GASTON execution engine in the PIMS.

As explained in Section 3, prior to CARDSS no information system was used in cardiac rehabilitation in the Netherlands, and therefore the system had to include not just decision support, but also a host system and database. This circumstance has considerably delayed the development process. However, it did enable the possibility to closely integrate CDSS functionalities with the host system, which was required to provide professionals with decision support concurrently with care. This type of workflow integration is known to be important for the effectiveness CDSSs [8;9]. However, we did have to develop a custom communication interface as no standards existed for this purpose [26]. Recently a HL7 draft standard interface specification for CDSS services was developed, known as the HL7 Decision Support Service standard [34]. To facilitate and stimulate the future development and implementation of CDSSs, we encourage the further development and use of such standards for CDSS integration into existing application architectures.

In this project, we implemented a mechanism to provide explanation facilities to CDSS users in the PIMS that did not rely on re-execution of the guideline by the CDSS, but instead built on storing chains of reasoning steps into a local database. This was done for pragmatic reasons, as GASTON's execution engine did not provide for such functionalities and could not put different guideline versions concurrently into operation1. However, the literature does not describe whether or how other CDSS execution engines can provide for such functionalities. Most CDSS come with explanation, and many studies have found that providing such facilities to CDSS users is important for improving guideline adherence [8;9;27;29-31]. Therefore, we recommend that more research should focus on the provision of explanation facilities, and that all CDSS execution engines should be equipped with such facilities. Also, we recommend that in future specifications of the HL7 Decision Support Service standard [34] the proposed communication interface includes provision of such explanation facilities.

Just as in many other western countries [35], the field of cardiac rehabilitation in the Netherlands is still professionalizing. Until the implementation of CARDSS, even no

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1 GASTON’s current version does support these functionalities
electronic patient record specific to cardiac rehabilitation was used in most outpatient clinics. These factors most likely facilitated the implementation of CARDSS, as it could help outpatient clinics to improve adherence to national guidelines’ recommendations. This assumption is supported by the fact that specialized rehabilitation clinics were less eager to implement CARDSS. These clinics had usually already developed a protocol for cardiac rehabilitation that was more detailed than the one described in the national guidelines. However, as standardization of cardiac rehabilitation was the aim of the Netherlands Heart Foundation, CARDSS does currently not support local guideline adaptations. As this has proven to be a barrier to the implementation of CARDSS in these specialized clinics, CARDSS should either support local guideline adaptations or the guidelines should be further elaborated to improve further implementation.

Another barrier limiting the implementation of CARDSS was that most Dutch specialized rehabilitation clinics already worked with information systems, but CARDSS was (and is) not interoperable with other information systems. Nowadays, also other CARDSS users often request such functionalities to avoid duplicate information entry. Therefore, future versions of CARDSS will support interoperability with other information systems to keep it being widely implemented.

**Future plans**

The reason for developing and introducing CARDSS was to improve adherence to the national cardiac rehabilitation guidelines. Although CARDSS was adopted by over 40 outpatient clinics in the Netherlands, this does not automatically mean that guideline adherence is increased. The cluster randomized controlled trial assessing the effect of the computerized decision support incorporated in CARDSS on guideline adherence is finished and its results are currently being analyzed. Results of this study will be reported elsewhere.

**Reference List**


Chapter 3. Development of CARDSS


Chapter 4

A pilot study with a computer-based guideline implementation system for cardiac rehabilitation

Based on Computers in Cardiology. 2005;32:323–326

Rick Goud
Arie Hasman
Nicolette de Keizer
Niels Peek
Abstract

Background: New national guidelines for cardiac rehabilitation (CR) were released in the Netherlands in 2004. To improve guideline implementation, a computer-based guideline implementation system with decision support functionalities, named CARDSS (Cardiac Rehabilitation Decision Support System) was developed concurrently. CARDSS assists in the decision making for CR goals and therapies by showing guideline recommendations to users. As system usability is critical for success, the objective of this pilot study was to evaluate CARDSS’ usability in practice.

Methods: A six-week pilot study with CARDSS was conducted in four CR centres. After the pilot study, CARDSS users were requested to fill in a questionnaire. As the new guidelines could also be a source for rejection of CARDSS, the questionnaire assessed users’ opinion separately on the guidelines and on CARDSS’ usability. In addition, all data stored in CARDSS, including log files, anonymized patient data, guideline recommendations, and therapy decisions were analyzed. Participants were interviewed to clarify findings.

Results: During the pilot study 134 patients were enrolled in CR with CARDSS. CARDSS was used by 11 different professionals. Five system bugs were identified which all could be resolved in one day. In addition, two problems with the guidelines were identified. Concordance to the guidelines on a patient level was 68% for CR therapies and 83% for CR goals. Overall, users were satisfied with CARDSS’ usability. Several changes were made to CARDSS after the pilot study, based on users’ recommendations.

Conclusion: Our results suggest that CARDSS is potentially feasible in practice. The high concordance of CR professionals to guideline-recommendations is promising, although the recorded data was not validated. To assess the effect of CARDSS on guideline concordance, a cluster randomized trial is being conducted amongst Dutch CR centres.
Introduction

Outpatient cardiac rehabilitation (CR) is a multidisciplinary rehabilitation and secondary prevention approach for patients who suffered a cardiac incident or underwent a cardiac intervention. The provision of CR is critical to both ensure that patients are in the best possible physical, psychological and social position to return to and maintain their normal place in society, and that their future cardiovascular risk is reduced [1-5]. CR has proven to be cost-effective in different economic evaluations conducted in North America and Europe [3]. However, in many Western countries CR services are under-utilized, poorly standardized and do not follow the available scientific evidence [3;6;7].

In the Netherlands cardiac rehabilitation is offered in about 100 outpatient clinics [8]. The first Dutch national guidelines for CR were published in 1996 [9]. Despite these guidelines, measurements showed that the CR programme offered to patients was often incomplete, the design was monodisciplinary instead of multidisciplinary, too little attention was paid to secondary prevention, and a great deal of eligible patients were not referred to CR [10]. With the aim to improve the provision of evidence-based cardiac rehabilitation and to reduce practice variation, new guidelines for CR were published in 2004 [11]. Consistent with international standards [2;3], these guidelines proclaim that cardiac patients should be offered an individualized multidisciplinary rehabilitation programme. To this end, the guidelines describe a needs assessment and therapy indication procedure which requires answering 15 to 40 questions about the patient's history and current situation. The answers give insight into the objective and subjective reduction of the patient’s physical capacity, the psychological and social functioning of the patient, and his or her risk behaviour. Several instruments, such as the questionnaire ‘quality of life for cardiac patients’ [12], are used to quantify the various aspects of the patient's condition. Eventually, it is determined which of 15 possible goals (e.g., ‘increase exercise capacity’, or ‘quit smoking’) should be set for the patient's rehabilitation programme and which of four different therapies (exercise, information, relaxation, and lifestyle change) are most appropriate for this purpose.

With the aim to increase concordance to the new CR guidelines, a computer-based guideline implementation system with decision support functionalities, named CARDSS (CArdiac Rehabilitation Decision Support System), was developed concurrently with the guidelines [13]. Systematic reviews on the effects of computerized decision support (CDS) have shown that CDS can improve practitioner performance and guideline concordance [14-17]. Known success factors for guideline-based CDS were taken into account during CARDSS’ development [13]. CARDSS actively assists its users, predominantly rehabilitation nurses and physiotherapists, in making therapy decisions for CR patients in concordance with the guideline
recommendations. Therefore CARDSS prompts users to assess and enter the necessary patient information, determines each patient's rehabilitation needs, and assists in formulating a patient-specific rehabilitation programme [13]. In addition, it provides various patient information management services (e.g., administration functionalities, visualisation of patient progress, and management reports) to users. The objective of this pilot study was to evaluate both the new guidelines and the usability of CARDSS in clinical practice.

Methods
To evaluate the feasibility of CARDSS, a six-week pilot study with the system was conducted in several Dutch CR outpatient centres. During the pilot study, CR professionals were requested to use the CARDSS software for assessing all their patients' needs for CR and select the CR goals and therapies that according to them are relevant for the patient concerned; the CARDSS system did show which CR goals and therapies the guidelines would recommend for the patient based on the collected needs assessment data. In addition, professionals were free to use CARDSS' other functionalities such as printing patient reports, generating management reports, and evaluating the progress of patients during the CR programme.

Participants
To be able to provide quick hands-on assistance in case of problems, it was decided to include only centres in the proximity of the Academic Medical Centre in Amsterdam, from which the pilot study was coordinated. Four centres in the Amsterdam region were invited to participate in the pilot study. All these centres accepted our invitation and agreed to actively use the CARDSS system for the needs assessment of every CR patient during the pilot study.

Study enrolment
Prior to the pilot study, one of the researchers (RG) assisted the ICT department of the participating centres in installing CARDSS on either one or more local computers or the hospital network. At the start of the pilot study users received a two-hour training course on working with CARDSS.
Since CARDSS was not yet used in a clinical setting, it was decided to start with the pilot study in the participating centre nearest to the Academic Medical Centre in Amsterdam. After ten days the other three centres were enrolled in the pilot study, with two to four days between each enrolment.
Data

Several sources of information were used to evaluate the usability and usefulness of CARDSS. First, CARDSS’ log files were analyzed to retrieve information on user logins and technical anomalies like system crashes. Secondly, concordance of the multidisciplinary team decisions with the guidelines was determined for all CR goals and therapies individually. Concordance was defined at patient level and implied treating patients who should have been treated and not treating patients who should have been untreated, according to the guideline. In addition, we determined the number of patients that were undertreated (withholding treatment from patients who should receive it) and overtreated (treatment of patients who should be left untreated).

Also, questionnaires were given to the caregivers at the end of the pilot study. The questionnaire addressed two different aspects: (i) users’ opinion on the recommendations of the guideline, (ii) users’ opinion on the usability of CARDSS and its decision support functionalities. The questions from the second section were partially based on the work of Trivedi et al. [18] but the questions were translated to Dutch and adapted to our situation. During personal interviews caregivers were asked to clarify some findings and provide suggestions for system improvements.

Results

During the pilot study a total of eleven caregivers used CARDSS during a period of six to eight weeks in the period of September to December 2003. Table 1 shows some general information on the use of the CARDSS software during the pilot study. The users found a total of five bugs in the system, each of which could be fixed within one day. Two bugs (i.e. not being able to enter text with an apostrophe, and not being able to adjust previously entered patient information) occasionally led to a crash of CARDSS, but no patient information was lost.

<table>
<thead>
<tr>
<th>Table 1. Information about the use of the software during the pilot study.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospital A</strong></td>
</tr>
<tr>
<td># caregivers</td>
</tr>
<tr>
<td># times logged in</td>
</tr>
<tr>
<td># bugs found</td>
</tr>
<tr>
<td># times telephonic or personal assistance provided</td>
</tr>
</tbody>
</table>

The number of patients enrolled in CARDSS during the pilot study was 134 as shown in Table 2. A total of 415 therapies was recommended. For 40 patients, one or more
Chapter 4. A pilot study with CARDSS

recommended therapies were not selected, and in three cases a not-recommended therapy was selected. In sum, concordance to the guidelines on a patient level was 68% for rehabilitation therapies. Table 2 shows that Hospital B and Hospital D often decided not to offer patients a therapy that was recommended by the guideline. During interviews the professionals from these hospitals indicated that this non-concordance to guideline recommendations was predominantly caused by the fact that they were unable to provide lifestyle change therapy to their patients due to a lack of facilities. When discarding the therapy decision in which a lack of facilities was the reason for non-concordance, guideline concordance was over 95%.

<table>
<thead>
<tr>
<th>Table 2. Information on the number of patients included in the pilot study and on the therapies and goals recommended by the guidelines and selected by the users.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No patients screened</strong></td>
</tr>
<tr>
<td><strong>Therapies</strong></td>
</tr>
<tr>
<td># Therapies recommended (avg per patient)</td>
</tr>
<tr>
<td># Recommended therapies not selected (%)</td>
</tr>
<tr>
<td># Not recommended therapies selected</td>
</tr>
<tr>
<td><strong>Goals</strong></td>
</tr>
<tr>
<td># Goals recommended (avg per patient)</td>
</tr>
<tr>
<td># Recommended goals not selected (%)</td>
</tr>
<tr>
<td># Not recommended goals selected</td>
</tr>
</tbody>
</table>

A total of 1024 rehabilitation goals was recommended by the system. For 22 patients, one or more goals that were recommended by the guidelines were not selected by the user, and for six patients, one or more goals were added to the ones recommended. In sum, concordance to the guidelines on a patient level was 83% for rehabilitation goals. However, professionals from hospital A, B, and C stated during interviews that they were not always consistent in adding or removing goals to patients’ rehabilitation plans. Data on concordance to goals might therefore be unreliable.
Table 3. Users’ opinion on the usability and feasibility of CARDSS

<table>
<thead>
<tr>
<th></th>
<th>Totally agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Totally disagree</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The system response times are fast enough.</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2. It is not hard to learn the working of the software</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3. Before the start of this pilot, I already had some general computer skills.</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>4. The colours and layout make the software attractive.</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5. The images and icons clarify the use and functionalities of the software.</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6. I can get to the required information without much effort.</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>7. The reports that can be printed are complete and clear.</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>8. The software is fun to work with.</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>9. Software functionalities are in line with our way of working.</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10. I found that using the system was useful.</td>
<td>3</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>11. The software makes the narrative guideline more comprehensible</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12. The software stimulated the use of the guideline and the decision tree.</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

NA = No answer

At the end of the pilot study, seven of the eleven questionnaires were returned. In one centre, three users jointly filled in one questionnaire. In another centre, two professionals did not fill in a questionnaire because they were too inexperienced with CARDSS to answer the questions.

Prior to this pilot study, only one of the participating CR professionals was familiar with the content of the revised needs assessment procedure described in the CR guidelines 2004. The majority of professionals (5/7) found that the CR guidelines 2004 were an improvement to the 1995/1996 guidelines. They found the quality of life questionnaire very useful for doing part of the screening (5/7), but several professionals considered guideline recommendations regarding the objective assessment of a patients’ exercise capacity (4/7) and the assessment of patient’s risk behaviour (3/6) not easily applicable in practice. For the objective assessment of a patients’ exercise capacity, the guidelines recommended conducting either of two exercise tests. However, professionals from two of the participating pilot hospitals...
Chapter 4. A pilot study with CARDSS

indicated that they lacked the facilities to carry out either of the two recommended exercise tests. Second, professionals indicated during interviews that in their opinion, the assessment of patient’s risk behaviour resulted in lifestyle change therapy being recommended too often by the guidelines. Upon analysis of the quantitative data of CARDSS, an inconsistency was discovered in the assessment of risk behaviour in the guidelines: a contra-indication for group-based therapy (e.g., emotional or social instability) was assessed in one part of the needs assessment procedure, but was not taken into account when recommending group-based lifestyle change therapy. This incidentally resulted in the lifestyle change therapy being recommended although a contra-indication existed.

Table 3 shows that the users were satisfied with the usability of CARDSS and the way that decision support was provided to users. Response times were fast enough (7/7) and it was easy to use (7/7) even though some caregivers indicated that they had hardly any experience with computers before the pilot study (3/7). The graphics made the software attractive (7/7) and the interfaces were logical and complete. The software was fun to use (5/7). Most caregivers agreed that the software makes the decision tree more comprehensive than the paper version (5/7). All of the respondents finally indicated that they would like to continue using CARDSS in their institutions if minor additional functionalities would be implemented (7/7). Some of the ‘minor’ additional functionalities to CARDSS proposed by professionals during the interviews were:

- It should be possible to collect patient information that is not described in the guideline’s needs assessment procedure, but that institutions or individual professionals consider relevant to properly conduct or evaluate the patient’s rehabilitation programme.
- It should be possible that patient’s quality of life questionnaire is filled in multiple times, for example during and after the rehabilitation programme, to evaluate the patient’s progress made during the rehabilitation programme.

Discussion

This paper described a pilot study that was conducted to evaluate the feasibility of the CARDSS guideline implementation system for CR. CARDSS’ users were positive about its functionalities and the way it provided decision support based on the recommendations of the CR guidelines 2004. All participating professionals indicated that they wanted to continue using CARDSS if minor additional functionalities were implemented. Results on guideline implementation were encouraging, with a guideline concordance of 68% for CR therapies on patient level. Adjusted for a lack of
facilities, guideline concordance is even above 95%, which is much higher than expected based on earlier measurements [19].

Several factors may have biased our results on guideline concordance. The pilot study was conducted to evaluate the feasibility of CARDSS and not to measure the actual guideline concordance of the teams in the four CR centres. Therefore no data audit was conducted to verify the quality of the data in CARDSS. Although all caregivers indicated they had accurately specified in CARDSS which therapies were offered to patients, this information could be unreliable. Therefore, it is possible that recommendations of the system were not followed without this fact being recorded in the CARDSS' database. Also, guideline concordance may have been positively influenced by the 'volunteer' and Hawthorne effects and a selection bias [20]. Finally, the findings on the effect of CARDSS are limited by the fact that we used no control group to determine the concordance level without the system or to measure the role of the 'checklist effect' [20].

With the help of the pilot study, two problems with the new guidelines were indentified. As CARDSS carries out the recommendations of the guidelines and therefore also includes these errors, this may have negatively influenced the opinion of users towards CARDSS' usability. The pilot study with CARDSS was conducted prior to the release of the guidelines. Therefore, the identified problems in the guidelines could be discussed during meetings with the guideline authors who resolved these issues prior to guideline publication: a third possible exercise test was introduced that could be performed by all hospitals and the erroneous recommendation was adjusted. Subsequently, also in an update of CARDSS these issues were addressed.

To be effective in improving guideline implementation, CARDSS should first be adopted in practice. System usability and usefulness are critical issues that determine whether or not the systems will actually be adopted in practice [17;18]. However, the new guidelines might also be a reason for rejection of CARDSS. As CARDSS was developed concurrently with the guidelines, they were not yet officially published and also not validated in a clinical setting with real patients. Therefore, the guidelines may not be optimally applicable in daily practice, professionals might disagree with certain choices made by the guidelines, or possible errors or contradictions may still exist. The pilot evaluation study results suggest that CARDSS meets the requirements of daily practice and that caregivers involved in CR are satisfied with the system's functionalities.

Currently, a large-scale cluster randomized trial is conducted among Dutch CR centres to rigorously assess the effect of the computerized decision support incorporated in CARDSS on guideline concordance. To adjust for potential sources of bias, the participating CR centres will either work with an intervention version of CARDSS,
having full functionality, or with a control version, which comprises patient records and information management services but provides no decision support. Both versions of CARDSS record patient data, guideline-based recommendations, and rehabilitation therapies that are actually pursued in each patient's programme. After a period of six months, the effect of receiving guideline-based recommendations on guideline concordance is assessed by comparing the data that have been recorded in the two arms of the trial. If the computerized decision support does enhance concordance, then future costs for maintaining and updating CARDSS are justified by more effective rehabilitation programmes.

Reference List


Chapter 5

Subjective usability of the CARDSS guideline-based decision support system

*Stud Health Technol Inform. 2008;136:193-8*

Rick Goud
Monique Jaspers
Arie Hasman
Niels Peek
Chapter 5. Subjective usability of CARDSS

Abstract

Clinical decision support systems (CDSSs) differ from other health information systems in their aim to directly influence the decision-making behaviour of healthcare professionals. As a result, CDSSs face additional challenges with respect to user acceptance. The objective of this study was to investigate subjective usability of a guideline-based CDSS for outpatient cardiac rehabilitation. The system, named CARDSS, was previously found to be effective in improving guideline adherence of rehabilitation professionals in a cluster randomized trial.

To assess CARDSS' usability, a modified version of the IBM Computer System Usability Questionnaire was sent to all 68 professionals from the 28 outpatient clinics that participated in the trial. The questionnaire was returned by 63 respondents (93%) from 27 clinics. Factors that influenced CARDSS' usability were identified using linear regression analysis.

Analysis showed that professionals who managed to smoothly integrate the system with their daily routine were more satisfied with ease of system use. Furthermore, a positive attitude of respondents towards CDSSs in general and a better agreement with the content of the national guidelines were positively correlated to satisfaction with CARDSS' overall usability and each of its sub-domains.
Introduction

Although clinical guidelines describe evidence-based best practices for specific healthcare conditions, adherence to guidelines in clinical practice is often found to be low [1]. Guideline-based computerized decision support systems (CDSSs) have proven to potentially be effective instruments for improving guideline adherence [2]. These CDSSs provide patient-specific recommendations to care professionals based on the guideline's recommendations. Despite of their potential benefit, however, CDSSs are still not widely adopted in healthcare [3].

Poorly designed CDSSs can lead to usability problems, users' dissatisfaction and may disrupt normal flow of clinical activities. So whether an information system will be adopted in medical practice depends, among other things, on the 'fit' between technology, user, and the tasks that need to be performed [4;5]. Evaluating users' satisfaction with the usability of the system in question is important to understand if and how such fit was achieved [6], also for CDSSs [7]. However, it is unknown what influences users' satisfaction with the usability of CDSSs [2] as CDSSs have been predominantly evaluated using quantitative methods that can not explain why the system was or wasn't adopted [2;3].

