Building an infrastructure to improve cardiac rehabilitation: from guidelines to audit and feedback
Verheul, M.M.

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BUILDING Infrastructure to IMPROVE Cardiac rehabilitation: from guidelines to audit and feedback

Mariëtte M. van Engen-Verheul
BUILDING AN INFRASTRUCTURE TO IMPROVE CARDIAC REHABILITATION: FROM GUIDELINES TO AUDIT AND FEEDBACK

Mariëtte M. van Engen-Verheul
COLOFON

Building an infrastructure to improve cardiac rehabilitation: from guidelines to audit and feedback.


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BUILDING AN INFRASTRUCTURE TO IMPROVE CARDIAC REHABILITATION:
FROM GUIDELINES TO AUDIT AND FEEDBACK

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Faculteit der Geneeskunde
“Het hart van de mens overdenkt zijn weg, maar de Heer bepaalt de richting die hij gaat”

Spreuken 16:9

Voor mijn ouders
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INTRODUCTION TO THE RESEARCH TOPICS AND CONTEXT

Building an infrastructure

The imperative for health systems to deliver better care, for more people and from fewer resources, is stronger than ever. There is a growing demand for care services, fuelled by the needs of ageing populations with an increasing prevalence of chronic diseases, the growth in healthcare technologies and historical high investments in health care services [1]. Therefore, the healthcare sector vigorously seeks opportunities to learn on, and apply what is best in practice. However, a variety of factors result into suboptimal learning of health systems: health data reuse is currently limited and delayed, and information management is too costly [2]. Some of these factors are socio-cultural: e.g. system complexity, parties determined to protect their vested interests or established professional norms around evidence-based practice. Other factors relate to availability and accessibility of data required to generate knowledge for guiding best decisions. This data is either unavailable, incomplete, outdated, inaccessible, not translated into meaningful information or just not used in daily practice by the decision makers. All these factors impede the learning of health systems. For example, it takes 17 years on average before validated clinical knowledge finds its way into routine clinical practice [3]. Improving the capability to share and reuse data generated in health systems—and harness its potential to generate knowledge rapidly and inform healthcare practice, research, political and individual patients’ decisions—is expected to induce considerable transformations [4, 5].

Within other sectors, individual organisations and collaborating groups have already created the necessary infrastructures to leverage their data for increased productivity, gain competitive advantage, and revolutionize business models. Attempts to employ these types of approaches to realise transformative impacts for one of the most challenging societal problems—improving health—did not result in similar success. The health sector can point to current examples of large clinical research networks, as well as increasing adoption of electronic patient record (EPR) systems and other information technologies. Yet this sector has not undergone the type of IT-enabled transformation, visible across other industries, to create an infrastructure supporting intensive data sharing and learning [6].

One widely conceived concept for realising necessary transformations, at significant scale and scope in the health domain, is generally known as the ‘Learning Health System’ (LHS) [7]. The LHS is defined as a vision for an integrated health system in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience. The goal is to seamlessly refine and deliver best practices for continuous improvement in health and healthcare [8]. Though articulated in various forms, the underlying concept is straightforward: harness the power of data and analytics to learn from every patient, and feed the “what works best” knowledge back to clinicians and all other stakeholders to create learning cycles of continuous improvement (see Figure 1).

Achieving a LHS requires exploration of methods to connect the multiple stakeholders and fragmented repositories of data and knowledge in the complex health ecosystem in one
infrastructure; enabling them to align with, and learn from each other over time [4]. This thesis explores on how we can use the LHS principles to realise such an infrastructure to connect physicians, other health professionals, managers, professional associations, EPR developers, patients and researchers in the field of cardiac rehabilitation (CR) in the Netherlands. The results may contribute in improving the field of CR care in general, increasing knowledge on facilitators of continuous learning and improvement, and identifying success factors for building an LHS infrastructure which can be used in CR and other domains of health care.

To improve
Health systems—at any level of scale—can become learning systems when they continuously and routinely, study and improve themselves by performing so called ‘Virtuous learning cycles’ [4]. Within the context of systematic quality improvement these cycles are also known as Plan-Do-Study-Act (PDSA) cycles, constituting a component of the Model for Improvement [9]. Basic principles of these two cycles are comparable. After a decision is made to study a problem of interest, data should be collected (step 1), assembled (step 2) and analysed (step 3), followed by interpretation of results (step 4) in order to lead to tailored messages (step 5), and followed by actual improvement actions (step 6). To evaluate changed practice and guarantee constant improvement over time, the learning cycle should have a continuous character.

In a large scale health system multiple stakeholders, like biomedical researchers, health care delivery parties, the government, and patient groups, all formulate their own problems of interest, resulting in multiple learning cycles. Without a supportive, integrated platform every cycle requires its own agreements, technology, staffing, analytics and dissemination mechanisms. In contrast, the LHS infrastructure supports multiple simultaneous learning cycles at the same time with one platform that empowers multiple and diverse stakeholders to individually and collectively drive innovation across the healthcare ecosystem. This platform provides data as a service to facilitate and intensify data sharing and (re)use. Such as, the LHS can underpin a host of unforeseeable innovations in data-, knowledge-, and evidence-driven health-care, bio-surveillance in the public interest, and health-related research and development [4]. In other words: “If you want to get 350,000 people per day across a river, do you build 350,000 rowboats? No, you build a bridge!” (Charles Friedman [10]).
Despite major improvements in diagnostics and interventional therapies, facing (multiple) chronic diseases remains a major health care and socio-economic burden. This burden increases and is closely correlated to economic growth and an ageing population [11]. Health behaviour change is a key component for chronic disease prevention. Studies have shown that 90% of type 2 diabetes, 80% of coronary heart disease (CHD), and 70% of all strokes are potentially preventable by a healthy lifestyle, including non-smoking, maintenance of a healthy bodyweight, regular physical activity, healthy eating habits, and moderate alcohol consumption [12]. Whereas treatment of traditional risk factors such as hypertension and dyslipidaemia is improving, inactivity and obesity are increasingly important determinants of cardiovascular mortality in The Netherlands [13]. Cardiovascular diseases, such as CHD, is the main cause of death in Europe, with around 4.1 million deaths per year [14] and they are accountable for 28% of the total number of deaths in the Netherlands [13]. Health authorities, care providers and the general population have started to recognize that the fight against chronic diseases like CHD, can only be won by lifestyle changes and prevention. As such, increasing investments in interventions for lifestyle changes and prevention are required [15]. Likewise, there is an overwhelming evidence on the efficacy of secondary prevention initiatives, including cardiac rehabilitation (CR), in terms of reduction in morbidity and mortality [16, 17].

Outpatient CR programs offer a cost-effective, multidisciplinary, comprehensive approach to address CHD risk factors and to support patient in restoring their optimal physical and psychosocial condition [15, 18]. CR is widely recommended for all CHD patients who have been hospitalized for an acute coronary syndrome (ACS) and for those who have undergone coronary revascularization (coronary artery bypass graft surgery [CABG] or percutaneous...
coronary interventions (PCI) or valvular surgery [15, 19]. Studies show that CR is also beneficial for patients with other chronic cardiovascular conditions such as stable angina pectoris (AP) and chronic heart failure (CHF) and for subjects with a high risk for developing cardiovascular disease [20]. CR teams usually include cardiologists, nurses, physical therapists, psychologists, dieticians, social workers, and rehabilitation physicians. The program starts with an extensive needs assessment procedure where data items concerning the patient’s medical, physical, psychological, and social condition and lifestyle are gathered [15, 21]. Based on the results and the patients’ preferences, an individualized rehabilitation programme is offered. This consists of multiple rehabilitation goals (e.g. ‘Optimize exercise capacity’ or ‘Regain emotional balance’) and usually up to four possible therapies: exercise training, education and counselling, lifestyle modification, and relaxation and stress management training and, if needed, several forms of individual therapy (e.g. by psychologists, social workers or dieticians) [15, 21].

In a recent Dutch population based cohort study carried out by our research group, it was shown that CR was associated with a 35% reduction in mortality over a follow-up period up to four years [22]. This effect of CR in the community is consistent with previous, comparable studies in the United States [23] and Canada [24]. Despite the known benefits of CR, and despite the widespread endorsement of its use [15, 25], CR services are yet often under-utilized, poorly standardized, and do not follow the available scientific evidence [26].

**From guidelines**

Clinical practice guidelines sum up available scientific evidence and/or expert opinions in systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances [27]. They may offer concise instructions on which diagnostic or screening tests to order, how to provide medical or surgical services, duration of hospital stay of patients, or other details of clinical practice. Guidelines are considered essential instruments to improve the quality of care as their potential benefits are reduced practice variation, reduced costs and improved patient outcomes. [28]. Despite their wide promulgation, professionals’ (like in the field of CR) often face multiple barriers to actually follow guideline recommendations.

A frequently used classification for barriers to guideline implementation is a division into individual (‘internal’) and environmental (‘external’) barriers [29]. Internal barriers concern professional’s knowledge of, and attitude towards guidelines. To improve these, computerized decision support (CDS) is known to be effective since it can provide guideline-based recommendations at the time and place where clinical decisions are made [30]. However, medicine is largely practiced by teams of healthcare professionals embedded within complex organisations. These professionals may also encounter external barriers hampering their ability to execute guidelines. These barriers stem from environmental factors related to the team, organisation or health system they work in; e.g. lack of resources, staffing shortages or maintenance and equipment problems.
An EPR system with computerized decision support (CDS) functionalities was previously developed in the Netherlands, to improve concordance with CR guideline recommendations for the patient tailored CR program [31]. Although the CDS has proven itself to be effective [32], the system has not improved concordance with all guidelines’ recommendations (e.g. uptake for the lifestyle change therapy), and both undertreatment of patients concerning the relaxation therapy, as well as considerable practice variation in concordance with guideline recommendations remained for all four therapies. Following insights from the literature on the different types of barriers to guidelines implementation, an intervention strategy with supplementary components directed at both internal and external barriers [29] might create the necessary conditions and resources for further improving CR guideline concordance. More research is therefore required to understand how CDS improved concordance with some of the CR guidelines and which additional strategies for change need to be considered to overcome the remaining barriers.

To audit and feedback
In other fields of health care, audit and feedback (A&F) on health care performance and outcomes have been shown to be an effective quality improvement method to overcome external barriers and improve professional performance [33]. In a setting where CDS is already used to provide patient-tailored advice in daily care at the individual professional level, A&F can be used in addition to extend behind the level of the individual professional and inform decisions on the medical team and organisational level [34]. A&F consists of providing health care professionals with an objective summary of their clinical performance over a specified period of time [33]. Clinical performance is typically measured by a set of performance indicators derived from clinical guidelines or expert opinion, each representing a certain quality aspect of care (e.g. patients receiving a treatment according to guideline recommendations, mortality rates or successful smoking cessation). Characteristics that may enhance the effect of indicator-based performance feedback are a combined with educational outreach visits, providing feedback multiple times, and involving the entire team in action-planning and goal-setting activities [33].

The LHS concept envisions that, in order to be successful, the learning system must be constructed to function bi-directionally [8]; meaning that it must have both an “afferent” mode of operation to assemble data for analysis (left part of the learning cycle in Figure 1) in addition to an “efferent” mode for disseminating the knowledge that results from the analysis back to the parties that provided the data (right part of the learning in Figure 1). This supports that, in a setting where an EPR with CDS is already used at the point of care (afferent mode), this intervention can be well combined with an A&F intervention (efferent mode). In that case automatically collected EPR data can serve as input for learning cycles with tailored messages to support improvement actions in daily practice. The feedback of the CDS system at the individual level is completed with feedback from the A&F intervention at the team and organisational level. Such an approach may support health care organisations to continuously and routinely, study and improve themselves.
AIMS OF THE THESIS

The overall aim of this thesis is to build an infrastructure, based on the LHS principles, to continuously improve professional performance in the field of CR. The infrastructure will integrate both technical and organisational components. The technical components should allow the co-use of data collected in the EPR with CDS, to realise an A&F system. The organisational components will concern the active involvement of all stakeholders to receive their necessary input and commitment for the optimal functioning of the technical infrastructure, and support services for multidisciplinary CR teams during outreach visits to actually use the A&F system and improve their performance by executing the LHS learning cycle. The thesis describes the learning process, the results of this approach, and the challenges involved. The work in this thesis elaborates on both previous research in the field of CR in the Netherlands as well as on previous studies on successful characteristics of interventions to improve health care, described in the literature. To achieve our goal, we addressed the following research aims:

1) To assess current improvement challenges in the field of CR
2) To develop an infrastructure to facilitate continuous improvement
3) To assess the effect of a web-based A&F system with outreach visits on professional performance

OUTLINE

Part I consists of chapter 2, 3 and 4 and focuses on assessing current improvement challenges in the field of CR. Chapter 2 describes the results of a qualitative study in the field of CR after the implementation of a computerized CDS system. Although the CDS system was effective in improving concordance with the guidelines recommendations, barriers for further improvement due to constraints within teams and organisations, and related to practicability of the underlying guidelines, remained. To address those barriers, Chapter 3 describes the process of embedding two learning cycles, starting with data collection from a computerized CDS system, in a continuous improvement strategy. This strategy combines the CDS system with a benchmark-feedback cycle and periodic updates of the underlying guidelines. As such, our strategy addresses not only the decision-making process of individual professionals but also decisions made at higher levels of clinical organisations in two knowledge-management cycles. Chapter 4 outlines a study that assessed CR uptake rates and identifies factors that determine uptake in a large insurance claim database in the Netherlands. As a previous European survey study estimated that fewer than half of eligible cardiovascular patients in Europe are referred to CR, our large population based cohort study assessed exact CR uptake rates using systematically recorded health insurance data.

Part II consists of chapter 5, 6, 7 and 8 and focuses on the development and improvement of the multiple components of the LHS infrastructure to connect the stakeholders and fragmented repositories of data and knowledge in the field of CR. Chapter 5 describes a mixed method
usability approach which we used to assess and improve the usability of the user interface of the CR EPR. The EPR is used by CR professionals to determine a patient-tailored rehabilitation program at the start of the rehabilitation. The recommendations for redesign for the study were implemented by the developers. Chapter 6 describes how we, together with representatives of all professional CR associations, revised the Dutch clinical algorithm for assessing patient needs at the start of the rehabilitation. This revision was based on identified problems CR professionals faced in daily practice. Chapter 7 presents a modified Rand method which we used to derive a set of quality indicators for CR. This method combines results from a literature search and guideline review with the knowledge of an expert and patient panel in an extensive rating and consensus procedure. Chapter 8 describes the development and first experiences of CARDSS Online; a web-based A&F system to facilitate continuous improvement by multidisciplinary care teams. The system is based on the principles of the continuous learning cycles to actively involve the teams in using indicator-based feedback to improve their clinical performance.

Part III consists of chapter 9, 10, 11 and 12. These chapters discuss the design and results of our randomized clinical trial (RCT) with the web-based A&F intervention combined with outreach visits. In Chapter 9 we describe the rationale and study protocol to evaluate the effect of the system in the field of CR where an existing CDS is already used to guide professionals’ decisions. We describe two outcome measures: guideline concordance and professional performance. Chapter 10 shows the preliminary result of the intervention on solely on the concordance with guideline recommendations. Chapter 11 shows the final results on both clinical performance measured by a set of quality indicators (care processes and patient outcomes) and guideline concordance. Chapter 12 describes the results of a study in which we used a structured qualitative approach, concept mapping, to assess experiences by CR teams who participated in the RCT. This method provided insight on organisational and workflow factors needed to successfully implement the web-based A&F intervention with outreach visits to improve the quality of CR care in the Netherlands.

Finally a summary and general discussion of all findings in this thesis is presented in Chapter 13. This chapter summarizes the results of all previous chapters, discusses them in the wider context of the LHS principles and elaborates on ideas for future research.
REFERENCES


PART I

IMPROVEMENT CHALLENGES IN THE FIELD OF CARDIAC REHABILITATION
THE EFFECT OF COMPUTERIZED DECISION SUPPORT ON BARRIERS TO GUIDELINE IMPLEMENTATION: A QUALITATIVE STUDY IN OUTPATIENT CARDIAC REHABILITATION.

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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 the influence of system characteristics on the effectiveness of CDSSs is studied, little is known about the relation between cognitive, organizational and environmental factors, and CDSSs’ effectiveness.

**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. [5].

**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 21 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 or procedural changes are required that users consider to be beyond their tasks and responsibilities.

**Keywords:** Clinical decision support systems; Qualitative evaluation; Guideline adherence; Cardiac rehabilitation
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] that supports conducting a needs assessment for CR as described in the guidelines. CARDSS actively guides users, predominantly rehabilitation nurses and physiotherapists, 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 computerized decision support: it automatically shows which types of therapy are 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. To improve CARDSS’ adoption, known success factors for guideline-based CDSSs were taken into account during its development [16,17].

In a recently conducted cluster randomised trial CARDSS was found to increase professional concordance to guideline-recommended therapies [18]. However, for one of the four CR therapies, lifestyle change therapy, there was no increase in concordance, and the overall concordance rates remained moderate also for education and relaxation therapy. There was also a large variation between different clinics in terms of therapy provision, working procedures, and assessed needs of patients [18]. 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 [19] 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 1 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 (MvEV and RG) prior to the interviews to be able to verify participants’ statements (triangulation [20]). 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 researcher (MvEV). She was accompanied by a senior researcher (RG or IH) during the first five interviews. If the three most recent interviews provided no new insights, no additional interviews were conducted (theoretical saturation [20]). Informed consent was obtained from all interviewees to audiotape the interview.
Barriers to guideline implementation

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

<table>
<thead>
<tr>
<th>Recommendations</th>
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</thead>
<tbody>
<tr>
<td><strong>Use of objective instruments</strong></td>
</tr>
<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>
</tr>
<tr>
<td><strong>The assessment of risk behaviour and lifestyle</strong></td>
</tr>
<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 min of moderate physical activity during at least 5 days, but preferably 7 days a week). Patients should be supported to adopt a physically active lifestyle when appropriate.</td>
</tr>
<tr>
<td><strong>Therapeutic decision making</strong></td>
</tr>
<tr>
<td>Patients should be offered education therapy according to their individual needs. 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. Patients should be offered lifestyle change therapy according to their individual needs.</td>
</tr>
</tbody>
</table>

Analysis

All interviews were transcribed verbatim for content analysis. Two researchers (RG and MvEV) 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 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] (Fig. 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 Fig. 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 did not 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 min. 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 their quantitative data suggested otherwise. Once confronted with the 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.
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 4 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 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 was still determined by a nurse’s subjective appraisal and not via an objective exercise test as recommended by the guidelines. In several clinics this was 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 [21] which is advocated by the guidelines. Most participants did not know the questionnaire or did not 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 did not use it prior to CARDSS because they found calculating and interpreting its results too laborious.

**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 out 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 do not 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>Internal barriers</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>External barriers</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>
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>
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<th>Sample comment</th>
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<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><strong>Environmental factors</strong></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>
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 was the main reason for non-adherence to guideline recommendations due to the stigma associated with psychological counselling. Some interviewees were non-adherent to guideline recommendations as they believed that relaxation and lifestyle change therapy was 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 saw 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’.
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 [22–24]. Therefore, to date little is known about the relation between cognitive, organizational, and environmental factors and the effectiveness of these systems [8,24,25]. 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 [22–24]. 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 [18], 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 2 years after the introduction of the CDSS. We nevertheless believe that the majority of relevant barriers was uncovered in our study because (i) there was a relatively large number of participants, (ii) quantitative data on clinics’ working procedures were used to verify participants’ comments, and (iii) the primary interviewer (MvEV) was not involved in the design and quantitative evaluation of the system [18,20]. Although
interviews with a group of nonCDSS 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 [26,27]. 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 [28]. 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 [29]. 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.

A recently conducted cluster randomised trial showed that CARDSS increased professional guideline concordance in therapeutic decision making for exercise therapy from 84.7% to 92.6%, for education therapy from 63.9% to 87.6%, and for relaxation therapy from 34.1% to 59.6% [18]. There was no (significant) change in the concordance to rules with respect to lifestyle change therapy (54.1% vs. 57.4%). The qualitative findings on therapeutic decision making that were reported here (Table 4) provide explanations for these quantitative results. Most of the persistent barriers in the table pertain to lifestyle change therapy (inertia to previous practice, patient factors) and relaxation therapy (lack of agreement, lack of reimbursement). The CDSS was not effective in reducing these barriers because they are not related to professional familiarity with the guidelines.

Generally speaking, recommendations from a clinical CDSS will not directly influence barriers that are outside the CDSS user’s professional responsibility. 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 1 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 [30].

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, during implementation one has to be aware of organizational and procedural changes that are required and are beyond the tasks and responsibilities of the users as to secure that the DSS can be used to its fullest breadth.

FUTURE RESEARCH

Although the literature emphasises that many different types of barriers to guideline implementation exist which may require different change strategies [5–7], little is known about the types of barriers that different change strategies can address [6,7]. Our results suggest that a CDS system alone is insufficient realize changes that users consider beyond their tasks, influence, and responsibilities. We are currently setting up a study to evaluate whether the provision of regular feedback reports to users and the management in addition to CDS can help to realize such changes.
SUMMARY POINTS

What was already known on this subject
- Although computerized decision support systems are found to be one of the most effective instruments for guideline implementation, these systems also regularly fail to improve the quality of care in practice.
- While the influence of system characteristics on the effectiveness of computerized decision support systems is studied, little is known about the relation between cognitive, organizational and environmental factors, and computerized decision support systems’ effectiveness.

What this study adds
- 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.
- Computerized decision support is not effective when organizational or procedural changes are required that users consider to be beyond their tasks and responsibilities. In that case other or additional guideline implementation instruments should be considered to empower CDSS users or involve the actual decision makers.

CONTRIBUTIONS

Rick Goud and Mariette van Engen-Verheul were the primary researchers of this study, supervised by Niels Peek, Nicolette de Keizer, Arie Hasman, Roland Bal and Irene Hellemans. All authors were involved in the conception and design of the study and the interpretation of the data. All authors contributed in the drafting of the manuscript, critically revised its content and approved its final version.

ACKNOWLEDGEMENTS

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REFERENCES


Barriers to guideline implementation


DESIGN OF A CONTINUOUS MULTIFACETED GUIDELINE-IMPLEMENTATION STRATEGY BASED ON COMPUTERIZED DECISION SUPPORT

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¹ Department of Medical Informatics, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands
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Implementation of clinical practice guidelines into daily care is hindered by a variety of barriers related to professional knowledge, collaboration in teams and organizations, and practicability of the guidelines. Clinical computerized decision support (CCDS) has been shown to be one of the most effective instruments to improve compliance to practice guidelines by tackling barriers related to professional knowledge. To address other barriers, however, additional interventions are needed. In this study, a continuous multifaceted guideline-implementation strategy was developed which is based on CCDS but extends beyond the professional knowledge barrier. Two additional interventions were designed and embedded with CCDS in a continuous quality improvement framework. First, to address barriers within teams and organizations guideline compliance data are periodically aggregated into feedback reports for care providers. Second, barriers related to practicability of the underlying guidelines are addressed in a guideline-maintenance cycle. A case study in the field of cardiac rehabilitation is presented to demonstrate the feasibility of the developed strategy.

**Key words**: Practice Guidelines as topic; Cardiac Rehabilitation; Health Care Quality, Access, and Evaluation
INTRODUCTION

Application of clinical practice guidelines can improve patient outcomes, reduce practice variation, and reduce costs of healthcare [1;2]. However, care professionals’ often do not follow the recommendations of practice guidelines, for a variety of reasons [3]. A main challenge in contemporary healthcare is therefore to increase the implementation of practice guidelines in routine care [4]. Dissemination of practice guidelines on paper alone has generally proved to be insufficient. Instead, a carefully designed strategy for change usually needs to be used for effective implementation of guidelines [5].

Before designing such a strategy it is important to identify the various barriers that professionals face when trying to incorporate practice guidelines into daily care [6]. A frequently used classification of those barriers to guideline implementation is the division into internal and external barriers by Cabana et al [6]. Here, ‘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. To overcome internal barriers, different implementation strategies exist such as professional educational, outreach visits, clinical computerized decision support (CCDS), and reminders [5]. Of those strategies CCDS is known to be highly effective because it provides relevant knowledge at the time and place clinical decisions are made [7,8].

However, modern medicine is no longer a matter of individual health care professionals but largely practiced as part of a team and embedded within complex organizations. Appropriate knowledge and attitudes of the individual are necessary but not sufficient for compliance to clinical standards. Professionals may also encounter so-called ‘external’ barriers which hamper their ability to execute guideline recommendations. These barriers stem from environmental factors related to the team, organisation or health system they work in [9]. Finally, glitches and impracticability’s in the guidelines in question (e.g., ambiguities, omissions, and contradictions) may impede execution of the guidelines’ recommendations [6].

Several studies have shown that for improving the implementation of clinical guidelines it is important to apply a multifaceted intervention with supplementary components [3]. In addition, to ensure that implemented changes persist over time, interventions preferably have a continuous character [10].

This paper presents a continuous, multifaceted guideline-implementation strategy that is based on computerized decision support but extends beyond the level of the individual professional. The strategy is illustrated with a case study in the field of cardiac rehabilitation.
MATERIALS AND METHODS

Several systematic reviews have been conducted concerning the effectiveness of different guideline-implementation interventions [3,11,12]. We based our strategy on the recurring conclusion in these reviews that multifaceted interventions targeting different barriers to change are more effective than single interventions. However, there is limited evidence concerning which combination of guideline implementation strategies is effective under which circumstances.

To guarantee a continuous character of the strategy, the continuous quality improvement (CQI) framework was taken as a starting point [13]. Within this framework an improvement is put into practice by planning it, trying it, observing the results, and acting on what is learned [14]. We note that to support these steps, it is necessary that data of the process being improved is collected, stored, and analyzed.

We chose to direct our strategy at two specific types of external guideline barrier, namely organisational barriers and guideline-related barriers. The key element is to use the CCDS as an input module for a clinical registry that collects data from similar care processes in different clinics into a central database. The CCDS registry will be the basis of two continuous improvement processes, a feedback process and a guideline-revision process. This is depicted in Figure 1 and will be described in more detail below.

The first component of our strategy consists of a CCDS system that is based on a formal (i.e., computer-interpretable) representation of the guideline to be implemented, and that is used in daily patient care to assist clinical decision making [15]. In a review of Shiffman et al it was shown that guideline adherence improved in 14 of 18 guideline-based CCDS systems in which it was measured [16]. In a later review of Kawamoto et al it was shown that CCDS systems in general significantly improve clinical performance [8]. In our strategy an existing CCDS system, aiming to overcome the professional knowledge barrier, is also used to collect clinical data in a central data registry. These data cover demographic and clinical characteristics of the patients, recommendations that were given by the system, the actual decisions that were made by its users, and outcomes of care. Using these data, compliance to the guidelines can be assessed at patient level by comparing system recommendations and actual decisions.

The second component is a benchmark-feedback loop. All clinics using the CCDS system and delivering data to the clinical registry receive feedback reports with benchmark information on a regular (e.g., monthly or quarterly) basis. The feedback reports contain graphical and descriptive (numerical) summaries of all clinic-specific data over the time period in question, with comparison to benchmark values (e.g. national target values or average performance within a peer group). Viewing personal performance within the context of peer performance is an effective motivator for change [17].
Figure 1 – Schematic depiction of proposed guideline-implementation strategy

**CCDS loop:** CCDS system provides guideline-based decision support to clinical professionals in daily care, based on data that are recorded at the bedside. **Feedback loop:** Data from CCDS systems at different clinics are collected and stored in a central data registry and used to generate feedback reports for each of the clinics. Reports steer discussions in team meetings where a quality improvement plan is formulated, which is subsequently implemented in daily patient care. **Guideline loop:** The data registry will also serve as input for a guideline revision process by analysing compliance levels. This is supplemented with qualitative information from the users and used by domain experts to formulate the revision, which is subsequently carried through in the knowledge base of the CCDS.

An essential part of the benchmark-feedback loop is that the reports are discussed during team meetings, and explanations are sought for deviations from benchmarks. Subsequently, organisational improvement initiatives should be formulated and implemented at the shop floor. An example where the benchmark-feedback loop is typically effective is absence of a resource needed to enable patients receiving a particular treatment. The individual professional will be confronted with CCDS advice to offer that treatment but will be unable to comply. The problem is that individual professionals are usually neither responsible nor empowered to acquire resources. When a feedback report reveals the non-compliance for this particular treatment, a team representative empowered to do so (typically a manager) can decide to acquire the resource, resulting in increased compliance to the guideline.

The third component of our strategy consists of a guideline maintenance cycle in which the CCDS data registry is used to identify guideline-related barriers for implementation. The first step of this cycle is to analyze the compliance data in the clinical registry in order to identify possible bottlenecks for carrying out the guideline’s recommendations. For instance, excessive complexity...
of a guideline can result in a consistently low compliance on specific parts. When a procedure is difficult to execute in daily practice professionals may choose to systematically replace this procedure by a simpler one. Another example is the existence of vagueness or ambiguities in the guideline. These may result in high inter-practice variation. When the guidelines are unclear how to assess a specific patient item, different clinics will choose their own assessment method, often resulting in variation among the clinics. A third example is the presence of inconsistencies within the guideline itself or with other guidelines. When the recommended treatment for a subgroup of patients differs between two guidelines, this can result in significant treatment variation for this subgroup, among the clinics.

The second step of the guideline-maintenance cycle is to identify the underlying causes of the phenomena that were observed in the first step. For this purpose the compliance data should be complemented with qualitative information gathered from professionals who use the CCDS, for example during interviews or focus groups.

The final step is to revise the guidelines based on the results from the first two steps in one or more meetings with domain experts. In these meetings identified bottlenecks for guideline implementation are discussed. When proposing revisions experts should be involved to guarantee accordance with the latest scientific evidence. Participation of professional associations in the revision process is advisable to guarantee approval and adequate support of the revised guidelines.

RESULTS

We describe the results of applying the developed strategy to a case study in the field of cardiac rehabilitation (CR). CR is a multidisciplinary treatment to help patients recover quickly from a cardiac incident or a cardiac intervention and improve their overall physical, mental and social functioning [18]. It has proven to be cost-effective in different economic evaluations conducted in North America and Europe [19]. However, in many Western countries cardiac rehabilitation services are under-utilized, poorly standardized, and do not follow the available scientific evidence [18]. Consistent with international standards [18;20], the Dutch Guidelines for CR 2004 state [21] that professionals should conduct a needs assessment procedure where data items concerning the patient’s medical, physical, psychological, and social condition and lifestyle are gathered. Based on the needs assessment procedure an individualized rehabilitation programme should be offered which consists of four possible therapies: exercise training, education and counselling, lifestyle change therapy, and relaxation and stress management training.

