Computerized decision support to improve guideline implementation in cardiac rehabilitation: the CARDSS project
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Chapter 9

General Discussion
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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 impracticabilities 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 be 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 effected 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.
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