Guideline-based CDSSs differ from other health information systems in that they aim to increase guideline adherence by influencing the behaviour of professionals. This makes that the factors influencing users' satisfaction with CDSS usability may also differ. Users' satisfaction with CDSS usability is presumably dependent on the general attitude of professionals towards being advised by a software system in their daily practice [5]. Novice professionals, who have little experience with prevailing protocols and guidelines, might be more open to advice than their more experienced colleagues. Also care professionals' attitude towards the guidelines underlying the CDSS may be critical to their satisfaction with a CDSS' usability. CDSSs that are well integrated into the existing working procedures and decision-making processes of healthcare professionals have proven to be more effective in terms of adherence to standards [8]. One may conjecture that the underlying mechanism is usability.

In this paper we report on a usability study that was carried out with a guideline-based CDSS for cardiac rehabilitation in the Netherlands, called CARDSS (CArdiac Rehabilitation Decision Support System). Cardiac rehabilitation is a multidisciplinary therapy that is provided after cardiac events (e.g. myocardial infarctions) and cardiac interventions (e.g. heart surgery). CARDSS actively guides professionals (primarily nurses and other paramedics) with conducting the needs assessment procedure for cardiac rehabilitation described in the national guidelines. This proceeds through a structured dialogue, prompting the professional to enter the necessary patient information and proposing the rehabilitation therapies that are considered
appropriate for the patient in question (‘consulting model’, [9]). Following the recommendations in the literature, CARDSS also provides various additional patient information management services and CARDSS’ design takes into account the working procedures specific to multidisciplinary outpatient care [8;10].

Recently a cluster randomised trial was carried out in 31 Dutch outpatient clinics to evaluate the effect of CARDSS on guideline adherence. The participating clinics either worked with an intervention version of the system that included decision support functionality, or with a control version that lacked decision support but otherwise had the same functionalities. Initial results of this trial show that the CDSS increased adherence to the guideline; detailed results will be published elsewhere.

To gain understanding in why and in what way CARDSS was effective, we evaluated which factors specific to CDSSs influenced our users’ satisfaction with CARDSS. This paper describes the results of this evaluation, which can help to understand which factors are important for the adoption of CDSSs in multidisciplinary outpatient settings aiming to influence the behaviour of non-physicians.

**Methods**

To evaluate the usability of CARDSS, a questionnaire was developed based on the IBM Computer System Usability Questionnaire (CSUQ) [11]. The CSUQ is developed to measure satisfaction of software users with respect to system usability, and contains 19 items related to users’ satisfaction with ease of system use, the quality and clarity of information and error messaging provided by the system, and the system’s interface quality. Each of the items is rated on a 7-point Likert scale. We excluded two items concerning the error handling of CARDSS in the calculation of scores for the ‘information quality’ subscale as we considered them non-specific to users’ satisfaction with a CDSS’ information quality.

To identify factors that influenced CARDSS’ usability, questions were added referring to the respondents’ clinical experience with cardiac rehabilitation, the way they integrated CARDSS in their working procedures, and the time increase per patient caused by using the system. In addition, questions were added to assess the respondents’ agreement with the content of the national cardiac rehabilitation guidelines (12 items) and their general attitude towards the use of CDSSs in healthcare (2 items). These latter items were also rated on a 7-point Likert scale. Also basic questions on the respondents’ age, gender, and computer literacy were included. For details of the entire questionnaire, we refer the reader to [12].

Questionnaires were sent to all 28 outpatient clinics that completed the trial with CARDSS and were asked to let professionals that worked with CARDSS fill in and
return the questionnaire. The questionnaire took about 15 minutes to complete. Respondents were allowed to answer ‘not applicable’ if they felt they had insufficiently worked with CARDSS to answer the question concerned. For each respondent we calculated the average scores for overall usability (19 items), ease of system use (subscale, 8 items), information quality (subscale, 5 items) and interface quality (subscale, 3 items). Average scores were also calculated for professionals’ agreement with the content of the national guidelines and their attitude towards CDSS in general. To analyze which factors influenced CDSS subjective usability, we performed univariate linear regression analysis adjusting for age, gender, study arm (intervention or control), and computer literacy of the respondents to correct for possible confounding. To correct for multiple testing a p-value of 0.01 was considered statistically significant.

Results

Table 1. Summary of questionnaire results

<table>
<thead>
<tr>
<th></th>
<th>n/a</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (mean ± SD)</td>
<td>–</td>
<td>42.8 ± 8.2</td>
</tr>
<tr>
<td>Male gender (%)</td>
<td>–</td>
<td>32%</td>
</tr>
<tr>
<td>Self-judged computer experience</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>Low literacy (%)</td>
<td></td>
<td>11 (18%)</td>
</tr>
<tr>
<td>Moderate literacy (%)</td>
<td></td>
<td>34 (54%)</td>
</tr>
<tr>
<td>High literacy (%)</td>
<td></td>
<td>18 (29%)</td>
</tr>
<tr>
<td>Clinical experience, years (median [interquartile range])</td>
<td>–</td>
<td>5 [2.5-14]</td>
</tr>
<tr>
<td>Integration of CARDSS into clinical workflow</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Concurrent: use CARDSS during patient visit (%)</td>
<td></td>
<td>16 (27%)</td>
</tr>
<tr>
<td>Serial: fill in paper during patient visit and use CARDSS afterwards (%)</td>
<td>44</td>
<td>69%</td>
</tr>
<tr>
<td>Time spend on needs assessment procedure per patient, minutes (median)</td>
<td>5</td>
<td>40-50</td>
</tr>
<tr>
<td>Time increase caused by CARDSS, minutes (median [interquartile range])</td>
<td>9</td>
<td>10 [0-10]</td>
</tr>
<tr>
<td>Agreement with content of cardiac rehabilitation guidelines (mean ± SD)</td>
<td>3</td>
<td>5.07 ± 0.72</td>
</tr>
<tr>
<td>Attitude towards use of CDSSs in general (mean ± SD)</td>
<td>3</td>
<td>5.65 ± 1.26</td>
</tr>
<tr>
<td>Overall usability (mean ± SD)</td>
<td>–</td>
<td>5.10 ± 0.85</td>
</tr>
<tr>
<td>Ease of system use (mean ± SD)</td>
<td>–</td>
<td>5.14 ± 1.08</td>
</tr>
<tr>
<td>Information quality (mean ± SD)</td>
<td>2</td>
<td>5.05 ± 0.87</td>
</tr>
<tr>
<td>Interface quality (mean ± SD)</td>
<td>3</td>
<td>5.10 ± 1.18</td>
</tr>
</tbody>
</table>

63 out of 68 (93%) cardiac rehabilitation professionals from 27 (out of 28) outpatient clinics returned the questionnaire (18 intervention centres, 41 respondents; 9 control centres, 22 respondents). Table 1 presents the summary results for the questionnaires. For the agreement with the content of cardiac rehabilitation guidelines and their attitude towards CDSS in general.
guidelines and the general attitude towards use of CDSSs a score (near) 1 indicates respectively a low agreement and negative attitude, while a score (near) 7 indicates respectively a high agreement and positive attitude. For the satisfaction with overall usability and each of its subscales a score (near) 1 indicates a low satisfaction and a score (near) 7 indicates a high satisfaction. There were no significant differences in characteristics and scores between respondents that worked with the intervention version and those who worked with the control version of CARDSS. Table 2 shows the results of the univariate linear regression analyses on factors influencing user satisfaction with CARDSS’ overall usability and its subscales.

Table 2. Results of univariate linear regression analyses to identify factors that influence usability

<table>
<thead>
<tr>
<th></th>
<th>Ease of system use (B ± SE)</th>
<th>Inform. quality (B ± SE)</th>
<th>Interface quality (B ± SE)</th>
<th>Overall (B ± SE)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, per 10 years increase</strong></td>
<td>-0.19 ± 0.17</td>
<td>-0.12 ± 0.14</td>
<td>-0.13 ± 0.19</td>
<td>-0.15 ± 0.13</td>
</tr>
<tr>
<td><strong>Female sex</strong></td>
<td>0.05 ± 0.30</td>
<td>0.14 ± 0.24</td>
<td>0.32 ± 0.32</td>
<td>0.10 ± 0.23</td>
</tr>
<tr>
<td><strong>Intervention arm</strong></td>
<td>0.09 ± 0.29</td>
<td>0.22 ± 0.23</td>
<td>0.31 ± 0.32</td>
<td>0.17 ± 0.23</td>
</tr>
<tr>
<td><strong>Computer literacy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low literacy ‡</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Moderate literacy</td>
<td>0.09 ± 0.38</td>
<td>0.34 ± 0.30</td>
<td>-0.06 ± 0.43</td>
<td>0.09 ± 0.30</td>
</tr>
<tr>
<td>High literacy</td>
<td>0.29 ± 0.42</td>
<td>0.37 ± 0.33</td>
<td>-0.22 ± 0.47</td>
<td>0.19 ± 0.33</td>
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<tr>
<td><strong>Clinical experience †</strong></td>
<td></td>
<td></td>
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<tr>
<td>4 years or less</td>
<td>0.78 ± 0.45</td>
<td>0.40 ± 0.37</td>
<td>0.28 ± 0.55</td>
<td>0.62 ± 0.36</td>
</tr>
<tr>
<td>5 to 12 years</td>
<td>0.40 ± 0.42</td>
<td>0.54 ± 0.35</td>
<td>0.23 ± 0.51</td>
<td>0.47 ± 0.33</td>
</tr>
<tr>
<td>more than 12 years ‡</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td><strong>Time increase by CDSS †</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No time increase</td>
<td>1.22 ± 0.39 *</td>
<td>0.25 ± 0.38</td>
<td>1.18 ± 0.54</td>
<td>0.83 ± 0.31 *</td>
</tr>
<tr>
<td>1 to 10 minutes</td>
<td>0.81 ± 0.36</td>
<td>0.44 ± 0.36</td>
<td>1.08 ± 0.51</td>
<td>0.75 ± 0.29</td>
</tr>
<tr>
<td>more than 10 minutes ‡</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td><strong>Workflow Integration CARDSS †</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concurrent use</td>
<td>1.08 ± 0.39 *</td>
<td>0.57 ± 0.34</td>
<td>0.75 ± 0.47</td>
<td>0.71 ± 0.31</td>
</tr>
<tr>
<td>Serial use ‡</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td><strong>Attitude decision support †</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agreement guideline content †</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

†: Adjusted for Age, Sex, Intervention arm, and Computer literacy
‡: reference category
*: Statistically significant at level p<=0.01
Discussion

In this study we analyzed which factors were related to subjective usability of CARDSS, a CDSS for outpatient cardiac rehabilitation. Several statistically significant associations were found.

Rehabilitation professionals that use the CARDSS system in their clinic are free to consult the system simultaneously with patient visits or to work on paper during visits and consult the system afterwards. Simultaneous consultation will often be more efficient as it avoids duplicate registration (on paper and electronically). Moreover, when the system is consulted afterwards, it may ask for patient items that were not discussed during the visit, creating an awkward situation. It is not surprising, then, that simultaneous users found the system more easy to use, as this is known to be related to integration of a system with users’ workflow patterns [13]. Similarly, professionals who reported that using the system caused no time increase were more satisfied with CARDSS’ ease of use. In this case, however, it is unclear whether poor workflow integration caused extra time and therefore dissatisfaction with the system, usability problems led to poor integration and time increase, or perhaps a mixture of both scenarios occurred.

We also found that CARDSS users who held a positive attitude towards CDSSs in general, or better agreed with the content of the national guidelines, found the system more usable than others. These results touch upon the concepts of usability and usefulness. High system usability does not directly imply that users likewise would perceive a system as useful. In the present case, however, subjective usability and subjective usefulness appear to be firmly related. It should be noted though that our usability study was conducted after users had worked with the system for at least six months, and we do not know their earlier opinions. So, our results could suggest that users who generally perceived CDSSs as useful better appreciated the usability of CARDSS, but also that users who were satisfied with CARDSS developed a positive attitude towards CDSS in general. Similarly, agreement with the guidelines underlying CARDSS may have caused users to find the system more usable, but it may also have been the other way round.

In this study we also analyzed the relation between clinical experience and subjective CDSS usability as we hypothesized that novice professionals, who have little experience with prevailing protocols and guidelines, might be more open to advice than their more experienced colleagues. Although our analyses indeed show that the clinical experience of professionals is negatively correlated to satisfaction with CARDSS’ usability, this correlation was not found to be statistically significant.
A limitation of this study is that questionnaires were only filled in by users from clinics that completed the CARDSS trial, and not by users from clinics that dropped out of the trial. At the start of the trial, four outpatient clinics that were assigned to the control arm of our study quit their participation because they reported that the benefits of using CARDSS without receiving guideline-recommended therapies did not outweigh the effort of learning to work with CARDSS. These users worked with CARDSS too short a time to judge its usability. However, as their reasons for not using the system were related to experimental conditions of usage during the trial and not to properties of the system itself, we do not believe that their exclusion has biased our findings.

The statistical analyses of this study assume that the points on a discrete Likert scale are equidistant, and that averaged responses from such a scale approximately follow a Normal (Gaussian) distribution. The latter assumption may be easily violated at the extremes of the response interval (1 through 7). Although most responses clearly indicate positive agreement (attitude/satisfaction), extreme responses were rare, and therefore these assumptions seem warranted in the present investigation.

In our study, some factors showed no statistically significant relation to the individual domains of subjective usability. However, the statistical power of our analysis is limited by our 63 respondents. Sample size calculation shows that we could have detected a difference between groups in subjective usability of 0.83 for CARDSS’ workflow integration, and 1.01 for computer literacy, clinical experience, and time increase by CDSS, when allowing Type I and Type II error risks of 0.01 and 0.20, respectively, and using the average standard deviation of 0.97. Therefore, if these factors do have an effect on subjective usability, the actual differences between groups are below one. We consider this limitation acceptable as such a difference would in many cases be smaller than one Lickert-scale unit.

**Conclusion**

Several systematic reviews have tried to identify factors that are related to the effectiveness of CDSSs in terms of improving adherence to standards [2,8]. To be effective in this sense, a system must first be adopted by practitioners, but there is little knowledge on factors that influence CDSS adoption [3]. This study contributes to the understanding of such factors.

The results of this study show that the subjective usability of an active, guideline-based CDSS consulted by non-physicians in an outpatient setting is related to workflow integration, general attitude towards CDSS, and agreement with the content of the guidelines that underlie the knowledge base.
Based on our findings we recommend CDSS developers and implementers to pay special attention to CDSS workflow integration to increase chances on successful system adoption. To further improve CDSS adoption, we recommend CDSS implementers to develop and apply educational strategies to improve sceptical future users’ general attitude towards CDSSs and agreement with the guideline underlying the CDSS. These recommendations apply to active, guideline-based CDSSs consulted by non-physicians at outpatient clinics, but they may well generalize to other settings.

Reference List

Chapter 6

The effect of guideline-based computerised decision support on decision making of multidisciplinary teams: A cluster randomised trial in cardiac rehabilitation

*British Medical Journal. 2009; In Press*

Rick Goud
Nicolette de Keizer
Gerben ter Riet
Jeremy Wyatt
Arie Hasman
Irene Hellemans
Niels Peek
Abstract

Context: Multidisciplinary cardiac rehabilitation is critical to physical and psychosocial recovery and cardiovascular risk reduction in cardiac patients, but its provision is still insufficiently evidence-based in many Western countries. Computerised decision support is an effective instrument to improve guideline concordance of individual professionals. However, its effect in multidisciplinary settings is still unknown.

Objective: To determine the extent to which computerized decision support can improve multidisciplinary team concordance with guideline-recommended therapy decisions.

Design: Multi-centre cluster randomised trial.

Participants: Multidisciplinary cardiac rehabilitation teams in Dutch centres and their cardiac rehabilitation patients.

Interventions: Teams were randomised to receive an electronic patient record system with or without additional guideline-based decision support. Teams were enrolled between January and December 2005. All teams were required to electronically document their therapy decisions for all patients visiting the cardiac rehabilitation outpatient centre for at least six months.

Main outcome measures: Concordance with guideline recommendations was assessed for two standard rehabilitation therapies, exercise and education therapy, and for two new but evidence-based rehabilitation therapies, relaxation and lifestyle change therapy. Concordance data were analysed using generalised estimating equations to account for intra-cluster correlation, and were adjusted for patient age, sex, indication for cardiac rehabilitation, centre volume and type of centre.

Results: Data from 21 centres, including 2787 patients, were analysed. Computerised decision support increased concordance with guideline-recommended therapy decisions for exercise therapy by 7.9% (control 84.7%; adjusted difference 3.5% [95% CI: 0.1 to 5.2%]), for education therapy by 25.7% (control 63.9%; adjusted difference 23.7% [15.5 to 29.4%]), and for relaxation therapy by 25.5% (control 34.1%; adjusted difference 41.6% [25.2 to 51.3%]). The concordance for lifestyle change therapy increased by 3.2% (control 54.1%; adjusted difference 7.1% [-2.9 to 18.3%]). Computerised decision support reduced both cases of over- and under-treatment.

Conclusions: In a multidisciplinary team motivated to adopt a computerised decision support aid that assists in formulating guideline-based care plans, computerised decision support can be effective in improving multidisciplinary team’s guideline concordance. Therefore, computerised decision support may also be considered to improve guideline implementation in such settings.
Introduction

One of the main challenges in contemporary healthcare is to increase the application of sound clinical evidence to routine care [1]. Although clinical practice guidelines are designed to promote effectiveness and discourage the use of ineffective treatments, guideline adherence in practice is often poor [1-3]. Dissemination of practice guidelines on paper alone has proven to be generally insufficient. Instead, a carefully designed change strategy usually needs to be deployed for effective guideline implementation [2;4-6].

Patient-tailored computerised decision support (CDS) to individual professionals at the point of care is one of the most effective methods to improve decision-making [1;4;5;7;8]. CDS has been shown to improve the decisions of individual professionals in cancer screening [9;10], vaccination [11], diabetes management [12;13], for (laboratory) test ordering [14;15], for drug dosing and prescribing [16;17], and in other settings [7]. However, CDS has also failed to improve practitioner performance [7;8;18;19], and it is unclear under which circumstances and settings it is optimally effective [7;20;21].

Specialist medical care is nowadays often provided not by individuals but by multidisciplinary teams [22-26]. Working in multidisciplinary teams integrates the professional knowledge and skills of different disciplines, and is generally considered to improve the coordination, quality, and continuity of patient care [22;24;25]. While individual decision making is mainly a cognitive process, decision making in teams is additionally influenced by the social context, such as the interpersonal relationships within the team [26;27]. It is unknown whether CDS can improve this process as all previous trials have evaluated the effect of CDS on the decisions of individuals.

This paper reports on a cluster randomised trial evaluating the effect of CDS on multidisciplinary team concordance with guideline-recommended therapy decisions in outpatient cardiac rehabilitation. Cardiac rehabilitation is a multidisciplinary secondary prevention strategy for patients who suffered a cardiac incident (e.g., a myocardial infarction) or underwent a cardiac intervention (e.g., heart surgery). Cardiac rehabilitation is critical to ensure that patients are in the best possible physical and psychosocial condition to return to and maintain their normal place in society, and to reduce their future cardiovascular risk [28-32]. Cardiac rehabilitation has proven to be cost-effective in economic evaluations conducted in North America and Europe [30]. However, in many Western countries cardiac rehabilitation practice is poorly standardised and does not follow the available scientific evidence [30;33;34].

The objective of this study was to determine the extent to which CDS can improve multidisciplinary team concordance with guideline-recommended therapy decisions.
Chapter 6. The CARDSS trial

To avoid contamination across patient groups due to teams learning from the system, a cluster randomised design was chosen [35]. As outpatient centres have only one multidisciplinary cardiac rehabilitation team, entire outpatient centres were the units of randomisation.

**Methods**

**Guidelines for cardiac rehabilitation**

To stimulate evidence-based cardiac rehabilitation services, the Netherlands Heart Foundation (NHF) and the Netherlands Society for Cardiology, patient interest and professional organisations respectively, published national guidelines for cardiac rehabilitation in 2004 [36]. Consistent with international standards [29;30;37], the national guidelines state that patients should be offered an individualised rehabilitation programme during which each of four therapies should be provided: two ‘standard’ therapies, namely exercise training and education therapy (education about the consequences of the patient’s disease), and two ‘new’ but evidence based therapies, namely lifestyle change therapy (risk-related behaviour adjustment), and relaxation and stress management training. To develop an individualised rehabilitation programme, the guidelines describe a needs assessment procedure which requires gathering of 15 to 40 data items concerning the patient’s medical, physical, psychological, and social condition and lifestyle. This procedure is generally conducted two weeks after discharge from the hospital after which, during weekly meetings, the multidisciplinary cardiac rehabilitation team decides upon the content of the patients’ rehabilitation programme based upon the information collected during the needs assessment procedure. The team, which usually includes physical therapists, nurses, psychologists, dieticians, social workers, and rehabilitation specialists or cardiologists, is jointly responsible for execution of this programme during the next six to twelve weeks. All outpatient cardiac rehabilitation services act under the responsibility of cardiologists.

**The CARDSS guideline implementation system**

To stimulate the implementation of these guidelines, an electronic patient record system with CDS functionalities named CARDSS (Cardiac Rehabilitation Decision Support System) was developed [38]. CARDSS actively guides users through the needs assessment procedure via a structured dialogue, prompting them to record the necessary information. In addition, CARDSS assists in formulating a patient-specific rehabilitation programme by providing computerised decision support: it automatically shows whether each of the four therapies is recommended by the
guidelines, based on the patient's needs assessment data. Upon request, CARDSS provides the rationale behind its recommendations and links to relevant research evidence.