For our case study we used data from a recent trial with the CArdiac Rehabilitation Decision Support System (CARDSS) system [22;23]. This system was developed in a combined guideline-development and formalization process of the Dutch Guideline for CR [24]. Via a structured dialogue CARDSS actively guides its users through the needs assessment procedure and formulates a preliminary rehabilitation programme containing the recommended therapies.
Furthermore it contains an Electronic Patient Record (EPR) for CR.

In a multicentre cluster-randomized trial CARDSS was provided to care professionals in 31 Dutch outpatient clinics to stimulate the implementation of the guideline. Participating clinics worked during a minimum of six months with either of two versions of CARDSS: an intervention version with full functionally or a control version with the EPR services but without the therapy recommendations from the CDSS. The trial data from 21 clinics, including 2787 patients, were analyzed on compliance with respect to guideline recommendations, assessed separately for each of the four rehabilitation therapies. CARDSS increased compliance with the recommended decisions for exercise training, education and counselling, and for relaxation therapy. For lifestyle change therapy there was no improvement. All data of the trial were collected in a central registry database. For further details of the trial, we refer the reader to [23].

The registry database included data on 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, psychological and social status, marital status, employment status and three lifestyle parameters (smoking status, eating habits, physical activity). These data were used to generate a feedback report for each of the 21 participating clinics. The reports summarized the deployment of needs assessment instruments, assessed risk behaviour and lifestyle parameters, and therapeutic decisions, outlined in the form of tables and charts. For each of the variables that was summarized in the report, also the grand mean and standard deviation (i.e. averaged over all 21 clinics) was reported as benchmark value. In order to leave sufficient room for interpretation and discussion in the team meetings, no other targets were included in the reports. The feedback reports were positively received by the clinics although there were some doubts about the quality and reliability of the data. Several clinics reported that they created facilities to offer lifestyle change programs to their patients after reading the report. However many clinics found it difficult to create time to discuss the report.

For the guideline-revision process, patterns of compliance to the guidelines were analyzed in the registry database. It appeared that for all the parameters relating to rehabilitation needs, there was significant variation among the clinics. The largest variation was found in the percentages of patients judged to have an insufficient exercise capacity, which ranged from 54.5% to 89.8%. Large variation was also found in the percentages of patients judged to have an unrealistic subjective exercise capacity (37.7% – 63.9%) and to have social problems (31.1% – 60.9%). To identify the causes of this variation, semi-structured interviews with 29 users of CARDSS were conducted. Barriers to change that were mentioned in the interviews were lack of facilities (e.g. to measure all patients’ exercise capacities with a bicycle test), vagueness/ambiguity in the guidelines (e.g. unclear how to assess anxiety and depression) and lack of agreement with the guidelines (e.g. criteria for a healthy lifestyle).

The combination of the quantitative compliance data with the qualitative data from the interviews showed that the variation and non-compliance were partly caused by guideline-related barriers. The results of both studies were discussed in a professional focus group set
up with representatives of several professional associations (cardiologists, rehabilitation and sport physicians, company doctors, nurse practitioners, physiotherapists, psychologists, social workers and dieticians). They were asked to present revisions to solve the assessed barriers which would fit into daily care practice using their knowledge of the literature. Because of the large variation in assessed patient needs between CR clinics, even if they worked according to the algorithm, the revised clinical algorithm advises against using clinical judgment only to assess any rehabilitation needs. In addition, it was decided to add specific instruments to assess the anxiety and depression and a healthy life style and cardiovascular risk.

DISCUSSION

In this study a continuous, multifaceted strategy to implement clinical practice guidelines was developed, and applied in a case study in the field of cardiac rehabilitation. The strategy combines CCDS with a benchmark-feedback loop and periodic updates of the underlying guidelines. As such, our strategy addresses not only the decision-making process of individual professionals but also decisions at higher levels of clinical organisations and in knowledge-management cycles.

A potential limitation of the benchmark-feedback loop is the assumption that a conferring structure with regular team meetings is present at the participating clinics. If this is not the case, sending feedback reports will probably not have impact as they are simply not discussed. Probably this was true in most clinics that participated in our case study because structural follow-up actions on the feedback reports were rare. A recent Cochrane review states that the effects of feedback are likely to be stronger when it is combined with educational meetings directed towards actively involving care professionals in the improvement process [25]. It may therefore be sensible to extend the benchmark-feedback loop in our strategy with educational meetings.

A notorious difficulty in benchmarking is choosing the appropriate target values. We choose to report the mean of all clinics but this can result in an undesirable, passive attitude in clinics whose performance is above average but not optimal. A different option is use full compliance to guideline recommendations as target value. However, this will often be unrealistic. In many clinical domains specific patient characteristics (such as comorbidities) require professionals to deviate from the guidelines. It is then unclear what the ideal compliance rate should be. A possible solution may be found in the Achievable Benchmarks for Care tool. In essence, this tool represents the average performance of the top 10% of the clinics being assessed. It encourages providers to strive for superior performance knowing that the target level of excellence has already been achieved by a select group of their colleagues [26].

An other explanation for difficulties during implementing changes in clinical practice is the presence of patient-related barriers [6]. This group of external barriers to guideline implementation is not specifically addressed in our strategy but could have played a role in our case study, for instance when patients were resistant or perceived no need for guideline
recommendations.

The clinical registry based on the CCDS data is used for both the feedback to professionals as well as for the analyses of guideline related barriers for guideline implementation. Results are depending on the data entered in the systems and it is important to avoid data entry errors. Professionals should be thoroughly trained to work with the system and it is advisable to perform periodic data audits to identify data entry errors. In addition, users of the system should be aware that data from all patients that are treated should be entered into the system to prevent a selection bias.

The main novelty in our strategy is found in the combination of different components that supplement each other in a single continuous quality improvement strategy. Our implementation strategy can be used to implement guidelines on multiple levels in health care as part of continuous quality improvement which is advocated as an important mechanism for promoting the implementation of best practices in medical care. However, in our case study the different components were only once applied to the field of CR. Continuous data collection and analyzing is necessary to assess the long-term utility. Further the strategy should be applied during other guideline implementation projects to learn more about its application in other health care settings.
REFERENCES


CARDIAC REHABILITATION UPTAKE AND ITS DETERMINANTS IN THE NETHERLANDS

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ABSTRACT

Aims: Despite its documented efficacy, cardiac rehabilitation (CR) is still not well implemented in current clinical practice. Aims of the present study were to assess CR uptake rates in the Netherlands, and to identify factors that determine uptake.

Methods: The cohort consisted of persons insured with Achmea Zorg en Gezondheid. Based on insurance claims, we assessed CR uptake rates in 2007 among patients with an acute coronary syndrome (ACS), patients who underwent coronary artery bypass graft surgery (CABG), percutaneous coronary intervention (PCI) or valvular surgery, and patients with stable angina pectoris (AP) or chronic heart failure (CHF). In addition, we evaluated the relation between CR uptake and demographic, disease-related and geographic factors, for patients with an ACS and/or intervention.

Results: The CR uptake rate in the entire cohort (n=35,752) was 11.7%. The uptake rate among patients with an ACS and/or intervention (n=12,201) was 28.5% as opposed to 3.0% among patients with CHF or stable AP (n=23,551). The highest CR uptake rate was observed in patients who underwent cardiac surgery (58.7%). Factors associated with lower CR uptake were: female sex, older age, elective PCI (as compared to acute PCI), unstable angina pectoris (as compared to myocardial infarction), larger distance to the nearest provider of CR, and co-morbidity.

Conclusion: A minority of Dutch patients eligible for CR received CR. Future implementation strategies should focus on females, elderly patients, patients with unstable angina pectoris and/or after elective PCI, patients with long travelling distances to the nearest CR provider, and patients with co-morbidities.

Key words: Cardiac Rehabilitation; Secondary Prevention; Health Care Quality
INTRODUCTION

Cardiac rehabilitation (CR) programs have been shown to reduce morbidity and mortality after cardiac events and therapeutic interventions, with reported relative risk reductions in all-cause and cardiac mortality of 20% and 26% respectively.\(^1\) Currently, CR is widely recommended for all patients with an acute coronary syndrome (ACS), and for those who have undergone coronary revascularization (coronary artery bypass graft surgery [CABG] or percutaneous coronary interventions [PCI]), or valvular surgery.\(^2,3\) Recent studies show that CR is also beneficial for patients with other chronic cardiovascular conditions such as stable angina pectoris (AP), chronic heart failure (CHF), and for subjects with a high risk for developing cardiovascular disease.\(^4\) Because chronic cardiovascular disease often reflects long-term patterns of unhealthy lifestyles, benefit is not automatically achieved through cardiac interventions and pharmacological management alone in these patients. Additional support to regain physical capacity, improve psychosocial condition and to achieve lifestyle changes is now considered a crucial part of the treatment of these patients.\(^2,5-7\)

Despite its documented efficacy and cost-effectiveness, CR is still not well implemented in current clinical practice. In the European Cardiac Rehabilitation Inventory Survey (ECRIS) it was recently estimated that fewer than half of eligible cardiovascular patients in Europe are referred to CR, with referral rates varying from less than 3% up to 90%.\(^8\) About half of the countries estimated the number to be lower than 30%. Although generally indicating low CR uptake rates, the results of this survey should be interpreted with caution as they were based on estimates by national CR organizations / working groups rather than on systematically recorded patient data. Moreover, CR referral rates may not reflect actual CR uptake rates,\(^8\) as referred patients may eventually not be enrolled into a CR program due to various reasons (e.g. lack of insurance coverage, lack of motivation, or a large travelling distance). Therefore, actual CR uptake rates may even be lower than referral rates. At current, little is known about precise CR uptake rates and factors that determine CR uptake in European countries. Therefore, the purpose of this study was to assess CR uptake rates for patients eligible for CR in the Netherlands and to identify demographic, disease-related, and geographic determinants related to this uptake.

METHODS

Cardiac rehabilitation in the Netherlands

Based on previous national and international guidelines, the Dutch CR guideline was updated in 2004.\(^10\) Traditional CR indications (ACS, including myocardial infarction and unstable AP, CABG, and PCI) were extended with other diagnoses/interventions: valvular surgery, stable AP, CHF, high risk groups for cardiac diseases, patients with an implantable cardioverter defibrillator [ICD], and patients who underwent cardiac transplantations. In these guidelines it was stated that patients entering CR should be offered an individualized rehabilitation programme with
a typical duration of 6 to 12 weeks, consisting of group-based therapies (exercise training, relaxation and stress management training, education therapy, and/or lifestyle change therapy) and, when indicated, of additional individual counselling (e.g. by a psychotherapist or dietician).

In the Netherlands it is mandatory to have health insurance. Reimbursement for outpatient CR is provided by all insurance companies on the condition that a patient is referred by a cardiologist. Only for a small group of patients (CHF or stable AP without intervention) CR is not completely covered.

Population
The cohort consisted of subjects insured for the entire year 2007 with Achmea Zorg en Gezondheid, a Dutch health insurance firm covering approximately 17% of the Dutch population (2.8 million insured persons) in that year. The population insured with Achmea includes people from all age categories and from both urban and rural areas. We assessed whether the Achmea population was representative for the Dutch population by comparing the percentages of subjects receiving open heart surgery and PCI in the study cohort with percentages obtained from a national registry.11-13

Patients were identified through administrative insurance claims during 2007. In The Netherlands, claims are filed according to a national classification system based on a combination of the hospital registration of diagnoses (International Classification of Diseases, 9th Revision, Clinical Modification [ICD-9-CM] codes)14 and applied therapeutic interventions. Based on indications for CR according to the Dutch guidelines for CR, the following patient groups were included: (10) patients who underwent CABG, valvular surgery and/or PCI (both acute and elective), and patients with ST-elevation MI (STEMI), non ST-elevation MI (non STEMI), unstable AP, stable AP, and CHF. Only patients who survived the first year following the cardiac event or intervention were included.

In patients with multiple diagnoses or interventions, indication for CR was attributed to a single diagnosis, assigning a higher priority to diagnoses and interventions with a higher expected CR uptake rate according to previous research.9,15,16 For instance, when a patient was diagnosed with unstable AP and had also undergone CABG, the indication for CR was attributed to CABG.

The following steps were used to select patients and their underlying diagnosis and/or intervention which indicated CR:

1) All patients who underwent one of the following interventions were retrieved from the database (in this order): CABG, valvular surgery, PCI acute and PCI elective. Each patient was retrieved only once.
2) For patients who underwent CABG, valvular surgery, or PCI, we linked one of the following diagnoses (established in the previous twelve months) to these interventions (in this order): STEMI, non STEMI, unstable AP, stable AP and CHF. If no diagnosis was found, patients were retained in the study dataset without listed diagnosis.
3) The database was searched again, selecting from the remaining patients those with the following diagnoses in the year 2007 (in this order): STEMI, non STEMI, unstable AP, stable AP or CHF. These groups include patients who did not undergo one of the aforementioned interventions during the study period.
Patients were categorised as having received CR when an insurance claim was filed for at least one CR treatment modality during the first 12 months after the cardiac event or intervention. Both claims by hospitals and specialized rehabilitation clinics were included. In hospitals, CR claims are filed by cardiologists both for individual counselling or for group-based education therapy. Additionally, claims can be filed by other health professionals for the CR needs assessment procedure, exercise training programs, and lifestyle change programs. Specialized rehabilitation clinics file claims according to the total amount of consulting hours spent on CR without specification of therapeutic modalities.

**Determinants of CR uptake**

In order to study determinants of CR uptake, we defined the following subgroups:

1. Patients who underwent one of the following interventions: CABG, valvular surgery, acute PCI, elective PCI (irrespective of diagnosis).
2. Patients with an acute coronary syndrome (ACS), including patients with STEMI, non-STEMI, and unstable AP, who did not undergo an intervention.

Patients with chronic cardiovascular disease without intervention were not analyzed for determinants of CR uptake, because, due to the chronic nature of these diagnoses, it cannot be excluded that these patients already participated in a CR program before the study period. In addition, as opposed to patients in the first two groups, CR is not always completely reimbursed in these patients.

Possible determinants of CR uptake that were analyzed included patient demographics (sex and age), disease related factors (type of intervention, diagnosis and co-morbidity) and distance to the nearest CR facility (i.e. shortest distance from the patient’s home to the nearest available CR facility based on zip codes). The presence of co-morbidities was based on pharmacy claims (Appendix I).

**Statistical analyses**

The proportion of patients receiving CR (CR uptake rate) was determined for all diagnostic groups. Subsequently, logistic regression analysis was performed to identify demographic (sex and age), disease related (intervention, diagnosis and co-morbidity based on medication use) and geographic (distance to nearest CR facility) determinants of CR uptake in two groups (i.e., patients who underwent an intervention and patients with an ACS without intervention). In order to evaluate the influence of the patient selection procedure on the results of this study, we performed a sensitivity analysis. In this analysis, the order in which the database was searched for interventions and diagnoses was switched (switching STEMI with non-STEMI and CABG with acute PCI) and, consequently, CR uptake rates and odds ratios were re-calculated. All analyses were performed using SAS Version 9.1 (SAS, Cary, NC, USA) and R version 2.13.1.17.
RESULTS

The percentages of people insured with Achmea receiving open heart surgery in 2007 (0.89%) or a PCI (2.06%) were similar to these percentages in the entire Dutch population (1.02% and 2.13%, respectively) in that year. Also for 2006 and 2008 these percentages were similar.

CR uptake rates

A total of 35,752 patients were included. Table 1 gives an overview of the cohort characteristics and CR uptake rates. The mean age of the included subjects was 67.5 ± 12.44 years; about half of the patients was at least 70 years of age (48.2%). The majority of the included patients were males (59.9%). The uptake rate of CR in the entire cohort was 11.7%. Among patients with an ACS and/or intervention (n=12,201) the CR uptake rate was 28.5%. From these, patients who underwent CABG or valve surgery had the highest uptake rate (58.7%) and patients with an ACS without an intervention had the lowest uptake rate (9.8%). The CR uptake rates in patients with chronic diagnoses (n=23,551) were substantially lower: 2.6% in patients with stable AP and 3.7% in CHF patients, with an overall CR uptake rate of 3.0%. Co-morbidity, as specified in Appendix I, was present in 44.1% of the included patients (n=15,778). The majority (55.9%) of the patients lived within 5 km of the nearest CR facility (n=19,974); the mean distance was 5.6 ± 5 km.

Determinants of CR uptake

Table 2 shows the results of the regression analysis on determinants of CR uptake among patients who underwent a therapeutic intervention (model 1) and patients with an ACS without intervention (model 2). In both models, female sex (OR: 0.82 and 0.59 respectively) and older age were associated with a lower CR uptake rate. Considering the type of intervention in model 1, patients who underwent cardiac surgery were more likely to get CR than patients who underwent acute PCI (OR: 2.76 for CABG, 1.78 for valvular surgery). Conversely, patients who underwent elective PCI were less likely to get CR as compared to patients after acute PCI (OR: 0.48). All co-morbidities that were studied (diabetes, diseases related to the locomotor apparatus, lung disease and psychiatric diseases) were associated with lower CR uptake rates in patients who underwent an intervention (model 1). In model 2, both patients with STEMI and non-STEMI were more likely to get CR than patients with unstable AP (OR: 9.26 and 8.51 respectively). Finally in both model 1 and 2, a larger distance to the nearest CR provider (i.e. > 15 km) was associated with a lower CR uptake in patients who underwent an intervention (OR 0.49, CI 0.39-0.62).
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patients (n)</th>
<th>Part of cohort (%)</th>
<th>Patients receiving CR (n)</th>
<th>CR uptake (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>21,432</td>
<td>59.9</td>
<td>3,087</td>
<td>14.4</td>
</tr>
<tr>
<td>Women</td>
<td>14,320</td>
<td>40.1</td>
<td>1,098</td>
<td>7.7</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 40</td>
<td>717</td>
<td>2.0</td>
<td>97</td>
<td>13.5</td>
</tr>
<tr>
<td>40 - 49</td>
<td>2,381</td>
<td>6.7</td>
<td>469</td>
<td>19.7</td>
</tr>
<tr>
<td>50 - 59</td>
<td>6,164</td>
<td>17.2</td>
<td>1107</td>
<td>18.0</td>
</tr>
<tr>
<td>60 - 69</td>
<td>9,029</td>
<td>25.3</td>
<td>1308</td>
<td>14.5</td>
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<tr>
<td>70 - 79</td>
<td>11,199</td>
<td>31.3</td>
<td>1009</td>
<td>9.0</td>
</tr>
<tr>
<td>80 - 89</td>
<td>5,837</td>
<td>16.3</td>
<td>191</td>
<td>3.3</td>
</tr>
<tr>
<td>&gt;= 90</td>
<td>425</td>
<td>1.2</td>
<td>4</td>
<td>0.9</td>
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<td>Diagnosis and intervention</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>ACS and/or intervention</td>
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<td>34.1</td>
<td>3,483</td>
<td>28.5</td>
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<tr>
<td>ACS with intervention</td>
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<td>19.6</td>
<td>2,975</td>
<td>42.4</td>
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<td>2,257</td>
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<td>1,325</td>
<td>58.7</td>
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<tr>
<td>PCI acute</td>
<td>1,735</td>
<td>4.9</td>
<td>889</td>
<td>51.2</td>
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<tr>
<td>PCI elective</td>
<td>3,017</td>
<td>8.4</td>
<td>761</td>
<td>25.2</td>
</tr>
<tr>
<td>ACS without intervention</td>
<td>5,192</td>
<td>14.5</td>
<td>508</td>
<td>9.8</td>
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<tr>
<td>STEMI</td>
<td>391</td>
<td>1.1</td>
<td>117</td>
<td>29.9</td>
</tr>
<tr>
<td>Non STEMI</td>
<td>695</td>
<td>1.9</td>
<td>180</td>
<td>25.9</td>
</tr>
<tr>
<td>Unstable AP</td>
<td>4,106</td>
<td>11.5</td>
<td>211</td>
<td>5.1</td>
</tr>
<tr>
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<td>23,551</td>
<td>65.9</td>
<td>702</td>
<td>3.0</td>
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<td>Stable AP</td>
<td>14,953</td>
<td>41.8</td>
<td>383</td>
<td>2.6</td>
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<td>CHF</td>
<td>8,598</td>
<td>24.0</td>
<td>319</td>
<td>3.7</td>
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<tr>
<td>Comorbidities</td>
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<td></td>
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<tr>
<td>Lung diseases</td>
<td>7,554</td>
<td>21.1</td>
<td>719</td>
<td>9.5</td>
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<td>Psychiatric diseases</td>
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<td>11.3</td>
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<td>10.1</td>
</tr>
<tr>
<td>Locomotor apparatus diseases</td>
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<td>2.5</td>
<td>109</td>
<td>12.2</td>
</tr>
<tr>
<td>Diabetes</td>
<td>7,343</td>
<td>20.5</td>
<td>707</td>
<td>9.6</td>
</tr>
<tr>
<td>None of the above</td>
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<td>55.8</td>
<td>2,612</td>
<td>13.1</td>
</tr>
<tr>
<td>Distance to nearest CR provider (km)</td>
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<td></td>
</tr>
<tr>
<td>0 – 5 km</td>
<td>19,974</td>
<td>55.9</td>
<td>2,298</td>
<td>11.5</td>
</tr>
<tr>
<td>5– 10 km</td>
<td>8,332</td>
<td>23.3</td>
<td>1,065</td>
<td>12.8</td>
</tr>
<tr>
<td>10 – 15 km</td>
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<td>10.3</td>
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<tr>
<td>&gt; 15km</td>
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<td>8.6</td>
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<td>1,713</td>
<td>4.8</td>
<td>166</td>
<td>9.7</td>
</tr>
<tr>
<td>Entire cohort</td>
<td>35,752</td>
<td>100.0</td>
<td>4,185</td>
<td>11.7</td>
</tr>
</tbody>
</table>

AP= angina pectoris; CABG= coronary artery bypass graft; CHF= chronic heart failure; CR = cardiac rehabilitation; km= kilometres; PCI= percutaneous coronary intervention; SD= Standard deviation; STEMI= ST-elevation myocardial infarction.
Table 2 – Logistic regression analysis of determinants of cardiac rehabilitation uptake in patients who underwent a therapeutic intervention (model 1), and patients with an acute coronary syndrome without intervention (model 2)

<table>
<thead>
<tr>
<th></th>
<th>Model 1 (intervention)</th>
<th>Model 2 (ACS, no intervention)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=7,009</td>
<td>n=5,192</td>
</tr>
<tr>
<td>(Intercept)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Odds ratio (95% CI)</td>
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<tr>
<td>Gender</td>
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<td></td>
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<tr>
<td>Male</td>
<td>4,940</td>
<td>reference category</td>
</tr>
<tr>
<td>Female</td>
<td>2,069</td>
<td>0.82 (0.73-0.93)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
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<tr>
<td>&lt; 40</td>
<td>118</td>
<td>2.24 (1.50-3.36)</td>
</tr>
<tr>
<td>40 - 49</td>
<td>568</td>
<td>3.23 (2.62-3.99)</td>
</tr>
<tr>
<td>50 - 59</td>
<td>1,562</td>
<td>2.60 (2.24-3.02)</td>
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<td>60 - 69</td>
<td>2,107</td>
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<td>2,084</td>
<td>reference category</td>
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<td>80 - 89</td>
<td>551</td>
<td>0.41 (0.32-0.52)</td>
</tr>
<tr>
<td>&gt;= 90</td>
<td>19</td>
<td>0.11 (0.01-0.82)</td>
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<td>Intervention</td>
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<td>CABG</td>
<td>1,799</td>
<td>2.76 (2.31-3.31)</td>
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<td>PCI (acute)</td>
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<tr>
<td>STEMI</td>
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<td>1.88 (1.6-2.21)</td>
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<tr>
<td>Non STEMI</td>
<td>725</td>
<td>1.45 (1.2-1.76)</td>
</tr>
<tr>
<td>Unstable AP</td>
<td>2,100</td>
<td>reference category</td>
</tr>
<tr>
<td>Stable AP</td>
<td>1,717</td>
<td>0.72 (0.62-0.84)</td>
</tr>
<tr>
<td>HF</td>
<td>74</td>
<td>0.66 (0.40-1.09)</td>
</tr>
<tr>
<td>None of the above</td>
<td>697</td>
<td>1.15 (0.90-1.46)</td>
</tr>
<tr>
<td>Comorbidity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diseases locomotor apparatus</td>
<td>151</td>
<td>0.69 (0.48-1.00)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1,344</td>
<td>0.70 (0.61-0.80)</td>
</tr>
<tr>
<td>Lung disease</td>
<td>1,203</td>
<td>0.85 (0.73-0.98)</td>
</tr>
<tr>
<td>Psychiatric disease</td>
<td>662</td>
<td>0.71 (0.59-0.86)</td>
</tr>
<tr>
<td>No comorbidity</td>
<td>4,263</td>
<td>reference category</td>
</tr>
<tr>
<td>Distance to nearest CR provider</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 5.00 km</td>
<td>3,705</td>
<td>reference category</td>
</tr>
<tr>
<td>5.00 – 9.99 km</td>
<td>1,664</td>
<td>1.07 (0.94-1.22)</td>
</tr>
<tr>
<td>10.00 – 14.99 km</td>
<td>860</td>
<td>0.84 (0.71-0.99)</td>
</tr>
<tr>
<td>&gt;= 15.00 km</td>
<td>417</td>
<td>0.49 (0.39-0.62)</td>
</tr>
<tr>
<td>Missing</td>
<td>363</td>
<td>0.67 (0.52-0.85)</td>
</tr>
</tbody>
</table>

ACS= acute coronary syndrome; AP= angina pectoris; CABG= coronary artery bypass graft; CHF= chronic heart failure; CI= confidence interval; CR= cardiac rehabilitation; km= kilometre; PCI= percutaneous coronary interventions; STEMI= ST-elevation myocardial infarction
Sensitivity analysis
Switching the order in which the database was searched for eligible patients (selecting non-STEMI before STEMI, and selecting acute PCI before CABG) resulted in minor changes in the allocations of patients to diagnostic and therapeutic categories, and small to negligible changes in CR uptake rates. In fact, for the group with an intervention or ACS, switching non-STEMI and STEMI resulted in the same number of patients classified as having received CR, whereas switching acute PCI and CABG caused 2 out of 12,201 patients (0.016%) previously classified as having received CR, being classified as not having received CR. In the logistic regression analysis, switching STEMI and non-STEMI priorities led to a mean absolute difference in odds ratios of 0.008 (model 1) and 0.002 (model 2), with largest differences observed for the non-STEMI coefficient (1.45 vs. 1.51, model 1) and (8.51 vs 8.52, model 2). Switching CABG and acute PCI (which could only have an effect on model 1) led to a mean absolute difference in odds ratios of 0.023, with the largest difference observed for the CABG coefficient (2.76 vs. 2.91).

DISCUSSION

This study demonstrates that among patients who were diagnosed with an ACS and/or therapeutic intervention (CABG, valve surgery or PCI), only 28.5% received CR within the following year. CR uptake was even lower in patients with chronic cardiovascular disease that were eligible for CR according to the Dutch guidelines (3.0%). Factors associated with lower CR uptake were: female sex, older age, type of intervention (i.e. higher CR uptake after CABG and lower CR uptake after elective PCI as compared to acute PCI), diagnosis (i.e. lower CR uptake in patients with unstable AP as compared with myocardial infarction), comorbidity and a larger distance to the nearest CR provider.

Although CR uptake rates in the present study were generally low, we found a higher CR uptake rate for patients after an ACS and/or intervention as compared to an insurance claim study in the United States (28.5% versus 12.2%) . There may be several explanations for this discrepancy. First, Suaya et al. included only patients of at least 65 years of age, whereas all age categories were included in the our study. As shown in the results of both studies older age is associated with a lower CR uptake rate. Second, differences in eligibility for CR reimbursement may play a role. For instance, in contrast with our study, CR after PCI was not reimbursed in the U.S. during the study by Suaya et al. Third, travelling distances to the nearest CR provider may be longer in the U.S. as compared to The Netherlands. Finally, as our study was performed 10 years later, the higher CR uptake may also be the consequence of the fact that cardiologists are now more familiar with CR guidelines. In agreement with Suaya et al. several other studies with varying patient populations and study designs from Australia, Canada and the United States also reported low CR uptake rates (<50% in almost all of the studies). Studies reporting CR uptake rates in European countries are scarce. In a questionnaire study in the United Kingdom among patients with acute myocardial infarction and after CABG/PCI in 2003-2004, CR uptake rate was estimated at 29%, which is comparable to our study. In earlier studies in European
countries, CR utilization was even lower: an observational study among French patients with an ACS in 1998-1999 demonstrated a CR referral rate of 23%; surveys in Spain and Portugal reported CR uptake rates among patients eligible for CR of 2% and 0.7% respectively.\textsuperscript{19,20}

In patients with chronic cardiovascular conditions (stable AP and chronic heart failure), the overall CR uptake rate was much lower than in patients with a recent event or revascularisation procedures (3% versus 28.5 %, respectively). A possible explanation for this relatively low percentage may be that these patients already received CR at an earlier stage during the course of their disease, leading to an underestimation of CR uptake in the present study. However, as we included only patients who were newly diagnosed during the study period, we believe that this was not the only explanation. Another important explanation may be the fact that CR is not completely reimbursed for these indications in The Netherlands. Finally, a lack of physician encouragement and the perception that CR is not beneficial for these patients, may explain these low CR uptake rates.\textsuperscript{21} Although previous studies on CR uptake in European countries did not assess CR uptake for chronic cardiovascular conditions, results of the ECRIS study suggest low CR uptake rates for these patients in most other European countries.\textsuperscript{8} For patients with stable AP and CHF, CR was provided routinely only in a small minority of European countries (7% and 14%, respectively), as opposed to 68% for patients after ACS and/or PCI, and 71% for patients after CABG.\textsuperscript{8} Yet, there is abundant evidence that CR, and in particular physical training, is highly effective both in patients with stable AP and CHF patients.\textsuperscript{22-25} Therefore, future studies should focus on development of implementation strategies for CR in these patient groups.