During the trial, the collection of the patient's needs assessment data was done by one or more members of the multidisciplinary cardiac rehabilitation team, usually a specialised nurse or therapist, during a 30 to 60 minute meeting with the patient. These members of the cardiac rehabilitation team recorded this patient data directly into CARDSS during the visit, or entered the data into CARDSS shortly afterwards. The data was subsequently used as input for the weekly multidisciplinary team meeting where all decisions regarding the patient's rehabilitation programme were made. The needs assessment data recorded in CARDSS, including its guideline-based therapy recommendations from the system, were always available during this meeting, either directly through CARDSS (e.g. projected on a screen), or on a paper report printed with CARDSS. The final therapy decisions of the team were recorded in CARDSS at the end of the meeting.

To facilitate user acceptance, CARDSS provided additional patient information management services, including registration, documentation, and calculation of summary statistics across patients [38,39]. In a pilot study in four cardiac rehabilitation centres, CARDSS was readily accepted and integrated into existing working procedures [40].

Participants
The national guidelines and CARDSS were jointly presented at a national conference on cardiac rehabilitation in January 2004. Six months later, the NHF surveyed all 101 Dutch cardiac rehabilitation centres for their interest in purchasing the system for €100 (approx. £83 UK, $130 US). Each interested centre was eligible to participate in the trial, except for the four centres that participated in the pilot study [40]. Participation required that the centre agreed to document the needs assessment of each cardiac rehabilitation patient seen during the trial in CARDSS. Trial participants were offered several incentives including reimbursement of CARDSS purchasing costs, free training, and free helpdesk services.

Intervention
Participating centres worked with either of two versions of CARDSS: an intervention version or a control version. The intervention version had full functionality, while the control version comprised all patient information management services but did not provide therapy recommendations. This way we controlled for the potential positive
effect of the information management services and dialogue structure provided by CARDSS on the decision making of rehabilitation professionals, a phenomenon known as the ‘checklist effect’ [41;42]. In the control arm, multidisciplinary teams selected rehabilitation therapies using their own judgment; the written guidelines could always be consulted on paper or electronically within CARDSS. Control arm teams could explain their decisions, but were not obliged to do so. Intervention arm teams could base their decisions on the system’s therapy recommendations. Non-concordance with guideline recommendations required recording of the reason, such as ‘patient refusal’, ‘lack of facilities’, ‘disagreement with guideline’, and ‘other’. At the start of the centre’s inclusion in the study, all multidisciplinary cardiac rehabilitation teams received a standardised training course, designed by the investigators, during which both the control and intervention versions of CARDSS were demonstrated to all teams. Teams participated in the study for at least six months, after which they all received the full version of CARDSS.

An external evaluator with extensive experience in evaluation of information technology in healthcare was consulted (JW) during the design of the study protocol and the intervention.

According to the medical ethics committee of the Academic Medical Centre in Amsterdam, the study required no formal approval.

**Outcome measures**

For all four cardiac rehabilitation therapies individually, concordance of the multidisciplinary team therapy decisions with the guidelines was used as the outcome measure. Concordance was defined at patient level and implied treating patients who should have been treated and not treating patients who should have been untreated, according to the guideline. To evaluate the effect of CDS on multidisciplinary team decision making, the proportions of concordant cases between the intervention and control arms were compared. In addition, we evaluated the effect of the CDS on undertreatment (withholding treatment from patients who should receive it) and overtreatment (treatment of patients who should be left untreated) of patients.

**Sample size**

Based on data from the pilot study [40], a mean of 22 eligible patients per month per centre and an average intra-cluster correlation coefficient (ICC) of 0.04 and average baseline concordance rate of 60% for all four cardiac rehabilitation therapies were used as estimators in the sample size calculation. Calculations showed that using a six-month follow-up would require 36 participating centres to detect a 10% absolute
difference in guideline concordance rate with 80% power at a Type I error risk (alpha) of 5%. Sample size [43] was calculated using the STATA statistical software package (Stata Corporation, College Station TX, USA).

**Randomisation and Allocation**

Concealed randomisation using variable block sizes was performed using dedicated software, stratified by type of centre (university hospital; autonomous rehabilitation centre, and non-university hospital). Non-university hospitals were also stratified by the mean number of new patients seen per month in the year prior to randomisation (less than 20; 20 to 30; more than 30).

After the standardised training course had been given by the project team, the centre in question received an email message with a key code that activated CARDSS and determined team allocation to control or intervention arm. Allocation could not be influenced by, and was unknown to, the investigator giving the course. Centres could not be blinded to allocation due to the character of the intervention.

**Data validation**

During the trial, all centres were asked to retain their original administration system (mostly the paper-based patient record) to record information on patients' rehabilitation programmes.

To assess the quality and completeness of record keeping in CARDSS, a data audit was conducted in each participating centre during or at the end of the trial. During the data audit, the records of ten cardiac rehabilitation patients created during the trial period were randomly selected from the centre's original administration system which served as a reference standard. First, to verify that all cardiac rehabilitation patients seen at participating centres had been entered into CARDSS, we checked if each of the selected patients had a record in CARDSS. Second, the quality of patient data stored in CARDSS was verified by comparing each of the ten patients' demographic information and therapy decisions recorded in the original administration system with the data in CARDSS.

If two or more selected patients were not found in CARDSS or if discrepancies in demographic information or therapy decisions existed in more than two records, all data of the centre in question were considered unreliable and were excluded from the analyses. If a centre passed the data audit, but data analysis showed that twenty percent or more of a centre's patient records missed any data necessary to determine guideline concordance, that centre was excluded from the analyses.
To reduce potential dilution of the treatment contrast by centres’ potential suboptimal performance in the initial phase (learning curve before reaching a plateau), the data of patients enrolled in the first two weeks of using CARDSS in each participating centre, with a minimum of ten patients, were excluded from the analyses. The outcome assessment was performed unblinded, but could not be influenced by the assessors as concordance data were not subject to judgement.

**Statistical analysis**

The effects of CDS on guideline concordance were estimated at the patient level, by fitting logistic regression models to the concordance data for the four types of therapy. Three patient-level variables (age, sex, and indication for cardiac rehabilitation) and two centre-level variables (weekly volume of new patients, and whether or not the centre is either a specialised rehabilitation centre or part of an academic hospital) were used as covariates to adjust for differences in case-mix between intervention and control group. Natural splines were used to model nonlinear effects of continuous variables (age and centre volume). Furthermore, to account for potential correlation of outcomes within centres, we used generalised estimation equations with exchangeable correlation [44;45]. Because of the small number of clusters, the analyses were repeated with jackknife estimators of variance [46;47]. In addition, the analysis described above was repeated to estimate the effect of CDS on undertreatment and overtreatment of patients. The statistical analyses were performed with SPLUS version 6.2 (Insightful Corp, Seattle, WA, USA).

**Results**

In October 2004, 40 centres who were interested in purchasing CARDSS were invited to participate in the trial. Thirty-five centres (88%) accepted this invitation. Of these, four centres were unable to implement the system before the end of the recruitment period because of inadequate ICT infrastructure. Figure 1 shows that the remaining 31 centres were assigned to the intervention arm (16 centres) or the control arm (15 centres). Centres were enrolled in the trial between January and December 2005. The last centre completed participation in the trial in July 2006.
Figure 1. Flow of centres through the trial.

CR: Cardiac rehabilitation, NL: the Netherlands, CDS: computerised decision support

The data audit revealed poor data quality in three intervention centres which were therefore excluded from the analysis; in these centres, participants reported that they were unaware that they had to record their therapy decisions in CARDSS after consulting its recommendations. Data from a further one intervention and one control centre were excluded as in both centres more than 70% of patient records missed one or more data items due to inappropriate system use. Data from 21 centres including 2787 patients were analysed. Table 1 lists the baseline characteristics of both trial arms at the level of centres and patients.

During the trial, five control arm centres discontinued their participation: Three control centres were reluctant to continue participation as they believed that the benefits of CARDSS without CDS did not compensate for the increased workload of learning to work with the system. One control centre had to stop participation due to a temporary lack of personnel and another centre accidentally deleted its CARDSS.
Chapter 6. The CARDSS trial

Table 1. Baseline characteristics of clusters and patients

<table>
<thead>
<tr>
<th>Centre-level variable</th>
<th>Interv. arm (n=12)</th>
<th>Control arm (n=9)</th>
<th>Interv. arm (n=4)</th>
<th>Control arm (n=6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients (median [IQR])</td>
<td>113 [85 to 150]</td>
<td>126 [78 to 171]</td>
<td>70 [61 to 93]</td>
<td>198*</td>
</tr>
<tr>
<td>Trial period in months (median [IQR])</td>
<td>7.4 [6.8 to 8.1]</td>
<td>8.1 [6.9 to 8.6]</td>
<td>8.8 [8.2 to 9.7]</td>
<td>7.8*</td>
</tr>
<tr>
<td>Number of patients per month (median [IQR])</td>
<td>14 [13 to 19]</td>
<td>15 [14 to 19]</td>
<td>8.1 [7.4 to 10.6]</td>
<td>18.3*</td>
</tr>
<tr>
<td>Stratum</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>5</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Medium</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Large</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Rehabilitation centres</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>University centres</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Patient-level variables</td>
<td>(n=1655)</td>
<td>(n=1132)</td>
<td>(n=335)</td>
<td>(n=198)*</td>
</tr>
<tr>
<td>Age (years) ± SD</td>
<td>60.6 ± 11.5</td>
<td>61.0 ± 11.3</td>
<td>61.1 ± 11.0</td>
<td>58.7 ± 11.4*</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>1198 (72%)</td>
<td>862 (76%)</td>
<td>253 (76%)</td>
<td>145 (73%)*</td>
</tr>
<tr>
<td>Indication for cardiac rehabilitation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart surgery (%)</td>
<td>633 (38.2%)</td>
<td>471 (41.6%)</td>
<td>163 (48.7%)</td>
<td>71 (35.9%)*</td>
</tr>
<tr>
<td>ACS (%)</td>
<td>678 (41.0%)</td>
<td>408 (36.0%)</td>
<td>127 (37.9%)</td>
<td>62 (31.3%)*</td>
</tr>
<tr>
<td>AP or PCI (%)</td>
<td>281 (17.0%)</td>
<td>173 (15.3%)</td>
<td>27 (8.1%)</td>
<td>38 (19.2%)*</td>
</tr>
<tr>
<td>Other (%)</td>
<td>63 (3.8%)</td>
<td>80 (7.1%)</td>
<td>18 (5.3%)</td>
<td>27 (12.6%)*</td>
</tr>
</tbody>
</table>

IQR: interquartile range

ppm: patients per month
SD: standard deviation

*: This information is based on only the data of one control arm centre that was excluded from the final analyses due to too much missing data. This information is not available for the five control arm centres that dropped out during the trial as they stopped registering their needs assessment data electronically.

††: The ‘Heart surgery’ group includes patients with a coronary artery bypass (CABG) surgery, and patients with a valvar surgery. The ‘ACS’ (Acute Coronary Syndrome) group includes patients with a myocardial infarction or instable AP (angina pectoris) with or without a PCI (Percutaneous Coronary Intervention). The ‘AP or PCI’ group includes patient with AP with or without a PCI. The ‘Other’ category includes ICD (Internal Cardio Defibrillator) patients, heart failure patients, patient with congenital heart disease, and patient that received cardiac rehabilitation based on another cardiac disease.
Table 2. Primary results of the trial. The table shows concordance rates and the difference in concordance with guideline recommendations for the four measured rehabilitation therapies between intervention and control group.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention</th>
<th>Control</th>
<th>Crude difference</th>
<th>Adjusted difference [95% CI]</th>
<th>ICC</th>
<th>NA (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nr of centres</td>
<td>12</td>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nr of patients</td>
<td>1655</td>
<td>1132</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concordance with guideline recommendations

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention</th>
<th>Control</th>
<th>Crude difference</th>
<th>Adjusted difference [95% CI]</th>
<th>ICC</th>
<th>NA (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise (#)</td>
<td>92.6% (1508)</td>
<td>84.7% (933)</td>
<td>7.9%</td>
<td>3.5% [0.1 to 5.2]</td>
<td>0.086</td>
<td>56 (2.1)</td>
</tr>
<tr>
<td>Education (#)</td>
<td>87.6% (1411)</td>
<td>63.9% (709)</td>
<td>25.7%</td>
<td>23.7% [15.5 to 29.4]</td>
<td>0.187</td>
<td>67 (2.4)</td>
</tr>
<tr>
<td>Relaxation (#)</td>
<td>59.6% (959)</td>
<td>34.1% (373)</td>
<td>25.5%</td>
<td>41.6% [25.2 to 51.3]</td>
<td>0.479</td>
<td>83 (3.0)</td>
</tr>
<tr>
<td>Lifestyle change (#)</td>
<td>57.4% (924)</td>
<td>54.1% (601)</td>
<td>3.2%</td>
<td>7.1% [-2.9 to 18.3]</td>
<td>0.110</td>
<td>67 (2.4)</td>
</tr>
</tbody>
</table>

NA: Data not available.

* Adjusted for age, sex, and diagnosis at the patient-level, and weekly volume of new patients and whether or not the centre is either a specialised rehabilitation centre or part of an academic hospital at the centre-level.

Figure 2. Concordance of the control and intervention centres with the guideline-recommended therapy decisions for the different therapies. Each box shows median value (line inside box), quartiles (box edges), extreme values (whiskers), and outliers (horizontal lines) within a category.
Table 2 shows the primary results of the trial. CDS increased concordance with guideline recommendations for the exercise, education, and relaxation therapy. The increased concordance with therapy decisions for the lifestyle change therapy was not statistically significant. Table 2 only reports the confidence intervals according to the standard GEE estimator as similar results were found with the jackknife estimator. The jackknife estimator did result in borderline significance for the exercise therapy (95% CI: 0.0 to 5.4%).

For all four therapies the actual ICC was higher than anticipated, especially for education and relaxation therapy. Guideline concordance in the control group for the exercise therapy was higher than had been estimated in the sample size calculation, but was much lower than estimated for the relaxation and lifestyle change therapy. Figure 2 shows the variation in concordance with guideline recommendations for each therapy.

Table 3. The number and percentage of patients that were correctly treated (true positives), correctly untreated (true negatives), overtreated (false positives), and undertreated (false negatives) for each individual cardiac rehabilitation therapy (3.1 to 3.4), separately for the intervention and control centres.

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Intervention Arm</th>
<th>Control Arm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exercise therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received Yes</td>
<td>1356 (83.2%)</td>
<td>853 (77.4%)</td>
</tr>
<tr>
<td>Recommended Yes</td>
<td>42 (2.6%)</td>
<td>69 (6.3%)</td>
</tr>
<tr>
<td>Total</td>
<td>1398 (85.5%)</td>
<td>922 (83.7%)</td>
</tr>
<tr>
<td>Received No</td>
<td>79 (4.8%)</td>
<td>100 (9.1%)</td>
</tr>
<tr>
<td>Recommended No</td>
<td>152 (9.3%)</td>
<td>80 (7.3%)</td>
</tr>
<tr>
<td>Total</td>
<td>231 (14.2%)</td>
<td>180 (16.3%)</td>
</tr>
<tr>
<td><strong>Relaxation therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received Yes</td>
<td>1278 (79.4%)</td>
<td>651 (58.6%)</td>
</tr>
<tr>
<td>Recommended Yes</td>
<td>43 (2.7%)</td>
<td>67 (6.0%)</td>
</tr>
<tr>
<td>Total</td>
<td>1321 (82.0%)</td>
<td>718 (64.7%)</td>
</tr>
<tr>
<td>Received No</td>
<td>156 (9.7%)</td>
<td>334 (30.1%)</td>
</tr>
<tr>
<td>Recommended No</td>
<td>133 (8.3%)</td>
<td>58 (5.2%)</td>
</tr>
<tr>
<td>Total</td>
<td>1434 (89.1%)</td>
<td>392 (35.3%)</td>
</tr>
<tr>
<td><strong>Education therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received Yes</td>
<td>248 (15.4%)</td>
<td>160 (14.4%)</td>
</tr>
<tr>
<td>Recommended Yes</td>
<td>14 (0.9%)</td>
<td>51 (4.6%)</td>
</tr>
<tr>
<td>Total</td>
<td>262 (16.3%)</td>
<td>211 (19.0%)</td>
</tr>
<tr>
<td>Received No</td>
<td>672 (41.7%)</td>
<td>458 (41.3%)</td>
</tr>
<tr>
<td>Recommended No</td>
<td>676 (42.0%)</td>
<td>441 (39.7%)</td>
</tr>
<tr>
<td>Total</td>
<td>1348 (83.7%)</td>
<td>899 (81.0%)</td>
</tr>
<tr>
<td><strong>Lifestyle change therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received Yes</td>
<td>920 (57.1%)</td>
<td>618 (55.7%)</td>
</tr>
<tr>
<td>Recommended Yes</td>
<td>690 (42.9%)</td>
<td>492 (44.3%)</td>
</tr>
<tr>
<td>Total</td>
<td>1610 (100%)</td>
<td>1110 (100%)</td>
</tr>
</tbody>
</table>
Table 3 shows the crude data on guideline recommendations and multidisciplinary teams’ therapy decisions for both study arms and for each of the four therapies. In both the intervention and control arm, undertreatment was more common than overtreatment, in particular for the relaxation, education, and lifestyle change therapies, with significant differences between the two study arms for the relaxation and education therapies. These therapies should have been given to 2310 (84.6% of all patients) and 2419 (88.6%) patients respectively, of which 1310 (56.7%) and 490 (20.3%) did not receive the recommended therapy. The adjusted difference between the control and intervention arm in undertreatment was 42.8% [1.1% to 68.0%] and 25.8% [14.9% - 33.6%] respectively, in favour of the intervention arm. A significant difference was also found for exercise therapy overtreatment. From the 343 patients (12.2% of all patients) who should not have been given exercise therapy, 111 patients (32.4%) did incorrectly receive this treatment. The adjusted difference in exercise therapy overtreatment between the two study arms was 25.7% [4.3% to 54.1%]. Other differences between the study arms were either not statistically significant or very small.

In the intervention arm, patient refusal was reported as the main reason for non-concordance with recommendations for exercise (77/121), education (127/199), relaxation (407/651), and lifestyle change therapies (381/686). Lack of sufficient facilities was another important reason for non-concordance with recommendations about lifestyle change (160/686) and relaxation therapy (68/651). In the control arm, recording of non-concordance was voluntary which resulted in reasons being recorded in only 152 (8%) of the 1821 non-concordant decisions. For those decisions, patient refusal was also the main reason for non-concordance with recommendations for all four therapies.

Discussion

Statement of principal findings

We found that computerised decision support improved the concordance of multidisciplinary cardiac rehabilitation teams’ decisions for three out of four rehabilitation therapies for which concordance with guideline recommendations was measured. CDS reduced both cases of over- and undertreatment.

Strengths and weaknesses of the study

Although recruiting participants for trials is always difficult, the recruitment for a CDS trial faces some additional challenges. In this study, entire multidisciplinary teams had to be recruited instead of individual professionals or patients, requiring not just one
professional but the entire team to be motivated to participate. In addition, motivated teams could only participate if i) their centre had an adequate IT infrastructure and ii) both the team and the centre’s IT department were willing and able to allocate resources for implementation of CARDSS within a limited time frame. For this reason only 31 of the 101 eligible centres were enrolled in the study, which is nevertheless among the largest numbers of participants in CDS evaluation studies to date [7]. It does restrict the generalizability of our results to settings where teams are motivated to work with a CDS aid and where sufficient IT support and facilities are available to implement the CDS system. However, as IT support and facilities are rapidly improving in most hospitals we believe that this requirement will be less of concern for such trials in the future.

Another potential source of bias in our results is the attrition rate. In the control arm, three centres discontinued participation as they found that it was not worth the effort implementing CARDSS in their daily practice without receiving decision support. In the intervention arm, three clinics were excluded from the analyses as they failed to properly record therapy decisions in CARDSS. Such dropouts make it impossible to perform a genuine intention-to-treat analysis. However, attrition did not seem to be related to guideline concordance, but to the fact that teams faced the additional barrier of implementing a new electronic patient record system, as well as learning to use the CDS aid. Therefore we believe that if CDS can be provided via an electronic patient record system that is already used on a routine basis, the additional benefit of CDS will be more easily realised.

In the intervention group, multidisciplinary teams were prompted to record the reason for non-concordance when they did not follow a recommendation of the system. This necessity to record the reason for non-concordance may have pressured the teams to follow the recommendations, thus increasing concordance with the guideline. Although we believe it is unlikely that entire teams let their decisions be affected by the necessity to motivate non-concordance, the effect size of this CDS feature is unknown.

In our study the research team also led the development of the CDS system. Garg et al. [7] found that this can lead to a potential bias in outcome assessment. However, a number of factors should have reduced the chances of such biases, including blinding of the investigators during the allocation procedure, objective outcome measures, and the involvement of an external evaluator (JW) and a statistician (GtR) from another department outside the project team.

In this study we measured the impact of CDS on concordance with guideline recommended therapy decisions by teams, which is a measure of care process quality. When evaluating the effect of quality improvement interventions it is common to use
such process measures instead of patient outcomes [7]. Process measures are even preferable over patient outcomes if the process measures are based on evidence or accepted standards of care[7;48], as is the case in cardiac rehabilitation [36].

**Strengths and weaknesses in relation to other studies**

Many studies have previously studied the effect of CDS on individual professional decision making. Two systematic reviews found that active CDS systems, i.e. systems that automatically provide individual professionals with advice, are more effective than passive systems, which require professionals to request advice [7;20]. Therapy recommendations rather than diagnostic advice and CDS at the time and location of decision making were also found to increase CDS' chances of success. These known success factors of CDS systems were taken into account during the development of CARDSS [38] and were judged favourably by its users in a usability study [49]. The positive opinion of professionals towards CARDSS is also reflected by the fact that it is still used in over 35 of the 101 outpatient centres in the Netherlands.

A cluster randomised trial is usually the most rigorous method to evaluate interventions intended to affect professionals' behaviour [50-52]. So far, however, only a few CDS evaluation studies have applied the cluster randomised design, and even fewer studies accounted for the clustering of patients in the statistical analysis [53]. Our study design ensured that the estimated effects of CDS could not be biased by the 'checklist' [41;42], 'Hawthorne', 'feedback', or 'carryover effects' described by Friedman and Wyatt [35] and our statistical analysis accounted for correlation of concordance measurements within centres [54].

**Meaning of the study**

Although multidisciplinary settings are common in contemporary healthcare, no studies have yet evaluated the effect of computerised decision support in such a setting [7]. In contrast to decision making by individual professionals, multidisciplinary decision making depends on social factors, such as the experience, profession, interpersonal relationships, and characters of team members [24-27]. Our results show that CDS can also be an effective instrument in multidisciplinary setting where such social factors play an important role in decision making.

This study shows that, in a multidisciplinary team motivated to adopt a computerised decision support aid that assists in formulating guideline-based care plans, computerised decision support can be effective in improving multidisciplinary team's guideline concordance. Based on our findings, we encourage the use of CDS aids in settings where multidisciplinary teams are motivated to use them.
Chapter 6. The CARDSS trial

Unanswered questions and future research

CDS did not improve guideline concordance for the lifestyle change therapy, and although guideline concordance for the relaxation therapy increased, there still existed considerable undertreatment. Although centres started to participate in the trial between one and two years after the release of the guideline in which these therapies were officially introduced, a considerable number of outpatient clinics still had insufficient facilities to offer these ‘new’ therapies to all eligible patients during the trial. The literature emphasises that many different types of barriers to guideline implementation exist which may require different change strategies [2;4;5], but little is known about the types of barriers that different change strategies, including CDS, can address [4;5]. Our results suggest that a CDS system alone is insufficient to improve guideline concordance when this requires additional resources, for example in increasing uptake of lifestyle change therapy. More research is therefore needed to understand how CDS improve guideline concordance and which additional change strategies need to be considered to overcome the remaining barriers.

Reference List


Chapter 6. The CARDSS trial


Chapter 7

Inter-practice variation in assessed patient needs for cardiac rehabilitation

Submitted for publication

Niels Peek
Rick Goud
Mariette van Engen-Verheul
Arie Hasman
Irene Hellemans
Nicolette de Keizer
Chapter 7. Variation in assessed patient needs for cardiac rehabilitation

Abstract

Objective: To determine inter-practice variation in assessed patient needs for cardiac rehabilitation, and identify the influence of different measurement instruments on assessed needs.

Methods: A prospective cohort study was conducted in 16 Dutch cardiac rehabilitation outpatient clinics from November 1, 2005 to October 31, 2006. Participating clinics assessed each patient’s rehabilitation needs, based on exercise capacity, psychosocial status, marital status, employment status, and lifestyle parameters. Intra-cluster correlation coefficients (ICCs) were calculated for all rehabilitation needs and lifestyle parameters, before and after adjusting for patient case mix, and stratified by assessment method.

Results: High ICCs were found for insufficient exercise capacity (0.301 ± 0.085), unrealistic subjective exercise capacity (0.165 ± 0.046), and social problems (0.188 ± 0.037); moderate ICCs were found for psychological problems (0.096 ± 0.027), absence of partner (0.052 ± 0.017), unhealthy eating habits (0.080 ± 0.026), and inactive lifestyle (0.059 ± 0.015); ICCs were low for expected work problems (0.010 ± 0.006) and smoking status (0.000 ± 0.001). Adjustments for case mix hardly influenced ICCs, but stratification by assessment method revealed large differences between results from clinical interviews and measurement instruments (bicycle ergometry or incremental Shuttle walk, MacNew quality of life questionnaire).

Conclusion: The assessments of cardiac rehabilitation needs are subject to moderate to high inter-practice variation, especially when they are solely based on clinical judgment. In addition, the numbers of patients judged to have rehabilitation needs are smaller in that case.
Introduction

Despite the evidence base for the effectiveness and cost-effectiveness of cardiac rehabilitation [1-4], the provision of cardiac rehabilitation services still vary widely across and within many Western countries. Estimates indicate that the majority (around 70%) of the patients eligible for cardiac rehabilitation do not receive it [5;6] and that access to cardiac rehabilitation varies geographically and between diagnosis groups [7;8]. Some clinics only provide exercise-based therapy, while others also treat emotional and psychosocial problems, and address secondary cardiovascular prevention by behaviour and lifestyle modification guidance [9;10].

One source of variation in rehabilitation therapies offered to cardiac patients is inconsistency in assessments of patient-specific rehabilitation needs by different care providers. Clinical guidelines emphasise the need to move away from a one-size-fits-all programme to personalised programmes that fit to needs of individual patients [11-13]. To determine these needs, it is important to conduct a structured needs assessment procedure with every patient before enrolment in the cardiac rehabilitation program. Many countries have developed guidelines for the assessment of rehabilitation needs [11-16], generally recommending to assess the patient's medical history, physical condition, psychosocial condition, and relevant lifestyle parameters (smoking habits, nutritional habits, and physical activity). Most of these items can be assessed during a clinical interview with the patient or with measurement instruments such as maximal exercise tests and questionnaires. To date, however, little is known about the consistency of needs assessment procedures, and whether clinical interviews and measurement instruments lead to similar results.

The aim of the current study was to determine the variation in assessed cardiac rehabilitation needs between different care providers in the Netherlands, and to identify the influence of different measurement instruments on averages and variation in assessed needs.

Methods

Data

A prospective cohort study was conducted in 16 Dutch cardiac rehabilitation outpatient clinics (two specialized rehabilitation clinics, one university hospital outpatient clinic, and thirteen non-university hospital outpatient clinics) from November 1, 2005 to October 31, 2006. Multidisciplinary teams in all these clinics recorded their patient data in the CARDSS patient information management system [17]. This system assists professionals in conducting the needs assessment
procedure for cardiac rehabilitation according to the Dutch guidelines [13] (see Appendix). Data quality was verified in a data audit that was conducted as a part of another recent study [18].

Data from all patients who started cardiac rehabilitation during the study period in one of the participating clinics were collected during the needs assessment procedure described in the guidelines [13]. The collected data included patient demographics (age and sex), reason for referral to cardiac rehabilitation (e.g. myocardial infarction, CABG, angina pectoris), objective exercise capacity, subjective (i.e., self-perceived) exercise capacity, psychosocial status, marital status, employment status and three lifestyle parameters (smoking status, eating habits, physical activity). As described in the guidelines, all data items could be collected through a clinical interview, but the objective exercise capacity could also be assessed with bicycle ergometry or the incremental Shuttle walk test [19], and subjective exercise capacity and psychosocial status could also be assessed with the Dutch translation of the MacNew health-related quality of life questionnaire [20;21]. Although the guidelines advise to employ these measurement instruments in the assessment of rehabilitation needs, this is not compelling. Furthermore, while the guidelines provide thresholds for interpreting MacNew scores, interpretation of the results of exercise testing is left to the rehabilitation professional. In some clinics the assessment of all rehabilitation needs was conducted by a single professional (e.g. a specialized nurse) while in other clinics the needs associated with different clinical domains were assessed by professionals from different disciplines.

Outcome variables

Outcome variables were nine dichotomous variables describing the rehabilitation needs of patients, as assessed by cardiac rehabilitation professionals during the multidisciplinary needs assessment procedure: insufficient objective exercise capacity, unrealistic subjective exercise capacity, psychological problems, social problems, absence of partner, expected problems at work, smoking, unhealthy eating habits, inactive lifestyle.

Statistical analysis

Intra-cluster correlation coefficients (ICCs) [22;23] were used to describe inter-practice variation in assessed rehabilitation needs. ICC values express the proportion of population-level variation in outcomes that is explained by variation in assessments between clinics, and range from zero (no inter-practice variation, high inter-practice reliability) to one (high inter-practice variation, poor inter-practice reliability).
For each of the nine outcome variables, ICCs were calculated before and after adjusting for variations in case mix (demography and reason for referral) between clinics, and before and after stratification by assessment method (bicycle ergometry vs. clinical interview for assessment of exercise capacity; MacNew quality of life questionnaire vs. clinical interview for assessment of subjective exercise capacity, psychological problems, and social problems). When a clinic had used an assessment instrument for less than 20 patients, the data of those patients were considered to be not representative and excluded from the stratified analysis. Stratification was not applied to the five other outcome variables because these were all assessed during clinical interviews.

Adjustments for case mix factors [24] was performed by multivariate logistic regression analyses, using natural splines for the continuous covariate (age) to account for nonlinear effects. All ICCs were estimated using generalized estimation equations with exchangeable correlation structure [25] and tested for deviation from zero. To correct for multiple testing, only p-values smaller than 0.01 were considered significant. In addition to analyzing variation, it was analyzed whether there were differences in average proportions in the results obtained with different instruments, for insufficient exercise capacity, unrealistic subjective exercise capacity, psychological problems, and social problems. The statistical analyses were performed with SPLUS version 6.2 (Insightful Corp, Seattle, WA, USA).

**Results**

Data from 4157 patients were collected. The median number of patients per centre was 221 (inter-quartile range 166 to 318). Table 1 shows baseline characteristics of the study population regarding demography, reasons for referral to cardiac rehabilitation, use of measurement instruments, and results of these measurements. Five clinics used the bicycle ergometry test for more than 20 patients, and only one clinic used the incremental Shuttle walk test for more than 20 patients. Therefore no distinction was made between bicycle ergometry and Shuttle walk test in the stratified analyses. Fourteen clinics used the MacNew quality of life questionnaire for more than 20 patients.

Table 2 displays the outcomes of the needs assessment procedures, averaged at the level of the study population and at the level of individual clinics. For all outcome variables except expected work problems and smoking status, there was significant variation in the clinics means. The largest variation was found in the percentages of patients judged to have an insufficient exercise capacity.
Chapter 7. Variation in assessed patient needs for cardiac rehabilitation

Table 1. Baseline characteristics of study population (n=4157)

<table>
<thead>
<tr>
<th>Demography</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ± sd)</td>
<td>61.3 ± 11.4</td>
</tr>
<tr>
<td>Male gender (#)</td>
<td>74.4% (3092)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reason for referral to cardiac rehabilitation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial Infarction * (#)</td>
<td>42.4% (1764)</td>
</tr>
<tr>
<td>Coronary artery bypass graft (#)</td>
<td>28.7% (1192)</td>
</tr>
<tr>
<td>Angina Pectoris * (#)</td>
<td>13.7% (570)</td>
</tr>
<tr>
<td>Cardiac valve operation (#)</td>
<td>7.8% (324)</td>
</tr>
<tr>
<td>Implantable Cardioverter Defibrillator (#)</td>
<td>2.5% (102)</td>
</tr>
<tr>
<td>Heart failure (#)</td>
<td>2.1% (88)</td>
</tr>
<tr>
<td>Other (#)</td>
<td>3.0% (125)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use of assessment instruments</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bicycle ergometry (10 clinics)</td>
<td>19.7% (818)</td>
</tr>
<tr>
<td>Shuttle walk test (3 clinics)</td>
<td>20.3% (842)</td>
</tr>
<tr>
<td>MacNew questionnaire (15 clinics)</td>
<td>77.1% (3203)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results of assessment instruments</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bicycle ergometry result, METs (mean ± sd, n=818)</td>
<td>5.66 ± 1.53</td>
</tr>
<tr>
<td>Shuttle walk test result, METs (mean ± sd, n=842)</td>
<td>5.71 ± 1.59</td>
</tr>
<tr>
<td>MacNew, physical domain score (mean ± sd, n=3203)</td>
<td>4.80 ± 1.14</td>
</tr>
<tr>
<td>MacNew, emotional domain score (mean ± sd, n=3203)</td>
<td>5.03 ± 1.13</td>
</tr>
<tr>
<td>MacNew, social domain score (mean ± sd, n=3203)</td>
<td>5.38 ± 1.08</td>
</tr>
<tr>
<td>MacNew, total score (mean ± sd, n=3203)</td>
<td>5.08 ± 1.00</td>
</tr>
</tbody>
</table>

MET: metabolic equivalent
* these categories include both patients that did and did not receive angioplasty

Table 2. Outcomes of needs assessment procedures, described at study population level and clinic levels, and intra-cluster correlation coefficients (n=4157, 16 clinics).

<table>
<thead>
<tr>
<th></th>
<th>population mean</th>
<th>clinic means, median [IQR]</th>
<th>ICC, mean ± sd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient exercise capacity (#)</td>
<td>78.8% (3275)</td>
<td>84.2% [54.5%-89.8%]</td>
<td>0.301 ± 0.085 (*)</td>
</tr>
<tr>
<td>Unrealistic subjective exercise capacity (#)</td>
<td>53.5% (2223)</td>
<td>53.8% [37.7%-63.9%]</td>
<td>0.165 ± 0.046 (*)</td>
</tr>
<tr>
<td>Psychological problems (#)</td>
<td>47.4% (1972)</td>
<td>52.2% [37.6%-58.0%]</td>
<td>0.096 ± 0.027 (*)</td>
</tr>
<tr>
<td>Social problems (#)</td>
<td>49.2% (2045)</td>
<td>54.7% [31.1%-60.9%]</td>
<td>0.188 ± 0.037 (*)</td>
</tr>
<tr>
<td>Absence of partner (#)</td>
<td>7.8% (323)</td>
<td>8.9% [7.1%-13.0%]</td>
<td>0.052 ± 0.017 (*)</td>
</tr>
<tr>
<td>Expected work problems (#)</td>
<td>7.5% (311)</td>
<td>7.4% [5.5%-9.9%]</td>
<td>0.010 ± 0.006</td>
</tr>
<tr>
<td>Smoker (#)</td>
<td>32.9% (1364)</td>
<td>32.1% [30.7%-34.3%]</td>
<td>0.000 ± 0.001</td>
</tr>
<tr>
<td>Unhealthy eating habits (#)</td>
<td>27.2% (1128)</td>
<td>27.9% [19.1%-35.2%]</td>
<td>0.080 ± 0.026 (*)</td>
</tr>
<tr>
<td>Inactive lifestyle (#)</td>
<td>57.9% (2399)</td>
<td>59.0% [45.5%-64.4%]</td>
<td>0.059 ± 0.015 (*)</td>
</tr>
</tbody>
</table>

IQR: Inter-quartile range
ICC: Intra-cluster correlation coefficient
* significant at the 0.01 level
Table 3 displays the outcomes of the needs assessment procedures after adjustment for variation in patient case mix between clinics, and, where possible, stratified by assessment method. A large variation in clinic means remained to exist for most outcome variables after adjusting for variation in patient case mix between clinics, and the adjusted ICCs are close to the unadjusted ICCs from Table 2. The assessment of patients’ exercise capacities by clinical interview led to a lower percentage of patients being judged as having an insufficiency than when bicycle ergometry or incremental Shuttle walk test was used (73.4% vs. 84.1%, p<0.01). In either case,

Table 3. Outcomes of needs assessment procedures after adjustment for case mix factors (demography, reason for referral to cardiac rehabilitation) and stratified by assessment method (n=4157, 16 clinics, unless mentioned otherwise).

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Adjusted population mean</th>
<th>Adjusted clinic means, median [IQR]</th>
<th>Adjusted ICC, mean ± sd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient exercise capacity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessed by clinical interview</td>
<td>78.5%</td>
<td>84.5% [55.9%-88.5%]</td>
<td>0.281 ± 0.083 (*)</td>
</tr>
<tr>
<td>(n=2472, 12 clinics)</td>
<td>73.4%</td>
<td>79.7% [60.2%-88.6%]</td>
<td>0.219 ± 0.132</td>
</tr>
<tr>
<td>Assessed with bicycle ergometry</td>
<td>84.1%</td>
<td>81.6% [57.4%-90.8%]</td>
<td>0.249 ± 0.086 (*)</td>
</tr>
<tr>
<td>or shuttle walk test (n=1665, 6 clinics)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unrealistic subjective capacity</td>
<td>53.9%</td>
<td>54.3% [39.8%-62.6%]</td>
<td>0.156 ± 0.044 (*)</td>
</tr>
<tr>
<td>Assessed by clinical interview</td>
<td>32.8%</td>
<td>27.9% [17.2%-47.3%]</td>
<td>0.031 ± 0.010 (*)</td>
</tr>
<tr>
<td>(n=1072, 10 clinics)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessed with MacNew, physical</td>
<td>62.3%</td>
<td>63.5% [52.3%-68.4%]</td>
<td>0.113 ± 0.026 (*)</td>
</tr>
<tr>
<td>domain (n=3063, 14 clinics)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychological problem</td>
<td>47.3%</td>
<td>52.6% [38.4%-56.7%]</td>
<td>0.098 ± 0.027 (*)</td>
</tr>
<tr>
<td>Assessed by clinical interview</td>
<td>17.1%</td>
<td>18.5% [16.3%-37.0%]</td>
<td>0.024 ± 0.025</td>
</tr>
<tr>
<td>(n=1072, 10 clinics)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessed with MacNew, emotional</td>
<td>57.2%</td>
<td>57.6% [54.2%-58.8%]</td>
<td>0.002 ± 0.002</td>
</tr>
<tr>
<td>domain (n=3063, 14 clinics)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social problem</td>
<td>48.8%</td>
<td>54.8% [30.8%-60.1%]</td>
<td>0.183 ± 0.037 (*)</td>
</tr>
<tr>
<td>Assessed by clinical interview</td>
<td>7.6%</td>
<td>6.40% [ 4.2%- 9.4%]</td>
<td>0.006 ± 0.006</td>
</tr>
<tr>
<td>(n=1072, 10 clinics)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessed with MacNew, social</td>
<td>62.8%</td>
<td>61.6% [56.3%-64.3%]</td>
<td>0.009 ± 0.003 (*)</td>
</tr>
<tr>
<td>domain (n=3063, 14 clinics)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absence of partner</td>
<td>7.9%</td>
<td>9.0% [ 6.5%-13.3%]</td>
<td>0.055 ± 0.016 (*)</td>
</tr>
<tr>
<td>Expected work problems</td>
<td>7.5%</td>
<td>7.1% [ 6.2%-10.2%]</td>
<td>0.009 ± 0.004</td>
</tr>
<tr>
<td>Smoker</td>
<td>32.9%</td>
<td>32.4% [30.5%-35.1%]</td>
<td>0.000 ± 0.001</td>
</tr>
<tr>
<td>Unhealthy eating habits</td>
<td>27.1%</td>
<td>27.4% [19.0%-35.4%]</td>
<td>0.081 ± 0.024 (*)</td>
</tr>
<tr>
<td>Inactive lifestyle</td>
<td>57.9%</td>
<td>59.0% [45.4%-63.4%]</td>
<td>0.064 ± 0.015 (*)</td>
</tr>
</tbody>
</table>

IQR: Inter-quartile range
ICC: Intra-cluster correlation coefficient
* significant at the 0.01 level
Chapter 7. Variation in assessed patient needs for cardiac rehabilitation

however, substantial variation remained between clinic means. In the evaluation of patients’ subjective exercise capacity, the difference was even larger. Here, clinical interviews led to 32.8% of the patient being judged as having an unrealistic subjective exercise capacity, whereas use of the physical domain of the MacNew questionnaire resulted in 62.3% of the patients being judged as such (p<0.01). The variation in clinic means is somewhat smaller when the MacNew is employed. Also for psychological and social problems, use of the MacNew leads to significantly higher percentages of patients that are assessed to have problems. For these two outcomes, both the clinical interview and usage of the MacNew lead to consistent (though different) results, with ICCs close to zero. The variation in assessed rehabilitation needs with respect to exercise capacity, subjective exercise capacity, and psychological and social problems is graphically depicted in Figure 1.

Figure 1. Variation in four assessed rehabilitation needs, adjusted by patient case mix and stratified by the assessment method used. Each box shows median value (line inside box), interquartile range (box edges), extreme values (whiskers), and outliers (horizontal lines).
For the remaining outcomes of the needs assessment procedure, inter-practice variations were low (smoking, expected work problems) to moderate (absence of partner, inactive lifestyle, unhealthy eating habits). The effects of variations in patient case mix were negligible.

**Discussion**

Our study shows that assessments of cardiac rehabilitation needs, in particular those pertaining to objective and subjective exercise capacities, psychosocial status, and eating habits, are subject to moderate to high inter-practice variation. This is especially true when the assessments are solely based on clinical judgment instead of clinical assessment instruments. Furthermore, the numbers of patients judged to have rehabilitation needs are smaller in that case.