The present study shows that, despite available evidence and adequate reimbursement, CR is still vastly underutilized in The Netherlands. The results of the European Inventory Survey suggest that this problem also exists in most other European countries. Therefore, it is important that strategies are developed to increase CR utilization. These strategies should particularly be aimed at subgroups that are less likely to receive CR. Considering patient characteristics, older age, female sex and the presence of comorbidity were all associated with a lower CR uptake rate in our study. These findings are in agreement with other studies.\textsuperscript{15,23,26-28} Yet, Suaya et al. showed that all sex and age groups had lower mortality rates among CR users than among matched nonusers, underlining the importance of CR in these subgroups.\textsuperscript{16} Proposed explanations for low participation of women in CR programs include lower referral by physicians, and less support/encouragement from healthcare personnel and spouses to participate in these programs.\textsuperscript{29} Low CR uptake in elderly patients and patients with comorbidities may also be explained largely by lower physician referral due to a low expected benefit by the physician.\textsuperscript{30} Therefore strategies aiming at improving CR uptake in these subgroups should be aimed at increasing physician awareness about the benefits of CR in these subgroups, for instance by using a computerized decision support system.\textsuperscript{31} Other strategies that have been shown to be effective are application of standardized clinical pathways and/or computer generated, automatic referral systems at discharge.\textsuperscript{32-34} However, it should be noted that these strategies may not be sufficient if patient or process related barriers play a predominate role (e.g. cost, lack of insurance coverage, time commitment). Therefore, interventions combining automatic referral with a personal discussion
with trained health care professionals are even more effective.\textsuperscript{35}

In addition to patient characteristics, diagnosis and type of treatment were also found to be determinants of CR uptake. Patients after CABG were most likely to receive CR. Unstable angina pectoris was associated with a substantial lower CR uptake rate as compared to patients with myocardial infarction. Although both national and international guidelines recommend CR for patients with unstable angina pectoris, these findings have also been reported in other studies.\textsuperscript{15,18,27,28} Again, increasing physician awareness of the benefits of CR in these patients and automatic referral at discharge may be effective for increasing CR uptake in this patient category. Finally, in agreement with another study,\textsuperscript{30} a larger distance to the nearest provider of CR was associated with a lower CR uptake. For these patients, CR participation may be increased by offering a home-based CR program.

\section*{Limitations}

Our study has several limitations. Using insurance claims we were not able to include several variables as possible determinants of CR uptake, such as left ventricular function and some risk factors (hypertension, body mass index and smoking behaviour). However, in a recent study by van Goel et al. in patients who underwent PCI, only smoking behaviour was of influence on CR uptake.\textsuperscript{23} Furthermore, the study design did not permit us to assess CR referral rates. Therefore, it is not possible to discern whether low CR uptake rates are actually caused by low referral rates or by patient-related factors such as motivation. In order to obtain a more detailed picture, future studies should assess both CR referral and uptake rates. Another possible limitation concerns the interpretation of CR uptake rates in patients with chronic diagnoses (group 3). As discussed, these rates may have been underestimated because these patients could have received CR before the study period. Therefore, these patients were not included in the evaluation of determinants of CR uptake. Finally, several diagnosis groups that may benefit from CR could not be studied due to the low number of patients (e.g. patients with heart transplantation, ICD, and congenital cardiac disease.

\section*{CONCLUSION}

In conclusion, a minority of Dutch patients eligible for CR actually received CR within the next year, with particularly low CR uptake rates in patients with chronic cardiovascular conditions (stable AP or CHF). Factors associated with low CR uptake include female sex, older age, elective PCI as compared to acute PCI or CABG, unstable AP as compared to myocardial infarction, long travelling distances to the nearest CR provider, and co-morbidities. These results underline the need for the development of implementation strategies specifically aimed at these subgroups.
ACKNOWLEDGEMENTS

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REFERENCES


PART II

AN INFRASTRUCTURE TO FACILITATE CONTINUOUS IMPROVEMENT
OPTIMIZING THE USER INTERFACE OF A DATA ENTRY MODULE FOR AN ELECTRONIC PATIENT RECORD FOR CARDIAC REHABILITATION: A MIXED METHOD USABILITY APPROACH

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ABSTRACT

Introduction: Cumbersome electronic patient record (EPR) interfaces may complicate data-entry in clinical practice. Completeness of data entered in the EPR determines, among other things, the value of computerized clinical decision support (CCDS). Quantitative usability evaluations can provide insight into mismatches between the system design model of data entry and users’ data entry behaviour, but not into the underlying causes for these mismatches. Mixed method usability evaluation studies may provide these insights, and thus support generating redesign recommendations for improving an EPR system’s data entry interface.

Aim: To improve the usability of the data entry interface of an EPR system with CCDS in the field of cardiac rehabilitation (CR), and additionally, to assess the value of a mixed method usability approach in this context.

Methods: Seven CR professionals performed a think-aloud usability evaluation both before (beta-version) and after the redesign of the system. Observed usability problems from both evaluations were analyzed and categorized using Zhang et al.’s heuristic principles of good interface design. We combined the think-aloud usability evaluation of the system’s beta-version with the measurement of a new usability construct: users’ deviations in action sequence from the system’s predefined data entry order sequence. Recommendations for redesign were implemented. We assessed whether the redesign improved CR professionals’ 1) task efficacy (with respect to the completeness of data they collected), and 2) task efficiency (with respect to the average number of mouse clicks they needed to complete data entry subtasks).

Results: With the system’s beta version, 40% of health care professionals’ navigation actions through the system deviated from the predefined next system action. The causes for these deviations as revealed by the think-aloud method mostly concerned mismatches between the system design model for data entry action sequences and users expectations of these action sequences, based on their paper-based daily routines. This caused non completion of data entry tasks (31% of main tasks completed), and more navigation actions than minimally required (146% of the minimum required). In the redesigned system the data entry navigational structure was organized in a flexible way around an overview screen to better mimic users’ paper-based daily routines of collecting patient data. This redesign resulted in an increased number of completed main tasks (70%) and a decrease in navigation actions (133% of the minimum required). The think-aloud usability evaluation of the redesigned system showed that remaining problems concerned flexibility (e.g. lack of customization options) and consistency (mainly with layout and position of items on the screen).
Conclusion: The mixed method usability evaluation was supportive in revealing the magnitude and causes of mismatches between the system design model of data-entry with users’ data entry behaviour. However, as both task efficacy and efficiency were still not optimal with the redesigned EPR, we advise to perform a cognitive analysis on end users’ mental processes and behavior patterns in daily work processes specifically during the requirements analysis phase of development of interactive healthcare information systems.

Key words: Usability Evaluation; Electronic Health Records; CCDS; Cardiac Rehabilitation.
INTRODUCTION

The primary aim of recording data in electronic patient records (EPRs) is to support the delivery of good care, clinical decision-making, communication between healthcare workers and continuity of care. Additionally, EPRs are a valuable source of quality assurance of medical practice and scientific research [1]. In achieving these aims, effective use of EPRs requires structured data entry; which may be a challenge for physicians when design and implementation of an EPR does not align with their cognitive and workflow requirements and preferences [1-3]. Poorly designed and cumbersome data entry interfaces can complicate structured EPR data entry during clinical practice, resulting in poor data quality and data incompleteness [4, 5]. This may consequently lead to suboptimal functioning of health information technology systems integrated in the EPR, e.g. reminder systems, computerized physician order entry and computerized clinical decision support (CCDS).

Of those systems, CCDS is one of the most effective strategies to improve clinical decision making [4, 6]. CCDS uses characteristics of individual patients to generate patient-specific recommendations (based on national guidelines, evidence analysis or expert opinion) at the time and place clinical decisions are made [7]. To do so, CCDS systems often require availability of a large number of patient data (demographic data, data on complaints, symptoms, previous history, physical examination, laboratory, and other tests). Clinicians, health care staff, or patients can manually enter the data into the system; in addition, the EPR can be queried for retrieval of patient data [6]. Despite their goal to improve the quality of care, systematic reviews of CCDS studies reported only an improvement in professional performance for somewhat more than half of the included studies [8, 9] and attempts to identify critical success factors for CCDS systems have provided inconsistent results [8]. CCDS systems that derive their data from EPRs may provide inadequate advices as a result from incompleteness of EPR data needed to generate that advice [10].

Users of computerized systems are known to acquire knowledge about the system design models through experience that form the basis for the construction of reasonable action sequences. To stimulate complete data collection, an EPR systems’ design model of data entry (“the way the designer represents the system’s data entry functionality to the user, including screen presentations, interaction structure, and object relationships”) should match the users’ data entry behaviour (“the way that users have internalized how the data entry should proceed based on their experiences from daily practice”) [11]. Consequently, evaluation of the usability of the data entry interface in EPR systems is an essential step in human-centered design to optimize the match between the systems’ design model and user’s behaviour of data entry. Several quantitative methods exist (e.g. sequential pattern analysis, keystroke models and log file analysis) to analyse or model navigation patterns and action sequences from system users [12, 13]. These measures can provide insight into mismatches between the user’s behaviour and systems’ design model, but not into the underlying system design aspects causing these mismatches. Mixed method usability evaluation studies may provide this insight, resulting in
concrete redesign recommendations and finally in improved usability of a system’s data entry interface [14, 15].

An EPR system with CCDS functionalities, called MediScore CARDSS, was developed to stimulate guideline implementation on cardiac rehabilitation (CR) throughout the Netherlands [16, 17]. To guarantee complete data collection of the patient’s overall condition, a beta and a redesigned version of the system were both assessed by a mixed method usability evaluation with end-users (CR professionals). The results of the usability evaluation of the beta system version were handed over to the developers to improve the design of the system. The aim of this study was to improve the usability of the data entry interface of this first system version. Additionally we assessed the value of a mixed method usability approach (measuring fit between the systems’ design model of data entry and users’ data entry behaviour both from a quantitative and qualitative perspective) in this context.

BACKGROUND

Clinical setting: cardiac rehabilitation in the Netherlands

CR is a multidisciplinary therapy to support recovery from a cardiac incident or intervention, with the aim to improve a patient’s physical and psychological condition [18]. CR is recommended for all patients who have been hospitalized for an acute coronary syndrome (ACS) and for those who have undergone a cardiac intervention [19]. A meta-analysis shows consistent evidence of the effectiveness of exercise-based and multimodal (e.g., psychosocial and stress management) CR interventions with regard to mortality and prevention of future cardiac events (relative-risk reduction 21–47%) [20]. The therapy is offered by multidisciplinary teams, which generally include cardiologists, specialist nurses (of whom one acts as the rehabilitation coordinator), physical therapists, psychologists, dieticians and social workers, and is supported by a medical secretarial office.

Consistent with international guidelines, the Dutch guidelines for CR state that patients should be offered an individualized rehabilitation program based on their medical, physical, and psychosocial needs [21]. Traditionally this program is formulated during a 30 to 60 minute clinical patient interview, usually performed by a specialized nurse, physiotherapist or social worker. To structure the interview the guidelines include a paper-based clinical algorithm defining an extensive needs assessment procedure (NAP) [22]. This algorithm was designed in collaboration with CR professionals and is used in practice by multidisciplinary CR teams throughout the Netherlands [23]. It consists of fifteen numbered flowcharts across five domains, each describing how to select rehabilitation goals and therapies based on 155 to 175 patient data items (including both general questions and eight standardized questionnaires). During the daily routine with the paper-based NAP patient interview, professionals can adapt the order of data collection to their own preferences and as such data collection is flexible. A structured NAP to base therapy decisions on is a commonly used strategy within disease management of chronic patients [24]. It is needed to reduce inter-practice variation in the offered health care
and is in line with recommendations from the Chronic Care Model. This model is widely used to improve quality of care for chronic patients [24].

**Context: The MediScore CARDSS system**

The MediScore CARDSS system was developed in 2010 by ItéMedical BV, a Dutch commercial vendor in healthcare IT. The system concerns registration of administrative patient data, entry of clinical and health-related patient data, and provides CCDS to support CR professionals in the selection of goals and therapies for a guideline-based and patient-tailored CR program.

The design model of the beta system version implemented data entry in the exact order of the flowcharts of the Dutch paper-based clinical algorithm for CR. The entry of clinical and health-related data was partially static (e.g., standard questionnaires for quality of life and lifestyle assessments) and partially dynamic (i.e., the flow through the charts depends on previously entered data). To ensure complete data entry during the NAP, the beta system version guided users in one predefined data entry order through 53 data entry screens to collect all data items required to generate a patient specific CR advice. Figure 1 shows one of the data entry screens of the beta system version. The flow through the system was supported with a ‘next button’ on each screen. Alternatively, navigation controls such as horizontal and vertical tabs displayed on both sides of the computer screen could be used when a user liked to deviate from the predefined data entry order. After entering all available patient data, the system provided its users with a patient-specific, guideline-based CR program, consisting of recommended rehabilitation goals and therapies. For each recommended goal and therapy professionals could either indicate that they adhere to the recommendation or that they did not follow the advice due to e.g. professional expertise, patient preferences, or lack of resources.
Figure 1 – Screenshot beta system version (MediScore CARDSS 2.0): NAP data entry concerning the patients’ social condition.

Figure 2 – Screenshot redesigned system version (MediScore CARDSS 3.0): grouped data entry of all static, standard questionnaires during the NAP.
METHODS

Study design
We performed a think-aloud usability evaluation with CR professionals of the data entry interface of a beta (MediScore CARDSS 2.0) and the redesigned (MediScore CARDSS 3.0) version of the system. We combined the think-aloud usability evaluation of the system beta-version with the measurement of a new usability construct: users’ deviations in action sequence from the system’s predefined data entry order sequence. Results on users’ deviations from the systems’ design model of data entry order were combined with explanations for these deviations as revealed by the think-aloud method. These results and recommendations for redesign were handed over to the developers, who reengineered the beta version of the system.

We assessed whether the redesigned system version improved users’ task efficacy and task efficiency; with task efficacy defined as the number of data entry tasks and subtasks completed, and task efficiency defined as the average number of mouse clicks needed to do so. A data entry task was considered completed when a user succeeded in completion of each of its subtasks. As a measure of task efficiency, we calculated the difference between the theoretical minimum and actual number of mouse clicks users needed to complete each of the data entry subtasks successfully.

Participants
At the start of our research five CR centres (out of the 91 centres in the Netherlands of which 12 located in specialized rehabilitation clinics [25]) signed an intention with the software developers to buy the CARDSS Online system. They all received a demonstration of the beta system version and a local, stand-alone copy for explorative use. Two of them were located in non-teaching hospitals, one in a teaching hospital and two in rehabilitation clinics. All five centres were invited by mail to participate and to name one or two representatives of the multidisciplinary teams who were used to perform the paper-based NAP patient interview and who would work with the system in the future. The centres all agreed and by phone we invited the proposed seven participants to discuss details of the study (two centres proposed two participants). Characteristics of the participants and their centres are shown in Table 1. As the think-aloud method provides a rich source of data, a sample of approx. 8 subjects suffices to gain a thorough understanding of task behaviour or to identify the main usability problems with a computer system [26]). From July until September 2010 all seven participants performed the think-aloud of the beta system version. Results and identified usability problems of the beta system version were handed over to the software developers in December 2010 and presented elsewhere [27]. Reengineering by the developers took until March 2012. By that time two of the participating centres (one teaching and one rehabilitation clinic) had decided not to purchase the redesigned system and two of our participants were unavailable for the second think-aloud usability evaluation. To keep a convenient sample of subjects we invited two new participants two CR centres (one teaching and one non teaching hospital) who in meanwhile had procured
the redesigned system (but still did not actually use it in daily CR practice). From April until September 2012 five + two participants performed the think-aloud of the redesigned system version. Results and identified usability problems of the redesigned system version were handed over to the software developers in March 2013.

Table 1 – Characteristics of participants.

<table>
<thead>
<tr>
<th>Center ID</th>
<th>Center type</th>
<th>Discipline</th>
<th>Participation in think aloud</th>
<th>Beta system version</th>
<th>Redesigned system version</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Teaching</td>
<td>Nurse</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Non-teaching</td>
<td>Nurse</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>Rehabilitation clinic</td>
<td>Social worker</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Rehabilitation clinic</td>
<td>CR medical secretary</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Non-teaching</td>
<td>Nurse</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>Non-teaching</td>
<td>Social worker</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Teaching</td>
<td>Physiotherapist</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

Think-aloud user testing

We used the think-aloud method [28] to evaluate usability problems and analyse causes underlying users’ deviations in action sequence from the system’s predefined data entry order sequence. The think-aloud method is generally considered the ‘gold standard’ in usability evaluation as it provides detailed insight into user system interaction problems [29]. Seven CR professionals familiar with the paper-based patient documentation for the NAP, and with explorative system experience, performed a CR NAP in their own clinic by use of both the beta and redesigned system version. They were asked to enter data from 1) a fictitious patient case and 2) a real patient case from their own clinic (order of cases switched between participants to improve task completion for both cases). For the system usability evaluation with the fictitious patient case, users received all patient data in the predefined system data-entry order. With the real patient case, users were asked to perform the NAP with the system by entering data derived from a paper record from a patient recently treated in their own clinic. In both cases basic system functionalities were covered by asking the users to complete several main data entry tasks.

During the usability evaluation of the beta system version, users had to perform a complete CR NAP divided in seven main data entry tasks: patient registration, entering data concerning the patient’s physical condition, psychological condition, social condition, cardiovascular risk profile and lifestyle, and finally selecting goals and therapies for a patient-tailored CR program. Due to changes in the redesigned system version, the second evaluation concerned users’ to perform the same NAP, but now divided across five main tasks: patient registration, entering data on static, standard questionnaires and results of physical examination, entering dynamic
data concerning the patients overall condition and finally the selecting of goals and therapies for the CR program. Table 4 and 5 give an overview of all main tasks defined for both system versions’ usability evaluations. Each main task itself was composed of several subtasks, e.g. defining the patient’s social condition required the entering of data about social functioning, the partner and work resumption. We identified a total of 41 subtasks per patient case for the beta system evaluation and 25 subtasks for the redesigned system evaluation. The amount of data items which needed to be entered during the think-aloud usability evaluation of both the beta and redesigned system version, was exactly the same. We performed 2-sample z-tests to compare sample proportions to assess whether task completion rates were different for the real and fictitious patient case and whether they improved in the redesigned system compared to its beta version.

**Assessment of navigation patterns and usability problems**

We used a mobile ‘usability lab’ consisting of a laptop with Morae™ software to capture screen, mouse gestures, keystrokes and the participant’s facial expressions and verbal reactions. Participants first performed a practice task to get accustomed with talking aloud before performing the two patient cases. All recorded data were analyzed with the Morae™ software. To assess the fit between the system’s design model with users’ data entry behaviour quantitatively in the beta system version, we measured the frequency with which users deviated from the system’s predefined data entry action through the CR NAP. As following the predefined data entry order sequence was important to attain data completeness, we used the number of deviations from the predefined system action sequence as a proxy of system quality on usability.

Data entry actions were first plotted in a graph to visualize individual navigational patterns for a thorough insight in the mismatches between the system’s design model of data entry and users’ data entry behavior. Thereafter, per user, a deviation percentage was calculated by dividing the number of actions in which he or she deviated from the next predefined system action by the total number of actions through the system. Herein, each of the 53 screens was considered one separate action. For instance, when a participant navigated through 50 screens in total, of which in 30 cases he or she went to the predefined next screen directly and in 20 cases to another screen, the deviation percentage was 40% (20/50). However, due to a completely flexible data entry structure in the redesigned system version, the construct used to assess navigational patterns could not be used again in the second usability evaluation.

To analyze the causes of participants’ deviations from the systems’ predefined data entry order qualitatively, all verbal protocols of participants were transcribed and verbal utterances and related video analysis were coded semi-bottom up by two researchers independently to reveal usability problems. Results of the researchers were compared to calculate inter-rater agreement (Cohen’s kappa statistic) which was interpreted according to the criteria published by Landis and Koch [30]. Thereafter discrepancies were resolved by discussion and, if needed, by consultation of a third researcher. Main usability problems revealed per participant were first listed by the two researchers independently to remove within and between participant
duplicates of usability problems revealed. The usability problems, which both researchers rated as actual usability problems, were summed up into one master usability problem list. Two researchers subsequently classified each usability problem description in the master usability problem list according to the heuristic classification described by Zhang et al as summarized in Table 3 [31] and on severity according to the severity rating scale (1 – cosmetic problem only, 2 – minor usability problem, 3 – major usability problem, and 4 – usability catastrophe) defined by Nielsen et al [32]. The software developers also rated each problem on severity. Their rating was combined with the rating of the research team in a median rating (including the inter quartile range [IQR]). The team of researchers and software developers discussed these ratings of usability problems to determine priorities for the redesign of the system. To assess whether severity ratings for each individual heuristic class and the overall ratings over heuristic classes significantly differed for the beta vs. the redesigned system version, we performed a Mann Whitney U test. Per heuristic, we determined the number of usability problems in both the beta and redesigned system version. As recommended, we only performed the Mann-Whitney test for those heuristics with a sample size of more than seven problems [33].

RESULTS

Participants
All nine CR professionals had over three years general computer experience, seven of them were female, and four of them had used a previous version of the system (from 2004 [34]). Usability evaluations were performed within two weeks after participants had received the local, stand-alone copy of the system for explorative use. Participants involved in the usability evaluation were: four nurses, two social workers, a supportive CR medical secretary and two physiotherapists. Mean age of the professionals was 41.2 years (range 27 – 58). Overall these participants represented both the different types of CR centres (located in teaching and non-teaching hospitals and specialized rehabilitation clinics) and the multiple disciplines who are involved in the paper-based NAP patient interview.

Usability evaluation beta system version
Navigational patterns - On average, in the beta system version users deviated in 40% of the actions taken from the predefined next system action. Table 2 and Figure 3 give an overview of users’ deviations in action sequence from the system’s predefined data entry order sequence, for all 14 patient cases. Overall, users more often seemed to deviate from the predefined data entry order sequence during the data entry process of the NAP for the real patient case using the interview report from one of their own paper records (46%), than during the data-entry process for the fictitious patient case (36%). However, due to the high inter-individual variation shown in Figure 3, we were not able to derive one typical user model of deviations in action sequence from the system’s predefined data entry order sequence. Each participant followed his or her own specific route through the data entry process with only few process actions overlapping.
Table 2 – Number of users’ deviations in action sequence from the system’s predefined data entry order sequence, compared to the total number of actions users performed in the beta version of the system.

<table>
<thead>
<tr>
<th>User</th>
<th>Fictitious patient case</th>
<th>Real patient case</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Deviations/ Total actions</td>
<td>%</td>
<td>Deviations/ Total actions</td>
</tr>
<tr>
<td>1</td>
<td>19 / 40</td>
<td>47.5</td>
<td>13 / 33</td>
</tr>
<tr>
<td>3</td>
<td>25 / 58</td>
<td>43.1</td>
<td>47 / 72</td>
</tr>
<tr>
<td>7</td>
<td>18 / 61</td>
<td>29.5</td>
<td>18 / 46</td>
</tr>
<tr>
<td>Sub total</td>
<td>62/159</td>
<td>39.0</td>
<td>78/151</td>
</tr>
<tr>
<td>2</td>
<td>29 / 46</td>
<td>63.0</td>
<td>27 / 47</td>
</tr>
<tr>
<td>4</td>
<td>14 / 61</td>
<td>23.0</td>
<td>26 / 56</td>
</tr>
<tr>
<td>5</td>
<td>25 / 86</td>
<td>29.1</td>
<td>7 / 53</td>
</tr>
<tr>
<td>6</td>
<td>14 / 47</td>
<td>29.8</td>
<td>14 / 27</td>
</tr>
<tr>
<td>Sub total</td>
<td>82/240</td>
<td>34.2</td>
<td>74/183</td>
</tr>
<tr>
<td>TOTAL</td>
<td>144 / 399</td>
<td>36.1</td>
<td>152 / 334</td>
</tr>
</tbody>
</table>

Main usability problems - Coding of the verbal think-aloud protocols of the beta system version resulted in a substantial agreement (kappa statistic of 0.61 [30]). Overall they revealed 45 main usability problems with a mean severity rate of 2.3. Table 3 gives an overview of the number of violations and a mean severity rate per heuristic. The heuristics most often violated were Consistency and standards (n=13) and Match between system and world (n=12). The heuristics with the highest severity rate (and violated more than once) were Users in control (3.5), Visibility of system state (3.0) and Match between system and world (2.9). An example of a usability problem classified as a Consistency and standards problem was “I do not know whether I need to use the button which says ‘Next’ or the button which says ‘Continue’ “. An example of a Visibility of system state problem was “I navigate back to the previous page to check whether the data I entered was actually stored”.

A severe and frequently mentioned problem, that was visible in users’ deviations from the predefined data entry order, was that users were searching for a more flexible data entry order more in line with their daily working practices during the paper-based NAP. They stated they were searching for a flexible, but grouped data entry option to first enter all static, standard questionnaires before they would enter the dynamic patient data (e.g. “Now I have filled in the questionnaire on psychological functioning I’m searching for the other questionnaires, however I cannot find them on tab”). This problem was classified as Match between system and world.
Figure 3 – Users’ deviations in action sequence from the system’s predefined data entry order sequence in the beta version of the system.
Table 3 – Usability heuristics as adopted from Zhang et al [31], the number of violations (N) and a median severity rate with inter-quartile range (IQR) per heuristic both before (beta-version) and after the redesign of the system. The Mann Whitney U test was performed to test group differences for the ratings both per heuristic only if sample size ratings was > 7 and overall from the usability evaluation of the beta and the redesigned system version.

<table>
<thead>
<tr>
<th>Heuristic</th>
<th>Beta system version</th>
<th>Redesigned system version</th>
<th>Mann Whitney U test p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>Median severity rate</td>
<td>N</td>
<td>Median severity rate</td>
</tr>
<tr>
<td>(IQR)</td>
<td>(IQR)</td>
<td>(IQR)</td>
<td>(IQR)</td>
</tr>
</tbody>
</table>
| 1 Consistency and standards| 13                  | 6                         | 2.5 (1.0 – 3.0)             | 1.5 (1.0 – 2.0) | 0.390  
| 2 Visibility of system state| 12                  | 2                         | 3.0 (2.3 – 3.8)             | 1.5 (1.0 – 2.0) | 0.015  
| 3 Match between system and world| 12                  | 1                         | 3.0 (2.3 – 3.0)             | 1.5 (1.0 – 2.0) | 0.226  
| 4 Minimalist| 12                  | 1                         | 3.0 (3.0 – 3.0)             | 1.5 (1.0 – 2.0) | 0.226  
| 5 Minimize memory load| 12                  | 1                         | 2.5 (1.8 – 3.0)             | 1.5 (1.0 – 2.0) | 0.226  
| 6 Informative feedback| 12                  | 1                         | 1.5 (1.0 – 2.0)             | 1.5 (1.0 – 2.0) | 0.226  
| 7 Flexibility and efficiency| 12                  | 1                         | 3.0 (2.0 – 3.0)             | 2.0 (1.0 – 2.0) | 0.226  
| 8 Good error messages| 12                  | 1                         | 3.0 (3.0 – 3.0)             | 2.0 (1.5 – 4.0) | 0.226  
| 9 Prevent errors| 12                  | 1                         | 3.0 (3.0 – 3.0)             | 2.0 (1.5 – 4.0) | 0.226  
| 10 Clear closure| 12                  | 1                         | 3.0 (3.0 – 3.0)             | 2.0 (1.5 – 4.0) | 0.226  
| 11 Reversible actions| 12                  | 1                         | 3.0 (3.0 – 3.0)             | 2.0 (1.5 – 4.0) | 0.226  
| 12 Help and documentation| 12                  | 1                         | 3.0 (3.0 – 3.0)             | 2.0 (1.5 – 4.0) | 0.226  
| TOTAL                     | 45                  | 30                        | 2.0 (1.3 – 2.3)             | 0.004          |
Task efficacy - Table 4 shows that users on average completed 2.1 out of the 7 main tasks (30%) needed to enter data for a complete CR NAP successfully with the beta system version. Concerning the subtasks they completed 30 out of the 41 (73%) successfully. The subtasks concerning patient registration had the highest completion rate (86%). Subtasks with the lowest completion rates, concerned entering data referring to a patient’s cardiovascular risk profile (62%) and lifestyle (64%). A trend was found with users completing fewer tasks when they entered the data of a real patient case (19% main task, and 63% subtask completion) compared the situation where they had to enter data of the fictitious patient case (41% main task, and 82% subtask completion). However, in our sample the difference was neither statistically significant for the main task (proportion test 95% CI -0.26 – 0.70; p= 0.3691) nor for the subtask completion (proportion test 95% CI -0.28 – 0.66; p= 0.426).

Task efficiency - With the beta system version, users on average needed 321 mouse clicks to complete the subtasks for the NAP for one patient; that is 146% (range 108% - 245%) of the minimum number of mouse clicks (241). For the fictitious patient case this was 156% (range 125% - 245%) of the minimum number of mouse clicks, and for the real patient case 136% (range 108% - 179%).

Usability evaluation redesigned system version

Redesign - The redesigned system version basically provides the same functionalities as the beta system version, although the design of the data entry interface was significantly changed. Both individual navigation patterns and the think-aloud protocols from the beta system evaluation showed that the systems’ design model of one predefined data entry order did not match users’ expectations of, and their actual navigational patterns through the system. Users continually searched for, and expressed their preferences of ways to enter the data in the system in more flexible manners. Users indicated that in their daily routine with the paper-based NAP they tend to collect patient data in various manners, depending on their individual workflow. Users were thus unable to construct a mental model that matched the system’s design model of one predefined data entry order. The mixed method usability evaluation revealed a need for a completely flexible data entry navigational structure of the interface.

The redesigned system provides 32 data entry screens to guide the user through the CR algorithm. Users can decide on a grouped data entry of all static, standard questionnaires (although this is not required) before entering the dynamic data patient data and receiving the decision support on the final patient-specific rehabilitation program. Figure 2 shows the data entry screens for all standardized questionnaires in the redesigned system version. Complete data collection is stimulated by showing users which data entry actions they already have finished and which actions they still need to complete. The ‘next button’ on each screen was removed and the number of horizontal and vertical tabs reduced. In the redesigned system version, users are supported in their flow through the system by guiding them back to an overview screen after they have entered and saved data. From this overview screen, users can
choose the next data item or questionnaire they prefer to enter. As a result of this fully flexible data entry interface user deviations in action sequence from the system’s predefined data entry order sequence could not be assessed in the redesigned system.

**Main usability problems** - Coding of the verbal think-aloud protocols of the redesigned system version resulted in a moderate agreement (kappa statistic of 0.53 [30]). The think-aloud usability evaluation of the redesigned system revealed 30 usability problems with an overall median severity of 2.0. This overall median severity was significant lower than the 3.0 overall median severity rating in the beta system version (Mann Whitney U test p= 0.004). Table 3 gives an overview of the number of violations and a mean severity rate per heuristic. The heuristics most often violated were Consistency and standards (n=6), Flexibility and efficiency (n=6) and Minimize memory load (n=5). The heuristics with the highest severity rate (and violated more than once) were Minimize memory load (2.3), Prevent errors (2.3) and Use users’ language (2.0). Problems related to incomplete data collection occurred in all heuristic classes e.g. in Consistency and standards (“I know that I still miss some dynamic data on the patients’ physical functioning, however I do not see where I can enter this data”), Flexibility and efficiency (“Why do I need to enter the same date for each questionnaire again”) and Visibility of system state (e.g. “I doubt whether the system is still saving data, as I have clicked on the ‘Save’ button but I’m not automatically redirected to the overview page”). Three usability problems were classified as violations of the heuristic Match between system and world with a mean severity of 1.5. A recurrent theme over all heuristics was lack of customization options for e.g. system default values (“We always plan the same amount of training sessions”) and terminology (“We use the term acute coronary syndrome which I cannot find in the list”).