A remarkable variation was seen in the assessments of reduced objective exercise capacity, even when bicycle ergometry or incremental Shuttle walk test was used. The explanation is probably that the guidelines do not provide thresholds for interpreting the test results: they should be interpreted “by considering the patient’s required level of physical activity in daily life”. Patients who performed bicycle ergometry and were judged to be deficient had a mean capacity of $5.43 \pm 1.44$ metabolic equivalents (METs) [19], while patients who were judged not to have a deficiency had a mean capacity of $6.32 \pm 1.58$ METs. Although this difference is statistically significant (Student’s t test, $p<0.01$), it is small and there is considerable overlap in objective capacities of the two groups. It seems that the guidelines leave considerable room for subjectivity here.

The strengths of this study are that all participating clinics agreed to work according to Dutch national guidelines for cardiac rehabilitation [13] and that all clinics used the same electronic information system [17] to record their data. We can therefore assume that there was a broad consensus about appropriate care and that little variation was caused by differences in information registration. Furthermore, most studies on medical practice variation are based on surveys and therefore express the views of professionals on given care. Our results are based on patient data from the participating clinics and thus reflect the care that was actually given to patients. An additional advantage of using patient-level data is that we were able to adjust the results for variations in case mix.

Because there was no golden standard for rehabilitation needs, we do not know whether clinical interviews lead to underestimates of rehabilitation needs or measurements with the MacNew questionnaire lead to overestimates of these needs. But several studies have shown that the MacNew is a valid and reliable psychometric
Chapter 7. Variation in assessed patient needs for cardiac rehabilitation

instrument for cardiac patients [21;26;27], and therefore it seems probable that the clinical interview is deficient. Besides these considerations, inter-practice variation, which was higher in the interview-only group, is a sign of suboptimal quality in itself. A system that produces variation cannot consistently deliver high-quality care.

Participation in our study was voluntarily but required that the CARDSS information system was used during the assessment of rehabilitation needs [17]. As information systems induce a ‘checklist’ effect [28] and tend to standardize clinical practice, the actual practice variation between cardiac rehabilitation clinics in the Netherlands is probably larger than was observed in our study.

Another limitation of the study is that information on patient case mix was limited to age, sex, and reason for referral to cardiac rehabilitation. Other factors, such as medical history, disease severity, and comorbidities may also have influenced the assessment of rehabilitation needs, and may explain some of the variance in assessed needs between clinics. Since however the adjustments for age, sex and reason for referral hardly influenced the observed variation, it is unlikely that additional factors would play an important role. Similarly, data on patient preferences and availability of facilities was not available for analysis. These are known sources of noncompliance to guidelines [29] and may have influenced the assessed rehabilitation needs.

Our study took place in standard, uncontrolled care and therefore the choice between clinical interviews and measurement instruments was not randomly allocated over patients. It is possible that rehabilitation professionals based their choice between the two assessment methods on characteristics of the patients involved. However, many of the participating clinics were consistent in their choice of assessment method. Based on this observation, we believe that our results are probably not confounded by unmeasured factors.

Ideally, patients with similar characteristics are provided with similar care irrespective of the healthcare provider they visit, but many forms of variation in medical practice have been reported over the last decades [30-32]. One major source of practice variation is the assessment of patients’ conditions and needs. In the cardiological field, local testing intensity has been shown to be an important determinant of the variable use of invasive cardiac procedures [33-35]. Our study is the first investigation of variation in assessed rehabilitation needs for cardiac patients. Clinical guidelines for cardiac rehabilitation emphasise the importance of assessing these needs, but few provide handles to do so. The guidelines of the American Heart Association [11] suggest to use symptom limited exercise testing to measure exercise capacity, but do not name specific instruments and provide no measurement instructions for any of the other domains. The British guidelines [12] advise to use the
Hospital Anxiety and Depression Scale [36] for assessing psychosocial status, but are silent about measurements in other domains. We did not find guidelines that provide instruments for assessing lifestyle parameters [11-16].

From the results of our study, we recommend that guidelines for cardiac rehabilitation provide well-defined and unambiguous procedures for assessing the rehabilitation needs of patients. Preferably, the needs are assessed by measuring various aspects of patients' medical, physical, and psychosocial condition with valid and reliable instruments, and indicative thresholds for interpreting the results are provided by the guidelines. Assessing the needs solely by clinical judgment should be avoided. Reliable and practical instruments should be developed for the assessment of cardiac patients' lifestyle parameters.

References


Chapter 7. Variation in assessed patient needs for cardiac rehabilitation


Appendix: The Dutch guidelines for cardiac rehabilitation

To improve the quality and consistency of cardiac rehabilitation services in the Netherlands new national guidelines for cardiac rehabilitation were released in 2004. Consistent with international guidelines, the Dutch guidelines for cardiac rehabilitation state that cardiac patients should be offered an individualized rehabilitation programme that fits to their specific needs. To this end, the guidelines describe a needs assessment and therapy indication procedure during which the patient’s exercise capacity, subjective exercise capacity, psychological condition, social condition, smoking habits, eating habits, and level of physical activity is assessed. This needs assessment procedure is generally conducted by a specialized nurse and sometimes by a physical therapist or social worker about two weeks after discharge from the hospital.

The guidelines state that all needs assessment domains can be assessed during a clinical interview with the patient, but advise the use of measurement instruments for some domains. To determine a patient’s exercise capacity the guidelines recommend using an exercise test, such as bicycle ergometry or an incremental shuttle walk test. To assess the patient’s subjective exercise capacity, psychological condition and social condition the guidelines recommend using the MacNew quality of life questionnaire which is an internationally used and validated questionnaire. The Dutch validated version of the MacNew is comparable to the English version and consists of 24 items related to three domains of health related quality of life (HRQL), namely physical (11 items), emotional (10 items) and social HRQL (7 items). Each of the items is rated on a 7-point Likert scale, where ‘1’ indicates poor and ‘7’ indicates good HRQL. Scores are calculated by averaging the responses to the items of each domain, while averaging all items provides a global score. According to the guidelines, patients have a realistic subjective exercise capacity if they have a sufficient exercise capacity and a score on the physical domain of the MacNew higher than or equal to 4.0, or an insufficient exercise capacity and a score on the physical domain of the MacNew lower than 4.0. The Dutch guidelines consider scores below 5.4 and 5.9, respectively, on the emotional and social domains of the MacNew reasons for enrolment in psychosocial counselling. The guidelines recommend no specific measurement instruments to assess lifestyle factors (smoking habits, eating habits, physical activity).
Chapter 8

The effect of computerized decision support on barriers to guideline implementation: A qualitative study in outpatient cardiac rehabilitation

Submitted for publication

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Mariette van Engen-Verheul
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Roland Bal
Arie Hasman
Irene Hellemans
Niels Peek
**Abstract**

*Context:* Computerized decision support systems (CDSSs) can be used to improve the implementation of clinical practice guidelines by changing the behaviour of care professionals. While effects of problem type and CDSS characteristics on guideline implementation are well studied, little is known about the relation between cognitive, organizational and environmental factors, and the effectiveness of CDSSs.

*Objective:* To assess the effect of CDSSs on cognitive, organizational, and environmental factors that hamper guideline implementation.

*Design:* In-depth, semi-structured interviews with care professionals, on reasons for improved adherence or persistent non-adherence to the prevailing guideline after successful adoption of a CDSS. All remarks regarding guideline implementation were extracted and classified using the conceptual framework from Cabana et al. (JAMA 1999;282(15):1458-65).

*Setting:* Outpatient cardiac rehabilitation clinics.

*Participants:* Care professionals that used the CARDSS decision support system for therapeutic decision making in cardiac rehabilitation.

*Results:* Twenty-nine rehabilitation nurses and physiotherapists from twenty-one Dutch clinics were interviewed. CARDSS improved guideline adherence by increasing its users’ familiarity with the guidelines’ recommendations and decision logic, by overcoming users’ inertia to previous practice, and by reducing guideline complexity for example by facilitating calculation and interpretation of data. If the system’s recommendations were shared with patients, refusal to participate in therapies reduced. CARDSS never incited users to target barriers related to organizational or environmental constraints.

*Conclusion:* Our results suggest that computerized decision support can improve guideline implementation by increasing the knowledge of preferred practice, by reducing inertia to previous practice, and by reducing guideline complexity. However, computerized decision support is not effective when organizational changes are required that users consider to be beyond their tasks and responsibilities.
Introduction

Application of clinical practice guidelines can improve patient outcomes, reduce practice variation, and reduce costs [1-3]. However, care professionals often do not follow the recommendations of practice guidelines [4]. This is due to various barriers that professionals may face when they try to incorporate practice guidelines into care practice [5]. These can be divided into internal and external barriers. Internal barriers relate to the professional's knowledge of and attitude towards the guidelines. For instance, a professional may not know the details of a particular guideline by heart, or may in certain cases disagree with its recommendations. External barriers are either related to the guidelines themselves (e.g., complexity of rules and recommendations), to the patient (e.g., patients may refuse therapies), to the organization (e.g., insufficient time or resources), or to other environmental factors (e.g., reimbursement policies). For effective guideline implementation, carefully designed change strategies are required to overcome these barriers [6;7].

Computerized decision support systems (CDSSs) are increasingly considered to be one of the most effective instruments to improve guideline implementation [6-10]. However, although the majority of evaluated CDSSs were effective in improving guideline implementation, occasionally CDSSs also proved ineffective [8;9]. While the influences of system characteristics and clinical task on effectiveness of computerized decision support have been well studied, little is known about cognitive, organizational, and environmental factors that affect the impact of these systems [8;9;11].

Despite its proven cost-effectiveness [12], cardiac rehabilitation (CR) services are underutilized and insufficiently evidence based in many western countries [12-14]. To improve the implementation of the Dutch multidisciplinary CR guidelines [15], a CDSS, named CARDSS (CArdiac Rehabilitation Decision Support System), was developed [16]. To improve CARDSS' adoption, known success factors for guideline-based CDSSs were taken into account during its development [16]. CARDSS actively assists its users, predominantly rehabilitation nurses and physiotherapists, in making therapy decisions for CR patients in concordance with the guideline recommendations. Therefore CARDSS prompts users to assess the necessary patient information, determines each patient’s rehabilitation needs, and assists in formulating a patient-specific rehabilitation programme [16]. In a recent cluster randomised trial [17], of which the results will be reported in detail elsewhere, CARDSS was found effective in increasing professionals’ concordance to guideline-recommended therapies. However, there remained a large variation between different clinics in guideline implementation in terms of therapy provision, working procedures, and assessed needs of patients. These findings indicate that CARDSS successfully targeted some barriers to guideline
implementation, but not all. The fact that CARDSS’ usability was judged positive by its users [18] and is still used in over 35 Dutch outpatient clinics, suggests that some barriers lie beyond the influence of a successfully adopted CDSS. In this paper we report on a qualitative study to understand which cognitive, organizational, and environmental barriers to guideline implementation were targeted by CARDSS and which barriers persisted. This study can provide valuable insight into the circumstances in which a CDSS can be effectively used as guideline implementation instrument.

**Methods**

**Participants**

CR professionals from all clinics that worked with CARDSS in January 2007 and used CARDSS for more than one year were considered eligible to participate in this qualitative study. All eligible professionals with an executive role in conducting and organizing the CR needs assessment and therapeutic decision making procedures (generally a rehabilitation nurse or physiotherapist) were invited to participate in this study.

**Interviews**

In-depth, semi-structured interviews were conducted with participants of the study to discuss if and why CARDSS did or did not improve the adherence of their team to guideline recommendations. Table 1 lists the different guideline recommendations that were addressed during the interviews. For each of these recommendations it was discussed with participants whether they systematically followed the recommendation prior to the introduction of CARDSS in their clinic, and whether this had changed after they started to use CARDSS. In addition, if participants reported that a recommendation was not systematically followed before or after the introduction of CARDSS, they were asked why, in their opinion, this was the case. Similarly, if participants reported a change in adherence to recommendations, they were asked to describe their perceived reasons for the change. Prior to the interviews, clinics’ quantitative data from CARDSS on the demography, needs assessment criteria, and therapy decisions for individual patients, were collected. This data was used to create a paper report for each clinic in which their recorded information regarding the recommendations presented in Table 1 were outlined in the form of tables and charts. Each clinic’s paper report was studied by two researchers (MV and RG) prior to the interviews to be able to verify participants’ statements (triangulation [19]). In case the participants found it difficult to reflect upon their adherence to a particular guideline
recommendation, or if a statement regarding guideline adherence appeared to be inconsistent with the paper report, the relevant data from the report were discussed with the participants.

Interviews were conducted by one independent junior researcher (MV). She was accompanied by a senior researcher (RG or IH) during the first five interviews, after which MV had become sufficiently acquainted with the field of CR to conduct the interviews independently. If the three most recent interviews provided no new insights, no additional interviews were conducted (theoretical saturation [19]). Informed consent was obtained from all interviewees to audiotape the interview.

Table 1. Recommendations of the cardiac rehabilitation guidelines that were discussed during interviews

<table>
<thead>
<tr>
<th>Use of objective instruments</th>
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<tbody>
<tr>
<td>An objective exercise test (a bicycle test or a Shuttle Walk Test) should be conducted prior to or during the needs assessment procedure to determine whether the patient’s exercise capacity needs to be increased.</td>
</tr>
<tr>
<td>The MacNew quality-of-life questionnaire should be filled in by all patients to assess whether there is a need for emotional or social counselling.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>The assessment of risk behaviour and lifestyle</th>
</tr>
</thead>
<tbody>
<tr>
<td>The smoking status of patients at the time of their cardiac incident should be assessed. Patients should be supported to quit smoking when appropriate.</td>
</tr>
<tr>
<td>It should be assessed whether patients’ dietary habits comply with the norms for a healthy nutrition (2 pieces of fruit and 7 ounces of vegetables a day, 2 portions of fatty fish a week, little salt, max 2 glasses of alcohol etc). Patients should be supported to develop healthy diet when appropriate.</td>
</tr>
<tr>
<td>It should be assessed whether patients comply with the Netherlands norm for healthy exercise (30 minutes of moderate physical activity during at least 5 days, but preferable 7 days a week). Patients should be supported to adopt a physically active lifestyle when appropriate.</td>
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</table>

<table>
<thead>
<tr>
<th>Therapeutic decision making</th>
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</thead>
<tbody>
<tr>
<td>Patients should be offered education therapy according to their individual needs</td>
</tr>
<tr>
<td>Patients should be offered exercise therapy according to their individual needs</td>
</tr>
<tr>
<td>Patients should be offered relaxation therapy according to their individual needs</td>
</tr>
<tr>
<td>Patients should be offered lifestyle change therapy according to their individual needs</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Analysis</th>
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<tbody>
<tr>
<td>All interviews were transcribed verbatim for content analysis. Two researchers (RG and MV) independently extracted all remarks from the interviews in which the participant i) addressed to be still non-adherent to a specific guideline recommendation at the time of the interview, ii) addressed that their adherence to a</td>
</tr>
</tbody>
</table>
specific guideline recommendation changed because of the introduction of CARDSS, iii) addressed that adherence to a guideline recommendation improved since, but not explicitly attributed them to, the introduction of CARDSS. The extracted remarks were assembled and compared. For all remarks selected by only one researcher, a third researcher (NdK) adjudicated upon inclusion in the analysis.

Three researchers (RG, NdK, NP) subsequently classified and analyzed all remarks according to the conceptual framework of Cabana et al. [5] (Figure 1). In this framework, reasons for physicians’ non-adherence to guidelines can be categorized as different types of internal barriers, affecting the knowledge or attitude of physicians towards the guideline, or as external barriers, related to either the patient, guideline, or environment of the physician, affecting their acting upon guideline recommendations (behaviour). However, it is also possible that external barriers affect the knowledge or attitude of physicians towards the guideline (e.g., guideline complexity causes inertia to previous practice). In Figure 1, this is illustrated by the arrows directing from the external barriers to several internal barriers. For each of the internal barriers identified in our study, it was therefore also determined if they were actually caused by an underlying external barrier.

Figure 1. Physician barriers to guideline adherence (adapted from Cabana et al. [5]).

Results

Eligible professionals from 25 clinics were invited to participate in our study. Except for one clinic who didn’t respond to our e-mail and telephone calls, one or more professionals from all clinics agreed to take part in the study. Interviews with 29 professionals (21 rehabilitation nurses, 7 physiotherapists, and 1 rehabilitation doctor) from 21 outpatient clinics were conducted after which theoretical saturation
was reached. To this end, professionals from the remaining three clinics were not interviewed.

All interviews were conducted in February and March 2007 and lasted between 30 and 60 minutes. During the interviews the paper reports proved to be a valuable instrument to discuss participants’ working procedures in detail. In most interviews, participants initially stated for one or more guideline recommendations that they worked according to the recommendation while trial data suggested otherwise. Once confronted with the trial data, participants refined their statements and elaborated upon their working procedures in detail.

The results of the study are presented in the following sections. All types of barriers that persisted or were reduced because of CARDSS are included in tables with a representative sample comment. Changes in procedures since, but not explicitly attributed to the introduction of CARDSS by respondents, are only discussed in the text. In case participants reported an internal barrier to guideline implementation that was however actually caused by an underlying external barrier, the internal barrier is included in the table and the underlying external barrier is discussed in the text.

**Barriers to the use of objective instruments**

Table 2 shows that both persistent and reduced barriers to using objective needs assessment instruments were identified. In many clinics a patient’s need for exercise therapy is still determined by a nurse’s subjective appraisal and not via an objective exercise test as recommended by the guidelines. In several clinics this is due to a lack of capacity at the clinic’s functional department (e.g., insufficient exercise bicycles). However, none of the participants tried to target these capacity problems. Only one clinic reported to have started conducting a Shuttle Walk Test instead as recommended by the guidelines (“We didn’t use the Shuttle Walk Test until CARDSS. We now do it before [the needs assessment procedure] and afterwards [after the CR programme]”). Several clinics reported that they do conduct an exercise test, but only after the therapy decisions have been made, making it impossible to take account of test results in the decisions. No participant had put effort into rescheduling these exercise tests with the functional department to solve this problem.

Most participants did report that CARDSS stimulated the use of the MacNew quality-of-life questionnaire [20] which is advocated by the guidelines. Most participants didn’t know the questionnaire or didn’t know how to apply it, but started to use the questionnaire because CARDSS guided them in its use and interpretation. CARDSS sometimes reduced professionals’ inertia to previous practice regarding the use of the
questionnaire: some of the participants didn’t use it prior to CARDSS because they found calculating and interpreting its results too laborious.

Table 2. Barriers to using objective instruments to assess the patient needs for cardiac rehabilitation. Barriers were either reduced (r) or persisted (p) after the introduction of CARDSS. A sample comment is listed with each barrier.

<table>
<thead>
<tr>
<th>Barrier</th>
<th>p/r</th>
<th>Sample comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal barriers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of familiarity</td>
<td>r</td>
<td>“We started to use the QoL questionnaire since the introduction of CARDSS. We immediately said to each other ‘this is a good instrument to use’.”</td>
</tr>
<tr>
<td>Inertia to previous practice</td>
<td>r</td>
<td>“We now use the QoL questionnaire more consistently. Before we had to send it to the psychologist who calculated and interpreted its scores. CARDSS made this much easier.”</td>
</tr>
<tr>
<td></td>
<td>p</td>
<td>“At the CR needs assessment we judge the exercise capacity of patients by clinical experience. The bicycle test is performed at the exercise programme...”</td>
</tr>
<tr>
<td>Lack of agreement</td>
<td>p</td>
<td>“We don’t see the surplus value of letting patients perform an exercise test within four weeks after cardiac surgery.”</td>
</tr>
<tr>
<td><strong>External barriers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environmental factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of time / resources</td>
<td>p</td>
<td>“At the end of the hospitalization, an exercise test is always performed for patients that suffered a myocardial infarction. But that isn’t a standard for all cardiac patients...because our capacity is just not sufficient.”</td>
</tr>
<tr>
<td>Organizational constraints</td>
<td>p</td>
<td>“...the results [of the bicycle test] are not yet here [at the CR needs assessment procedure] by the time we see the patient again. The cardiologist usually does not have his report finished yet. However some patients know what their own results were.”</td>
</tr>
</tbody>
</table>

**Barriers to assessment of risk behaviour and lifestyle**

Several interviewees reported that CARDSS had improved the assessment of risk behaviour and lifestyle of patients. CARDSS users are automatically prompted to record various aspects of each patient’s lifestyle. This raised the awareness that attention should be paid to lifestyle assessment and lifestyle change. Nevertheless, the assessment of lifestyle parameters was often not carried according to the recommendations of the guideline because rehabilitation professionals disagreed with the guideline, had poor expectations of the methods prescribed by the guideline, stuck to previous practice, or because there were external barriers related to patient factors and guideline factors (Table 3). However, all internal barriers to the assessment of risk behaviour and lifestyle reported by participants appeared to be caused by
underlying patient and guideline factors. Participants frequently reported that the criteria for a healthy lifestyle presented in the guidelines are too stringent, and the associated assessment procedures are too shallow. For instance, many patients know what the norms for healthy nutrition are and claim that they do follow them. Interviewees stated that they often don’t believe these claims, but the guideline offers no instruments to objectify patients’ dietary habits. As a result, the assessment of dietary habits is subject to considerable variation among clinics; some use BMI as a proxy, others simply ask their patients whether they have unhealthy eating habits, while others try to assess the patients’ dietary habits by self-developed methods. Similar barriers were found for the assessment of the patient’s exercise habits. Respondents stated that they would like to put more effort in lifestyle assessment, but that the guideline should provide more elaborate and practical directions.

Table 3. Barriers to using the proper assessment of the risk behaviour and lifestyle of patients. Barriers were either reduced (r) or persisted (p) after the introduction of CARDSS. A sample comment is listed with each barrier.

<table>
<thead>
<tr>
<th>Barrier</th>
<th>p/r</th>
<th>Sample comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal barriers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of familiarity</td>
<td>r</td>
<td>“Since CARDSS we focus more on these [lifestyle related] questions.”</td>
</tr>
<tr>
<td>Inertia to previous practice</td>
<td>r</td>
<td>“Before CARDSS we hardly paid any attention to it [assessment of eating habits], but now we do, because we are automatically prompted for it.”</td>
</tr>
<tr>
<td></td>
<td>p</td>
<td>“If I would ask about [healthy eating habits] extensively it would take me a lot of time.”</td>
</tr>
<tr>
<td>Lack of agreement</td>
<td>p</td>
<td>“We do not follow the guideline but use the BMI to assess eating habits instead. The guideline prescribes two ounces of vegetables [per day], two pieces of fruit [per day] and a minimum of two portions of fatty fish [a week], but I do not know anyone who complies to that.”</td>
</tr>
<tr>
<td>Lack of outcome expectancy</td>
<td>p</td>
<td>“The eating habits of patients are difficult to determine. I generally use the BMI [body mass index] of patients as a guideline. This way all patients are judged similar. Because patients always say that they do it [eat healthy].”</td>
</tr>
<tr>
<td><strong>External barriers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient factors</td>
<td>p</td>
<td>“We assess the lifestyle of patients based on what they tell us, but of course you don’t know whether that is the truth. It is hard to determine because you need to question very deeply...Nowadays everybody knows what you should eat and drink. ‘No I eat healthy and I use liquid fats’, but for some people I just don’t believe that.”</td>
</tr>
<tr>
<td>Guideline factors</td>
<td>p</td>
<td>“We determine that [unhealthy eating habits] by reading patients that list [of healthy eating habits presented in the guideline] and ask ‘do you do this?’ Then people usually say ‘yes I know and follow them’... I just don’t think that asking about the list is sufficient.”</td>
</tr>
</tbody>
</table>
Barriers in therapeutic decision making

In therapy decision making, participants reported persistent barriers to guideline implementation related to inertia to previous practice, a lack of agreement, patient refusal, a lack of time or resources, organizational constraints, and a lack of reimbursement (Table 4). Participants often reported that they do not follow the guidelines’ decision-making rules with respect to lifestyle change and relaxation therapy due to a lack of facilities and resources. This was usually also the underlying cause for participants’ inertia to previous practice. In some outpatient clinics a lack of management priority was reported as a reason for not following the guideline. However, none of the participants had tried to establish a lifestyle change therapy since the introduction of the CDSS by discussing the lack of facilities or resources with their managers or cardiologists. Some centres did start to offer relaxation therapy to patients after CDSS introduction, but only within the limits of the available resources: it was usually offered as part of their exercise or lifestyle change therapy and not separately, as the guideline recommends. Clinics that did have the facilities to offer lifestyle change therapy frequently reported that patient refusal is the main reason for non-adherence to guideline recommendations due to the stigma associated with psychological counselling. Some interviewees are non-adherent to guideline recommendations as they believe that relaxation and lifestyle change therapy is recommended too often.

Use of CARDSS reduced barriers in therapeutic decision making related to a lack of familiarity with the guidelines, inertia to previous practice, and patient refusal (Table 4). Some participants stated that they changed their CR programme because the CDSS provided them with more insight in, and made them more aware of, their working procedures. Several interviewees report that they changed their CR programmes since the use of the CDSS, but often found it hard to say whether that was actually attributable to the CDSS (“Whether it was because of CARDSS I don’t know, but we came to realize that it was important to have it [relaxation therapy]”). Although several participants reported that the CDSS changed their decisions regarding lifestyle change and relaxation therapy, no changes in decision making regarding the exercise and educational therapies were mentioned. However, a clear change that was reported was the following. Several participants confront patients with the recommendations provided by CARDSS during the needs assessment procedure. These participants reported that patients are now more willing to participate in lifestyle change therapy as they see that CARDSS, and thus the national guideline, recommends that they should do so (“We notice that patients say ‘Well if the system says that it is good for me to follow that therapy, I will do so.’”). Patients seemed to be more receptive to guideline recommendations than to ‘professional opinion’.
Table 4. Barriers to therapy decision making according to guideline recommendations. Barriers were either reduced (r) or persisted (p) after the introduction of CARDSS. A sample comment is listed with each barrier.

<table>
<thead>
<tr>
<th>Barrier</th>
<th>p/r</th>
<th>Sample comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal barriers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of familiarity</td>
<td>r</td>
<td>“We have become more aware of its [relaxation therapy] importance. That is why we incorporated it in our exercise therapy.”</td>
</tr>
<tr>
<td>Inertia to previous practice</td>
<td>r</td>
<td>“What has changed that we have become more aware of certain things. We now offer CR to more patients, mostly on a psycho-social basis.”</td>
</tr>
<tr>
<td></td>
<td>p</td>
<td>“We don’t have lifestyle change therapy. We have not thought about it yet. I think that is just because of a lack of time.”</td>
</tr>
<tr>
<td>Lack of agreement</td>
<td>p</td>
<td>“Relaxation therapy is always recommended [by the guideline]. If exercise therapy is recommended, then relaxation therapy is also recommended.”</td>
</tr>
<tr>
<td><strong>External barriers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient factors</td>
<td>r</td>
<td>“At first there were only few patients who wanted to participate in lifestyle change therapy. The resistance was very high. This has improved greatly because of CARDSS since we now tell patients ‘see, according to the computer programme you should follow it’.”</td>
</tr>
<tr>
<td></td>
<td>p</td>
<td>“Patients often have a lot of resistance towards it [lifestyle change therapy]...They say ‘I will not see a psychologist because there is nothing wrong with me’.”</td>
</tr>
<tr>
<td>Environmental factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of time / resources</td>
<td>p</td>
<td>“It [exercise therapy] is currently full due to a lack of accommodation. The physiotherapist says he just wants five patients in his group, because otherwise the hall is too small for sports activities.”</td>
</tr>
<tr>
<td>Organizational constraints</td>
<td>p</td>
<td>“I wished that we could put more effort in our CR programme. However our hospital is now in a turbulent situation and then CR is not the main priority.”</td>
</tr>
<tr>
<td>Lack of reimbursement</td>
<td>p</td>
<td>“The insurance companies do not reimburse relaxation therapy.”</td>
</tr>
</tbody>
</table>

**Discussion**

In this study we have identified cognitive, organizational, and environmental barriers to guideline implementation in cardiac rehabilitation, and assessed which barriers were successfully levelled by the introduction of a CDSS. We found that the CDSS improved guideline implementation by increasing its users’ familiarity with the recommendations and decision logic of the guidelines, by overcoming users’ inertia to previous practice, and by reducing guideline complexity, for example by facilitating calculation and interpretation of assessment results. If CDSS recommendations were
shared with patients, fewer patients refused to participate in psycho-social therapy. Environmental barriers related to a lack of time or resources, organizational constraints, and a lack of reimbursement, were never reduced by the CDSS.

Previous studies of the effects of CDSSs have predominantly relied on quantitative methods [8]. Although such methods can point out whether or not the evaluated system was successful in improving practitioner performance (e.g. guideline adherence), they cannot provide insight into why or how the CDSS in question was or was not effective [21-23]. Therefore, to date little is known about the relation between cognitive, organizational, and environmental factors and the effectiveness of these systems [8;23;24]. Our study provides a start in filling this gap.

In our study, the assessment of barriers to guideline adherence may have been biased by using the framework of Cabana et al [5]. This framework was designed for classifying the reasons why physicians do not follow guideline recommendations but we used it to assess which barriers are reported by nurses and physiotherapists. These are the main types of care professionals in cardiac rehabilitation. The categories that were defined by Cabana et al. may not be suitable for these types of care professionals, resulting in a classification that is too coarse. Because the reported barriers are evenly distributed over the categories defined by Cabana et al., we do not believe that this is the case though.

A qualitative approach is the best method to get insight into reasons why guideline implementation was or was not improved [21-23]. However, such methods have some limitations. The answers of the participants of our study may have been socially desirable or prone to recollection bias, and several participants remarked that they found it difficult to attribute the changes to CARDSS. These circumstances may have negatively influenced the completeness of our results. For instance, CARDSS' quantitative evaluation showed that the system stimulated its users to let their therapy decisions better correspond to recommendations in the guidelines, but none of the interviewees in the current study explicitly remarked that the CDSS influenced their decisions concerning exercise and education therapies. Either such changes in therapeutic decision making go by unnoticed or participants did not remember these behavioural changes at the time of the interview, which was held nearly two years after the introduction of the CDSS. We nevertheless believe that the majority of relevant barriers was uncovered in our study because there was a relatively large number of participants, because quantitative data on clinics' working procedures were used to verify participants’ comments, and because the primary interviewer (MV) was not involved in the design and quantitative evaluation of the system [19]. Although interviews with a group of non-CDSS users might have been on option,
triangulation would be difficult as no quantitative data of these CR outpatient clinics are available.

The results of our study cannot be generalized to CDSSs that are not yet adopted and implemented in practice. It is known that the implementation of a CDSS is a challenge of its own as it affects the working procedures of its users [25;26]. Also, the generalizability of our results might be restricted to settings where these users are predominantly nurses and paramedics. However, contemporary healthcare is increasingly shifting towards care models in which specialised nurses are responsible for the ‘case management’ of patients [27]. This study therefore provides important insights into the effectiveness of CDSSs in these types of care models.

It is known that involving patients in therapy decision making increases their feeling of autonomy and motivation and to manage their disease [28]. In this study we found that confronting patients with on-screen CDSS recommendations resulted in an increased patient receptiveness towards participation in psycho-social programmes. This finding supports the recommendation by Kawamoto et al [11] to share a CDSS’ advice with patients to improve CDSS effectiveness.

Recommendations from a CDSS cannot directly influence barriers that exist at other departments than the one where the CDSS is used. Similarly, when a care professional cannot follow a guideline’s recommendation because there is a lack of facilities or there are other organizational constraints, computer advice will not help. One could hypothesize that CDSS users, once regularly confronted such advice that they are unable to follow, would bring these problems to the attention of their superiors. Although all study participants used the CDSS for over one year, none of them actually put effort in overcoming these ‘higher level’ barriers. For example, no outpatient clinic tried to change the planning of bicycle test appointments with the functional department in order to have the test results available to inform therapy decisions. Apparently, CDSSs like CARDSS do not incite its users to realize changes that, according to its users, exceed their ‘own’ tasks, responsibilities, or control. This phenomenon, that barriers faced by front-line, non-physician, hospital workers do not reach managers, doctors, and policy makers, was also described by Tucker and Edmondson [29].

Our results suggest that CDSSs, consulted by nurses or physiotherapists, can improve adherence to guidelines by increasing the knowledge of preferred practice and facilitating the guidelines’ application in practice. In case such barriers hamper guideline implementation, we recommend policy makers and guideline implementers to consider the use of a CDSS as an implementation strategy. However, if changes in the organization of care are required that are beyond the working procedures, responsibilities, and control of CDSS users, other or additional guideline
implementation instruments should be considered to empower CDSS users or involve the actual decision makers.

Reference List


Chapter 9

General Discussion
Chapter 9. General Discussion

Introduction

The objective of this thesis was to gain understanding of the deployment and effectiveness of guideline-based computerized decision support (CDS) in multidisciplinary outpatient care. To this end we developed, implemented, and evaluated a CDS system for multidisciplinary cardiac rehabilitation that was based on the Dutch Cardiac Rehabilitation Guidelines 2004 [1]. In order to reach the above mentioned objective we formulated several research questions that were addressed in Chapter 2 to Chapter 8.

Q1: How to develop a computerized decision support system that can assist professionals in working according to the Cardiac Rehabilitation Guidelines 2004?

Q2: Do cardiac rehabilitation professionals consider the developed system usable and useful in practice?

Q3: Does the provided computerized decision support improve implementation of the Cardiac Rehabilitation Guidelines 2004?

In this chapter we synthesize and discuss the results from the previous chapters to provide answers to these research questions. Subsequently we discuss the strengths and weaknesses of our research, also in relation to other studies, and discuss the meaning of our findings. Finally, we conclude with some recommendations for further research.

Statement of principal findings

The development of a guideline-based computerized decision support system for cardiac rehabilitation

To address research question Q1 we divided the development of the guideline-based CDS system into two steps; the formalization of the Cardiac Rehabilitation Guidelines 2004 (Chapter 2) and the actual development of a CDS system based on the formalized guidelines (Chapter 3).

To reduce common guideline formalization problems caused by vagueness, inconsistencies and other errors in guidelines, the Cardiac Rehabilitation Guidelines 2004 were formalized concurrently with their development. Central assets of this parallel guideline development and formalization strategy were the early involvement of formalization specialists and formalization tools, cooperation between guideline authors and formalization specialists in the development of a summary flowchart, and
verification of the guideline model prior to dissemination. In Chapter 2 we found that this strategy helped to identify several vague and inconsistent recommendations and impracticalities in the narrative guidelines that could be resolved before publication. In addition, the strategy ensured consistency between the narrative and formalized guideline. Results from Chapters 6, 7 and 8 however showed that there still existed a considerable variation between clinics in the assessed needs of and therapy decision for patients. Therefore, although our parallel guideline development and formalization strategy does help to improve quality of narrative guidelines, these higher quality guidelines can still be implemented very differently across healthcare providers.

The actual development of the CARDSS system was addressed in Chapter 3. Just like the formalization of the guideline, the system was developed concurrently with the guideline, which had the benefit that guideline authors could be involved in the system’s requirement analyses. As no electronic patient record (EPR) system for cardiac rehabilitation was yet in use in Dutch outpatient clinics, the CARDSS system had to provide EPR functionalities as well as CDS functionalities. This had the advantage that CDS and EPR functionalities could be closely integrated. The system actively guides professionals in conducting the needs assessment procedure described in the guidelines through a structured dialogue, prompting them to enter the necessary patient information. Subsequently they are provided with the therapies and goals that are recommended by the guidelines for the patient in question. Several additional CDS-related and patient information management related functionalities were added to increase the system’s chances of adoption. These functionalities include providing professionals with the rationale behind a recommendation, giving insight into relevant guideline information and scientific evidence, evaluating the progress of patients during cardiac rehabilitation, providing useful patient summaries, and calculation of summary statistics across patients.

The development of CARDSS was complicated by the fact that it had to be a comprehensive system with both CDS and EPR functionalities while in first instance we only wanted to provide and evaluate the effect of CDS. First, considerable time and expertise is required to develop a system that provides the required functionalities and is useful in practice. Second, as the system was actively used by professionals on a daily basis, users had to have access to technical and functional support. Third, as professionals regularly requested additional functionalities, an infrastructure for software updates had to be set up. These factors made that this project required considerable time and resources. To limit the resources needed for and facilitate the execution of this type of research, we recommend researchers that are planning to conduct a CDS evaluation study to develop a CDS system that operates in the background of an existing EPR system, if available.
Users’ satisfaction with the CARDSS system

To address research question Q2 first a pilot study was conducted to test the usability of a first version of CARDSS. This pilot study was described in Chapter 4. Chapter 5 describes a study on the users’ satisfaction with CARDSS that was conducted after the CARDSS trial. In both studies users were positive about CARDSS’ usability and usefulness. CARDSS’ users were positive towards its ease of use, its quality and clarity of information, and the system’s interface quality. Professionals, even those with little computer experience, found CARDSS easy to use and stated that the system increased their understanding of the Cardiac Rehabilitation Guidelines 2004. The satisfaction about CARDSS’ usability was higher for professionals that managed to successfully integrate the system into their working procedures. Furthermore, a positive attitude towards CDS systems in general and towards the content of the Cardiac Rehabilitation Guidelines 2004 was positively related to satisfaction about CARDSS’ usability. Based on the recommendations by participants in the pilot study several changes were made and several functionalities were added to the CARDSS software to improve its usability and usefulness.

Based on the fact that CARDSS was adopted in practice and is still used in over 30 Dutch outpatient clinics we believe that the development and implementation of CARDSS was successful. A limitation of the system however is that communication with other data systems is not supported. This restricts its implementation in new clinics as data exchangeability nowadays is a requirement in all Dutch hospitals and rehabilitation clinics. Another issue is that most centres working with CARDSS now use it as their primary administration system for cardiac rehabilitation. Therefore, users ask for training sessions, extended technical and functional support, and additional functionalities. CARDSS is currently being handed over to a professional software development company that will extend and improve the functionalities and support of CARDSS to meet the needs of current and future users.

The effect of CDS on implementation of the cardiac rehabilitation guidelines

The final research question of this thesis, Q3, was addressed in Chapter 6, Chapter 7, and Chapter 8. In the cluster randomized trial with CARDSS we found that CDS was an effective strategy to improve guideline concordance of multidisciplinary cardiac rehabilitation teams. Team guideline concordance increased significantly for three of the four offered therapies. In the qualitative study on the effect of CDS we found that CDS was effective to improve guideline implementation if it facilitated the application of the guidelines in practice and thus supported professionals in changing their
working procedures. In addition, sharing guideline recommendations with patients increased their willingness to participate in the cardiac rehabilitation programme. However, we found the CDS was primarily effective because it increased users’ familiarity with guideline recommendations. Interestingly none of the participants reported that their decision making for exercise and education therapy had changed because of the CDS. However, these were two of the therapies for which the trial had shown that the CDS increased concordance. This suggests that healthcare professionals are not fully aware of the effect of an intervention such as CDS on their knowledge and decision making.

Despite the positive effect of CDS on overall guideline concordance, we found that there is room for further improvement. For both the lifestyle change therapy and relaxation therapy a considerable undertreatment of patients still exists. We found that this was mainly caused by a lack of facilities or other organizational barriers in the centres concerned. Although it is logical that barriers such as a lack of facilities hamper following the guidelines, one might hypothesize that, when confronted with guideline non-concordance on a daily basis, teams would soon try to address these organizational barriers. However, despite the fact that CARDSS was used in centres one to two years, none of the teams even discussed these organizational barriers with their management or with other departments involved. Another source for variation between clinics we found was that when the needs of patients were assessed by clinical judgment of professionals a considerable difference and variation in these needs of patients was found compared to when patients’ needs were assessed by measurement instruments. The variation in the assessed needs of patients might also explain part of the variation in therapy decisions between centres.

In these studies we found that CDS can be an effective instrument to improve guideline implementation in multidisciplinary settings with motivated professionals. CDS increases professionals’ knowledge of preferred practice and facilitates guideline interpretation and application. Therefore a CDS system can also be considered to improve guideline implementation in other multidisciplinary settings. However, if guideline implementation requires changes in the organization of care that professionals consulting the CDS consider beyond their direct responsibilities or control, the provision of CDS alone appears to be insufficient to realize such changes. In case guideline implementation is hampered by organizational constraints or environmental barriers, other or additional change strategies should be considered.
Strengths and weaknesses of the study

A strength of our research is that we first conducted a pilot study with the CARDSS system before its widespread implementation and evaluation. The pilot study provided us with insight in the professionals’ satisfaction with CARDSS usability and usefulness. Based on the findings from the pilot study several changes and additional functionalities were implemented in CARDSS before the main evaluation study. If such a pilot study had not been conducted, the trial with CARDSS might have failed as some changes would not have been implemented and users might have been less positive about CARDSS usability and usefulness.

We believe that another strength of our research is that the CARDSS project was supported by two important stakeholders: the Netherlands Heart Foundation and the Netherlands Society of Cardiology, a patient interest and professional organization respectively. As these stakeholders believed CARDSS was an important key to the implementation of the Cardiac Rehabilitation Guidelines 2004, they presented the guidelines and CARDSS jointly to the field during a national congress on cardiac rehabilitation. In addition, these stakeholders continued to support the further development, implementation, and evaluation of CARDSS. As the support from these influential stakeholders appeared to convince professionals in the field to use the CARDSS system and participate in our trial, we believe it has been critical to the success of this project.

A difficulty in our research was that we were not just able to implement a CDS system that operated in the background of an existing EPR. To participate in our study, teams had to replace their traditional administration system, usually a paper-based or word processor based system, and learn to work with a comprehensive EPR system, instead of just learning to work with the CDS. Therefore, participation in our CDS evaluation study required motivation and willingness to invest considerable time and resources from both the cardiac rehabilitation team as well as the centre’s IT department. This fact limited uptake of CARDSS and led to attrition in our CDS evaluation study. We believe that this type of research on CDS will become easier when EPR systems through which CDS can be provided are more common in medical practice.

In our trial we analyzed whether different types of rehabilitation therapy were initiated according to guideline recommendations, without taking into account the duration or intensity of treatments. We considered this the most appropriate outcome measure as the cardiac rehabilitation guidelines do not specify how many sessions each therapy should entail and how many sessions should be attended. However, such an outcome measure has some limitations. First, although two teams might both offer ‘the same’ therapy to a patient, the actual organization and provision of this therapy might be rather different. For example, we found that some teams that offered
relaxation therapy had set up a separate and comprehensive therapy, while other teams offered relaxation therapy as a part of the exercise therapy. In our analyses these teams are similarly concordant. Second, our outcome measure assumes that undertreatment is just as bad as overtreatment. It can be questioned whether these two premises are valid. Third, several participants reported that patients less often refused to participate in psychosocial therapies when recommendations from CARDSS were shared with them. As only three participants shared CDS recommendations with patients we believe that this effect of changes in patients’ behaviour by the CDS did not greatly affect our results. However with our process measure we were unable to quantify this effect.