**Task efficacy** - Table 5 shows that users on average completed 3.8 out of the 5 main tasks (76%) needed to perform a complete CR NAP successfully with the redesigned system version. Compared to completion of main tasks in the beta system version (30%), the improvement was statistically significant (proportion test 0.46; 95% CI 0.05 – 0.87; p= 0.0263). Concerning the subtasks they completed 20 out of the 25 (79%) successfully. Compared to completion of subtasks in the beta system version (73%), the improvement was not statistically significant (proportion test 0.06; 95% CI -0.29 - 0.41; p= 0.7362). The subtasks concerning the selection of goals and therapies for the patient specific CR program (93%) and patient registration (91%) had the highest completion rates. The subtasks with the lowest completion rates were entering dynamic data concerning the patients overall condition (55%) and results of a patient’s physical examination (79%). A trend was found with users completing fewer subtasks when they entered the data of a real patient case (31% completion for main tasks and 70% for subtasks) compared to the situation where they had to enter data of the fictitious patient case (77% main task and 87% subtask completion). However, in our sample this difference was neither statistically significant for the main task (proportion test 0.46; 95% CI -0.16 – 1.08; p= 0.1445) nor for the subtask completion (proportion test 0.17; 95% CI -0.34 – 0.68; p= 0.5129).
Task efficiency - With the redesigned system version, users on average needed 267 mouse clicks to complete subtasks for the NAP for one patient: 133% (range 106% - 216%) of the minimum number of mouse clicks (n=201). For the fictitious patient case this was 129% (range 117% - 193%) of the minimum number of mouse clicks, and for the real patient case 138% (range 106% - 216%).

Table 4 – Results of the usability evaluation of beta system version: Tasks and subtasks completed and mouse clicks needed.

<table>
<thead>
<tr>
<th>Beta system version</th>
<th>Task 1 Patient registration</th>
<th>Task 2 Data physical condition</th>
<th>Task 3 Data psychological condition</th>
<th>Task 4 Data social condition</th>
<th>Task 5 Data cardiovascular risk profile</th>
<th>Task 6 Data lifestyle</th>
<th>Task 7 Selection goals + therapies</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td># subtasks per task / # mouse clicks minimally required</td>
<td>4 6 7 5 7 8 4 41</td>
<td>49 85 59 23 29 40 54 339</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fictitious patient case

<table>
<thead>
<tr>
<th></th>
<th>Task completion</th>
<th>Average subtask completion</th>
<th>Average mouse clicks needed for completed subtasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task completion</td>
<td>6/7 0/7 6/7 4/7 2/7 1/7 1/7</td>
<td>96% 83% 98% 89% 73% 70% 75%</td>
<td>151% 114% 109% 164% 240% 131% 182%</td>
</tr>
</tbody>
</table>

Real patient case

<table>
<thead>
<tr>
<th></th>
<th>Task completion</th>
<th>Average subtask completion</th>
<th>Average mouse clicks needed for completed subtasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task completion</td>
<td>4/7 0/7 2/7 2/7 0/7 0/7 1/7</td>
<td>75% 62% 61% 71% 51% 59% 75%</td>
<td>145% 108% 139% 131% 194% 117% 115%</td>
</tr>
</tbody>
</table>
Table 5 – Results of the usability evaluation of redesigned system version: Tasks and subtasks completed and mouse clicks needed.

<table>
<thead>
<tr>
<th>Redesigned system version</th>
<th>Task 1 Patient registration</th>
<th>Task 2 Data psychosocial questionnaires</th>
<th>Task 3 Data physical examination</th>
<th>Task 4 Data overall condition</th>
<th>Task 5 Selection goals + therapies</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td># subtasks per task / # mouse clicks minimally required</td>
<td>3 / 53</td>
<td>8 / 87</td>
<td>4 / 37</td>
<td>6 / 21</td>
<td>4 / 105</td>
<td>25 / 303</td>
</tr>
</tbody>
</table>

Fictitious patient case

<table>
<thead>
<tr>
<th>Task completion</th>
<th>6/7</th>
<th>7/7</th>
<th>7/7</th>
<th>1/7</th>
<th>6/7</th>
<th>5.4/7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average subtask completion</td>
<td>95%</td>
<td>100%</td>
<td>100%</td>
<td>52%</td>
<td>96%</td>
<td>87%</td>
</tr>
<tr>
<td>Average mouse clicks needed for completed subtasks</td>
<td>120%</td>
<td>117%</td>
<td>128%</td>
<td>156%</td>
<td>193%</td>
<td>129%</td>
</tr>
</tbody>
</table>

Real patient case

<table>
<thead>
<tr>
<th>Task completion</th>
<th>4/7</th>
<th>2/7</th>
<th>0/7</th>
<th>0/7</th>
<th>5/7</th>
<th>2.2/7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average subtask completion</td>
<td>86%</td>
<td>70%</td>
<td>57%</td>
<td>57%</td>
<td>89%</td>
<td>70%</td>
</tr>
<tr>
<td>Average mouse clicks needed for completed subtasks</td>
<td>106%</td>
<td>108%</td>
<td>116%</td>
<td>216%</td>
<td>201%</td>
<td>138%</td>
</tr>
</tbody>
</table>

DISCUSSION

Statement of principal findings

We performed a mixed method usability evaluation of a data entry module of an EPR system with CCDS in the field of CR. We combined the think-aloud method with the new construct ‘users’ deviations in action sequence from the systems’ predefined data entry order sequence’. With the systems’ beta version, healthcare professionals deviated strongly and with high inter-individual variation from the systems’ predefined data entry order. The think-aloud evaluation of the beta system version showed that users’ expectations of action sequences to be performed in the system, which were based on their daily paper-based patient documentation routines, mismatched the system design model of one predefined data entry order (mismatch between system and world). Other usability issues concerned e.g. consistency in button names, colors and position of data entry fields and visibility of saved data items. Given these mismatches between the beta version system design and the users’ daily paper-based documentation routines, they probably were hindered in the construction of an adequate mental model of the system (the way the user perceives that the system works based on his mental processes) [11]. Possibly, due to the fact that CR professionals did not construct such a mental model of the system, they may have been less capable to use the system properly and vice versa. Low system usability may have hindered users in the construction of an adequate mental model of the system. The mismatch resulted in incompletion of data-entry tasks and a higher number
of navigation actions than required. In the redesigned system version, usability issues were solved by the designers within available resources. To better adapt to users’ expectations and support the construction of adequate mental models by users on how the system works, the data entry navigational structure was organized completely flexible around an overview screen. With the redesigned system, users completed more data-entry tasks while they performed less navigational actions. The think-aloud evaluation of the redesigned system revealed remaining usability problems. They mainly concerned lack of flexibility (e.g. customization options related to defaults and terminology) and still problems with consistency (mainly with layout and position of items on the screen).

Strengths and weaknesses of the study
A strength of our study is that we used a mixed method approach which combines the think-aloud method with the new usability construct on users’ deviations. Using this construct we were able to visualize that all users deviated strongly from the systems’ predefined data entry order, however all differently. This showed that although all users struggled to construct their mental model on data entry in the system, they did not share a common or general mental model on data entry. By combining measurements of this new usability construct with the analyses of the think-aloud user sessions, we revealed the usability problems causing users’ deviations. We obtained a detailed insight into the mismatches in the user's data entry behaviour and the systems’ design model of data entry. This mixed approach allowed us to infer specific recommendations to optimize the systems’ design model for meeting users’ differing expectations concerning data entry order and supporting users in the construction of an adequate mental model of the system’s data entry modes.

Other strengths of our study are that we assessed CR professionals’ task efficacy and efficiency and number and severity of usability problems detected both before and after, so in the beta and redesigned system version. Hence, the results of this combination of quantitative and qualitative measurements revealed additional necessity and recommendations for redesign in the before study. Though our study (purposely) was more qualitative than quantitative in nature, our results indicate that the mixed method we applied to direct our redesign efforts was supportive in improving the data entry interface of the new system version.

Our study has some limitations as well. First, the tasks we defined for the usability evaluations were based on the guidelines for the CR NAP, which require the entry of an enormous set of patient data items (155-175). Entering such an amount of data asks for a strong commitment of the professional to finish this task. This challenges the design of the data entry interface compared to situations wherein users are supposed to enter a smaller amount of patient data. Second, the inter-rater agreement of the coding of verbal protocols of the redesigned system evaluation was only moderate (compared to a substantial inter-rater agreement of coding of verbal protocols concerning the beta system evaluation). More extensive pilot testing and discussion between the two researchers responsible for coding in the beginning of the coding process might have resulted in a higher inter-rater agreement. However, as explained, the
disagreements in coding were resolved by consultation with a third researcher. Together, causes underlying these differences in coding were revealed, after which final consensus on codes could easily be reached. Third, the Dutch clinical algorithm for the CR NAP on which the beta system version was based, was revised in 2010 and during the time of the usability evaluation not yet completely implemented in most Dutch CR clinics. The usability issues revealed may likewise be caused by system users’ unfamiliarity with the content of the algorithm. Fourth, usability issues concerning flexibility and consistency remained after the system’s redesign effort. Although we shared all our findings and recommendations for redesign with the system developers, we did not demonstrate our recommendations graphically through mock ups. A provision of mock-ups could possibly have assisted the developers in preventing possible misinterpretations of our redesign proposals, and usability issues remaining in the redesigned system. Finally, we did not evaluate the usability of the CARDSS system in daily practice, during clinical interviews of CR professionals with their patients. Field-based evaluation of the CARDSS system after its implementation in Dutch CR clinics may therefore reveal additional usability issues concerning mismatches of the system design model with CR professionals’ workflow. We aim to perform such an ‘in vivo’ evaluation of CARDSS as part of our future work focussing on improving CR care quality in the Netherlands. For such a field-based usability evaluation of CARDSS, we will combine observations of professionals in daily practice with screen logging, synchronous audio recording of CR professionals verbal utterances and semi-structured interviewing with the CR professionals.

Strengths and weaknesses in relation to other studies
The mixed method approach we used allowed for both a quantitative analysis of suboptimal navigational patterns of users through the system and a qualitative analysis of explanation of the usability issues causing these patterns. While we used the new construct ‘users’ deviations in action sequence from the system’s predefined data entry order sequence’, other usability studies of health information systems have applied somewhat similar quantitative methods to gain insight into health professionals’ systems’ navigational patterns in relation to their task performance [13, 35, 36]. Zheng et al [13] used sequential pattern analysis as a quantitative measure to uncover recurring user interface navigational patterns in an EPR system, whereas Lacerda et al. [35] used a keystroke-level model (KLM) to assess the efficiency of action sequences in two interfaces with differing interaction modes of a telecardiology system. Further, Kelders et al. [36] applied log file analysis in combination with a survey and real time usability tests to assess the usability of a web-based health intervention. A shortcoming of quantitative methods when applied without qualitative methods is however, that they do not provide detailed insight into the usability issues causing the mismatches between the users’ data entry behaviour and the system’s design model of data entry that led to suboptimal navigation patterns and task incompletion.

To reveal usability problems resulting from the mismatch between predefined system action sequences and the daily working routines of healthcare professionals, several other
usability studies of health information systems have applied qualitative methods only [5, 37-39]. For instance, Peute et al [37] performed a qualitative study using the cognitive walkthrough and think-aloud user sessions to reveal usability problems in a computerized physician ordering (CPOE) system. Second, Beuscart et al [38] performed a heuristic evaluation and both in-lab and on-site usability tests for the evaluation of a CPOE medication system. Finally, Rose et al [39] conducted multiple focus group and field study sessions with primary care physicians to improve the usability of a management module of a widely deployed web-based EPR. In all these, qualitative usability methods were useful in revealing usability problems concerning mismatches of the systems’ design model and the users’ system behaviour in various types of healthcare information systems. However, we combined our qualitative think-aloud method with the construct on users’ deviations from predefined system action sequences (see Figure 3). While the details on the usability problems as revealed by the think-aloud sessions were helpful in defining proposals for the system’s redesign, the visualization of the construct on users’ deviations was especially useful in clarifying the mismatches of users’ navigational patterns with the system design model of data entry to the system designers. In a single glance the figure pointed out the need for an update of the system data entry model.

Furthermore, although the studies using qualitative methods only, succeeded in proposing specific recommendations for a system redesign, none of them included a usability analysis afterwards. In our study we did perform a mixed-method usability analysis of the redesigned system version to gain insight in its usability and CR professionals’ performance in terms of their task efficiency and efficacy.

**Meaning of the study**

Our mixed method usability approach appeared helpful in improving the usability of the redesigned MediScore CARDSS system. The improved system’s design model better fitted each users’ daily documentation routines. As a consequence, CR professionals were better supported in building an adequate user model of how the redesigned system works. However, the think-aloud user sessions with the redesigned system version revealed that both task efficiency (completeness of data collection) and task efficacy (number of mouse clicks) were still not optimal as well as that usability problems remained. As we found recurrent usability problems in the redesigned system version related to e.g. consistency and flexibility, visualisation of proposed design solutions could have made our recommendations more clear. Concrete visual examples could have been a better way of communicating both usability problems and our recommendations to the system designers. Healthcare professionals seem to balance technological and work demands, all in an efficient and cost effective way. When confronted with usability problems, they may see a greater need to work around intended work practices and search for alternative routes in the system to perform their tasks (workarounds) [40, 41]. While we intended to make the beta system version more usable by making it more flexible, we may likewise have increased the options for CR professionals to work around certain data entry tasks. However, since the redesigned system version alerted the CR professionals on
uncompleted data entry tasks, such possible workarounds presumably did not negatively impact their final task efficiency and efficacy. Further, closely observing CR professionals in their daily routines of NAP data collection in the requirements analysis phase could have prevented some essential usability flaws in the beta system version. These observations would at least have revealed the variations in NAP data collection practices and the need for a flexible system data entry mode to accommodate CR professionals’ individual practices during paper-based NAP.

Using the think-aloud method during the requirements analysis phase, Jaspers et al [42] developed a cognitive task model reflecting pediatric oncologists’ task behavior in searching through a paper-based patient record as input for a prototype user interface of an EPR system. Likewise, Verhoeven et al [43] analyzed using the think-aloud method the processing of paper-based infection control guidelines by health care workers, to develop a user-oriented website for the communication of these guidelines. Finally Kilsdonk et al [44] developed an information processing model through an analysis of think-aloud protocols and used the model as input for the design of a CCDS user interface to support pediatric oncologists.

Based on these three studies, we advise to apply cognitive methods like the think-aloud method to analyze end users’ mental processes and behavior patterns in daily work processes specifically during the requirements analysis phase of interactive healthcare information systems such as EPRs. These insights may support designs of interactive healthcare information systems that are consistent with the users’ daily working routines [11, 42]. As a consequence, such system designs may simplify the construction of users’ mental models on how the system works.

CONCLUSION

The mixed method usability evaluation was supportive in revealing the magnitude and causes of mismatches between the system design model of data-entry with users’ data entry behaviour. However, as both task efficacy and efficiency were still not optimal with the redesigned EPR, we advise to perform a cognitive analysis on end users’ mental processes and behavior patterns in daily work processes specifically during the requirements analysis phase of development of interactive healthcare information systems such as EPRs. These insights may be of help in designing interactive healthcare information systems that map on users’ daily working routines, which may simplify the construction of users’ mental models on how the system works. Such an approach may ultimately lead to more efficient and effective healthcare information systems and more satisfied users.
SUMMARY TABLE

What was already known on the topic
- The value of computerized clinical decision support (CCDS) within an electronic patient record (EPR) is, among other things, determined by the completeness of data entered into the system.
- Mixed method usability evaluation studies may provide insight into mismatches between the system design model of data entry and users’ data entry behaviour to optimize the usability of a system’s data entry interface.

What this study added to our knowledge
- A mixed method usability evaluation combining the think-aloud method with the new usability construct ‘users’ deviations in action sequence from the system’s predefined data entry order sequence’ was helpful to visualize and name usability problems for user deviations from the systems’ predefined data entry order.
- The mixed method approach was supportive in revealing the magnitude and causes of mismatches between the system design model of data-entry with users’ data entry behaviour.
- CR professionals completed more main tasks with fewer navigation actions with the revised version of the system.

AUTHOR’S CONTRIBUTIONS

MvEV, NP and NdK had the basic idea for this study. Together with LP and MJ they were involved in the development of the protocol. MvEV performed the usability evaluations and processed the think-aloud protocols. MvEV, MJ and LP drafted the manuscript. All authors were involved in the critical revision of the paper for intellectual content. All authors read and approved the final manuscript.

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REVISION OF THE DUTCH CLINICAL ALGORITHM
FOR ASSESSING PATIENT NEEDS IN CARDIAC
REHABILITATION BASED ON IDENTIFIED
IMPLEMENTATION PROBLEMS

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ABSTRACT

**Background:** Despite all available evidence of its effectiveness, cardiac rehabilitation and secondary prevention (CRSP) is still insufficiently implemented in current clinical practice. Based on an analysis of implementation problems, recently the Dutch clinical algorithm for the assessment of patient’s CRSP needs was revised. The purpose of this paper is to describe the revision process and its results to improve CRSP guideline implementation.

**Methods:** The NICE Guidelines manual for conducting guideline revisions was followed. Information on the use of the algorithm in practice was collected from electronic medical records and by conducting semi-structured interviews. Next, an expert advisory group identified the problems for use in daily practice and defined the scope for the revision. A multidisciplinary guideline development group subsequently wrote the revised algorithm.

**Results:** A large variation in assessed patient needs was observed between CRSP clinics. Assessment based on clinical judgment was found to be a source of practice variation and is therefore avoided in the revised algorithm. It was decided to add assessment instruments for anxiety and depression, cardiovascular risk factors, stress, attitude of partner, and lifestyle parameters.

**Conclusion:** The Dutch clinical algorithm for assessing patient needs for CRSP was revised using a combination of patient data from routine practice, knowledge from academic experts, and experience from field experts. The revised algorithm is a practical tool consisting of assessment instruments to improve CRSP guideline adherence in the Netherlands. This algorithm may be also useful for other Western countries to organize their CRSP needs assessment procedure.

**Key words:** Practice Guidelines; Cardiac Rehabilitation; Health Care Quality, Access, and Evaluation; Information systems
INTRODUCTION

Cardiac rehabilitation and secondary prevention (CRSP) programs have been shown to reduce morbidity and mortality in cardiac patients and are therefore recommended by the European Society of Cardiology (ESC) (1), the American Heart Association (AHA) and the American College of Cardiology (ACC) (2). Nonetheless, in most European countries fewer than half of eligible patients participate in a CRSP program (3). Also the CRSP practice is poorly standardised and does not follow the available scientific evidence (4;5). Causes include absent or inadequate legislation, funding, professional guidelines and information systems in many countries (3). Guidelines can improve CRSP practice by founding and supporting clinical decisions related to organizing and executing the CRSP program (6). However, professional adherence to guidelines may be hindered by a variety of barriers related to professional knowledge and attitude, task delegation and collaboration in teams, and impracticabilities of the guidelines themselves (7). The overcome the last barrier, the European Association of Cardiovascular Prevention and Rehabilitation (EACPR) has released a position statement containing practical recommendations on the core components and goals of CRSP (1).

Based on this guideline and other international guidelines (1;8;9), national guidelines on the core components and goals of CRSP were published in the Netherlands in 2004 (10). They state that after hospitalization for cardiac incidents and interventions patients should be offered an individualized rehabilitation program based on their medical, physical, and psychosocial needs. To this end, the guidelines included a clinical algorithm that describes an extensive needs assessments procedure which can be used for all patients entering the CRSP program. In general, clinical algorithms are designed by expert physicians for use by paramedical personnel who have been assigned certain routine care tasks (11). The Dutch algorithm for CRSP describes a branching logic to assess data concerning patient health status in order to identify rehabilitation and secondary prevention goals for a patient-tailored rehabilitation program. This program can contain four possible group-based therapies (exercise training, education, lifestyle change counselling, and relaxation therapy) and several forms of individual therapy.

Concurrently with the algorithm, a patient information system with computerized decision support (CDS) functionalities was developed to collect patient data and to guide users through the needs assessment procedure (12). A recent trial in 21 clinics showed that the system increases the adherence with the guideline-recommended therapeutic decisions (13). The trial data offered a unique opportunity to analyze the use of different parts of the algorithm of which participants during the study period mentioned that they were impracticable. The purpose of the current study was to revise the Dutch algorithm for CRSP based on implementation problems in daily clinical practice. As the algorithm is consistent with international guidelines for CRSP, the results of this study can support other Western countries in organizing the needs assessment procedure for their CRSP program.
METHODS

Dutch clinical algorithm for CRSP (2004 guidelines)
The clinical algorithm for CRSP is a flowchart to which professionals can refer during the needs assessment prior to starting the actual rehabilitation program. This procedure is usually carried out by a nurse practitioner, and covers objective and subjective exercise capacity, psychological and social functioning and risk behaviour. Within each of these domains the patient’s health status is assessed by questionnaires, biometric screening, and clinical interviewing. A maximum of 40 data items is assessed to obtain a patient-tailored rehabilitation program. Figure 1 depicts a schematic representation of the needs assessment procedure.

The algorithm describes assessment instruments and threshold values to select patient-specific goals from a list of fifteen potential CRSP goals. Important assessment instruments in the 2004 algorithm are the symptom-limited exercise test on a bicycle ergometer (14) and the MacNew health-related quality of life questionnaire (15). Although the 2004 algorithm advises to employ these and other instruments, assessment of patient needs based on clinical judgement was also allowed. After establishing of the relevant rehabilitation goals, decisions are made with respect to treatment, resulting in the final CRSP program. When a patient is unusually complex there are built-in safeguards in the algorithm, leading to referrals to specialized professionals (e.g. a cardiologist or clinical psychologist) for advanced assessment. They further define specific parts of the CRSP program, which may then consist of individual therapy.

Figure 1 – Schematic representation of the needs assessment procedure, as prescribed by the Dutch Guidelines. For each domain the algorithm describes assessment instruments that allow CRSP professionals to decide on patient specific rehabilitation goals and to make therapeutic decisions.
NICE Three Steps Model

We revised the algorithm for CRSP using a modified version of the Three Steps Model as described in the Guidelines manual for conducting guideline revisions from the National Institute for Health and Clinical Excellence (NICE) (16). This qualitative model describes the process, frequency and methods for partial updating clinical practice guidelines. Figure 2 gives an overview of the modified NICE Three Steps Model. Each step will be discussed in more detail below. A description of our methods in more detail can be found in Appendix I.

Figure 2 – Overview of the modified Three Steps Model that was used to revise the clinical algorithm for CRSP, based on (16).

Step 1a: Collecting information – Reliability of assessed CRSP needs: In order to analyze the reliability of the assessed patients’ CRSP needs, patient data recorded with the CDS system were used to study inter-practice variation. The recorded data items included patient demographics, reason for referral to CRSP, objective exercise capacity, subjective (i.e., self-perceived) exercise capacity, psychological and social status, marital status, employment status and lifestyle parameters (smoking status, dietary habits, physical activity). Intra-cluster correlation coefficients (ICCs) (17) adjusted for variations in case mix were computed as reliability measure to quantify inter-practice variation.
Step 1b: Collecting information – Interviews with CRSP professionals: Data of a qualitative study was used to assess experiences of professionals in applying the algorithm (18). Semi-structured interviews were conducted with 29 professionals who worked with the CDS system to address adherence to different guideline recommendations for the needs assessment procedure. All remarks from the interviews regarding problems with the use of the algorithm during the needs assessment, were analyzed and classified by two researchers (MvE and RG) using the conceptual framework of Cabana et al (7). This framework distinguishes barriers to guideline adherence, such as knowledge and attitude of professionals, and patient, guideline, and environmental factors.

Step 2: Expert advisory group – Scope definition and proposals for revision: A multidisciplinary, academic expert advisory group was asked to use their domain expertise and knowledge of the literature to define the scope of the revision and to propose evidence based revisions. Inputs were the results of Step 1a (a list of inter-practice variation of the assessed patient needs) and Step 1b (a list of guideline-related barriers for use of the algorithm in daily practice) and key areas from the CRSP literature, identified by the experts. When revisions concerned the selection of clinical assessment instruments, the experts used the criteria for reviewing health status measurement instruments developed by the Scientific Advisory Committee (SAC) of the Medical Outcomes Trust (19).

Step 3: Guideline development group – Selection and elaboration of the final revisions: The guideline development group was formed including members of Dutch professional associations of all disciplines involved in CRSP, together with two researchers (MvE and NP) having technical expertise with guideline revisions. During three meetings we asked the group to discuss the result of Step 2 (the scope for the revision including the revisions suggested by the expert advisory group) using their expertise of practical use and feasibility of the algorithm in daily practice. The meetings took place in a meeting centre of the Dutch Society of Cardiology. This centre is centrally situated in the Netherlands and within easy reach of the participants. During the discussion the group focused mainly on the burden and interpretability for the professionals (SAC criteria 5 and 6). Based on their clinical expertise, the revisions of the experts were either adapted, complemented or rejected. After this procedure, a final revision of the algorithm was composed.

RESULTS

Step 1a: Collecting information – Reliability of assessed CRSP needs: Data from 4157 patients were recorded in the CDS system in sixteen rehabilitation clinics. The median number of patients per clinic was 221. The mean age of the study population was 61.3 years (SD 11.4) and 74.4% was male. Of the patients referred to cardiac rehabilitation 42.4% was diagnosed with a myocardial infarction, 28.7% underwent a CABG procedure and 13.7% were diagnosed with
angina pectoris. We found high intra-cluster correlation coefficients (ICC) values for seven out of nine variables representing assessed CRSP needs. Hence the reliability of CRSP needs assessed with the 2004 algorithm was poor. Appendix II mentions the ICC value per variable representing assessed CRSP needs, both described at study population level and at clinic level.

*Step 1b: Collecting information – Interviews with CRSP professionals:* From the interviews we identified a variety of barriers to perform the cardiac rehabilitation needs assessment according to the way it was described in the algorithm. Several barriers related to attitude, (e.g., lack of agreement), but also a number of external barriers (e.g. guideline complexity) were mentioned. Examples of the remarks and identified barriers are listed in Table 1.

A number of professionals reported that one recommendation in the 2004 algorithm, the use of the MacNew questionnaire to determine emotional and social functioning of the patient, was not followed in their clinic. For convenience’s sakes they preferred to use their clinical judgment. Furthermore, professionals often reported that they disagreed with the recommended assessment method of lifestyle parameters, e.g. asking the patient whether he or she adhered to the Dutch dietary norms. Instead they preferred for example the patient’s BMI to determine dietary habits.

**Table 1** – Samples of the remarks and the identified barriers for implementation of the algorithm as extracted from the interviews with the cardiac rehabilitation professionals.

<table>
<thead>
<tr>
<th>Item</th>
<th>Comment</th>
<th>Identified barrier*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective exercise capacity</td>
<td>“In our organisation it isn’t achievable to have the results of the symptom-limited exercise test during the intake.”</td>
<td>Organisational constraints</td>
</tr>
<tr>
<td></td>
<td>“In our clinic we perform a symptom-limited exercise test after a patient has started an exercise program, not before the intake in the program, during the intake clinical expertise is also allowed.”</td>
<td>Guideline related factors</td>
</tr>
<tr>
<td>MacNew questionnaire (emotional and social functioning)</td>
<td>“If we don’t agree with the result of the MacNew, we use our clinical expertise to assess the emotional and social functioning.”</td>
<td>Lack of agreement</td>
</tr>
<tr>
<td></td>
<td>“We only use the MacNew if we think a patient is able to fill it in. But in most cases we use our clinical expertise.”</td>
<td>Lack of outcome expectancy</td>
</tr>
<tr>
<td>Anxiety and depression</td>
<td>“The psychologist sees all patients. He uses several questionnaires on depression. The algorithm doesn’t advise a list for this item.”</td>
<td>Guideline related factors</td>
</tr>
<tr>
<td>Cardiovascular risk profile</td>
<td>“We use the blood pressure and lipid profile to specify secondary prevention goals for the patient but this is absent in the algorithm.”</td>
<td>Guideline related factors</td>
</tr>
<tr>
<td>Dietary habits</td>
<td>“The algorithm doesn’t mention an instrument for dietary habits, so we use the BMI to determine this. Most patients say they do eat healthy but we don’t think they really follow the norms.”</td>
<td>Guideline related factors</td>
</tr>
<tr>
<td>Physical activity</td>
<td>“Determining the physical activity is hard. In most cases I use the BMI to decide if a patient needs an exercise program.”</td>
<td>Guideline related factors</td>
</tr>
</tbody>
</table>

* Based on the framework of Cabana et al concerning barriers to guideline adherence (7).
Step 2: Expert advisory group – Scope definition and proposals for revision: For the expert advisory group we approached nine different academic experts from various disciplines. They decided that all items concerning outcomes of the needs assessment with high interpractice variation (see Appendix II) and all guideline related barriers identified from the interviews (see Table 1) needed revision. In addition, the experts identified four new key areas for inclusion in the algorithm: anxiety and depression, stress, cardiovascular risk profile, and alcohol consumption. Finally, they proposed revisions for all identified problems. Table 2 gives an overview of the recommendations from the 2004 algorithm and a summary of the problems for use in daily practice as identified by the experts, including the proposed revisions to solve these problems.

Most deficiencies in the algorithm were related to the type of prescribed assessment instrument, especially when clinical judgment was allowed in the needs assessment procedure. In these cases, the experts determined univocal assessment instruments and stated that using these instruments should be obligatory. For example, the MacNew questionnaire was selected because this instrument is translated and validated for a Dutch population (20) (SAC criterion 3, Validity).

Step 3: Guideline development group – Selection and elaboration of the final revisions: Table 2 gives an overview of the final revisions of the algorithm composed by the guideline development group based on the scope of the expert advisory group. Several types of revision are described. The first revision type is advice against using a clinical interview alone to assess the rehabilitation needs. In the revision, instruments like the symptom-limited exercise test and the MacNew questionnaire are recommended. The second type of revision concerns the adding of the four new key areas as proposed by the experts. The third type of revision concerns adding assessment instruments for items which were unstructured assessed during the clinical interview in the 2004 algorithm (instruments to measure attitude of partner, resumption of work, smoking status, physical activity and dietary habits). The entire revised algorithm is in English available on http://kik.amc.uva.nl/KIK/reports/TR2011-03.pdf.

One of the new key areas, the cardiovascular risk profile, has resulted in new rehabilitation goals. The risk profile provides an overview of risk factors for cardiovascular diseases and can be used in clinics to specify four secondary prevention goals with accompanying interventions: optimize weight, optimize blood pressure, optimize diabetic therapy, and optimize cholesterol levels. Interventions to work on these goals are multidisciplinary and contain both exercise training and lifestyle change therapy as well as individual treatment by a cardiologist to optimize medication use.
Table 2 – Recommended assessment instruments in the Clinical Algorithm 2004, identified problems for use in daily practice, proposed revisions by expert advisory group, and revised recommendations in the Clinical Algorithm Cardiac Rehabilitation 2010.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Item</th>
<th>Instruments Clinical Algorithm 2004</th>
<th>Identified problems for use of the algorithm in daily practice (expert advisory group)</th>
<th>Proposed revisions (expert advisory group)</th>
<th>Final revisions: Instruments Clinical Algorithm 2010 (guideline development group)</th>
</tr>
</thead>
</table>
| **1. Physical functioning**   | Objective exercise capacity                | Symptom-limited exercise test (14) or clinical judgment | Variation data: Large variation in clinical means  
Interviews: Professionals mostly use clinical judgment. No consensus about safety of exercise test for complex patients.                                                                 | Always perform a symptom-limited exercise test. Alternative is a shuttle interval test. For complex patients (e.g. with heart failure) perform test under special supervision. | Symptom-limited exercise test for all patients (14). Alternative is a shuttle interval test. Complex patients receive an exercise test under special supervision (29). |
|                               | Subjective exercise capacity               | MacNew QoL questionnaire (15) or clinical judgment | Variation data: Large variation.  
Interviews: Professionals mostly use clinical judgment.                                                                                                                                  | Always use the MacNew QoL questionnaire.                                                                                                                                  | MacNew QoL questionnaire (15)                                                                                                                                       |
| **2. Psychological functioning** | Emotional functioning                      | MacNew QoL questionnaire (15) or clinical judgment | Variation data: Moderate variation.  
Interviews: Professionals mostly use clinical judgment.                                                                                                                                   | Always use the MacNew QoL questionnaire.                                                                                                                                  | MacNew QoL questionnaire (15)                                                                                                                                       |
|                               | Anxiety and Depression                     | Absent                              | Interviews: CRSP guidelines describe need to measure anxiety and depression.  
New key area: Literature describes need to take presence of anxiety and depression into account in CRSP.                                   | Measure presence of anxiety and depression with a questionnaire suitable for heart patients. HADS and PHQ are recommended.                                                | Hospital Anxiety and Depression Scale (HADS) (30), Patient Health Questionnaire (PHQ) (31) (recommended) |
|                               | Stress                                     | Absent                              | Interviews: CRSP guidelines describe need to measure stress.  
New key area: Literature describes the importance of taking presence of stress into account in CRSP.                                                                                 | Measure presence of stress.                                                                                                                                         | Clinical interview, 5 questions from the INTERHEART study (32)                                                                                                         |
### 3. Disruption or treat to social functioning

<table>
<thead>
<tr>
<th>Social functioning</th>
<th>MacNew QoL questionnaire (15) or clinical judgment</th>
<th>Variation data: Large variation. Interviews: Professionals mostly use clinical judgment.</th>
<th>Always use the MacNew QoL questionnaire.</th>
<th>MacNew QoL questionnaire (15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attitude of partner</td>
<td>Clinical interview, unstructured</td>
<td>Interviews: CRSP guidelines describe need to involve the patient's partner, it should be clarified how.</td>
<td>Perform a structured assessment of the attitude of the patient's partner.</td>
<td>Clinical interview, 3 questions</td>
</tr>
<tr>
<td>Resumption of work</td>
<td>Clinical interview, unstructured</td>
<td>Interviews: CRSP guidelines describe need to give attention to resumption of work, it should be clarified how.</td>
<td>Perform a structured assessment of the patient's professional situation and current resumption status. Possibly the company doctor should be contacted.</td>
<td>Clinical interview, 2 to 7 questions (two stage screening)</td>
</tr>
</tbody>
</table>

### 4. Cardio-vascular risk profile

| Cardio-vascular risk profile | Absent | Interviews: CRSP guidelines describe need to assess the patient's cardiovascular risk profile. New key area: International guidelines underline need to take cardiovascular risk profile into account in CRSP. | Perform assessment of modifiable cardiovascular parameters. | Physical examination (body weight, waist circumference, blood pressure) and laboratory evaluation (cholesterol, HbA1c) |

### 5. Lifestyle

<table>
<thead>
<tr>
<th>Smoking status</th>
<th>Clinical interview (3 to 4 questions)</th>
<th>Interviews: Algorithm is not in line with guidelines concerning tobacco cessation therapy.</th>
<th>Assess smoking habits; when necessary, treat according to tobacco addiction guidelines.</th>
<th>Clinical interview, 1 to 4 questions (two stage screening) and specific treatment advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical activity</td>
<td>Clinical interview, unstructured</td>
<td>Variation data: Moderate variation Interviews: Current activity norm is too strict. It is also unclear how to assess physical activity without getting socially desirable answers.</td>
<td>Perform a structured assessment of the patient's physical activity with the Monitor 'Physical activity and Health' or the SQUASH questionnaire.</td>
<td>Monitor 'Physical activity and Health' (33)</td>
</tr>
<tr>
<td>Dietary habits</td>
<td>Clinical interview, unstructured</td>
<td>Variation data: Moderate variation Interviews: Current norm is too strict. It is unclear how to avoid socially desirable answers. Full assessment takes to much time.</td>
<td>Perform individual assessment by a dietician in case of hypertension, hypercholesterolemia, obesity or diabetes.</td>
<td>Individual assessment by dietician in case of hypertension, hypercholesterolemia, obesity, or diabetes</td>
</tr>
<tr>
<td>Alcohol consumption</td>
<td>Absent</td>
<td>New key area: CRSP guidelines describe risks of alcohol consumption. Alcohol addiction is undesirable in group-based rehabilitation.</td>
<td>Assess alcohol consumption and addiction with the Five Shot questionnaire.</td>
<td>Five Shot questionnaire (34)</td>
</tr>
</tbody>
</table>
DISCUSSION

Summary of results
Despite all available evidence on its effectiveness, CRSP is still insufficiently implemented in current clinical practice. Based on an analysis of implementation problems a thorough revision was conducted of the Dutch clinical algorithm for the assessment of patient's CRSP needs. The algorithm was extended with assessment instruments for anxiety and depression, cardiovascular risk factors, stress, absence of partner, and lifestyle parameters (smoking, physical activity, and alcohol consumption), and excludes the option of using only clinical judgment to assess CRSP needs (Table 2). The revised algorithm may also be used to support implementation of CRSP in other Western countries.

Strengths of the study
Clinical practice guidelines serve to foster evidence-based medical practice, reduce practice variation, and manage the delegation of tasks between clinical professionals (21). However, implementation may be difficult and requires separate attention (7). Revisions of practice guidelines are often based on systematic reviews of the literature and consensus among clinical experts (22) but tend to neglect implementation issues. Our revision of the Dutch clinical algorithm for CRSP screening is, in contrast, largely based on observed implementation problems. These problems were identified by analyzing data that were recorded in daily care practice and by interviewing practitioners that had frequently used the algorithm. By using this methodological triangulation, qualitative input may help to explain quantitative information about the success or failure of an intervention (23). In our study the data showed which parts of the algorithm had implementation problems and the interviews showed why professionals experienced problems with these specific parts. Taking into account these local circumstances during guideline development and implementation can change clinical practice (24).

For revision of the algorithm we used a structured, formal consensus procedure from the NICE Institute. During the procedure both the expert advisory group and the guideline development group used the predefined SAC criteria (19) to judge assessment instruments that were included in the algorithm. By adding instruments to determine patients’ needs, the revised algorithm provides a practical elaboration of the guidelines which could be the missing link for a successful implementation. In fact, the Cardiac Rehabilitation Section of the EACPR has provided recommendations for the assessment of patient needs and goals of CRSP interventions, stressing the fact that integration of these assessments into daily practice is still inadequate (1).

Meaning of study
There are several reasons why medical professionals do not adhere to clinical guidelines and protocols (7). Broadly speaking, these reasons may be classified as internal (i.e. relating to the professional's own knowledge or attitude) or external (i.e. relating to the guideline or protocol, to organizational factors, or to patient cooperation). In our study, we found that professionals
faced external barriers related to shortcomings of the clinical algorithm itself and invented their own solutions to remediate them. For instance, the 2004 algorithm recommended that patients be asked whether they adhered to the Dutch dietary and physical activity norms (10). Most people have however difficulties in assessing their own lifestyle habits and tend to give socially desirable responses to such questions (25;26). Many CRSP professionals had invented their own solutions to deal with this problem, for instance by posing additional questions. The resulting assessments were subject to high inter-practice variation because there was no standardized assessment method.

The revised algorithm recommends using assessment instruments to determine patients’ rehabilitation needs, reasonably resulting in a needs assessment procedure less sensitive to local interpretations and inter-practice variation. As the Dutch guidelines for cardiac rehabilitation are consistent with national guidelines in other countries (1;8;9), we expect the results of our study to be generalizable. In other countries the revised algorithm can be used as starting point for setting up clinical algorithms for CRSP screening as well to refine and clarify the steps of the needs assessment procedure. Furthermore, the clinical algorithm can be used in addition to the recommendations from the EACPR on the core components and goals of the content of a CRSP program (1).

Limitations of the study
This study has several limitations. We did not conduct a systematic literature search to identify new scientific evidence. Furthermore, asking the professional CRSP associations to send an official representative for the guideline development group resulted in a group with mostly practice experts and no academic experts. The risk in this was that only revisions would be made which were practical but not supported with evidence in literature. Although not the entire cardiac rehabilitation guidelines were rewritten but just the algorithm, we tried to minimize this risk. We asked the academic expert advisory group to focus on the scientific evidence for the revisions the proposed. By involving them in the revision process we believe the revisions are evidence based.

Although we tried to solve as many barriers we found in the interviews with the CRSP professional as possible, the revised algorithm may not solve barriers classified as patient related barriers (e.g. specific comorbidity or logistic problems), barriers related to the attitude of professional (e.g. lack of outcome expectancy or motivation) or external barriers (e.g. lack of resources). To solve these barriers alternative solutions at the organisational level of CRSP clinics might be needed to optimize the implementation of the algorithm.

Unanswered questions and future research
Although we tried to make the algorithm a representation of the latest practical and scientific insights, not all proposed revisions could be carried through because in some cases there was no consensus among the clinical experts and there existed no conclusive scientific evidence either. Especially in the physical and psychosocial domains there was a lack of consensus at several
points. Therefore, there is still a need in these domains for an overview of available assessment instruments and their applicability for cardiac patients.

In addition we suggest that more research is carried out concerning the validity and reliability of assessment of patient needs by clinical judgment. During our study it was assumed that clinics using clinical judgement (instead of a predefined assessment instrument) underestimated the rehabilitation needs and caused high inter-practice variation. However, to date little is known about the consistency and evaluation of needs assessment procedures (27). We found one study in which assessment instruments identified almost twice the amount of patients as having multiple unexplained physical symptoms in comparison with identification of these problems by their GP (28). More research can show what is in general the difference between results from clinical judgment compared to assessment instruments.

CONCLUSION

The revised clinical algorithm describes a practical procedure for assessing patient needs in cardiac rehabilitation. We used a structured consensus procedure to revise the algorithm in which both academic experts and CRSP professionals were involved. The revised algorithm advises to use assessment instruments, where possible, to determine patient needs. It was decided to add instruments to assess anxiety and depression, cardiovascular risk factors, stress, attitude of partner and risk behavior (smoking, physical activity, and alcohol consumption). The algorithm will be used by all Dutch cardiac rehabilitation professionals but can also support other Western countries in organizing the needs assessment procedure and in setting up a clinical algorithm for their CRSP program.
ACKNOWLEDGEMENTS

The authors would like to thank all the professional CRSP associations represented in the Guideline Development Group for their contribution:

NVVC – Netherlands Society for Cardiology (‘Nederlandse Vereniging voor Cardiologie’)
VRA – Society of Rehabilitation Physicians (‘Vereniging van Revalidatieartsen’)
VSG – Society for Sport Medicine (‘Vereniging voor Sportgeneeskunde’)
NVAB – Netherlands Society for Labour and Company Medicine (‘Nederlandse Vereniging voor Arbeids- en Bedrijfsgeneeskunde’)
NVHVV – Netherlands Society for Cardiac Nurses (‘Nederlandse Vereniging voor Hart- en Vaat Verpleegkundigen’)
VHVL – Society for Cardiac and Lung Physiotherapy (‘Vereniging voor Hart-, Vaat- en Longfysiotherapie’)
NIP – Netherlands Institute of Psychologists (‘Nederlands Instituut van Psychologen’)
LOMH – National Session Social Workers Cardiac Rehabilitation (‘Landelijk Overleg Maatschappelijk werkers Hartrevalidatie’)
NVD – Netherlands Society of Dieticians (‘Nederlandse Vereniging van Diëtisten’)
HVG – Cardiovascular patients Organization (‘De Hart&Vaatgroep’)

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REFERENCES


MODIFIED RAND METHOD TO DERIVE QUALITY INDICATORS: A CASE STUDY IN CARDIAC REHABILITATION

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ABSTRACT

Quality indicators (QIs) are increasingly used to summarize quality of care and to give professionals’ performance feedback. We have previously developed a continuous multifaceted guideline implementation strategy that integrates computerized decision support with feedback on QIs and benchmarking. This paper focuses on development of QIs, and presents results of a case study in the field of cardiac rehabilitation. We present a modified Rand method that combines results from a literature search and guideline review with knowledge of an expert and patient panel in an extensive rating and consensus procedure. All sources contributed to the final set of 18 QIs for cardiac rehabilitation.

Key words. Quality Indicators, Health Care; Cardiac Rehabilitation
INTRODUCTION

Improving quality and outcomes of care is a central theme in current health care policy. Clinical practice guidelines are considered essential instruments to improve the quality of care as their potential benefits are improved patient outcomes, reduced practice variation, and reduced costs. Despite wide promulgation however, professionals’ often do not follow guideline recommendations. A frequently used classification of barriers to guideline implementation is a division into individual (‘internal’) and environmental (‘external’) barriers [1]. Internal barriers relate professional’s knowledge and attitude towards guidelines. To improve these, computerized decision support (CDS) is known to be effective because it can provide guideline-based recommendations at the time and place where clinical decisions are made [2]. However, medicine is largely practiced as part of a team and embedded within complex organizations. Professionals may also encounter external barriers which hamper their ability to execute guidelines. They stem from environmental factors related to the team, organisation or health system they work in. It is therefore important to apply an implementation strategy with supplementary components directed at both internal and external barriers [1].

Feedback on health care performance and outcomes has been shown to be an effective quality improvement method to overcome external barriers and can be used in addition to CDS [3]. It prompts professionals to change their behaviour if they receive feedback that their practice does not meet benchmark values (e.g., national target values or average performance within a peer group). Feedback reports contain results on quality indicators (QIs), i.e. quantitative measures to monitor and evaluate the quality of particular health care processes that affect patient outcomes [3]. QIs help professionals and their managers to identify suboptimal care and opportunity to improve quality and outcomes of care. Several methods exist for developing QIs, each with strengths and limitations. The first goal of this paper is to present a comprehensive method, which combines strengths from multiple methods to develop a QI set. The second goal is to apply our method and present a QI set developed during a case study in the field of cardiac rehabilitation (CR).

METHODS

To develop a QI set, a procedure developed by the Rand Corporation [4] is often used. Like other QI development methods this procedure combines scientific evidence and expert opinion using a consensus technique. Preliminary QIs extracted from the literature are anonymously rated by an expert panel. In a next round the panel meets to discuss, rerate and gain consensus. Criticisms of the Rand procedure include the lack of transparency in applying the definition of appropriate care, and weak reliability of the rating and consensus procedures. Also the lack of patient involvement and the fact that clinical practice guidelines are not consulted are mentioned [5].

To overcome these criticisms, we have modified the Rand procedure with successful elements of rating and consensus procedures from other QI development methods. First
we defined appropriate care based on specific judgement criteria from the Organisation for Economic Co-operation and Development (OECD) [6]. Secondly we increased the reliability of the rating procedure by using a 5-point Likert scale for each criterion, as is often used in the Delphi technique [7]. Thirdly we structured the consensus procedure during the discussion meeting of the expert panel by applying the Nominal Group Technique (NGT) [8]. Finally we extended the number of consulted sources for QIs, adding a patient panel and review clinical practice guidelines in CR.

Case study – We applied our modified Rand method to the field of CR. CR is a multidisciplinary therapy to support heart patients recover from a cardiac incident or intervention, and aims to improve their overall physical, mental and social functioning. Consistent with international guidelines, the Dutch guidelines for CR state that patients should be offered an individualized rehabilitation programme based on a needs assessment procedure. The guidelines mention all items which need to be collected during this procedure. An EPR with CDS facilities, based on the guidelines, was developed to overcome internal barriers and evaluated in a cluster randomized trial. It was shown that CDS considerably improved guideline adherence. However, the trial also revealed persisting barriers for implementation of the guidelines at organisational levels [9]. To overcome also these external barriers we developed a multifaceted guideline implementation strategy, which expands our CDS intervention with a benchmark-feedback loop including feedback reports on QIs [10].

RESULTS

The modified Rand method (see Figure 1) consists of consultation of four sources (experts, patients, literature and guidelines) to collect information QIs. This is translated into a draft QI set which is rated on paper by the expert panel. Finally the expert panel meets to discuss and gain consensus on the final QIs. The steps in Figure 1 will be described in more detail now, followed by their application in the case study.

Expert and Patient Panel – A questionnaire about quality characteristics is sent to consult both an expert panel and a Patient Panel. The expert panel should include professionals from all disciplines involved in the field of interest. They are asked to mention characteristics of excellent care service and what they would need to know about another clinic to assess their quality. The Patient Panel is asked to describe positive and negative experiences during their treatment. From the answers provided by experts and patients, quality characteristics of the health services are abstracted.
**Literature Search** – Search terms concerning the field of interest (e.g., CR), are combined with MeSH terms and keywords referring to quality assurance, process and outcome assessment or quality indicators. From all included articles QIs and outcome measures related to high quality of the health service are abstracted.

**Review of Guidelines** – The prevailing guidelines in the field of interest are reviewed to identify procedural and structural properties of high quality health services. Guidelines do not often describe a desirable level of outcomes of care but they do mention minimum procedures, standards and facilities that services should include.

**Case study:** We invited 40 Dutch experts to our expert panel of whom 38 agreed to participate. The experts included professionals from all disciplines involved in CR (cardiologists, rehabilitation and sport physicians, company doctors, nurse practitioners, physiotherapists, psychologists, social workers, dieters, and CR managers). Also we asked 30 patients of four CR clinics to take place in the patient panel of whom 15 participated. Overall, 92 different quality characteristics of CR were mentioned. The PubMed search identified 314 articles in which 15 QIs and 24 different outcome measures of CR services were mentioned. Most frequently used outcome measures related to exercise therapy and quality of life. Few outcome measures related to patient satisfaction and professional performance. Furthermore, the CR guidelines in the Netherlands were reviewed, from which we extracted 34 procedural quality characteristics and three structural properties of CR services.

**Translation of Results** – The results of the four sources are translated into a draft QI set using the OECD framework on QIs [6]. This framework describes how concepts of health care should be measured by grouping them into dimensions and formulate them according criteria of importance, scientific soundness and feasibility.

**Rating on Paper** – The draft QI set is presented to the expert panel. They rate all QIs on a Likert scale from 1 (total disagreement) to 5 (total agreement) based on three criteria: (i) The QI has a clear relationship with one or more patient outcomes; (ii) The QI can be a departure point for improvement actions; (iii) Information regarding the QI is easy to record [6]. For each QI the mean score per criterion, the standard response levels of individual experts. The rated QI set is ranked and shortened by mean score.
Case study: Based on the four sources we assembled a draft set of 81 quality QIs for CR. The draft set was structured into four clusters reflecting the chronological phases of CR (referral, needs assessment, evaluation, and follow-up) and one cluster concerning organization of care. In each cluster the QIs were classified as relating to either process, structure, or outcomes of care. Twenty-two experts rated the draft QI set. The highest ranked QI (patient’s lifestyle is assessed during needs assessment for CR) had a mean overall score of 4.47. The lowest ranked QI (CR patients improve their cognitive functioning) had a score of 2.94.

Group Discussion – The NGT is used to lead the expert panel towards consensus through rounds of debate, discussion and an anonymous voting process [8]. Input for the discussion is the ranked QI set, the experts discuss the set and select the final QIs.

Case study: We presented the QIs with their ranks, structured into clusters, to the expert panel. The panel voted for the QIs they preferred in an anonymous voting procedure. The results were shown on a screen and discussed. After hearing different opinions, the panel voted again in the light of the discussion to gain consensus. The final QI set and their original sources are presented in Table 1.
Table 1 – Final QI set for CR (E= Expert panel, P= Patient panel, L= Literature and G= Guidelines).

<table>
<thead>
<tr>
<th>Nr</th>
<th>Type</th>
<th>Quality indicator</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Outcome</td>
<td>Patients improve their exercise capacity during rehabilitation</td>
<td>E x x x</td>
</tr>
<tr>
<td>2</td>
<td>Outcome</td>
<td>Patients improvement their quality of life during rehabilitation</td>
<td>E x x x</td>
</tr>
<tr>
<td>3</td>
<td>Outcome</td>
<td>Amount of time needed to start resumption of work</td>
<td>E x</td>
</tr>
<tr>
<td>4</td>
<td>Outcome</td>
<td>Patients quit smoking</td>
<td>E x</td>
</tr>
<tr>
<td>5</td>
<td>Outcome</td>
<td>Patients meet the physical activity norms</td>
<td>E x x</td>
</tr>
<tr>
<td>6</td>
<td>Process</td>
<td>Average time between hospital discharge and start of rehabilitation</td>
<td>E x</td>
</tr>
<tr>
<td>7</td>
<td>Process</td>
<td>Complete data collection during needs assessment for rehabilitation</td>
<td>E x x</td>
</tr>
<tr>
<td>8</td>
<td>Process</td>
<td>Patients are offered a rehabilitation programme tailored to their needs</td>
<td>E x x x x</td>
</tr>
<tr>
<td>9</td>
<td>Process</td>
<td>Patients finish their rehabilitation programme</td>
<td>E x</td>
</tr>
<tr>
<td>10</td>
<td>Process</td>
<td>Rehabilitation goals are evaluated afterwards</td>
<td>E x x</td>
</tr>
<tr>
<td>11</td>
<td>Process</td>
<td>Cardiovascular risk profile is evaluated afterwards</td>
<td>E x</td>
</tr>
<tr>
<td>12</td>
<td>Process</td>
<td>Patients receive a discharge letter</td>
<td>E x</td>
</tr>
<tr>
<td>13</td>
<td>Process</td>
<td>Cardiologists receive a report after the rehabilitation</td>
<td>E x</td>
</tr>
<tr>
<td>14</td>
<td>Structure</td>
<td>Rehab professionals work with a multidisciplinary patient record</td>
<td>E x</td>
</tr>
<tr>
<td>15</td>
<td>Structure</td>
<td>Specialized education for patients with chronic heart failure</td>
<td>E x</td>
</tr>
<tr>
<td>16</td>
<td>Structure</td>
<td>Long-term patient outcomes are assessed</td>
<td>E x</td>
</tr>
<tr>
<td>17</td>
<td>Structure</td>
<td>Clinics perform internal evaluations and quality improvement</td>
<td>E x</td>
</tr>
<tr>
<td>18</td>
<td>Structure</td>
<td>Patients participate in patient satisfaction research</td>
<td>E x</td>
</tr>
</tbody>
</table>

**DISCUSSION**

In the current study we modified the Rand method to develop QIs for measuring and reporting on quality of care. In our method results from a literature and guideline search are combined with the knowledge of an expert and patient panel in an extensive rating and consensus procedure. We applied our method to the field of CR, where the final QIs set showed that the four sources are complementary. We believe that using all sources results in a well-founded QI set covering all aspects of the health service of interest. Notably, the expert panel mentioned only few QIs related to outcomes of care. Furthermore, many QIs mentioned by the patient panel did not make it to the final QI set because they were opinion-based (e.g., friendly treatment). Our experience with the multidisciplinary expert panel during the group discussion was positive. Because of the early involvement and the reflection of all disciplines in CR, the panel showed great commitment to the QI development process. We believe this will ease implementation and acceptability of the final QI set in daily practice. However, actual benefits (quality improvement) and costs (registration time) can only be assessed afterwards.
To improve the data collection needed to report on QIs, the QI database should ideally be linked to an already existing data collection system such as an EPR. The next step in our research project is to implement the QI set in all clinics that already use an EPR for CR with CDS functionalities. During a multicenter randomized clinical trial the clinics will also receive feedback on the developed QI set in combination with educational meetings to overcome both internal and external barriers for guideline implementation. We expect that our modified Rand method to develop QIs can also be applied in other medical domains to further improve quality and outcomes of care.

ACKNOWLEDGEMENTS

The authors would like to thank the Committee for Cardiovascular Prevention and Rehabilitation of the Netherlands Society of Cardiology and the National Multidisciplinary Assembly on Cardiac Rehabilitation for their contribution to the development of QIs for CR.
REFERENCES


A WEB-BASED SYSTEM TO FACILITATE LOCAL, SYSTEMATIC QUALITY IMPROVEMENT BY MULTIDISCIPLINARY CARE TEAMS: DEVELOPMENT AND FIRST EXPERIENCES OF CARDSS ONLINE

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Continuous monitoring and systematic improvement of quality have become increasingly common in healthcare. To support multidisciplinary care teams in improving their clinical performance using feedback on quality indicators, we developed the CARDSS Online system. This system supports (i) monitoring of indicator-based performance, (ii) selecting aspects of care that need improvement, (iii) developing a quality improvement (QI) plan, and (iv) periodically adjusting the QI plan. During educational outreach visits, the system actively involves the team in the improvement effort, and guides them through the process of systematic QI without needing extensive knowledge of the underlying concepts. During the implementation of the system in the field of cardiac rehabilitation (CR) in the Netherlands, we have conducted the first outreach visits to four CR teams. During the visits, the teams formulated QI plans consisting of 4 to 7 improvement goals, each goal accompanied by 1 to 5 QI actions. Currently, we are evaluating the effect of CARDSS Online on the quality of CR in the Netherlands in a cluster randomized trial.

Key words: Quality improvement; Quality indicators; Healthcare; Cardiac rehabilitation; Guideline adherence.
INTRODUCTION

There is persistent room for improvement in health care, but the complexity of healthcare systems makes it difficult to achieve change. A common approach to changing complex systems is systematic quality improvement (QI), which focuses on improving a system’s underlying processes rather than on correcting mistakes of individuals. It relies on data from healthcare professionals’ own setting and encourages working in multidisciplinary QI teams. The teams’ performance should guide them in improving their practice by the Plan-Do-Study-Act (PDSA) cycle, a part of the Model for Improvement [1]. However, clinicians may not be familiar with the fundamental concepts of systematic QI [2], and it is often difficult to actively involve them in activities other than patient care. This makes undertaking successful local QI initiatives a challenging endeavor.

The Model for Improvement consists of two parts: (i) three fundamental questions, which can be addressed in any order (‘What are we trying to accomplish’, ‘How will we know that a change is an improvement’ and ‘What changes can we make that will result in improvement’), and (ii) the PDSA cycle to test and adjust changes in real work settings [1]. The model is not meant to replace change models that organizations may already be using, but rather to accelerate improvement [1].

Performance feedback is a crucial element within the Plan and the Study step in the PDSA cycle. A recent Cochrane review concluded that such feedback may be more effective when it includes both an action plan and explicit goals [3]. This matches goal-setting theory, which states that feedback and goals are indeed a successful combination, especially when the goals are well-specified [4]. The theory also suggests that people tend to be more committed to attaining a certain goal if they are involved in setting it. Goal commitment further increases if (the outcome of) goal attainment is seen as important, and if people believe they are capable of accomplishing it. An electronic system that would incorporate knowledge on goal setting as well as the principles of systematic QI to reach these goals might be an effective way of involving and guiding clinicians in improving their practice.

In the scientific literature, few systems have been described that support the process of systematic QI or its constituents. Some systems have been developed to provide structured performance feedback [5,6]. However, these systems do not support application of systematic QI principles and effective goal-setting. In the Cochrane review on audit and feedback, only one of the included studies described integration of feedback and goal-setting, but software tools were lacking [7]. Although commercial software often offers the functionality to extract management information from electronic patient records (EPRs), to our knowledge, these systems do not support systematic QI or performance benchmarking.

This paper describes the development and first experiences of CARDSS Online, a system that facilitates local, systematic QI by actively involving multidisciplinary care teams in the entire PDSA cycle and goal setting process. Currently, the system is being implemented in the field of cardiac rehabilitation (CR) in the Netherlands.
CHAPTER 08

METHODS

Clinical context
CR is a therapy provided by multidisciplinary care teams to support heart patients recover from a cardiac incident or intervention, and aims to improve their physical and psychological condition [8]. A recent meta-analysis of RCTs shows consistent evidence of the effectiveness of exercise-based and multimodal (e.g. psychosocial and stress management) CR interventions with regard to mortality and cardiac events (relative-risk reduction: 21-47%) [9]. It has proven to be cost-effective in different economic evaluations conducted in North America and Europe [10]. However, in many Western countries, cardiac rehabilitation services are under-utilized, poorly standardized, and do not follow the available scientific evidence [11]. Also, in the Netherlands, CR uptake is low [12].

Consistent with international standards, the Dutch Guidelines for CR [13] state that professionals should conduct a needs assessment procedure where 80 to 130 data items concerning the patient's medical, physical, psychological, and social condition and lifestyle are gathered. Based on the needs assessment procedure, an individualized rehabilitation programme should be offered which consists of nineteen possible goals (e.g. ‘Optimize exercise capacity’ or ‘Regain emotional balance’) and four possible therapies: exercise training, education and counseling, lifestyle change therapy, and relaxation and stress management training.

In the Netherlands, two EPR systems for CR clinics exist (MediScore CARDSS® and CR Module CS-EZIS.Net®). Both systems are based on the Dutch guidelines for CR and strictly follow the same data model. In addition, both systems contain computerized decision support functionalities which were previously shown to improve guideline concordance [14]. Currently, twelve CR clinics (about 13% of all CR clinics in the Netherlands) work with one of these systems.