Guideline implementation strategies should ideally aim at targeting specific barriers [2]. In our research we did not study the existing barriers to following the Cardiac Rehabilitation Guidelines 2004 prior to the development and introduction of CARDSS. Therefore we were ignorant of possible barriers to guideline implementation in this field and were not sure whether CDS would be a good instrument to try and improve guideline implementation in our situation. In our study we found that there existed organizational barriers to following the guideline that were not overcome by the introduction of CDS. Therefore we recommend that possible barriers to guideline implementation be studied prior to developing an implementation strategy. This way the strategy can be tailored to the barriers at hand and thus has the best chances of improving the quality of care.

**Strengths and weaknesses in relation to other studies**

Although many CDS evaluation studies have been conducted [3;4], descriptions of the development and functionalities of these systems are scarce [4]. Such descriptions of CDS systems are useful for both researchers and developers that are involved in CDS development and evaluation initiatives [5]. In addition, they are needed to gain more insight into characteristics and functionalities of CDS systems that are important to the effectiveness of such systems in practice [4]. A strength of the research described in this thesis is that it discusses the entire process from the development to the implementation and evaluation of a CDS system.

Another strength is that our study design ensured that the measured effect of CDS could not be biased by ‘checklist’, ‘Hawthorne’, ‘feedback’, or ‘carryover’ effects [6], and our trial is among the CDS evaluation studies with the largest numbers of participants to date [3]. In addition, our CDS evaluation study is one of the few studies that applied a cluster randomized design to determine the effect of CDS [3] and accounted for the intra cluster correlation (ICC) of concordance observations within
clinics [7]. In our study the ICC’s for all four therapies was higher than estimated based on the pilot study. The ICC for the relaxation therapy was even 0.48, which is one of the highest ICCs ever reported in an implementation study [8]. This was caused by the fact that a large variation in the concordance with relaxation therapy recommendations existed; some teams were almost always concordant while others lacked the facilities to offer relaxation therapy. Had these ICC’s been neglected in the statistical analysis, the uncertainty in the effect of CDS would have been seriously underestimated [8].

Unique about this project is that our research is the first to provide insight into the provision and effectiveness of CDS in a multidisciplinary setting. Specialist medical care is nowadays often provided not by individuals but by multidisciplinary teams [9-13]. By working in multidisciplinary teams the professional knowledge and skills of different disciplines have to be integrated. This is generally considered to improve the coordination, quality, and continuity of patient care [9;11;12]. While individual decision making is mainly a cognitive process, decision making in teams is additionally influenced by the social context, such as the interpersonal relationships within the team [13;14]. However, to date CDS development and evaluation efforts mainly focused on improving the performance of individual practitioners [3;4;15].

To date little is known about the relation between cognitive, organizational, and environmental factors and the effectiveness of CDS systems [3;16;17]. Our study is a first step in filling this gap. Previous studies of the effects of CDS have predominantly relied on quantitative methods [3], which cannot provide insight into why or how the interventions affected the behaviour and actions of healthcare professionals or patients [18;19]. For this purpose qualitative methods are needed. A strength of our research is that we combined quantitative and qualitative methods to study the effect of CDS on guideline implementation. The literature recommends combining qualitative and quantitative research methods in such evaluation studies [6;17].

**Implications of this research**

One of the great challenges in contemporary healthcare is to ensure the provision of evidence-based medicine in everyday healthcare [19]. Although clinical practice guidelines are considered essential instruments for this purpose [19;20], their uptake in practice is disappointingly low [2;20]. Traditionally much time and effort is put in the development of clinical practice guidelines while their implementation is given much less consideration [2;21]. This despite the fact that effective guideline implementation requires a well-designed implementation strategy [2;20;21]. Guideline development and implementation are often also treated as two distinct
activities. In this project the guideline and guideline implementation strategy were developed concurrently and collaboratively. We experienced that such an approach provides both benefits to the quality of the guideline as well as to the guideline implementation strategy. Based on these findings we think that evidence-based medicine initiatives should not solely revolve around the development of guidelines but instead focus on change management in which guideline development and guideline implementation are two equally important steps with the same goal.

We believe that the project basis on which guidelines are typically developed and disseminated is another limitation to reaching evidence-based practice [22]. The Cardiac Rehabilitation Guidelines 2004 were also developed in this manner. In such an approach the guideline is considered finished and complete after dissemination; it is not structurally evaluated and no resources are available for revisions. However, inconsistencies, omissions, vagueness or other errors that hamper the guideline’s application in practice might be identified or new research evidence may become available. In this project, studying guideline implementation indentified several shortcomings that have led to the current revision and re-evaluation of the Cardiac Rehabilitation Guidelines 2004. Based on our experience we believe the development and implementation of a guideline should not be a one-shot activity but a continuous quality improvement (CQI) initiative [23]. Working according to the quality cycle (develop, implement, evaluate, and revise the guidelines) might not only improve the quality of published guidelines, but may also help to increase the effectiveness of guideline implementation strategies. Therefore such a strategy may bring evidence based medicine closer to reality.

When conducting a cluster randomized trial, standardization is essential to minimize the chances of biasing study results. For our evaluation study we had to develop a single comprehensive system that had to be used in a similar way by participants from different centres. Also, we had to provide a standardized training course to all participants. However, this standardization led to a low uptake and high attrition in our study. By having to develop a standardized ‘one size fits all’ system we automatically excluded centres that already used another information system for cardiac rehabilitation or were used to working in a way that was not supported by the system. In addition, for some centres the standardized training course appeared to be insufficient leading to inadequate system use or complaints about the effort needed to learn to work with the system. These problems might have been avoided if a tailored training course was given to centres based on their specific needs. Our experience in this project illustrates that in quality improvement projects there is a friction between practice and research: while research requires standardization, widespread implementation in practice requires flexibility.
Chapter 9. General Discussion

Just like in any industry, processes in the provision of healthcare can be divided in primary, secondary, and tertiary processes [25]. In healthcare, the primary process is the actual provision of care by professionals. Secondary processes support the primary processes such as logistics or the work done at administrative departments. Finally, tertiary processes manage the primary and secondary healthcare processes. One of the important success factors of CDS systems described in the literature is the provision of decision support at the point of decision making, thus in the heart of the primary process of care [4;15]. In our research CDS at the point of decision making was indeed effective in case guideline concordance was hampered by a lack of familiarity with guideline recommendations or by inertia to previous practice. However, a downside to such CDS at the point of decision making appeared to be that it was ineffective to realize changes that existed in the secondary and tertiary care process. Although these limitations of the effectiveness of CDS might only exist when targeted at nurses and other paramedics, our findings suggest that CDS provided in the primary process of care is only effective to realize changes in the same process level. Therefore, whether or not the provision of CDS at the point of decision making is effective depends on the existence of barriers to guideline implementation in the primary process of care.

Recommendations for future research

In the last decade, many research groups have focussed on the development of frameworks to facilitate the development, maintenance, and implementation of CDS systems [26-30]. However, none of the descriptions of existing CDS development frameworks address whether or how they provide users with insight in the rationale behind a recommendation (i.e. answering the 'how'-question in traditional expert systems). As both our research as well as two systematic reviews [4;15] suggest that such explanation services are important for the adoption and effectiveness of the CDS, there is a need for more research on how such functionalities can be provided. Also, as such explanation services appear to be inherent to CDS systems, we recommend that CDS development frameworks should be extended to provide such functionalities.

In our research, several participants reported that sharing the recommendations provided by the CDS with patients helped to improve patient adherence. In their review, Kawamoto et al also found indications that sharing the recommendations of a CDS system with patients improve CDS effectiveness [4]. One possible explanation is that involving patients in therapy decision making increases their feeling of autonomy and motivation to manage their disease [31]. In that case the effect is not specific to CDS. However, it might also be related to the fact that patients either have more trust in either the advice of the CDS or the guideline than in the professionals’ opinion.
More research on this issue is needed to be able to gain more insight in whether and how sharing CDS recommendations with patients can increase the effectiveness of CDS in clinical practice.

The implementation of a guideline often requires that the existing working procedures of professionals, teams, or even the entire organization are changed. Our findings suggest that, although CDS can be effective in changing the primary process of care, it is insufficient to realize changes in supportive and managerial processes. However, changes at these levels are also often required for optimal guideline implementation. Therefore other or additional guideline implementation instruments should be sought for that do realize such changes. As to date still little is known about in what way guideline implementation strategies are effective in improving guideline implementation [2;16;32], more research on this topic is needed.

Many studies on ways to improve the effectiveness of either guidelines or guideline implementation strategies have been conducted [22;23;33-36]. We believe that the development and implementation of a guideline should be an integrated and continuous process. However, to our knowledge guideline development and implementation initiatives are rarely managed and evaluated as a CQI strategy. Therefore we recommend researchers to study whether managing a guideline development and implementation initiative as a CQI project could facilitate bringing evidence based medicine closer to practice.

Reference List


Chapter 9. General Discussion


Summary
One of the main challenges in contemporary healthcare is ensuring that patients receive treatment that is optimally effective according to current scientific evidence. The development and implementation of clinical practice guidelines is considered essential for this purpose. Working according to these guidelines improves patient outcomes, reduces practice variation, and reduces costs of patient care. However, the uptake of guidelines in clinical practice is still low due to different barriers related to the knowledge, attitude, and environment of healthcare professionals.

Despite the large evidence base for their effectiveness and cost-effectiveness, cardiac rehabilitation services are poorly standardised and do not follow the available scientific evidence in many Western countries. Cardiac rehabilitation is a multidisciplinary secondary prevention strategy for patients that have had a cardiac incident (e.g., a myocardial infarction), underwent a cardiac intervention (e.g., heart surgery), and for patients with heart failure. Cardiac rehabilitation is critical to ensure that cardiovascular disease patients are in the best possible physical, psychological and social condition to return to and maintain their normal place in society. In addition, cardiac rehabilitation is important to reduce patients' future cardiovascular risks. To improve the quality of cardiac rehabilitation in the Netherlands, the Netherlands Heart Foundation and the Netherlands Society of Cardiology released new cardiac rehabilitation guidelines in 2004. In these guidelines, the assessment of patient’s needs for cardiac rehabilitation forms an important subject. The project described in this thesis revolved around these Cardiac Rehabilitation Guidelines 2004 and their use in practice by cardiac rehabilitation teams in the Netherlands.

To work according to new clinical practice guidelines it is often required that healthcare providers change their existing working procedures according to guideline recommendations. Disseminating guidelines on paper among their target groups is found to be insufficient to enforce the required change in practice. Ensuring that professionals actually work according to guidelines in practice requires the application of carefully designed change strategies. Providing professionals with computerized decision support (CDS) (i.e. patient-specific advice or interpretation of data at the point of care) has been found to be one of the most effective instruments to improve the use of guidelines in practice. However, although many studies have evaluated the effect of CDS on decision making behaviour of individual healthcare professionals, no studies had yet investigated the effect of CDS in a multidisciplinary setting. Specialist medical care is nowadays often provided not by individuals but by multidisciplinary teams. While individual decision making is mainly a cognitive process, decision making in teams is additionally influenced by the social context, such as the interpersonal relationships within the team. The objective of the CARDSS (Cardiac Rehabilitation Decision Support System) project, described in this thesis, was
to gain an understanding of aspects of the development, deployment, and effectiveness of a guideline-based computerized decision support system in a multidisciplinary setting.

To be able to provide guideline-based CDS, the guideline's recommendations for data gathering, data interpretation, and decision making need to be translated into a computer interpretable format, a process called guideline formalization. In published accounts, guideline formalization is done after publication of the guideline concerned. However, as guidelines often contain ambiguous and vague concepts and recommendations, omissions, inconsistencies, and other errors, both guideline formalization and the development of a CDS system has shown to be problematic without a close collaboration with guideline authors. In Chapter 2 the potential benefits of the concurrent development and formalization of a guideline are evaluated. The principles of a strategy in which a guideline was formalized concurrently with guideline development were not yet described in the literature. Therefore, we developed a strategy that combines the principles of existing methodologies for guideline development, knowledge engineering and guideline formalization. Central assets of this strategy are the early involvement of guideline formalization specialists (e.g., medical informaticians) and guideline formalization tools, cooperation between guideline authors and formalization specialists in the development of a clinical algorithm, and verification of the formalized guideline prior to dissemination. We found that this strategy helped to identify vague and inconsistent recommendations and impracticalities in the narrative guidelines that could be resolved before publication. In addition, the strategy ensured consistency between the narrative and formalized guideline. Findings from this research suggest that the developed parallel guideline development and formalization strategy can be beneficial to both the quality of narrative guidelines as well as to the guideline formalization process.

Chapter 3 addresses the actual development of the CARDSS system. The system was developed concurrently with the guideline, which had the benefit that guideline authors could be involved in the system's requirements analysis. In general, CDS systems operate in the background of existing electronic patient record (EPR) systems. However, as no EPR system for cardiac rehabilitation was yet in use in Dutch outpatient clinics, the CARDSS system had to provide EPR functionalities as well as CDS functionalities. Although this complicated the development of CARDSS, it had the advantage that CDS and EPR functionalities could be closely integrated. It was decided to let CARDSS actively guide professionals in conducting the needs assessment procedure described in the guidelines through a structured dialogue, prompting them to enter the necessary patient information. Subsequently they are provided with the therapies and goals that are recommended by the guidelines for the patient in
question. Several additional CDS-related and patient information management related functionalities are added to increase the system’s chances of adoption. These functionalities include providing professionals with the rationale behind a recommendation, giving insight into relevant guideline information and scientific evidence, evaluating the progress of patients during cardiac rehabilitation, providing useful patient summaries, and calculation of summary statistics across patients.

To determine whether a first version of CARDSS was usable in practice, a six-week pilot study was conducted in four outpatient clinics. This pilot study is described in Chapter 4. After the pilot study, CARDSS users were requested to fill in a questionnaire. In addition, all data stored in CARDSS, including log files, anonymized patient data, guideline recommendations, and therapy decisions were analyzed. Participants were interviewed to clarify findings. During the pilot study, 11 different cardiac rehabilitation professionals used CARDSS to assess the rehabilitation needs for 134 patients. Five system bugs were identified which all could be resolved in one day. CARDSS’ users were positive about its usability and usefulness. Professionals found CARDSS easy to use even though some users indicated that they had hardly any experience with computers before the pilot study. Most professionals found that CARDSS increased their understanding of the cardiac rehabilitation needs assessment procedures when compared to consulting the narrative guidelines. In addition, all participants indicated they wanted to continue using CARDSS, provided that several additional functionalities were implemented. Based on users’ recommendations several changes were made to CARDSS after the pilot study.

In Chapter 5 the results of a more rigorous study on CARDSS’ usability are described. To evaluate the usability of CARDSS, a questionnaire was developed based on the IBM Computer System Usability Questionnaire (CSUQ). To identify factors that influenced CARDSS’ usability, questions were added referring to the respondents’ clinical experience with cardiac rehabilitation, the way they integrated CARDSS in their working procedures, and the time increase per patient caused by using the system. In addition, questions were added to assess the respondents’ agreement with the content of the national cardiac rehabilitation guidelines and their general attitude towards the use of CDS systems in healthcare. Also basic questions on the respondents’ age, gender, and computer literacy were included. Questionnaires were sent to all 68 professionals from the 28 outpatient clinics that participated in a cluster randomized trial with CARDSS. 63 respondents (93%) from 27 clinics returned the questionnaire. CARDSS’ users were positive towards its ease of use, its quality and clarity of information, and the system’s interface quality. The results of this study showed that satisfaction on the usability of CARDSS was higher in professionals that had successfully integrated CARDSS into their working procedures. Furthermore, a
positive attitude of respondents towards CDS systems in general and a better agreement with the content of the national guidelines were positively correlated to satisfaction with CARDSS’ overall usability and each of its sub-domains.

CARDSS was developed to improve the use of the Cardiac Rehabilitation Guidelines 2004 in daily practice. By providing patient-specific, active guideline-based CDS to cardiac rehabilitation professionals we aimed to bring team therapy decisions closer to guideline recommendations, and achieve a consistency of care across outpatient clinics. Chapter 6, Chapter 7, and Chapter 8, describe three studies that were conducted to provide insight into this issue.

**Chapter 6** describes a cluster randomized trial with CARDSS that was conducted to measure the effect of CDS on multidisciplinary team concordance to guideline recommended therapies. Participating centres worked with either of two versions of CARDSS: an intervention version or a control version. The intervention version had full functionality, while the control version comprised all patient information management services but did not provide therapy recommendations. This way we controlled for the potential positive effect of the information management services and dialogue structure provided by CARDSS on the decision making of rehabilitation professionals, a phenomenon known as the ‘checklist effect’. In the control arm, multidisciplinary teams selected rehabilitation therapies using their own judgment; the written guidelines could always be consulted on paper or electronically within CARDSS. Guideline concordance was assessed for four rehabilitation therapies, namely exercise training, education therapy, relaxation therapy, and lifestyle change therapy. Data from 21 centres, including 2787 patients, were analysed. Results from this trial showed that CDS significantly increased concordance with guideline-recommended therapy decisions for exercise therapy by 7.9%, for education therapy by 25.7%, and for relaxation therapy by 25.5%. CDS reduced both cases of over- and under-treatment. These findings showed that CDS can also be an effective instrument to improve the decision making of multidisciplinary teams. However, CDS was not evenly effective in all outpatient clinics and not for all therapies. CDS did not improve guideline concordance for the lifestyle change therapy which was, across both study arms, received by only 26% patients for which it was recommended. Similarly, despite the positive effect of the CDS, there remained still considerable undertreatment for relaxation therapy. Both the lifestyle change therapy and relaxation therapy were newly introduced in the Cardiac Rehabilitation Guidelines 2004. It appeared that a considerable number of clinics lacked the facilities to offer these therapies to all eligible patients. In addition, there remained to exist a large variation between centres in their levels of guideline concordance for all four therapies.
The studies in Chapter 7 and Chapter 8 were conducted to gain insight into reasons for persistent non-concordance and variation in following the guidelines between centres. In Chapter 7 we determine the variation between centres in assessed patient needs for cardiac rehabilitation, and measured the influence of different assessment methods on assessed needs. Intra-cluster correlation coefficients (ICCs), a measure to express inter-practice variation, were calculated for all rehabilitation needs and lifestyle parameters, before and after adjusting for patient case mix, and stratified by assessment method. High ICCs, indicating a high inter-practice variation, were found for insufficient exercise capacity (0.301), unrealistic subjective exercise capacity (0.165), and social problems (0.188). Moderate ICCs were found for psychological problems (0.096), absence of partner (0.052), unhealthy eating habits (0.080), and inactive lifestyle (0.059). Adjustments for case mix hardly influenced ICCs, but stratification by assessment method revealed large differences between results from clinical interviews and measurement instruments. The assessment by clinical interview led to fewer patients being judged as having an insufficient exercise capacity compared to when a measurement instrument (e.g., bicycle ergometry) was used (73.4% vs. 84.1%). In either case, however, substantial variation remained between clinic means. When assessed by clinical interview, 32.8% the patients were judged as having an unrealistic subjective exercise capacity, whereas use of the MacNew quality of life questionnaire resulted in 62.3% of the patients being judged as such. Even greater differences between clinical interview and the use of the MacNew questionnaire were found for the psychological and social problems. The variation in clinic means was somewhat smaller when the MacNew was employed. This study shows that assessments of cardiac rehabilitation needs are subject to moderate to high inter-practice variation. This is especially true when the assessments are solely based on clinical judgment instead of clinical assessment instruments. Furthermore, the numbers of patients judged to have rehabilitation needs are smaller in that case. Therefore, we recommend that guidelines for cardiac rehabilitation provide well-defined and unambiguous procedures for assessing the rehabilitation needs of patients and that assessing the needs solely by clinical judgment should be avoided.

Chapter 8 describes a qualitative study amongst CARDSS users to understand in which circumstances CDS was and was not effective in improving guideline use in practice. In-depth, semi-structured interviews were conducted with care professionals, on reasons for improved guideline concordance or persistent non-concordance after successful adoption of CARDSS. Twenty-nine rehabilitation nurses and physiotherapists from 21 Dutch clinics were interviewed. We found that CARDSS improved guideline use by increasing its users’ familiarity with guidelines’ recommendations and decision logic, by overcoming users’ inertia to previous practice, and by reducing guideline complexity, for example by facilitating calculation
of scores and interpretation of data. Finally, participants reported that sharing guideline recommendations with patients increased their willingness to participate in the cardiac rehabilitation programme. We were also able to identify circumstances in which the CDS was ineffective in either improving concordance to guideline recommendations or consistency of care. Also this study showed that part of the variation in needs assessment procedures and therapy decisions were caused by room for subjective judgment in the cardiac rehabilitation guidelines. However, persistent non-concordance to guideline recommendations was mainly caused by a lack of facilities or resources, a lack of reimbursement, or a lack of priority from other parts of the organization. For example, many outpatient clinics still lacked the facilities to provide relaxation therapy or lifestyle change therapy to all eligible patients. Some clinics hadn’t even developed such a therapy three years after guideline introduction. This fact explained the high undertreatment of patients for some therapies and, as some centres did have sufficient facilities, a large variation in concordance between centres.