Quality indicators
A set of 18 quality indicators for the field of CR was developed using a modified RAND method [15]. This method combines results from a literature search and guideline review with the knowledge of CR experts and patients in an extensive rating and consensus procedure. From these 18 quality indicators, five indicators address structures (e.g., presence of preconditions to be adherent to CR guidelines), eight indicators address processes (e.g., frequency with which clinical measurement instruments are employed), and five indicators pertain to outcomes of CR (e.g., changes in patient health status after rehabilitation). All quality indicators can be derived from the data that is collected with the two EPR systems mentioned above. Both systems possess functionalities to extract the relevant data from the clinic’s database. Extracted data collections consist of (i) patient identification and hospitalization data (31 items), (ii) CR needs assessment data (80-130 items), (iii) data on selected rehabilitation goals and therapies (79 items), and (iv) CR evaluation data containing results on selected goals and therapies (105 items).
System requirements

The goal of the CARDSS Online system is to actively involve and support multidisciplinary CR teams in improving their clinic’s performance. It should guide them through the process of systematic QI without needing extensive knowledge of the underlying concepts. We designed the system to be primarily employed during educational outreach visits and based on measured quality in terms of the 18 indicators. During these visits, at least two members of the local multidisciplinary CR team, their manager, and the responsible cardiologist are present, jointly acting as the clinic’s QI team. All team members have a login code to access the system, but during visits one of them operates as chairperson, navigating through the system, while the others watch a projection of the screen on a beamer.

The QI team has four main tasks: (i) monitoring their clinic’s performance as defined by the CR quality indicator set, (ii) selecting aspects of care that need improvement, (iii) developing a QI plan, consisting of feasible improvement goals and associated actions, and (iv) monitoring the progress on the QI plan and adjusting it accordingly. Based on the Model for Improvement (which is one approach to systematic QI) [1], goal setting theory [4], and knowledge from previous studies on performance feedback [3,16,17], we defined system requirements that are associated with these four QI tasks.

Monitoring of indicator-based performance – Data on performance play a pivotal role within the Model for Improvement. First of all, they help answering one of the three questions to be asked before entering the PDSA cycle: ‘How will we know that a change is an improvement?’.

Secondly, when entering the cycle, performance feedback provides the basis for the Plan and the Study phase [1], where feedback is a summary of clinical performance over a specific period of time [3]. Generating feedback on the 18 quality indicators is, therefore, an apparent system functionality. In the Plan phase, the QI team can use this feedback as the starting point for determining which indicators (i.e., aspects of their practice) warrant an improvement effort. Also, by revealing the (lack of) progress in relation to improvement goals in the Study phase, the feedback may be a moderator of effective goal setting [4].

Selecting aspects of care that need improving – The feedback should facilitate the QI team’s decision on which aspects of care warrant starting a QI initiative. Therefore, the team needs a comparison of their local performance to an explicit standard of excellence (‘benchmark’) [3,4], which is typically based on predefined targets or observed performance in practice. Although a standard of excellence may guide the QI team in selecting the ‘right’ aspects to improve, it does not guarantee that they are dedicated to make the actual effort in matching the benchmarks. To increase the team’s commitment, the system should enable them to select those aspects of their practice that they perceive as important and feasible to improve within their local context [4].
Developing the QI plan – For each selected indicator, the QI team needs to answer the second question from the Model for Improvement; ‘What are we trying to accomplish?’ refers to formulating improvement goals. Locke and Latham suggested that goals should be well-specified to increase the effectiveness of goal setting [4]. For example, goals should be time-specific, measurable, and include information on who is primarily responsible for accomplishing it [1]. To ensure commitment to goal attainment, the QI team should have the opportunity to be involved in the goal setting process [4]. Per goal, answering the third Model for Improvement question – ‘What changes can we make that will result in an improvement’ – results in a set of concrete QI actions. Identifying reasons for underperformance as well as suggestions for (proven) improvement strategies may help teams to define effective actions [1].

The set of all goals and associated actions together form the QI team’s action plan. Ivers and colleagues suggested that such an action plan is formulated in order to increase the impact of performance feedback [3].

Adjusting the QI plan – With their QI plan at hand, the team enters the Do phase of the PDSA cycle to execute the actions in the daily practice of their clinic. In the Study phase, the performance feedback will reveal if this has actually resulted in attaining the improvement goal or not [1]. Based on this knowledge, the team needs to decide if any new actions should be added to the plan, and if the existing ones are either completed or should be continued or cancelled.

RESULTS

System architecture
CARDSS Online was designed as a web-based application which can be consulted by CR clinics. At the server side, CARDSS Online consists of a Microsoft SQL Server database and a Java web application running on Apache Tomcat for generating the graphical user interface in HTML. The Java application consults and performs calculations on the database by calling stored SQL procedures. At the client side, clinics can use any browser that is capable of rendering HTML and executing JavaScript.

The system architecture is shown in Figure 1. CARDSS Online consists of five components: (i) a data upload tool, (ii) a data validation and import tool, (iii) a relational database containing all imported data, derived values for quality indicators, and QI plans, (iv) a feedback report tool, and (v) a QI plan tool.
Figure 1 – System architecture of CARDSS Online

System description
After login into CARDSS Online, users can choose between four principal functionalities of the system: uploading datasets that were extracted from their EPR system; receiving feedback on quality indicators; generating and updating QI plans; and entering information about their local QI team.

Upload – The data upload tool allows the QI team to upload datasets that are extracted from their local EPR database to CARDSS Online. The data format is generic (e.g. a CSV file). These datasets are subsequently checked for validity and imported to the CARDSS Online database.

Feedback – Figure 2 shows a screenshot from the feedback report page in CARDSS Online. Performance results on structure indicators are always ‘yes’ or ‘no’ values. Results on process and outcome indicators are typically means and percentages. After clicking on an indicator, a pop-up screen opens with detailed information about data underlying the calculation, national averages for comparison, and benchmark values.

To assist the QI teams with selecting the indicators that require improvement, a colored icon next to each indicator score indicates whether the performance is acceptable (green checkmark), borderline (orange checkmark), or poor (red exclamation mark). Threshold values for these interpretations are determined with the achievable benchmarks of care (ABC) method [16]. ABCs are calculated from the performance of all members in a peer group. In essence, the achievable benchmark represents the average performance for the top 10% of clinics being assessed. Adjustments are made to account for differences in the numbers of patients per clinic and also to allow the inclusion of clinics with small numbers of eligible patients without unduly distorting the overall performance assessment [16]. Guided by the colored icons users can make a pre-selection of quality indicators they would like to take into account for improving their performance. Each of the pre-selected indicators is subsequently rated by the entire team on importance (5 categories), feasibility (5 categories) and expected time needed for improvement (3 categories). CARDSS Online then orders the indicators based on assigned ratings, and the
team can select indicators for inclusion in the QI plan. The number of indicators to be selected for the final plan is unlimited, but during the outreach, visiting teams are encouraged to focus on a small number instead of trying to improve all at once.

**Figure 2 – Screenshot CARDSS Online (feedback report)**

**QI plan** – Per quality indicator included in the improvement plan, users can specify in free text the problem, presumed causes, improvement goal, and concrete actions on how to reach that. The system does not provide tools, other than documentation, for systematic problem analysis or suggestions for improvement actions. For each action, the names of responsible team members and a deadline have to be entered.

During, but also in between, follow-up outreach visits, the team can access the system to revise the existing QI plan based on new results on the quality indicators. For each action, users can enter if it was completed, cancelled, or should be continued. Actions marked as ‘to be continued’ are automatically transferred to the revised QI plan belonging to the new cycle.

**First experiences**
Currently, seven CR clinics have uploaded patient data that was extracted from their local EPR database to CARDSS Online. Overall, data from 1130 patients was uploaded, representing a mean of 161.4 (range 64 to 442) patients per clinic. Below, we describe our experiences with CARDSS Online during the first four educational outreach visits to discuss the indicator-based feedback and develop QI plans.
The local QI teams consisted of 5 professionals on average. All teams included a nurse, a physiotherapist, a cardiologist and a manager (one manager and cardiologist were unable to attend the meeting). Three teams had a caregiver from an additional discipline (sport physician, psychologist or social worker). The duration of the visits was between two and three hours. Besides structuring the discussion on measured performance and the action plan, the investigator instructed the team on how to use the system. Since we expect no further instruction to be required, subsequent visits will probably take less time.

Feedback – The feedback reports gave rise to substantial discussions about local performance within the QI teams. Often, there was a tension between a wish to improve (e.g. ‘We should improve the content of our lifestyle change therapy to better adapt it towards patients’ needs and wishes’) and various barriers at the organisational level (e.g. ‘Our psychologist is too busy and we need to cut back on our expenses’).

The colored icons focused the discussion on aspects of care where performance was below accepted levels (e.g. ‘The red checkmark indicates that the percentage of patients finishing their lifestyle change therapy is too low’). The comparison with national averages and benchmark values was often especially convincing to managers and cardiologists with respect to the need to start improvement actions (e.g. ‘On a national level, 85% of the patients finish their lifestyle change therapy, in our clinic, only 54%’). In the fervour of the discussion, the mean number of indicators pre-selected for possible QI was 6 (range 5 to 8). The rating of the pre-selected indicators on importance, feasibility and time-frame, forced the QI team to discuss their performance more rationally and to make choices for the final selection. During the rating, there was often already a whole range of potentially important and feasible improvement actions passed in review (e.g. ‘Perhaps we can ask the social worker to improve our lifestyle therapy’). The mean number of selected indicators for inclusion in the final QI plan was 5 (range 4 to 7). The indicator ‘Percentage of patients with an evaluation of the rehabilitation goals afterwards’ was selected by all four clinics for their QI plan, and ‘The average time between hospital discharge and start of rehabilitation’ by three clinics. Furthermore, most indicators selected were process indicators (3 to 6), instead of structure or outcome indicators (either none or only one).

QI plan – After the preceding discussion, the QI teams were encouraged to actually formulate and enter problems, presumed causes, improvement goals and actions into the system. During this step, the system stimulated them to make the goals measurable (e.g. ‘We aim to improve the percentage of patients finishing their lifestyle program from 54% towards 70% within half a year’). The breaking down of a goal into multiple actions made it manageable for the team (e.g. ‘(i) Checking which patients abandoning their lifestyle change therapy and why; (ii) Organizing a brainstorm with the social worker and nurse to discuss new content for the therapy; etc.’). The mean number of actions per QI goal was 2 (range 1 to 5). Entering one or more responsible team members and a deadline into the system made the action real for the QI team (e.g., the social worker and nurse noted the planned date for the brainstorm in their
personal agendas). At the end of the meeting, all four QI teams were enthusiastic about the outreach visits and using CARDSS Online. One cardiologist stated that ‘We have many ideas for QI, but often they stay fuzzy. The meeting and the system were very helpful to capture our ideas, talk about them and crystallize them into a plan to operationalize.’

DISCUSSION

In the current study, we developed CARDSS Online, a system to support local, systematic QI in multidisciplinary care teams, and presented the first experiences during the implementation in the field of CR in the Netherlands. CARDSS Online is based on the principles of systematic QI including the Model for Improvement with the PDSA cycle [1] and results from literature that underline the importance of a QI action plan with concrete, self-formulated goals rated as important and feasible[3,4]. CARDSS Online distinguishes itself from existing QI interventions by actively involving multidisciplinary care teams in using indicator-based feedback to improve their clinic’s performance, without needing extensive knowledge of underlying QI concepts. The system can easily be used in other healthcare domains by replacing the underlying database and adapting the SQL procedures.

Previous research in the field of CR showed that computerized decision support can improve guideline concordance of multidisciplinary teams’ decisions [14]. However, to address barriers for guideline concordance at management and organizational levels, additional interventions are required [18]. For this reason we introduced the CARDSS Online system, accompanied with quarterly outreach visits to local QI teams, to specifically involve the management and organizational level in the QI process [19].

Our study has some limitations. A prerequisite for working with CARDSS Online is the electronic availability of patient data. The current CR clinics that work with an EPR for CR should probably be classified as innovators [20] and are therefore not a representative sample of all Dutch CR clinics. However, during regular contacts with the field, we have noticed a growing interest and we expect to include another 10 CR clinics within the next few months. A second limitation is that we can currently only report on the experiences with CARDSS Online during the first four outreach visits to CR clinics. Broader implementation of the system is needed to assess actual benefits (quality improvement) and costs (time needed for developing and performing QI actions) of CARDSS Online.

Currently, we are performing a cluster randomized trial to assess the effectiveness of CARDSS Online accompanied by quarterly educational outreach visits on the quality of care (guideline concordance and performance on quality indicators) in the field of CR in the Netherlands. A qualitative process evaluation will be used to gain insights into actual exposure and barriers and success factors of CARDSS Online as experienced by participating clinics.
CONCLUSION

A web-based system to facilitate local, systematic QI by multidisciplinary care teams, called CARDSS Online, was developed. The system supports active involvement in the entire Plan-Do-Study-Act cycle and goal setting process by guiding its users during (i) monitoring of indicators-based performance (including a visual comparison to benchmark values), (ii) selecting indicators for QI that are locally perceived as important and feasible, (iii) developing a QI plan including QI goals and concrete actions to accomplish these goals, and (iv) periodically adjust the QI plan based on new results on the quality indicators and ongoing experiences in the daily care process. The first experiences with the system in four CR clinics are promising. The effects of CARDSS Online on the quality of CR in the Netherlands are currently assessed in a cluster randomized trial.

ACKNOWLEDGEMENTS

The authors would like to thank all current study sites for their participation in our research with the CARDSS Online system: Rijnlands Revalidatie Centrum, Leiden; Máxima Medisch Centrum, Veldhoven; BovenIJ Ziekenhuis, Amsterdam; NijSmellinghe Ziekenhuis, Drachten; Albert Schweitzer Ziekenhuis, Dordrecht; Ikazia Ziekenhuis, Rotterdam and Tergooi Ziekenhuizen, Hilversum/ Blaricum.
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PART III

EFFECT OF A WEB-BASED AUDIT AND FEEDBACK SYSTEM WITH OUTREACH VISITS
EVALUATING THE EFFECT OF A WEB-BASED QUALITY IMPROVEMENT SYSTEM WITH FEEDBACK AND OUTREACH VISITS ON GUIDELINE CONCORDANCE IN THE FIELD OF CARDIAC REHABILITATION: RATIONALE AND STUDY PROTOCOL

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Background: Implementation of clinical practice guidelines into daily care is hampered by a variety of barriers related to professional knowledge and collaboration in teams and organizations. To improve guideline concordance by changing the clinical decision-making behavior of professionals, computerized decision support (CDS) has been shown to be one of the most effective instruments. However, to address barriers at the organizational level, additional interventions are needed. Continuous monitoring and systematic improvement of quality are increasingly used to achieve change at this level in complex health care systems. The study aims to assess the effectiveness of a web-based quality improvement (QI) system with indicator-based performance feedback and educational outreach visits to overcome organizational barriers for guideline concordance in multidisciplinary teams in the field of cardiac rehabilitation (CR).

Methods: A multicenter cluster-randomized trial with a balanced incomplete block design will be conducted in 18 Dutch CR clinics using an electronic patient record with CDS at the point of care. The intervention consists of (i) periodic performance feedback on quality indicators for CR and (ii) educational outreach visits to support local multidisciplinary QI teams focusing on systematically improving the care they provide. The intervention is supported by a web-based system which provides an overview of the feedback and facilitates development and monitoring of local QI plans. The primary outcome will be concordance to national CR guidelines with respect to the CR needs assessment and therapy indication procedure. Secondary outcomes are changes in performance of CR clinics as measured by structure, process and outcome indicators, and changes in practice variation on these indicators. We will also conduct a qualitative process evaluation (concept-mapping methodology) to assess experiences from participating CR clinics and to gain insight into factors which influence the implementation of the intervention.

Discussion: To our knowledge, this will be the first study to evaluate the effect of providing performance feedback with a web-based system that incorporates underlying QI concepts. The results may contribute to improving CR in the Netherlands, increasing knowledge on facilitators of guideline implementation in multidisciplinary health care teams and identifying success factors of multifaceted feedback interventions.

Key words: Quality improvement, Quality indicators, Health care, Cardiac rehabilitation, Guideline adherence
BACKGROUND

Concordance to clinical practice guidelines can improve patient outcomes, reduce practice variation, and reduce costs of health care [1-3]. However, implementation of guidelines into daily care is hindered by a variety of barriers related to decision-making behavior of health care professionals and collaboration in teams and organizations [4]. An electronic patient record (EPR) information system with computerized decision support (CDS) functionalities was previously developed to stimulate guideline implementation in cardiac rehabilitation (CR) in the Netherlands [5,6]. Although the CDS system was effective in improving concordance with the guidelines recommendations, there remained a considerable non-concordance due to organizational constraints (e.g., lack of time or resources) [7]. Therefore, we hypothesize that guideline implementation with CDS systems directed at professionals may be more powerful if used in conjunction with other interventions directed at the decision-making processes at the organizational level [8]. This paper describes the design of an evaluation study of a multifaceted intervention combining indicator-based performance feedback and educational outreach visits to improve guideline implementation in a context of multidisciplinary CR teams working with an EPR with CDS already.

The problem: persisting external barriers to guideline implementation

Poor concordance to clinical practice guidelines is due to various barriers that professionals may face when they try to incorporate practice guidelines into daily care. An often-used classification of those barriers is the division into internal and external barriers [9]. Internal barriers relate to professional knowledge of, and attitudes towards, the guidelines. For instance, professionals may not be familiar with the details of a guideline or may disagree with its recommendations. However, because health care professionals often work within complex organizations, appropriate knowledge and attitudes of professionals are necessary but not sufficient to implement guidelines. Professionals may also encounter external barriers which hamper their ability to execute guideline recommendations. These barriers concern environmental factors related to the organization or health system professional work in, such as a lack of resources. External barriers also include barriers related to patients (e.g., patients may refuse therapies) and to the guidelines themselves (e.g., ambiguities, omissions, and contradictions).

Of the different implementation strategies to overcome barriers to guideline implementation (e.g., education, outreach visits, CDS, and reminders [10]), those providing patient-specific recommendations at the time and place where professionals make clinical decisions are most likely to be effective [2]. A recent systematic review and meta-analysis demonstrated that, in general, CDS increases the chance that recommended therapies are actually prescribed by 57% (odds ratio 1.57; 95% confidence interval 1.35 to 1.82) [11]. In individual trials, however, CDS is not always effective. A systematic review in the area of chronic disease management (including CR) shows that CDS led to significant improvements in the process of care in only 25 out 48 trials (52%) [12]. Attempts to identify critical success factors for CDS systems have
provided inconsistent results, and it seems likely that these factors are highly dependent on the time and context of the intervention [13]. Overall, this seems to suggest that CDS is an effective instrument to overcoming internal barriers (i.e., related to clinical decision-making of professionals) to guideline implementation. However, external barriers are probably not addressed by CDS interventions.

This phenomenon that barriers faced by front-line professionals do not reach their managers and policy makers was also described by Tucker and Edmondson [14]. Clinicians may not be familiar with underlying concepts to address external barriers [15] and often lack time to be actively involved in activities other than patient care. This makes successfully overcoming external barriers a challenging endeavor. Therefore, we hypothesize that besides CDS, additional interventions are needed to also address external barriers related to decision-making processes at the organizational level of the health care clinic professional work in.

**Solving the problem: overcoming external barriers by providing a quality improvement intervention with performance feedback and outreach visits**

A common approach to changing complex organizations is systematic quality improvement (QI), which focuses on improving an organization’s underlying processes. It relies on data from health care professionals’ own setting and encourages working in multidisciplinary QI teams. The teams’ performance should guide them in improving their practice by the plan-do-study-act (PDSA) cycle, a part of the Model for Improvement [16] (see Figure 1). Performance feedback is a crucial element within the plan and the study step in the PDSA cycle. Quality indicators—i.e., quantitative measures to monitor and evaluate the quality of health care processes that affect patient outcomes [17]—commonly serve as a basis for the feedback. The assumption is that it prompts professionals to change their behavior if they see that their practice does not meet benchmark values (e.g., national target values or average performance within a peer group). A recent Cochrane review on the effect of audit and feedback reported a median absolute increase in compliance with desired practice of +4.3% (interquartile range (IQR) 0.5% to 16%) on dichotomous measures (e.g., proportion of patients adhering to their therapy plan) and +1.3% (IQR 1.3% to 28.9%) on continuous measures (e.g., time between referral and intake). The reviewers suggested audit and feedback to be most effective if provided by a supervisor or colleague, more than once, both verbally and in writing, if baseline performance is low, and if it includes explicit targets and an action plan. Furthermore, the effect of indicator-based performance feedback is likely to be stronger when it is combined with educational meetings, directed towards actively involving care professionals in the improvement process [17].
Based on the literature on feedback, we hypothesize that complementing CDS with a performance feedback and outreach visit intervention might be an effective way to involve front-line professionals and their managers together in overcoming external barriers to improve their practice. This matches the conclusion of a substantial proportion (although not all) of systematic reviews concerning the effectiveness of different guideline-implementation interventions [10,18-21]. They indicate that effective strategies often have multiple components and that the use of single-component strategies is less effective [21]. Change is possible, but generally requires comprehensive approaches at different levels (doctor, team practice, hospital, wider environment), tailored to specific settings and target groups [20].

**Aim and objective**

Given the positive effect of CDS on decision-making behavior of health care professionals but the remaining practice variation caused by organizational barriers, the development and assessment of an intervention tailored to external barriers to change are necessary. This study aims to intervene on factors influencing the implementation of guidelines at the organizational level in a setting where an existing CDS is used to guide professional decisions. We hypothesize that a web-based QI system with indicator-based performance feedback and educational outreach visits to multidisciplinary care teams will overcome the organizational constraints for changes needed to improve guideline concordance [22]. Table 1 describes the motivation of the elements included in the developed multifaceted intervention based on both the literature and from earlier studies performed in the field of CR by our research group.
### Table 1 – Previous studies: improving guideline concordance in the field of CR

<table>
<thead>
<tr>
<th>Study</th>
<th>Description of the studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Tackling internal barriers: CDS</td>
<td>To stimulate the implementation of the Dutch CR Guidelines, an EPR with CDS functionalities named CARDSS (cardiac rehabilitation decision support system) was previously developed [5]. After entering patient data, CARDSS provides its users with a patient-specific, guideline-based rehabilitation program, consisting of recommended rehabilitation goals and therapies. The effect of the system was evaluated in a cluster-randomized trial in 21 CR clinics, which showed that the system increased concordance to the CR guideline: CR professionals using the system better adapted the CR therapy to patients’ needs [7]. Data from the same trial however pointed out that there remained to exist a large variation in CR practice across clinics. For instance, the percentage of patients participating in exercise training varied from 41% in one clinic to 100% in another and the percentage of patients participating in education and counseling programs varied from 39% to 96%.</td>
</tr>
<tr>
<td>II. Persisting barriers after introduction of CDS</td>
<td>After the trial a qualitative study was conducted to investigate which barriers were reduced and which barriers persisted after introduction of the CDS system [8]. Results from semi-structured interviews with 29 CR professionals showed that the system succeeded in overcoming professional knowledge barriers. For instance, professionals were more aware of the need to use objective instruments to assess patients’ needs and of the therapy decision rules as described in the guidelines. However, two remaining barriers for guideline concordance frequently mentioned were organizational and guideline-related barriers; both can be classified as external barriers according to Cabana et al [9].</td>
</tr>
<tr>
<td>III. Tackling external guideline-related barriers: revision of the guidelines</td>
<td>To overcome guideline-related barriers, the clinical algorithm for assessing patient needs in CR was revised [23]. We combined patient data collected by CARDSS and input from academic and practical experts. Assessment of patient needs based on clinical judgment was found to be a source of practice variation and was therefore avoided in the revised algorithm by adding several standardized assessment instruments.</td>
</tr>
<tr>
<td>IV. Tackling external organization-related barriers: pilot study with feedback</td>
<td>To address the remaining organizational-related barriers, a once-only benchmark-feedback loop was introduced in a pilot study in 21 clinics [22]. Data from the CDS system at different clinics were collected, stored in a central data registry, and used to generate paper feedback reports with benchmark information for each of the clinics. The reports aimed to steer discussions in team meetings, encouraging them to formulate QI plans. Although the reports were positively received by the clinics, many were unable to create time to discuss and actually act upon the report.</td>
</tr>
<tr>
<td>V. Developing quality indicators</td>
<td>For providing quality feedback to CR clinics, we developed a national preliminary set of quality indicators. This was performed in close collaboration with an expert (representatives from all disciplines involved in CR) and patient panel using a modified Rand method [24]. Within this method, results from both panels were combined with results from a literature search and guideline review in an extensive rating and consensus procedure. Table 2 shows the final set including 18 quality indicators regarding guideline concordance (e.g., complete data collection during needs assessment) and other quality aspects perceived relevant by both panels (e.g., patients participate in satisfaction research). Based on user experiences during this trial, we aim to select a subset of quality indicators to be rolled out on a national level.</td>
</tr>
</tbody>
</table>
The key objective of the study is to assess the effectiveness of a web-based QI system with periodic performance feedback on quality indicators for CR and educational outreach visits to multidisciplinary QI teams to overcome organizational barriers for guideline concordance in the field of CR in the Netherlands. Primary outcome will be the impact of our intervention on concordance to the national CR guidelines (concerning CR needs assessment and therapy indication procedure). Secondary outcomes are changes in performance of CR clinics measured by changes in structure, process, and outcome indicators for CR and changes in practice variation on these indicators. A qualitative process evaluation (concept-mapping methodology) will be used to assess experiences from participating CR clinics and to gain insight into factors which influence implementation of the intervention. The results of this study can be used by those involved in QI of the CR care in the Netherlands. More in general, our study results may contribute to a better understanding of factors that influence the implementation of practice guidelines and can be used to set up multifaceted guideline implementation programs in other fields of health care.

METHODS

Study design
The effect of the intervention will be evaluated in a multicenter cluster-randomized study with a balanced (2 × 2) incomplete block design. Cluster-randomization is chosen to avoid contamination among professionals within the same clinic [25]. During the trial, clinics will be divided into two study arms (A and B). Using the multidisciplinary character of CR treatment, each arm will receive the intervention (a web-based QI system with feedback and educational outreach visits) directed at one out of the two domains described in the CR guidelines [26]. Clinics allocated in arm A will receive the intervention directed at improving guideline concordance for the psychosocial domain, clinics in arm B for the physical domain (see Figure 2 for an overview of the study flow). In this way, both study arms will serve as each other’s control. For all participating clinics, the study period is 1 year.

Clinical setting: cardiac rehabilitation in the Netherlands
The study will take place in Dutch CR clinics that already work with an EPR with CDS at the point of care. CR is a therapy provided by multidisciplinary care teams to support heart patients recover from a cardiac incident or intervention, and aims to improve their physical and psychological condition [27-31]. CR is recommended for all patients who have been hospitalized for an acute coronary syndrome (ACS) and for those who have undergone coronary revascularization (coronary artery bypass graft surgery [CABG] or percutaneous coronary interventions [PCI]) or valvular surgery [32,33]. Recent studies show that CR is also beneficial for patients with other chronic cardiovascular conditions such as stable angina pectoris (AP) and chronic heart failure (CHF) and for subjects with a high risk for developing cardiovascular disease [34]. A recent meta-analysis shows consistent evidence of the effectiveness of exercise-based and multimodal
Figure 2 – Study flow.
(e.g., psychosocial and stress management) CR interventions with regard to mortality and prevention of future cardiac events (relative-risk reduction 21–47%) [35]. CR teams usually include cardiologists, physical therapists, nurses, psychologists, dieticians, social workers, and rehabilitation physicians. It has proven to be cost-effective in different economic evaluations conducted in North America and Europe [29]. However, in many Western countries, CR services are under-utilized and poorly standardized and do not follow the available scientific evidence [36]. A recent study in the Netherlands shows that only a minority of patients eligible for CR actually receive it [37]. The CR uptake rate was 28.5% among patients with an ACS and/or intervention. From these, patients who underwent CABG or valve surgery had the highest uptake rate (58.7%) and patients with an ACS without an intervention had the lowest uptake rate (9.8%) [37].

Context: the use of CDS in participating CR clinics
All participating CR clinics use an EPR with CDS based on the most recent version of the CR guidelines [26]. The CDS provides advice on a patient-tailored rehabilitation program based on the needs assessment procedure. This procedure requires gathering 80 to 130 data items concerning the patient’s health status and rehabilitation needs. A clinical algorithm describing a branching logic to assess the data is part of the guidelines [38]. The rehabilitation program can contain four possible group-based therapies: exercise training (optimize exercise capacity with physical restrictions); education therapy (about consequences of the patient’s disease); lifestyle change therapy (risk-related behavioral adjustment); relaxation and stress management training (learning to manage tension in daily practice); and if needed, different forms of individual therapy (e.g., by psychologists). During the needs assessment procedure, the CDS advice can immediately be discussed with the patient to set the final rehabilitation program.

Intervention
We will carry out a multifaceted guideline implementation intervention that consists of two elements: (i) quarterly feedback on quality indicators for CR, provided as part of a web-based QI system and (ii) educational outreach visits using the same system to set up a QI plan together with a local QI team. Table 3 gives an overview of the complete intervention for both study arms.
### Table 2 – Elements of the multifaceted guideline implementation intervention for both study arms per cardiac rehabilitation therapy

<table>
<thead>
<tr>
<th>Study arm</th>
<th>Nr</th>
<th>Type</th>
<th>Quality indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1</td>
<td>Structure</td>
<td>Specialized education for patients with chronic heart failure</td>
</tr>
<tr>
<td>A</td>
<td>2a</td>
<td>Process</td>
<td>Complete data collection during needs assessment for rehabilitation (concerning psychological and social functioning, and lifestyle factors)</td>
</tr>
<tr>
<td>A</td>
<td>3</td>
<td>Process</td>
<td>Patients receive a discharge letter to stimulate continuation of lifestyle changes at home</td>
</tr>
<tr>
<td>A</td>
<td>4</td>
<td>Outcome</td>
<td>Patients quit smoking</td>
</tr>
<tr>
<td>A</td>
<td>5</td>
<td>Outcome</td>
<td>Patients improved their quality of life during rehabilitation</td>
</tr>
<tr>
<td>B</td>
<td>2b</td>
<td>Process</td>
<td>Complete data collection during needs assessment for rehabilitation (concerning physical functioning and, cardiovascular risk factors)</td>
</tr>
<tr>
<td>B</td>
<td>6</td>
<td>Process</td>
<td>Cardiovascular risk factors are evaluated after rehabilitation</td>
</tr>
<tr>
<td>B</td>
<td>7</td>
<td>Outcome</td>
<td>Patients improve their exercise capacity during rehabilitation</td>
</tr>
<tr>
<td>B</td>
<td>8</td>
<td>Outcome</td>
<td>Patients meet the physical activity norms</td>
</tr>
<tr>
<td>B</td>
<td>9</td>
<td>Outcome</td>
<td>Amount of time needed to start resumption of work</td>
</tr>
<tr>
<td>A and B</td>
<td>10</td>
<td>Structure</td>
<td>Rehab professionals work with a multidisciplinary patient record</td>
</tr>
<tr>
<td>A and B</td>
<td>11</td>
<td>Structure</td>
<td>Long-term patient outcomes are assessed</td>
</tr>
<tr>
<td>A and B</td>
<td>12</td>
<td>Structure</td>
<td>Patients participate in patient satisfaction research</td>
</tr>
<tr>
<td>A and B</td>
<td>13</td>
<td>Structure</td>
<td>Clinics perform internal evaluations and quality improvement</td>
</tr>
<tr>
<td>A and B</td>
<td>14</td>
<td>Process</td>
<td>Average time between hospital discharge and start of rehabilitation</td>
</tr>
<tr>
<td>A and B</td>
<td>15</td>
<td>Process</td>
<td>Patients are offered a rehabilitation program tailored to their needs</td>
</tr>
<tr>
<td>A and B</td>
<td>16</td>
<td>Process</td>
<td>Patients finish their rehabilitation program</td>
</tr>
<tr>
<td>A and B</td>
<td>17</td>
<td>Process</td>
<td>Rehabilitation goals are evaluated afterwards</td>
</tr>
<tr>
<td>A and B</td>
<td>18</td>
<td>Process</td>
<td>Cardiologists receive a report after the rehabilitation</td>
</tr>
<tr>
<td>Study arm</td>
<td>CR therapy</td>
<td>Elements</td>
<td>Description of the elements</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------</td>
<td>----------</td>
<td>------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>A</td>
<td>Exercise training</td>
<td>CDS</td>
<td>Computerized decision support system at the point of care based on the most recent guidelines for CR</td>
</tr>
<tr>
<td></td>
<td>Relaxation and stress management training</td>
<td>CDS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Education therapy</td>
<td>CDS</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Feedback</td>
<td>Quarterly feedback reports on quality indicators for CR for arm A and B (see Table 2), monitoring of own performance over time, comprehensive benchmarking CR clinic's performance to the other participating clinics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Educational outreach visits</td>
<td>On site educational outreach visits after sending the feedback reports, supporting discussion of feedback results within a local QI team, supporting this team to define, implement and monitor a QI plan by means of a web-based QI system (CARDSS Online)</td>
</tr>
<tr>
<td>B</td>
<td>Exercise training and physical activity</td>
<td>CDS</td>
<td>Feedback</td>
</tr>
<tr>
<td></td>
<td>Relaxation and stress management training</td>
<td>CDS</td>
<td>Feedback</td>
</tr>
<tr>
<td></td>
<td>Education therapy</td>
<td>CDS</td>
<td>Educational outreach visits</td>
</tr>
<tr>
<td></td>
<td>Lifestyle change therapy (excluding physical activity)</td>
<td>CDS</td>
<td></td>
</tr>
</tbody>
</table>

i) Feedback. Each 3 months, all participating clinics will receive feedback on a set of quality indicators for CR [24], based on data that are recorded by the CDS system. Feedback reports will be presented within the web-based QI system called CARDSS Online, which was specifically developed for this study [39]. Within this system, clinics can monitor their performance on the quality indicators listed in Table 2. Figure 3 shows a screenshot from the feedback report page in CARDSS Online. After clicking on an indicator button, a pop-up screen opens with detailed information about data underlying the calculation, national averages for comparison, and benchmark values. Feedback will be attuned to the research arm concerned: clinics allocated in arm A will receive feedback on quality indicators referring to psychosocial domain; clinics allocated in arm B will receive feedback on indicators referring to the physical domain. Both arms will receive feedback on indicators referring to general processes and structures (see Table 2).
To assist the QI teams with selecting the quality indicators requiring improvement, a colored icon next to each indicator score indicates whether the performance is acceptable (green checkmark), borderline (orange checkmark), or poor (red exclamation mark). In addition, results will be compared to statistics from the same clinic during earlier periods to quantify change. When a clinic's average for a given indicator is poor or differs (both in positive and negative sense) from previous results, this will be discussed during the outreach visits. Icon colors are automatically determined by the CARDSS Online system, using predefined rules (see Appendix I).

### Outreach visits
Feedback reports will be received by all participating clinics on a 3-month basis and followed by outreach visits to support interpretation of the report and to draft a QI plan. This approach was chosen to match the conclusion from the Cochrane review that the feedback may be more effective when it includes both an action plan and explicit goals [17]. During development of the QI plan content, additionally, the goal-setting theory, stating that feedback and well-specified goals are indeed a successful combination, was used. The theory emphasises that people tend to be more committed to attaining a certain goal if they are involved in setting it, if (the outcome of) goal attainment is seen as important, and if people believe they are capable of accomplishing it [40]. To this end, each clinic needs to set up a local QI team with the responsibility to define, implement, and monitor a QI plan including concrete QI goals based on self-identified issues in the feedback reports.

- **QI team:** Setting up a QI team implies the allocation of at least two CR team members for an average of 3 h per month (anyhow, the nurse acting as rehabilitation coordinator and one person from another discipline) and two members for an average of 1 h per month (a cardiologist and a representative from the management) during the study.
QI plan: The QI team can use CARDSS Online to grade indicators that the team aims to improve based on importance (five categories), feasibility (five categories), and expected time needed (three categories). CARDSS Online then ranks the indicators based on assigned ratings, and the team can select indicators for final inclusion in the QI plan. In principle, all quality indicators can be selected for improvement, but teams are encouraged to focus on a small subset of three to four indicators during each 3-month cycle. For each quality indicator included in the QI plan, users can specify the problem, presumed causes, improvement goal, and concrete actions on how to reach that goal. CARDDS Online does not provide tools, other than documentation, for systematic problem analysis or suggestions for improvement actions. For each action, the names of responsible team members and a deadline for achievement has to be entered.

Four to six weeks after the first outreach visit, a telephone call will take place with the chair of the local QI team to discuss and support resolution of possible problems that occur during the implementation of the QI plan. Three months after the first round of feedback, a new feedback report is composed and becomes available in the system. During, but also in between, outreach visits, local QI teams can access CARDSS Online to provide status updates on actions listed in the current QI plan.

During the study period of 1 year, all clinics will receive four feedback reports, four outreach visits, and (at least) one telephone call. All visits will be carried out by the same investigator (MvEV) who has a health sciences background; she has been involved in the development of the CR quality indicator set [24] and has several years of experience with CR guideline implementation [41].

CARDSS online - The system was designed as a web-based application which can be consulted by all participating CR clinics. We designed the system to be primarily employed during educational outreach visits with the clinic’s QI teams. At the server side, CARDSS Online consists of a Microsoft SQL Server database and a Java web application. At the client side, clinics can use any web browser that is capable of rendering HTML and executing JavaScript. Development of the system and the architecture are described in more detail elsewhere [39].

Participants
Inclusion criteria (clinic level) - All CR clinics that use an EPR for CR with CDS during the CR needs assessment procedure and that are willing to dispose their data for research and to set up a QI team are eligible to participate in the study. There are 91 CR clinics in the Netherlands, the majority affiliated with hospitals [42]. Twelve clinics are located in specialized rehabilitation centers [42], who have regional functions and can treat simple but especially more complex referred patients. Both types of clinic work according to the same guidelines and are eligible to participate in the study.

In the Netherlands, there are two commercial vendors of CDS systems for CR that can be
used for data collection. Both systems have been validated for their advice being completely consistent with the guidelines. Also data collection in these systems is in line with the minimal dataset of our study. The minimal dataset is based on the set of 18 quality indicators for CR (see Table 2) and consists of (i) patient identification data (31 items), (ii) CR needs assessment data (80–130 items, see Table 4), (iii) data on selected rehabilitation goals and therapies (79 items), and (iv) CR evaluation data (105 items). Clinics that use one of the CDS systems automatically collect the right data items. The price of both systems depends on contract conditions, but amounts on average to €20,000 for purchase and to €4,000 per year for service, updates, and maintenance.

Table 4 – Items which need to be measured during the needs assessment procedure according to recommendations in the Cardiac Rehabilitation Guidelines [26,38]

<table>
<thead>
<tr>
<th>Domain</th>
<th>Item</th>
<th>Clinical Algorithm Cardiac Rehabilitation 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Physical functioning</td>
<td>Objective exercise capacity</td>
<td>Maximal symptom limited exercise tolerance test.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For patients with heart failure: completed with a spiroergometry (VO2max) test [43].</td>
</tr>
<tr>
<td></td>
<td>Subjective exercise capacity</td>
<td>MacNew Quality-of-Life questionnaire (27 questions) [44,45]</td>
</tr>
<tr>
<td>2. Psychological functioning</td>
<td>Emotional function</td>
<td>MacNew Quality-of-Life questionnaire (27 questions) [44,45]</td>
</tr>
<tr>
<td></td>
<td>Anxiety and Depression</td>
<td>Option 1: Generalized Anxiety Disorder scale (GAD-7, 7 questions) [46] in combination with the Patient Health Questionnaire (PHQ-9, 9 questions) [47]</td>
</tr>
<tr>
<td></td>
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<td>Option 2: Beck Anxiety Inventory (BAI, 21 questions) [48] in combination with the Beck Depression Inventory (BDI, 21 questions) [49]</td>
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<td>Option 3: Hospital Anxiety and Depression Scale (HADS, 14 questions) [50]</td>
</tr>
<tr>
<td>3. Social functioning</td>
<td>Social function</td>
<td>MacNew Quality-of-Life questionnaire (27 questions) [44,45]</td>
</tr>
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<td></td>
<td>Social support</td>
<td>Option 1: Multidimensional Perceived Social Support Scale (MPSSS, 12 questions) [51,52]</td>
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<tr>
<td></td>
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<td>Option 2: ENRICH Social Support Inventory (ESSI, 7 questions) [53]</td>
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<td></td>
<td>Life Partner</td>
<td>Clinical interview (3 questions)</td>
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<td>Resumption of work</td>
<td>Clinical interview (10 to 18 questions)</td>
</tr>
<tr>
<td>4. Cardiovascular risk profile</td>
<td>Cardiovascular risk profile</td>
<td>Physical examination (obesity, blood pressure), blood testing (cholesterol and diabetes)</td>
</tr>
<tr>
<td>5. Lifestyle factors</td>
<td>Smoking status</td>
<td>Clinical interview (1 to 4 questions) and specific treatment advice</td>
</tr>
<tr>
<td></td>
<td>Physical activity</td>
<td>Monitor ‘Physical activity and Health’ (4 questions) [54]</td>
</tr>
<tr>
<td></td>
<td>Dietary habits</td>
<td>Individual screening by dietician (in case of hypertension, hypercholesterolemia, obesity, or diabetes)</td>
</tr>
<tr>
<td></td>
<td>Alcohol consumption</td>
<td>Five Shot questionnaire (5 questions) [55,56]</td>
</tr>
</tbody>
</table>
Inclusion criteria (patient level) - All consecutive CR patients that undergo the needs assessment procedure in one of the participating clinics will be included in the study. Clinics that participate in the study agree to enter all data of these patients in their EPR.

Recruitment
To promote participation and avoid volunteer effects, all CR clinics that use an EPR with CDS will receive a written invitation and, when they agree, will be visited by a member of the CARDSS team. During this introduction, the study protocol is explained to all team members, including the manager and cardiologist. Furthermore, the study is announced at national meetings of professional CR associations and during the 2-yearly national CR conference (visited by more than 350 professionals). After agreement on participation, the responsible administrator of the CR department (often the manager or the executive board of the hospital) must sign a consent form to formalize the organization’s commitment.

Outcome measures
As in most guideline implementation studies, the proposed intervention is targeted at health care providers and is therefore expected to have a direct effect on process outcomes and to have only indirect, long-term effects on patient outcomes. The primary outcome measure will therefore be concordance, at patient level, to national CR guidelines with respect to the needs assessment (concordance of clinical decisions with the guidelines, for four group-based therapies). We will measure whether patients are treated according to the recommendations of the guidelines (i.e., treating patients who should have been treated and not treating patients who should have been untreated).

Secondary outcome measures are changes in performance of participating clinics as measured by 18 quality indicators for CR (see Table 2) and changes in practice variation on these indicators. Table 1 describes how the indicator set was developed [24].

Data collection and validation
During the trial, participating CR clinics will use one of the two available commercial EPR systems with CDS. Each month, participating clinics are requested to extract data from their EPR, and submit it to the CARDSS Online system. After submission, the data are checked for validity and imported to the CARDSS Online database.

To measure data quality and completeness, a data audit will be conducted in each participating clinic at the end of the trial. To do so, we will ask access to an independent, local data source (preferably a digital agenda listing appointments for all therapies offered to CR patients). First, we will use this data source to check if our registration of therapies is correct, i.e., whether these therapies were indeed attended by the patient. To this end, 20 patients randomly selected from our database will be looked up in the independent data source. Second, we will use this source to check if our database is complete, i.e., whether all data of CR patients treated at the clinic also exist in our database (no missing patients). Therefore, 20 patients
randomly selected from the independent source will be looked up in our database. When no independent data source is available, we will ask the clinic in question to interview ten randomly selected patients over the telephone about the therapies they have followed and to check if their answers match our database. Thereafter, we will ask the clinics if we can interview ten randomly selected patients during a therapy session to see if their data is present in our database and if the therapy programs match.

If two or more of the selected patients from the independent source cannot be found in our database or if discrepancies in therapeutic data exist in more than five records, we will consider all the data of the clinic in question to be unreliable and exclude that clinic from the analyses.

Sample size
To calculate the minimally required number of CR clinics participating in the trial, data from a previous trial (concerning the effect of CDS on guideline concordance) was used [7]. Calculations were based on the normal approximation to the binomial distribution, using a type I error risk (alpha) of 5% and 80% power. Also, we assumed that participating clinics will see 350 CR patients, on average, during the study period of 1 year, and that there will be a design effect of 23.0 due to clustering. This is based on an intra-cluster correlation coefficient (ICC) of 0.063, which is the median ICC for process variables found in 21 studies, reported by Campbell et al. [57].

In the previous study [7], CDS increased concordance with guideline-recommended therapeutic decisions for exercise training from 84.7% to 92.6%. To demonstrate a further increase to 97.6% (+5%) in the current study, at least 19 participating clinics (6,712 patients) are required under the assumptions given. For education, the concordance level previously rose from 63.9% to 87.6%. Demonstrating a further increase to 95.1% (+7.5%) requires 14 participating clinics (5,057 patients). For relaxation therapy, the previous study showed an increase from 34.1% to 59.6%, and showing an additional increase to 74.6% (+15%) requires ten participating clinics (3,517 patients). For lifestyle change therapy, finally, no significant effect of CDS was observed in the previous study (57.4% vs. 54.1%). To prove that the current intervention causes an increase from 57.4% to 72.4% (+15%) will also require that 13 clinics (3,632 patients) participate. Based on these results, we aim to include at least 19 CR clinics in our study.

Randomization and allocation
We will randomly allocate CR clinics (clusters) to one of the both study arms, stratified by the number of patients per month entering the CR program: small (up to 30 patients) versus large (30 patients or more). Allocation is based on randomization with variable block size (two or four), performed with dedicated computer software written in the statistical programming language R (version 2.13.1). To conceal allocation, the software is used to generate a list of unique codes for both strata, where each code corresponds to an allocation (study arm A or B).
Three researchers will be involved in the allocation procedure. When a clinic is willing to participate, the first researcher (MvEV) will determine its stratum and communicate that to a second researcher (NdK) (without naming the clinic involved). The second researcher will look up the next unique code on the list for this stratum and pass that code to a third researcher who can determine the study arm, based on the given code. Using this procedure, both the second and third researchers are fully blinded for the allocation of clinics to the study arms during the procedure. The first researcher is not blinded but can however during this procedure not influence the allocation. Due to the characteristics of the intervention, it will not be possible to blind participants or the investigators providing the intervention.

**Statistical analysis**

For the primary outcome measures, we will use mixed-effect logistic regression analysis [7,58], including clinic as random effect, to assess the effect of the intervention. Included covariates will be study arm, time since study start, and time × arm interaction. We will focus on the interaction term to assess the difference in change over the study period between the two arms—that is, the effect of the intervention—because we expect concordance to improve gradually.

For the secondary outcome measures, a similar analysis will be conducted, though replacing the logistic function by another link function as appropriate. Changes in practice variation will be assessed by including a random coefficient for ‘time since study start’ in the regression model and comparing the variation in estimated quality scores before and after the study.

**Process evaluation**

The quantitative trial results will be completed by a qualitative process evaluation to assess experiences with the implementation of our intervention from participating CR clinics. To this end, we will employ a semi-structured qualitative research method known as concept mapping [59]. This method typically consists of the following five steps: In the first step (preparation), the research team decides on an open-ended focus question. In our study, this will likely be a question such as ‘Which circumstances facilitate systematic QI with CARDSS Online in your clinic?’ In the second step (generation), representatives of the QI teams of participating clinics meet in focus group sessions (six to eight persons) and are asked to develop a set of statements that address the focus. We note that the concept-mapping method does not require that consensus is sought during the focus group sessions; the participants may disagree and conflicting statements may come out. In the third step (structuring), all QI team members of participating clinics are asked to structure the statements from the previous step by grouping them into categories that make sense to them and by rating them by importance and feasibility. In our study, this step is conducted over the internet with dedicated software (Concept Systems software version 4.0 [60]). During the fourth step (representation), an analysis algorithm implemented in the same software takes the collected grouping and rating data and generates a visual conceptual map using multidimensional scaling and hierarchical cluster analysis. In the fifth step (interpretation), labels and interpretations for the various parts of the map are developed.
Ethics
The Institutional Review Board (IRB) of the Academic Medical Center (Amsterdam, the Netherlands) waived formal IRB approval. Our study database is registered according to the Dutch Personal Data Protection Art. In January 2012, the study was registered under the acronym ‘CARDSS-II trial’ in the Dutch Trial Register (NTR3251) [61].

DISCUSSION

Study aim and hypothesis
The aim of this cluster randomized trial is to assess the effectiveness of a web-based QI system with indicator-based performance feedback and educational outreach visits to overcome organizational barriers for guideline concordance in multidisciplinary teams in the field of CR in the Netherlands. As the study will be conducted in CR clinics already using an EPR with CDS at the point of care, the intervention is compared to receiving this EPR with CDS alone. We hypothesize that our intervention will enable multidisciplinary CR teams to successfully target organizational barriers to improving guideline concordance. The results of this study are expected in 2015.

Strengths and limitations
A unique feature of our study is that we provide performance feedback within a web-based system that incorporates all important QI concepts. The system supports local QI teams to follow all steps of the QI process (monitoring indicator-based performance; selecting aspects of care which need improvement and developing a QI plan), resulting in explicit improvement goals with concrete actions and a time schedule. The outreach visits further increase active involvement in the process as the teams are encouraged to regularly meet and to specify goals they see as importantly attainable. To our knowledge, this is the first study to rigorously evaluate the effect of such an intervention in multidisciplinary teams. Second, we developed our multifaceted intervention based on an extensive analysis of barrier (see Box 1). During this analysis, persisting organizational barriers in the field of CR were revealed after the introduction of an EPR with CDS. We tailored and pilot-tested our intervention to specifically address these barriers during educational outreach visits with the multidisciplinary CR teams. During the visits, we specifically involved their managers in the discussion on the performance feedback and the implementation of QI actions. Third, we optimized agreement of CR professionals with the indicator set. This set was developed based on national guidelines and evidence from international literature and in close collaboration with representatives from all disciplines involved in CR [24] in the Netherlands. Fourth, as participating clinics are already working with the EPR with CDS functionality, they do not need to change their workflow for data collection and participation in the study. Finally, by using a balanced block-design with both study arms receiving part of the intervention, we minimize the risk that clinics lose their motivation to participate. We expect that this, in combination with the minimal workflow disruption, will
maximize CR clinics’ willingness to participate and to minimize loss to follow-up.

Our study design also has some limitations. First, only CR clinics that use an EPR with CDS that facilitates registration of our minimal dataset are eligible to participate. Second, these clinics should be willing to dispose their data for research and to allocate resources to set up a QI team (volunteer bias). These two criteria may lead to the selection of a non-representative sample of CR clinics because eligible clinics are less likely to be understaffed and more likely to have information technology support to facilitate routine collection of CR data. The generalizability of our results will thus be limited to CR clinics that are motivated and equipped to systematically monitor and improve the quality of care they deliver. The essence of our intervention is that QI teams are free to formulate any improvement action, including those not specifically targeted at improving concordance to a specific guideline recommendation. Although this maximizes the involvement of the team in the improvement process and the commitment to goal attainment, it weakens the link between our intervention and primary outcome measure. By measuring changes in performance on the entire set of quality indicators as a secondary outcome, we aim to assess the direct relation between our intervention and performance changes. However, as is common in guideline implementation studies, these performance changes will only have indirect, long-term effects on patient outcomes. Fourth, the block randomization might cause underestimation of the effect size as clinics might start to improve both CR domains and not just the domain covered in their study arm because the intervention has raised their awareness for QI. Finally, the feedback on quality indicators will not automatically be corrected for differences in patient mix. However, during the trial, participating clinics can always request additional analyses on their data like, e.g., correction for patient mix to interpret their quality indicator results.

Potential implications for practice and future research

Our study has both potential implications for practice and future research. First, it provides a better understanding of factors facilitating implementation of guidelines in multidisciplinary care teams. The results of our study may inform similar initiatives in other medical domains on how to use indicator-based performance feedback and outreach visits for improving the quality of care.

Second, it may influence the practice of CR and secondary prevention of cardiovascular disease in the Netherlands. The Dutch Health Care Inspectorate has recently demanded CR clinics to improve the quality of their programs based on the results of a quality assessment under all CR clinics in the Netherlands [42]. When our intervention appears to be successful, the Netherlands Society of Cardiology (NVVC) may decide to promote a national implementation of our intervention to meet the Inspectorate’s demand. In addition the process evaluation may result in valuable pointers to take into account when continuing the intervention. As such, the results of the study are relevant for all health care professionals and their organizations involved in cardiac aftercare in the Netherlands.
Finally, the results will guide future research that aims to identify success factors of feedback interventions. Our web-based QI system incorporates indicator-based performance feedback with involvement of multidisciplinary QI teams in developing and monitoring a local QI plan with explicit goals and is supported by educational outreach visits. Quantifying the effect of our intervention together with the qualitative data from the process evaluation will contribute to knowledge on potential barriers to using indicator-based feedback for improving the quality of care and how they can be overcome effectively.

AUTHORS’ CONTRIBUTIONS

NP, NdK, and MvEV had the basic idea for this study and were involved in the development of the protocol. MvEV, NP, NdK, and SvdV drafted the manuscript. NP planned the statistical analyses. All authors were involved in the critical revision of the paper for intellectual content and its final approval before submission. All authors read and approved the final manuscript.

ACKNOWLEDGEMENTS

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The study setup was funded by ZonMw, the Netherlands Organization for Health Research and Development. The project is known as ZonMw project number 170883002. This study execution is funded by the Department of Medical Informatics, Academic Medical Centre/University of Amsterdam, Amsterdam, The Netherlands (internal funding).
APPENDIX I

Rules to set icon colors in CARDSS Online

- Structure (yes or no) indicators: The value ‘yes’ is considered acceptable (green), the value ‘no’ borderline (orange) if less than 50% of all clinics has yes, and poor (red) if more than 50% has yes.

- Frequency indicators (percentages): The interpretation is depending upon the mean value of all clinics. If this mean value is less than 66%, a value above 66% is considered acceptable (green); a value between 33% and 66% or a value up to 10% less than the value of all clinics is considered borderline (orange); and all other values are considered poor (red). If the mean value off all clinics is above 66%, a value up to 10% less than the value of all clinics is considered acceptable (green); a value above 33% is considered borderline (orange); and all other values are considered poor (red).

- Numeric non-frequency indicators (e.g., average increase in exercise capacity before and after the rehabilitation): Thresholds were determined by consulting the prevailing guidelines where possible, and otherwise based on observed distributions in previous studies or determined by consulting clinical experts. Also they depend on the mean value of all clinics. For instance, an average increase in exercise capacity above 10% is considered acceptable (green) if the mean value of all clinics is not above 20%; between 0% and 10% as borderline (orange) if the mean value of all clinics is not above 20%; and all other values, e.g., a decrease in exercise capacity, are considered poor (red).
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IMPROVING GUIDELINE CONCORDANCE IN MULTIDISCIPLINARY TEAMS: PRELIMINARY RESULTS OF A CLUSTER-RANDOMIZED TRIAL EVALUATING THE EFFECT OF A WEB-BASED AUDIT AND FEEDBACK INTERVENTION WITH OUTREACH VISITS

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ABSTRACT

Despite their widespread use, audit and feedback (A&F) interventions show variable effectiveness on improving professional performance. Based on known facilitators of successful A&F interventions, we developed a web-based A&F intervention with indicator-based performance feedback, benchmark information, action planning and outreach visits. The goal of the intervention was to engage with multidisciplinary teams to overcome barriers to guideline concordance and to improve overall team performance in the field of cardiac rehabilitation (CR). To assess its effectiveness we conducted a cluster-randomized trial in 18 CR clinics (14,847 patients) already working with computerized decision support (CDS). Our preliminary results showed no increase in concordance with guideline recommendations regarding prescription of CR therapies. Future analyses will investigate whether our intervention did improve team performance on other quality indicators.
INTRODUCTION

The widespread uptake of electronic patient records (EPRs) provides unprecedented opportunities to monitor clinical performance and improve care quality. As such, audit and feedback (A&F) interventions based on interrogating EPR databases are increasingly used to aid health care professionals in improving their performance. A&F provide care professionals with an objective summary of their clinical performance over a specified period of time [1]. Yet despite their expanded use, A&F interventions show variable effectiveness on improving quality of care. A recent Cochrane review of 140 randomized trials of A&F interventions reported a median 4.3% absolute improvement (interquartile range 0.5% to 16%) in quality of care, with a quarter of the studies showing a strong positive effect, but with another quarter showing a negative or null effect [1].

Previous studies have attributed much of the observed variability in effect of A&F interventions to feedback design characteristics and contextual factors. They suggested A&F to be most effective if baseline performance is low, when feedback is provided by a supervisor or colleague, more than once, both verbally and in writing, and when it includes explicit targets and an action plan [1-4]. Furthermore, the effect of indicator-based performance feedback is likely to be stronger when it is combined with educational meetings [1]. Other suggested effect modifiers are the perceived quality of the data underlying the feedback, motivation and interest of the recipient, organizational support for quality improvement (QI), and how performance targets or benchmarks are derived [5]. Besides these literature results we had a conjunctional expectancy based on the actuality that modern medicine, including the care for chronically ill patients, is not just a matter of individual professionals but largely the responsibility of multidisciplinary teams embedded in complex organizations. Therefore we expected that, specifically in chronic disease management, engaging the entire multidisciplinary teams and their managers in the QI process is an important success factor of A&F interventions [6]. We developed a multifaceted A&F intervention that both incorporates successful characteristics described in the literature [1-5] and that is specifically directed at multidisciplinary teams [7]. It comprises the use of a web-based system that provides periodic performance feedback with benchmark comparisons and support for concrete QI action planning. In combination with educational outreach visits the systems facilitates active team engagement in improving their performance [8].

We implemented our intervention in the field of cardiac rehabilitation (CR) in the Netherlands. Within this field an EPR system with computerized decision support (CDS) functionalities was previously developed to stimulate concordance with guideline recommendations for the patient tailored CR program [9]. Although the CDS has proven to be effective [10], there remained considerable non-concordance due to a lack of resources and other organizational constraints [11]. Further improvement of guideline concordance required organizational and procedural changes that individual users considered to be beyond their own tasks, influence and responsibilities. Use of the CDS system alone was insufficient for inciting users to involve decision makers at team and organizational level to realize those changes [11]. This finding
stressed the need for an intervention specifically directed at the decision-making processes at these levels to create the necessary conditions and resources for further improving guideline concordance. Hence, guideline concordance was one of the targeted behaviors of our A&F intervention.

We performed a multicenter cluster randomized trial to assess the effect of a multifaceted A&F intervention on clinical performance of multidisciplinary teams in the field of CR. In this paper we present preliminary results regarding the intervention’s effect on concordance of CR therapies with guideline recommendations.

METHODS

Setting: cardiac rehabilitation and computerized decision support
CR is a therapy provided by multidisciplinary care teams to support cardiac patients recovering from a cardiac incident or intervention on both the physical and psychosocial domain [12, 13]. CR is recommended for all patients who have been hospitalized for an acute coronary syndrome (ACS) and for those who have undergone a cardiac intervention [12, 14]. A meta-analysis shows consistent evidence of the effectiveness of exercise-based and multimodal (e.g., psychosocial and stress management) CR interventions with regard to mortality and prevention of future cardiac events (relative-risk reduction 21–47%) [15]. CR teams usually include cardiologists, physical therapists, nurses, psychologists, dieticians, social workers, and rehabilitation physicians. However, in many Western countries, CR services are under-utilized and poorly standardized and do not follow the available scientific evidence [16]. A recent study in the Netherlands shows that only a minority of patients eligible for CR actually receive it [17]. The CR uptake rate was 28.5% among patients with an ACS and/or intervention.

Consistent with international standards, the Dutch Guidelines for CR [18] state that professionals should conduct an extensive needs assessment procedure (NAP) where 80 to 130 data items concerning the patient’s medical, physical, psychological, and social condition and lifestyle are gathered. Based on this procedure, a patient-tailored rehabilitation program should be prescribed which can contain up to four group-based therapies: two psychosocial therapies (disease-specific education; lifestyle modification) and two physical therapies (exercise training; relaxation and stress management training), and can be supplemented by individual counselling (e.g., by a psychologist, dietician or social worker) when needed. In the Netherlands, there are two commercial vendors of EPR systems with CDS for CR (referred to as EPR1 and EPR2) that can be used for data collection. Both systems are based on the Dutch guidelines for CR [18] and follow the same data model. They guide their users through the NAP and provide advice for the decision about each out of the four considered CR therapies for the prescribed CR program [19]. However, one of the EPRs is a stand-alone product in which, based on results of usability evaluation of a beta version of the system [20], the data entry navigational structure is organized flexible around an overview screen. Complete data collection is stimulated by showing users which steps of the NAP they already have finished and which steps they still need...
to complete. The other system is integrated into the hospital EPR from one vendor and offers a more straightforward data entry structure. This system does not provide feedback on finished NAP steps. After data collection in both systems, the patient specific CDS advice is discussed with the patient. Thereafter the prescribed CR program, including the decisions for each out of the four CR therapies (which can deviate from the CDS advice), are recorded in the EPR. While we focus on prescribed therapies in this study, we note that there are sometimes discrepancies between prescriptions and therapies that are actually received by patients. After participation in the program (which typically lasts for 6-12 weeks), patient are reassessed to determine results.