The research in this thesis has shown that we succeeded in developing and implementing a comprehensive guideline implementation system for cardiac rehabilitation that is useful in practice. In addition, this research shows that CDS can be an effective instrument to improve guideline use in multidisciplinary settings. CDS increases professionals’ knowledge of preferred practice and facilitates guideline interpretation and application. Therefore CDS could be considered to improve guideline use also in other multidisciplinary settings. However, if following the guideline requires changes in the organization of care that professionals consulting the CDS consider beyond their direct responsibilities or control, the provision of CDS alone appears to be insufficient to realize such changes. More research is needed to understand which additional instruments or strategies should be developed to overcome organizational constraints or environmental barriers to following guidelines.
Samenvatting
Samenvatting

Één van de belangrijkste uitdagingen in de hedendaagse gezondheidszorg is om ervoor te zorgen dat patiënten de behandeling krijgen die volgens de huidige wetenschappelijke inzichten het meest effectief is. De ontwikkeling en implementatie van medische richtlijnen wordt gezien als een belangrijke stap om dit doel te bereiken. Het werken volgens richtlijnen kan de uitkomsten van patiënten verbeteren, kan de variatie in geleverde zorg verminderen, en de kan de kosten van de gezondheidszorg terugdringen. Echter, de toepassing van richtlijnen in de dagelijkse medische zorg is nog steeds beperkt door barrières die te maken hebben met de kennis, attitude, en omgeving van zorgprofessionals.

Ondanks het grote aantal onderzoeken dat de kosteneffectiviteit ervan aantoont, wordt hartrevalidatie in veel westere landen nog weinig gestandaardiseerd en niet conform de richtlijnen aangeboden. Hartrevalidatie is de zorg die geboden wordt aan patiënten na een cardiaal incident (zoals een hartinfarct), een cardiale interventie (zoals een dotterbehandeling), en aan patiënten met hartfalen. Hartrevalidatie is cruciaal om ervoor te zorgen dat hartpatiënten in een zo goed mogelijke fysieke, psychische, en sociale conditie verkeren om hun plaats in de samenleving weer in te nemen. Ook is hartrevalidatie belangrijk om de kans op toekomstige problemen met hart en vaten te verminderen. Om de kwaliteit van hartrevalidatie in Nederland te verbeteren hebben de Nederlandse Hartstichting en de Nederlandse Vereniging voor Cardiologie in 2004 nieuwe richtlijnen voor hartrevalidatie gepubliceerd. Binnen deze richtlijnen speelt de indicatiestelling, waarin de revalidatiebehoeften van de patiënt worden bepaald, een belangrijke rol. Het project dat beschreven staat in dit proefschrift draaide om deze Richtlijnen Hartrevalidatie 2004 en de toepassing ervan in de dagelijkse praktijk door Nederlandse hartrevalidatieteams.

Het werken conform nieuwe richtlijnen vereist vaak dat zorgverleners en instellingen hun bestaande manier van werken moeten veranderen. Het is gebleken dat het verspreiden van richtlijnen op papier onvoldoende is om de noodzakelijke veranderingen teeweg te brengen. Om ervoor te zorgen dat zorgverleners conform de richtlijnen gaan werken is het noodzakelijk dat er goed uitgewerkte en doordachte veranderstrategieën worden toegepast. Een van de meest effectieve instrumenten om het gedrag van zorgverleners te beïnvloeden is elektronische beslissingsondersteuning (eng. computerized decision support, CDS) in de vorm van adviezen die specifiek voor de patiënt en de klinische context in kwestie zijn. Hoewel veel studies het effect van CDS op de beslissingen van individuele professionals hebben gemeten, was het effect van CDS in een multidisciplinaire setting nog niet onderzocht. Dit terwijl medische zorg tegenwoordig meestal door teams wordt verleend in plaats van door een individuele zorgverlener. Waar het nemen van beslissingen door individuele zorgverleners voornamelijk een cognitief proces is,
worden beslissingen in teams ook beïnvloed door sociale factoren zoals de relatie tussen professionals binnen het team. Het doel van het CARDSS (Cardiac Rehabilitation Decision Support System) project dat beschreven staat in dit proefschrift, was inzicht te krijgen in aspecten van de ontwikkeling, implementatie, en effectiviteit van een richtlijngebaseerde CDS systeem in een multidisciplinaire setting.

Om richtlijngebaseerde CDS te kunnen geven is het nodig dat de procedures en aanbevelingen die beschreven staan in de richtlijn worden geformaliseerd, dat wil zeggen omgezet in een voor de computer interpreteerbare taal. Richtlijnformalisering gebeurt vrijwel altijd nadat de richtlijn in kwestie is gepubliceerd. Echter, omdat richtlijnen vage termen, dubbelzinnige aanbevelingen, inconsistenties, omissies en andere onduidelijkheden kunnen bevatten, is zowel richtlijnformalisering als de ontwikkeling van een CDS systeem problematisch gebleken indien er niet nauw wordt samengewerkt met de auteurs van de richtlijn. In Hoofdstuk 2 onderzoeken wij de mogelijke voordelen van de gelijktijdige ontwikkeling en formalisering van een richtlijn. De principes van een dergelijke strategie waren nog niet beschreven in de literatuur. Om die reden hebben wij een strategie ontwikkeld die bestaande methoden voor richtlijnontwikkeling en richtlijnformalisering combineert. Kernpunten van deze strategie zijn de vroegtijdige betrokkenheid van formaliseringsdeskundigen (bv medisch informatiekundigen), het gebruik van software voor richtlijnformalisering, nauwe samenwerking tussen richtlijn auteurs en formaliseringsdeskundigen in de ontwikkeling van een klinisch algoritme dat de richtlijn samenvat, en grondige verificatie van de richtlijn voorafgaand aan publicatie. Bij toepassing in het hartrevalidatiedomein ondervonden wij dat deze strategie hielp om zowel vage, inconsistente, als moeilijk toepasbare aanbevelingen in de richtlijn op te sporen. Deze problemen konden worden verholpen voordat de richtlijn werd gepubliceerd. Bovendien zorgde de strategie voor een goede correspondentie tussen de papieren en de geformaliseerde richtlijn. Bevindingen uit dit onderzoek suggereren dat een strategie waarbij een richtlijn tijdens het ontwikkelproces wordt geformaliseerd voordelen biedt voor zowel de kwaliteit van de papieren richtlijn als voor de richtlijnformalisering.

Hoofdstuk 3 beschrijft de ontwikkeling en functionaliteiten van het CARDSS systeem. CARDSS is tegelijkertijd met de richtlijn ontwikkeld, hetgeen als voordeel had dat de richtlijnauteurs betrokken konden worden bij het bepalen van de eisen aan het systeem. Meestal functioneren CDS systemen in de achtergrond van bestaande elektronische patiëntendossiers (EPDs). Echter, aangezien er nog geen EPD systeem voor hartrevalidatie in Nederlandse instellingen in gebruik was, moest CARDSS zowel EPD- als CDS-functionaliteiten bieden. Hoewel dit de ontwikkeling van CARDSS compliceerde, had het als voordeel dat de EPD- en CDS-functionaliteiten sterk konden
worden geïntegreerd. Er werd besloten om CARDSS professionals op een actieve manier te laten ondersteunen bij het uitvoeren van de indicatiestelling voor hartrevalidatie zoals beschreven in de richtlijnen. Gebruikers van het systeem worden middels een dialoogstructuur gevraagd om relevante patiëntgegevens in te voeren. Vervolgens toont CARDSS voor de patiënt in kwestie de door de richtlijn aanbevolen doelstellingen en therapieën voor hartrevalidatie. Een aantal additionele CDS-gerelateerde en administratieve functionaliteiten zijn toegevoegd om de kans op acceptatie en gebruik van CARDSS in de praktijk te vergroten. Zo krijgen professionals bijvoorbeeld inzicht in de redenen achter een aanbeveling van de richtlijn, wordt toegang geboden tot relevante informatie uit de richtlijn, kan de voortgang van de patiënten tijdens de revalidatie bijgehouden worden, kunnen patiëntverslagen worden geprint, en kunnen managementgegevens gegenereerd worden.

Om te bepalen of de eerste versie van CARDSS bruikbaar was in de praktijk is een pilotstudie van zes weken uitgevoerd in een viertal poliklinieken. Deze pilotstudie is beschreven in Hoofdstuk 4. Na afloop van de studie werd aan de gebruikers gevraagd om een vragenlijst in te vullen. Bovendien werden alle in CARDSS opgeslagen gegevens, waaronder logbestanden, geanonimiseerde patiëntgegevens, richtlijnaanbevelingen en therapiebeslissingen, geanalyseerd. Gebruikers werden geïnterviewd om de bevindingen te kunnen verklaren. Gedurende deze studie hebben 11 verschillende hartrevalidatieprofessionals CARDSS gebruikt om bij 134 patiënten een indicatiestelling voor hartrevalidatie uit te voeren. In totaal werden vijf fouten in het systeem ontdekt die allemaal binnen een dag konden worden verholpen. De gebruikers waren positief over de bruikbaarheid van CARDSS. Zij vonden CARDSS gemakkelijk in het gebruik ondanks het feit dat sommigen aangaven nauwelijks ervaring met computers te hebben gehad voorafgaand aan de pilotstudie. De meeste professionals gaven aan dat CARDSS hun kennis over de indicatiestelling voor hartrevalidatie meer verbeterde dan bij het gebruik van de papieren richtlijn. Alle gebruikers gaven aan CARDSS te willen blijven gebruiken, mits een aantal kleine aanpassingen zou worden doorgevoerd. Na afloop van de studie is CARDSS aangepast op basis van de aanbevelingen van gebruikers.

Hoofdstuk 5 beschrijft de resultaten van een uitgebreidere studie naar de bruikbaarheid van CARDSS. Om de bruikbaarheid van CARDSS te meten werd een vragenlijst ontwikkeld op basis van de IBM Computer Usability Questionnaire (CSUQ). Om te bepalen welke factoren de bruikbaarheid van CARDSS beïnvloedden, werden vragen toegevoegd over de ervaring van gebruikers met hartrevalidatie, de manier waarop CARDSS geïntegreerd is in hun manier van werken, en de extra tijd per patiënt die het gebruik van het systeem vergde. Bovendien zijn vragen toegevoegd met betrekking tot de tevredenheid met de Richtlijn Hartrevalidatie 2004 en de attitude
ten opzichte van CDS systemen in het algemeen. Ten slotte zijn ook vragen over de leeftijd, het geslacht, en computerervaring van de gebruikers toegevoegd. Er zijn vragenlijsten gestuurd naar 68 professionals in 28 poliklinieken die deelnamen aan een clustergerandomiseerde studie met CARDSS. Drieënzeventig respondenten (93%) uit 27 poliklinieken vulden de vragenlijst in. De gebruikers van CARDSS waren positief over het gebruiksgemak, de kwaliteit en duidelijkheid van de informatie, en over de gebruikersinterface van het systeem. Gebruikers die CARDSS succesvol hadden geïntegreerd in hun manier van werken waren meer tevreden over CARDSS dan degenen waarbij dat niet het geval was. Bovendien was een grotere tevredenheid met de richtlijn en een positieve houding ten opzichte van CDS systemen positief geassocieerd met de tevredenheid over CARDSS.

CARDSS werd ontwikkeld om het gebruik van de Richtlijn Hartrevalidatie 2004 in de praktijk te verbeteren. Door hartrevalidatieprofessionals te voorzien van patiëntsspecifieke, actieve beslissingsondersteuning hoopten wij de therapiebeslissingen van hartrevalidatieteams meer in overeenstemming met de richtlijn te brengen. De studies beschreven in Hoofdstuk 6, 7, en 8 zijn uitgevoerd om hierover meer inzicht te krijgen.

**Hoofdstuk 6** beschrijft een clustergerandomiseerde studie naar de invloed van CDS op de overeenstemming van therapiebeslissingen van multidisciplinaire teams met aanbevelingen in de richtlijn. Deelnemende instellingen werkten met één van twee mogelijke versies van CARDSS: een interventieversie of een controleversie. De interventieversie had alle functionaliteiten, terwijl de controleversie alle EPD-gerelateerde en administratieve functionaliteiten, maar geen therapieadviezen bood. Op deze manier werd rekening gehouden met het potentiële effect dat uitgaat van de gestructureerde manier van werken die altijd wordt afgedwongen door informatiesystemen (het ‘checklist effect’). In de controlearm moesten teams hun therapiebeslissingen baseren op hun eigen inzicht; maar de geschreven richtlijn kon daarbij altijd geconsulteerd worden (op papier, of elektronisch via CARDSS). Richtlijnaderentie werd bepaald voor vier hartrevalidatieën, namelijk bewegingstherapie, voorlichting over de ziekte en haar gevolgen (informatieprogramma), ontspanningstherapie, en leefstijltherapie. Gegevens van 2787 patiënten uit 21 instellingen zijn geanalyseerd. Resultaten van deze studie lieten zien dat CDS de adherentie van teams aan de richtlijn significant verbeterde voor bewegingstherapie met 7,9%, voor het informatieprogramma met 25,7%, en voor ontspanningstherapie met 25,5%. CDS verminderde zowel de onder- als overbehandeling van patiënten. Deze resultaten geven aan dat CDS inderdaad een effectief instrument kan zijn om het beslisgedrag van multidisciplinaire teams te verbeteren. Echter, CDS was niet even effectief in alle instellingen en voor alle
Samenvatting

therapieën. Voor leefstijltherapie, dat in beide studiearmen slechts aan 26% van de patiënten werd gegeven waarvoor de richtlijn dat had aanbevolen, verbeterde CDS de richtlijnadherentie niet. Ook was er, ondanks het positieve effect van CDS, nog steeds sprake van een aanzienlijke onderbehandeling in ontspanningstherapie. Zowel leefstijltherapie als ontspanningstherapie zijn nieuw geïntroduceerd in de Richtlijn Hartrevalidatie 2004. Een aanzienlijk aantal instellingen bleek nog niet de faciliteiten te hebben om deze therapieën aan voldoende patiënten aan te bieden. Daarnaast bleef er een aanzienlijk variatie bestaan tussen instellingen in de mate van richtlijnadherentie voor alle vier de therapieën.

De studies die beschreven staan in Hoofdstuk 7 en 8 zijn uitgevoerd om inzicht te krijgen in redenen waarom CDS in sommige gevallen wel, en in andere gevallen niet, effectief was om adherentie aan de richtlijn te verbeteren en variatie tussen instellingen te verminderen. In Hoofdstuk 7 hebben we de variatie tussen instellingen in vastgestelde revalidatiebehoeften van patiënten bepaald en de invloed van verschillende meetmethoden op de vastgestelde behoeften bepaald. Intracluster correlatiecoëfficiënten (ICCs), een maat om variatie tussen groepen of instellingen uit te drukken, werden berekend voor alle revalidatiebehoeften en leefstijlparameters, voor en na correctie voor case mix, en gestrafificeerd naar de gebruikte meetmethode. We vonden hoge ICCs, wijzende op een grote variatie tussen instellingen, voor het oordeel van professionals of het inspanningsniveau van de patiënt voldoende was, of de patiënt een realistische inschatting van het eigen inspanningsniveau kon maken, en of de patiënt problemen had in het sociale functioneren. Matige ICCs werden gevonden voor het oordeel van professionals over de aanwezigheid van psychische problemen, de afwezigheid van een partner, ongezonde voedingsgewoonten, en een inactieve leefstijl van de patiënt. Correctie voor patiëntkarakteristieken beïnvloedde de ICCs nauwelijks, maar stratificatie naar meetmethode liet grote verschillen zien tussen resultaten van klinische interviews en meetinstrumenten. Deze studie laat zien dat de bepaling van de hartrevalidatiebehoeften van patiënten onderhevig is aan matige tot hoge variatie tussen instellingen. Dit is voornamelijk het geval wanneer alleen gebruik gemaakt wordt van klinische interviews om de behoeften van patiënten te bepalen. Ook leidt een klinisch interview zonder ondersteuning van metingen tot een onderschatting van revalidatiebehoeften. Om deze reden adviseren wij dat hartrevalidatierichtlijnen goed gedefinieerde en ondubbelzinnige procedures beschrijven om de revalidatiebehoeften van patiënten te bepalen en dat klinische interviews worden aangevuld met resultaten van objectieve metingen.

Hoofdstuk 8 beschrijft een kwalitatieve studie onder CARDSS-gebruikers naar het onderscheid tussen de situaties waarin CDS wel, en de situaties waarin CDS niet, effectief was om adherentie aan de richtlijn te verbeteren. Met
hartrevalidatieprofessionals werden semigestructureerde interviews gehouden om te achterhalen wat de redenen waren voor adherentie en non-adherentie aan de richtlijnen, voor en na de introductie van CARDSS. Negenentwintig verpleegkundigen en fysiotherapeuten uit 21 Nederlandse instellingen werden geïnterviewd. We vonden dat CARDSS adherentie aan de richtlijn verbeterde door de kennis van gebruikers over de richtlijnen te verbeteren en door professionals te helpen om hun werkwijze te veranderen, bijvoorbeeld door automatisch de totaalscores van vragenlijsten te berekenen en te interpreteren. Bovendien rapporteerden enkele professionals dat de bereidheid van patiënten om deel te nemen aan het hartrevalidatieprogramma toenam wanneer zij de adviezen van het systeem onmiddellijk deelden met de patiënt. We waren ook in staat enkele situaties identificeren waarin CDS niet effectief was om het gebruik van de richtlijn en de consistentie van de zorg te verbeteren. Ook uit deze studie bleek dat een deel van de variatie tussen instellingen werd veroorzaakt door de ruimte voor subjectieve inschattingen die de richtlijn bood. Echter, het niet volgen van de richtlijn werd voornamelijk veroorzaakt door een gebrek aan faciliteiten en middelen, beperkte vergoedingen, of een gebrek aan prioriteit bij andere delen van de organisatie. Veel instellingen misten bijvoorbeeld de faciliteiten om aan alle benodigde patiënten leefstijltherapie of ontspanningstherapie aan te bieden. In sommige instellingen waren deze faciliteiten zelfs drie jaar na het verschijnen van de richtlijn nog helemaal niet aanwezig. Dit verklaart de grote onderbehandeling van patiënten voor sommige therapieën en, aangezien sommige instellingen wel voldoende faciliteiten hadden, de grote variatie in adherentie tussen instellingen.

Het onderzoek in dit proefschrift heeft laten zien dat het gelukt is om een uitgebreid richtlijnimplementatiesysteem voor hartrevalidatie te ontwikkelen en uit te zetten in de Nederlandse praktijk. Bovendien laat dit onderzoek zien dat CDS ook een effectief instrument kan zijn om het gebruik van richtlijnen in een multidisciplinaire setting te verbeteren. CDS verbetert de kennis van professionals met betrekking tot de richtlijn en vergemakkelijkt de interpretatie en toepassing van de richtlijn. CDS zou daarom ook overwogen worden in andere multidisciplinaire settings. Echter, als implementatie van de richtlijn vereist dat er veranderingen in de organisatie van zorg worden doorgevoerd die de verantwoordelijkheden of invloed van de gebruikers van het CDS systeem overstijgen, dan lijkt CDS op zichzelf onvoldoende om dergelijke veranderingen te brengen. Meer onderzoek is nodig naar welke additionele instrumenten of strategieën benodigd zijn om dergelijke organisatorische barrières tot richtlijngebruik te slechten.
Dankwoord
Dankwoord

Zoals bij de meeste belangrijke mijlpalen in iemands leven, was de uitvoering van mijn promotieonderzoek en het schrijven van dit proefschrift absoluut onmogelijk geweest zonder de hulp en steun van mensen in mijn directe en indirecte omgeving. Daarom wil ik iedereen die mij in de afgelopen jaren op enigerlei wijze van raad of daad heeft voorzien via deze manier ontzettend bedanken. Een aantal mensen wil ik echter in het bijzonder noemen.

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Amsterdam, februari 2009
Curriculum Vitae
Curriculum Vitae


Sinds de start van zijn afstudeerstage bij de Nederlandse Hartstichting en de afdeling Klinische Informatiekunde van het AMC (KIK) in november 2002 is Rick bezig met het CARDSS project dat in dit proefschrift beschreven staat. Tijdens zijn stage is hij begonnen met de ontwikkeling van het CARDSS systeem en heeft dit systeem sinds maart 2004 doorontwikkeld, deels tijdens zijn aanstelling als junior onderzoeker bij de KIK en deels als freelancer in opdracht van de Nederlandse Hartstichting. In mei 2004 behaalde hij zijn doctoraal Medische Informatiekunde. In oktober 2004 is hij fulltime in dienst gestreden bij de KIK als onderzoeker en is zijn promotieonderzoek naar het effect van beslissingsondersteuning op de implementatie van de Richtlijn Hartrevalidatie 2004 officieel gestart.

In september 2005 is Rick parallel aan zijn promotieonderzoek gestart met een schakeljaar aan het Instituut Beleid en Management Gezondheidszorg aan de Erasmus Universiteit Rotterdam. In september 2006 is hij gestart met de Master Zorgmanagement aan dezelfde universiteit en heeft deze succesvol afrond in augustus 2007.

Sinds maart 2009 is Rick werkzaam als strategisch consultant bij Gupta Strategists, een strategisch adviesbureau dat zich richt op de gezondheidszorg. Hij woont in Amsterdam samen met zijn vriendin Fenna van Breda. Zij zijn in verwachting van hun eerste kindje.