**Study design**
The effect of the intervention was evaluated in a multicenter cluster-randomized study in which each CR clinic received the A&F intervention, but its contents were randomly limited to one of two complementary domains that jointly constitute CR: the psychosocial domain (disease-specific education; lifestyle modification) or the physical domain (exercise training; relaxation and stress management training). In this way, both study arms served as each other’s control, and we minimized the risk of clinics dropping out of the study because they did not receive any intervention. Cluster-randomization was chosen to avoid contamination among professionals within the same clinic. We refer to the study protocol for further details of the experimental design [7].

**Eligible CR clinics and patients**
All CR clinics that used an EPR with CDS during the NAP and that were willing to share their data for research and to set up a local QI team were eligible to participate in the study. There were 91 CR clinics in the Netherlands, the majority affiliated with hospitals [21]. Twelve clinics were located in specialized rehabilitation clinics [21], which have regional functions and can treat both simple and more complex referred patients. All types of clinics were eligible to participate in the study, provided that they worked with either one of two commercial EPR systems for CR that could be used for data collection for our study. During the inclusion period of the trial from July 2012 until December 2013, this was the case for 22 clinics. The study dataset consisted of (i) patient identification data (31 items), (ii) CR needs assessment data (80–130 items), (iii) data on selected rehabilitation goals and therapies (79 items), and (iv) CR evaluation data (105 items). All consecutive CR patients that underwent the NAP in one of the participating clinics during the study period were eligible for enrollment in the study. Clinics that participated agreed to enter all data of these patients in their EPR.

**Intervention**
Our multifaceted A&F intervention was provided through a web-based system, called CARDSS Online [8]. When designing the intervention we followed the A&F literature which underlines the importance of combining periodic performance feedback with benchmark comparisons, action planning with concrete, self-formulated goals, and educational outreach visits to actively involve
care professionals in a continuous QI process. To this end CARDSS Online supports four tasks: 
(i) monitoring of indicator-based performance by means of quarterly feedback reports including 
benchmark information, (ii) selecting indicators for QI that are locally perceived as important and 
upon which improvement is deemed feasible, (iii) developing a QI plan consisting of QI goals 
and concrete actions to accomplish these goals, and (iv) during follow-up iterations updating 
the QI plan based on new performance measurements and experiences with executing the QI 
actions in practice. Benchmark comparisons were summarized by a colored icon next to each 
indicator score which depicted whether the performance was acceptable (green checkmark), 
borderline (yellow checkmark), or poor (red exclamation mark). The benchmark comparisons 
were based on the clinic’s performance score and the average score across all clinics (details 
available in [7]).

Educational outreach visits were held following each feedback report. During these 
visits CARDSS Online was used to guide the clinics’ local QI teams through the process of 
systematically defining, implementing and monitoring QI actions. The QI teams consisted of 
at least one local CR coordinator (usually a specialized nurse), one professional from another 
discipline (e.g. a physical therapist), their manager and the responsible cardiologist. The visits 
were chaired by an investigator (MvEV) who supported the QI team with interpretation of the 
feedback and drafting (or during follow-up visits monitoring and updating) a concrete QI plan. 
Indicators were included in the plan based on the benchmark information and discussion on 
importance, feasibility, and expected time needed to improve. For each quality indicator, the QI 
team could specify the problem, presumed causes, improvement goal, and concrete actions on 
how to reach that goal. If clinics agreed upon extended participation after the minimum study 
period of one year (comprising of four A&F iterations), they received up to two more quarterly 
feedback reports in combination with telephone support rather than a face-to-face visit.

We previously developed a set of eighteen primary quality indicators to provide 
performance feedback in our system [22]. This was done in close collaboration with an expert 
panel (representatives from all disciplines involved in CR) and patient panel, using a modified 
RAND method [22]. Results from both panels were combined with results from a literature 
search and guideline review in an extensive rating and consensus procedure. The expert panel 
did not select concordance of prescribed therapies with the guidelines as one of the eighteen 
primary quality indicators. However, the tailoring of CR programs to individual needs of patients 
is an important quality theme in CR, and indirectly reflected by many indicators that were 
chosen. Furthermore, we did include concordance of prescribed therapies with the guidelines 
in the feedback reports, which enabled QI teams to include improvement actions aimed at 
guideline concordance in their QI plans. Besides results on indicators and concordance, the 
feedback also included patient characteristics (e.g. age and diagnosis), information referring 
to general processes (e.g. time between discharge and NAP) and structures (e.g. presence of 
patient satisfactory research) to reduce the risk of attrition.
Outcome measurement
Our intervention was targeted at health care professionals and was therefore expected to have a direct effect on process outcomes but only an indirect, long-term effect on patient outcomes. The outcome measure was therefore concordance to national CR guidelines regarding the CR program that was prescribed during the NAP. We defined concordance at the level of the patient; it implied prescribing therapy to patients who should be treated and not prescribing therapy to patients who should be untreated, according to the guidelines. This was determined for each of the four group-based therapies separately.

Cluster randomization and allocation
Randomization of CR clinics was stratified by size (more/less than 30 patients starting CR per month). Per stratum, we generated a randomization scheme with randomly assigned block sizes of either two or four CR clinics using dedicated software. This scheme was concealed to those enrolling and assigning CR clinics [7]. Due to the character of the intervention, it was not possible to blind participants or those involved in providing the intervention.

Statistical analysis
For each of the four CR therapies (education, lifestyle modification, exercise training, and relaxation training) we performed a separate mixed-effect logistic regression analysis [10, 23] to assess the effect of the intervention on concordance with guideline recommendations. To this end we included covariates study arm, time, and the interaction between study arm × time. We focused on the interaction term to assess the difference in change over the study period between the two arms—that is, the effect of the intervention—because we expected concordance to improve gradually. We used random effects to model the variation in baseline concordance between clinics (random intercept for each clinic) and the variation in change in concordance over time (random slope for time). To adjust for differences in case mix between the study arms, we included in our analysis three patient level variables (age, sex, and indication for CR) and two clinic level variables (weekly volume of new patients, and whether the clinic is a specialized rehabilitation center or part of a university or teaching hospital) as covariates.

Patients who were seen in the last month of a clinic's study period were excluded from the analysis because their prescription data was often not yet complete. We also excluded patients for whom the indication for CR was missing. Furthermore, for each of the four analyses of guideline concordance on specific CR therapies we excluded patients for whom it could not be determined whether the prescription of that therapy concordant with the guideline (either because the guideline's recommendation or the actual prescription could not be determined).
RESULTS

Participants
Of the 22 eligible CR clinics 18 clinics accepted our invitation to participate in the trial, of which twelve clinics were assigned to intervention arm A (receiving multifaceted A&F intervention on psychosocial therapies), and six to arm B (receiving intervention on physical therapies) (see Figure 1). CR clinics were enrolled in the study between July 2012 and December 2013. On average, the time between randomization and the first educational visit was 3.5 months (standard deviation [SD] 0.7). The average time between subsequent visits was 4.0 months (SD 1.4). Table 1 shows the baseline characteristics of clinics and patients. During the study period a total of 14,847 patients were seen for a NAP in the participating CR clinics. After exclusions in the overall database 11,932 patients were included for the analyses on concordance per CR therapy. The analyses were performed on data from 10,730 (education), 10,774 (lifestyle modification), 10,953 (exercise training), and 8,804 (relaxation training) patients.

Figure 1 – Flow diagram of CR clinics through the trial.
Table 1 – Baseline characteristics of clinics (N=18) and patients (N=11,932) per study arm; values are numbers (%), unless indicated otherwise.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Arm A (A&amp;F on psychosocial domain)</th>
<th>Arm B (A&amp;F on physical domain)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number participating</td>
<td>12 (66.6)</td>
<td>6 (33.3)</td>
</tr>
<tr>
<td>Median (min-max) number of patients per year</td>
<td>431 (183–1,156)</td>
<td>370 (256–988)</td>
</tr>
<tr>
<td>Stratum ‘large’ (&gt;30 patients monthly starting CR)</td>
<td>6 (50.0)</td>
<td>3 (50.0)</td>
</tr>
<tr>
<td>Use of EPR1</td>
<td>9 (75.0)</td>
<td>1 (16.7)</td>
</tr>
<tr>
<td>CR outpatient clinic type:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-teaching hospital</td>
<td>7 (58.3)</td>
<td>3 (50.0)</td>
</tr>
<tr>
<td>Teaching hospital</td>
<td>2 (16.7)</td>
<td>3 (50.0)</td>
</tr>
<tr>
<td>University hospital or specialized rehabilitation center</td>
<td>3 (25.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number included in analyses</td>
<td>7,692</td>
<td>4,240</td>
</tr>
<tr>
<td>Mean (SD) age in years</td>
<td>64.9 (11.4)</td>
<td>65.8 (11.8)</td>
</tr>
<tr>
<td>Male gender</td>
<td>5,533 (71.9)</td>
<td>3,027 (71.4)</td>
</tr>
<tr>
<td>Indications for CR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACS with revascularization</td>
<td>4,446 (57.8)</td>
<td>2,489 (58.7)</td>
</tr>
<tr>
<td>ACS without revascularization</td>
<td>440 (5.7)</td>
<td>386 (9.1)</td>
</tr>
<tr>
<td>Elective CABG or valvular surgery</td>
<td>1,262 (16.4)</td>
<td>598 (14.1)</td>
</tr>
<tr>
<td>Elective PCI</td>
<td>517 (6.7)</td>
<td>321 (7.6)</td>
</tr>
<tr>
<td>Other elective interventions</td>
<td>341 (4.4)</td>
<td>113 (2.7)</td>
</tr>
<tr>
<td>CHF or stable AP, no intervention</td>
<td>252 (3.3)</td>
<td>179 (4.2)</td>
</tr>
<tr>
<td>Other diagnosis, no intervention</td>
<td>434 (5.6)</td>
<td>154 (3.6)</td>
</tr>
</tbody>
</table>

Abbreviations: A&F= audit and feedback, ACS= acute coronary syndrome, AP= angina pectoris, CABG= coronary artery bypass graft surgery, CHF= chronic heart failure, CR= cardiac rehabilitation, EPR= electronic patient record, PCI= percutaneous coronary intervention, QI= quality improvement, SD= standard deviation.

Implementation of the intervention

Table 2 shows detailed information on how, and to what extent, the main components of the A&F intervention were implemented in the participating clinics. Due to limited availability of the QI team, one clinic in arm A completed only three A&F iterations during the study period instead of four. There were no differences in QI team size, number of indicators selected as QI goal and number of actions per goal in the QI plan, attendance to the visits, and mean study period between the two study groups. Attendance to the visits remained the same during the study period. The mean number of selected QI goals in each QI plan decreased from 8.0 (SD 2.4) during the initial A&F iteration to 5.0 (SD 3.2) in the final iteration. QI teams in both groups reportedly resolved 1.8 of these QI goals per A&F iteration, on average.
Table 2 – Implementation of the multifaceted A&F intervention in daily practice per study arm; values are mean (SD) unless indicated otherwise.

<table>
<thead>
<tr>
<th>Implementation of the A&amp;F intervention</th>
<th>Arm A (A&amp;F on psychosocial domain)</th>
<th>Arm B (A&amp;F on physical domain)</th>
</tr>
</thead>
<tbody>
<tr>
<td>QI teams</td>
<td>Range</td>
<td>Range</td>
</tr>
<tr>
<td>Length of study period per clinic in months</td>
<td>19.8 (6.0)</td>
<td>12 – 30</td>
</tr>
<tr>
<td>Number of A&amp;F iterations</td>
<td>4.6 (1.0)</td>
<td>3 – 6</td>
</tr>
<tr>
<td>Size of local multidisciplinary QI team</td>
<td>7.5 (2.8)</td>
<td>3 – 13</td>
</tr>
<tr>
<td>Number of QI team members attending outreach visits</td>
<td>5.4 (1.9)</td>
<td>1 – 11</td>
</tr>
<tr>
<td>Number (%) of QI teams receiving first telephone follow-up</td>
<td>5 (41.7)</td>
<td>n.a.</td>
</tr>
<tr>
<td>Number (%) of QI teams receiving second telephone follow-up</td>
<td>3 (25.0)</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

**QI action planning**

| Number of indicators selected as QI goal in QI plan | 6.9 (3.1) | 1 – 14 | 6.3 (2.5) | 0 – 10 |
| Mean number of actions per QI goal in QI plan | 1.9 (0.5) | 1.0 – 3.3 | 1.6 (0.4) | 1.0 – 2.6 |
| Number of achieved QI goals per follow-up A&F iteration | 1.7 (1.5) | 0 – 5 | 1.9 (1.5) | 0 – 6 |
| Number of unachieved QI goals in final A&F iteration | 5.9 (3.5) | 1 – 13 | 3.5 (2.2) | 0 – 7 |

Abbreviations: A&F= audit and feedback, CDS= computerized decision support, CR= cardiac rehabilitation, n.a.= not applicable, QI= quality improvement, SD= standard deviation.

**Effect of the intervention**

Table 3 compares crude concordance rates between baseline (first three months) and follow-up (remaining time in the study period) for each of the four therapies. Despite random allocation of the participating clinics into two study arms, Chi-squared testing showed significant differences in baseline concordance for lifestyle modification (p<0.001), exercise (p=0.004), and relaxation training (p<0.001) between the two study groups. Table 3 also presents the results of the mixed-effect logistic regression analyses, which compare the trend in concordance over time between intervention and control groups while adjusting for patient age, sex, and indication for CR and adjusting for clinic type and weekly patient volume. No significant differences were found for any of the four therapies. For three of the four therapies (education, lifestyle modification, and exercise training) there were few missing data (around 10%) with respect to recommended and prescribed care, but for relaxation training we found missing data in 26.2% of cases. This was due to six clinics having substantially lower data quality for the relaxation therapy. A sensitivity analysis in which we excluded these clinics from our dataset did not yield different results.
Table 3 – Concordance rates and difference in concordance between study arms for the four prescribed CR therapies (N=12,111).

<table>
<thead>
<tr>
<th>CR therapies</th>
<th>Crude concordance at baseline a)</th>
<th>Crude concordance at follow-up b)</th>
<th>Adjusted odds ratio (95% CI) c)</th>
<th>N (Clinics)</th>
<th>Missing values d)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td>Intervention</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>Psychosocial domain (A&amp;F intervention for arm A)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>87.5% (1,411/1,612)</td>
<td>81.2% (375/462)</td>
<td>90.4% (5,045/5,584)</td>
<td>71.3% (2,191/3,072)</td>
<td>1.28 (0.65 to 2.54)</td>
</tr>
<tr>
<td>Lifestyle</td>
<td>63.0% (1,023/1,624)</td>
<td>34.3% (155/452)</td>
<td>63.2% (3,548/5,610)</td>
<td>25.9% (800/3,088)</td>
<td>0.75 (0.14 to 4.03)</td>
</tr>
<tr>
<td>Physical domain (A&amp;F intervention for arm B)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise</td>
<td>82.6% (399/483)</td>
<td>89.9% (1,460/1,625)</td>
<td>83.6% (2,667/3,191)</td>
<td>95.1% (5,378/5,654)</td>
<td>0.58 (0.24 to 1.38)</td>
</tr>
<tr>
<td>Relaxation</td>
<td>38.8% (124/320)</td>
<td>72.6% (976/1,345)</td>
<td>51.6% (1,211/2,348)</td>
<td>82.5% (3,952/4,791)</td>
<td>0.4 (0.06 to 2.79)</td>
</tr>
</tbody>
</table>

Abbreviations: A&F= audit and feedback, CDS= computerized decision support, CI= confidence interval, CR= cardiac rehabilitation.

a) Observed concordance during first 3 months of study period.
b) Observed concordance after baseline period until end of study.
c) Odds ratio of improvement in guideline concordance after receiving the A&F intervention for 1 year versus no intervention; adjusted for patients’ age, gender, indication for CR, and clinics’ type and size.
d) Patients for whom the CDS could not provide advice caused by missing data and/or it was not recorded whether the therapy was included in the patients’ CR program.
DISCUSSION

Summary of findings
Our multifaceted A&F intervention did not increase concordance of prescribed CR therapies with guideline recommendations. There appeared to be a high variation in baseline performance and data quality between participation CR clinics. Especially for the relaxation training we had a high percentage of missing data on guideline concordance. Although our intervention facilitated active engagement of local multidisciplinary QI teams in setting their own performance improvement goals, the teams often did not succeed in completing the actions that were needed to achieve those goals.

Strengths and weaknesses of this study
The main strength of our study is that we designed our multifaceted A&F intervention based on both existing knowledge from the literature on effective characteristics of A&F interventions [1-5] and an extensive analysis of potential barriers to further increase guideline concordance in the field of CR [11]. The use of CARDSS Online combined with outreach visits actively involved local QI teams, including managers and cardiologists, in the improvement process. By the development and regularly update of a QI plan with concrete, self-formulated goals, we focused on the decision-making processes at the organizational level to create the necessary conditions for improving guideline concordance. Also, as participating clinics were already working with an EPR with CDS functionality, they did not need to change their workflow to participate in the study and collect data. This pragmatic aspect of our study design may have optimized CR clinics' willingness to participate and minimized the loss to follow-up. Although this resulted in a relatively large sample of CR clinics in which all different CR clinic types were represented, there were large differences in baseline performance between participants.

A limitation of our study is that only CR clinics that used an EPR with CDS that facilitates registration of our study dataset were eligible to participate. These clinics needed to be willing to share their data for research and to allocate resources to establish a QI team. This potentially resulted in a volunteer bias, as eligible CR clinics were less likely to be understaffed and more likely to have information technology to facilitate routine collection of CR data. The generalizability of our results may thus be limited to clinics that are motivated and equipped to systematically monitor and improve the quality of care they deliver. Second, the intervention allowed QI teams to formulate any improvement actions, even if those were not specifically targeted at improving concordance to a specific guideline recommendation. Although this may have optimized the engagement of the team in the improvement process and the commitment to goal attainment, it undermined the connection between the intervention and our primary outcome measure. This link was further diluted because the set of quality indicators chosen by the expert panel did not include guideline concordance for prescribed CR therapies as a separate indicator. However, we did include concordance statistics on each of the four therapies in our feedback reports. In addition, clinics might have started to improve both CR domains and not just the domain
covered in their study arm because the intervention has raised their overall awareness for QI. Last, sometimes there are discrepancies between prescriptions and therapies that are actually received by patients caused by e.g. quality of the content of therapies or patient motivation. The effect of our intervention on received rather than prescribed CR therapies might be different.

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

Our multifaceted A&F intervention included the development and revision (up to five times) of a QI plan based on indicator-based performance in quarterly feedback reports. Such iterative cycles and repeated use of data over time are generally considered key features to improve health care processes. However a recent systematic review of studies employing the plan-do-study-act method, showed that less than 20% of such studies use iterative cycles of change, and only 14% of them repeatedly use data over time [24].

Furthermore, the combination of A&F with both web-based guidance through the process of systematically developing a QI plan and outreach visits to encourage the local QI team to regularly monitor the feedback and update their plan, stimulated engagement of the QI team. Although this is a known characteristic of effective A&F interventions [1-5], other studies struggle with active engagement of health care professionals in goal setting and action planning to improve their performance [25-27]. Ivers et al [27] performed a qualitative study to understand the usefulness of A&F among family physicians and examined barriers to using it to improve quality of care. Their main findings address some general concerns during implementation of A&F interventions to improve professional performance. Participants reported that the feedback increased their awareness of gaps between ideal and actual performance. This resulted mainly in efforts to “try harder” patient by patient. Key barriers to acting upon feedback in a systematic manner included a perceived discordance between population-level quality targets and patient-centered care (“It [A&F] talks about whole populations as opposed to the one individual and I think my approach to this job is the one person at a time”), as well as competing priorities at both the patient and organizational levels (“How much time do you want your doctor devoting to that [A&F], because the more … the less time I am [devoting] to the patient”). A qualitative analysis which is currently underway should point out if similar barriers were present during the implementation of our multifaceted A&F intervention.

**Meaning and implications of findings**

Further analyses should point out whether participating clinics were able to improve their performance on individual quality indicators, and whether this was related to the selection of these quality indicators in QI plans and to achieving self-formulated improvement goals. If there was indeed improvement on individual indicators, the failure to achieve progress in concordance of prescribed CR therapies with guideline recommendations is probably due to a poor link between these indicators and guideline concordance of therapeutic prescriptions. If there is no improvement on individual indicators, then our A&F intervention has simply failed to stimulate clinicians to work on QI actions outside their daily routine. The large number of unattained QI
goals (Table 2) points in this direction.

According to Ancker et al [28] the evaluation of health information systems, like our web-based A&F intervention, often show mixed results. This may be in part attributable to the evaluation frameworks used. They developed a model for evaluation, named the Triangle Model, in which they emphasize the sociotechnical view that organization, technology, and users influence and change each other during implementation processes. The lack of success of our web-based A&F intervention might not have only depended on the technology used but also on the organizations and professionals involved. Similarly, the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) framework [29] emphasizes that a thorough needs analysis should be performed to determine organizational readiness before initiating change. This might uncover underlying issues within the institution (e.g. equipment problems or staffing shortages) which first should be resolved to make the QI effort succeed [29]. Also the Systems Engineering Initiative for Patient Safety (SEIPS) model [30] presents a broad approach with a focus on system design and its impact on processes and outcomes. This model describes the structure of a health care organization as a work system with five components (person, tasks, tools and technologies, physical environment, organizational conditions) who interact with each other and affect both work (e.g. maintenance and supply chain management) and clinical care processes. Both processes in turn influence the patient, employee, and organizational outcomes of care [30]. Capturing more detailed predictor variables about the technology, users, and the surrounding context might have increased the ability to interpret our findings of process variables (e.g. organization – professional processes such as culture and workflow [28]) during the evaluation of our intervention.

Future work

Although A&F interventions are increasingly used to aid health care professionals in improving their performance, they might not qualify as the best basis for improving concordance of prescribed therapies with guideline recommendations. Our future work will include results on the intervention’s effect on concordance of the received CR therapies with guideline recommendations, as well as results on team performance (the intervention’s effect on all quality indicators); and results of a qualitative process evaluation. During this evaluation we use the concept mapping methodology (including focus group sessions) to explore experiences from participating CR clinics with the intervention to gain insight into barriers and facilitators of the implementation.
CONCLUSION

A web-based A&F intervention with outreach visits did not increase concordance of prescribed CR therapies with guideline recommendations in a pragmatic evaluation using EPRs for data collection. There appeared to be a high variation in baseline performance and in data quality among participating CR clinics. Although QI teams in the clinics formulated QI goals and associated actions at the start of each quarterly A&F iteration, most goals were not attained. We recommend to align data registration in participating clinics before starting an A&F intervention that uses EPRs for data collection. Future analyses should show whether our intervention did improve the overall CR team performance measured by change in quality indicators results, complemented with qualitative information on factors which influenced the implementation of the A&F intervention.
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EFFECT OF A WEB-BASED AUDIT AND FEEDBACK INTERVENTION WITH OUTREACH VISITS ON CLINICAL PERFORMANCE OF MULTIDISCIPLINARY TEAMS: A CLUSTER-RANDOMIZED TRIAL IN CARDIAC REHABILITATION

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Submitted for publication
ABSTRACT

Objective: To assess the effect of a web-based audit and feedback (A&F) intervention with outreach visits to support decision making by multidisciplinary teams.

Design: Multi-centre cluster-randomised trial.

Setting: Comprehensive cardiac rehabilitation (CR) in the Netherlands.

Participants: Multidisciplinary teams in Dutch CR centres. Teams were enrolled in the study between July 2012 and December 2013 and received the intervention for at least one year.

Intervention: Teams received a web-based A&F intervention with feedback on clinical performance; facilities for goal setting and action planning; and educational outreach visits. Teams were randomised to either receive feedback that was limited to psychosocial rehabilitation (study group A) or to physical rehabilitation (study group B).

Main outcome measure: Difference in performance between study groups in eleven care processes and six patient outcomes, measured at patient level. Secondary outcomes included effects on guideline concordance for the four main CR therapies.

Results: Data from eighteen centres (14,847 patients) were analysed, of which twelve centres (9,353 patients) were assigned to group A, and six (5,494 patients) to group B. During the intervention a total of 233 quality improvement goals was identified by participating teams, of which 49 (21%) were achieved during the study period. Except for a modest improvement in data completeness (4.5% improvement per year; 95% CI 0.65 to 8.36), we found no effect of our intervention on any of our primary or secondary outcome measures.

Conclusion: Within a multidisciplinary setting our web-based A&F intervention engaged teams to define local performance improvement goals, but failed to support them in actually completing the improvement actions that were needed to achieve those goals. Future research should focus on improving the actionability of feedback on clinical performance and on addressing the socio-technical perspective of the implementation process.

Key words: Quality improvement, Quality indicators, Health care, Cardiac rehabilitation, Guideline adherence, Feedback
INTRODUCTION

The number of chronically ill patients is increasing, requiring hospitals to reconsider their role and responsibility in chronic disease management [1, 2]. At the same time, health organisations are under public pressure to increase their accountability, and to deliver optimally efficient and effective care [3]. The field of cardiac rehabilitation (CR) typically faces these challenges. CR offers cardiovascular disease patients a need-based, cost-effective, multidisciplinary approach to regain physical capacity, improve psychosocial condition, achieve lifestyle changes, and reduce future cardiovascular risk [4-7]. The efficacy of CR has been studied extensively [6, 8], and was recently shown to be associated with a substantial survival benefit [9]. However, lack of guideline concordance limits the ability of CR to reach its full potential [10-12]; computerised clinical decision support (CDS) has previously been shown to have the potential to improve this [13]. However, considerable non-concordance remained due to organizational and procedural barriers not being addressed because individual CDS users considered them beyond their own influence and responsibility [14]. This finding stressed the need for an intervention specifically directed at decision-making processes at the team rather than at an individual level. This coincides with the approach advised by the American Heart Association (AHA) [11], advocating that entire multidisciplinary CR teams should implement coordinated, joint efforts to reinforce the importance of outpatient CR among healthcare systems, providers and the public [11].

The AHA also promotes the use of quality indicators to monitor and improve clinical performance; for example using audit and feedback (A&F) strategies. A&F involves providing professionals with periodic objective summaries of their clinical performance [15], and is considered to be effective because it can support professionals in assessing their own clinical performance [15]. Previous studies suggested A&F to be most effective if feedback is provided by a supervisor or colleague, more than once, both verbally and in writing; if baseline performance is low; if it includes explicit goals and an action plan; and if combined with educational meetings [15-18]. Other suggested effect modifiers are the perceived quality of the data underlying the feedback, motivation and interest of the recipient, organizational support for quality improvement (QI), and the way in which performance targets or benchmarks are derived [19].

We developed a multifaceted A&F intervention that incorporated all these successful characteristics described in the literature [15-19] to improve clinical performance in the field of CR in the Netherlands [20]. To further maximise its effect, our intervention specifically focused on engaging multidisciplinary teams and their managers rather than individual professionals [20]. The objective of this study was to assess the effectiveness of the multifaceted A&F intervention in a cluster-randomised trial among CR centres in the Netherlands. We measured effects on eleven care processes and six patient outcomes for CR (primary outcomes). Our secondary outcomes included overall performance, data completeness, and difference in guideline concordance with respect to prescribing CR therapies.
METHODS

Study design
Centres participating in the trial were randomised to receive feedback limited to either psychosocial rehabilitation (disease-specific education and lifestyle modification; study group A) or physical rehabilitation (exercise training and relaxation and stress management training; study group B). In this way, both groups received an intervention, whilst serving as each other’s control. We refer to the study protocol for further details of the experimental design [20].

Eligibility of participants
Dutch CR centres working with an electronic patient record (EPR) system for CR were eligible to participate. Multidisciplinary CR teams included cardiologists, physical therapists, nurses, psychologists, dieticians, social workers, and/or rehabilitation physicians. Teams were required to allocate dedicated time for study activities from at least the local CR coordinator (usually a specialized nurse), a cardiologist, one professional from another discipline, and the centre's manager. Recruitment took place from July 2012 until December 2013. All CR patients who started rehabilitation in one of the participating centres during the study period were eligible for inclusion in our analyses. CR is recommended for all patients who have been hospitalized for an acute coronary syndrome (ACS) and for those who have undergone a cardiac intervention [21, 22]. Patients entering outpatient CR in The Netherlands are offered a comprehensive, individualized rehabilitation programme with a typical duration of 6–12 weeks, consisting of one or more of the four group-based therapies supplemented by individual counselling when indicated. Consistent with international guidelines the Dutch guidelines for CR [23, 24] state that the individualized programme should be based on a needs assessment procedure where data items concerning the patient’s physical and psychosocial condition are gathered.

Intervention
Our intervention aimed to engage local multidisciplinary teams by providing them with at least four A&F iterations including quarterly feedback reports of their clinical performance in combination with outreach visits. To this end, we designed a web-based A&F system [25] that supported four tasks: (i) monitoring clinical performance, (ii) selecting specific care processes and patient outcomes for improvement, (iii) goal setting and QI action planning (iv) revising selected processes and outcomes, goals and actions in the plan during follow-up iterations to facilitate continuous performance improvement [26].

Monitoring clinical performance was facilitated by feedback reports consisting of performance scores on a set of indicators; each indicator represented a care process or patient outcome for CR. The performance scores were accompanied by benchmark information represented by ‘traffic light’ coloured icons (Figure 1). Red, yellow, or green colours were assigned based on the centre’s performance score relative to peer performance using the concept of achievable benchmarks [20]. A grey colour was assigned if there were insufficient data (< 10 patients) available to compute...
a score. The processes and outcomes in the indicator set were defined in close collaboration with a panel of CR professionals [27]. The eight indicators related to processes and outcomes of psychosocial rehabilitation were only shown to centres in group A, whereas group B only saw the nine indicators related to processes and outcomes of physical rehabilitation (Appendix I). All these processes and outcomes were measured as dichotomous variables at patient level. To reduce the risk of attrition, we also showed nine indicators related to general CR processes (four patient and five centre level) to centres in both groups (see Appendix II).

During the educational outreach visits, the team selected a number of indicators based on their importance, feasibility, and expected time required to improve each of them. For each process or outcome in the QI action plan, the team could specify the problem, presumed causes, improvement goal, and concrete actions on how to reach that goal. Visits were facilitated by an investigator (MvE or WG). After one year with four A&F iterations, centres were offered two up to two additional iterations with educational outreach via telephone.

Outcome measures
Our primary outcome was the difference in improvement between the two study groups with respect to each of the eleven care processes and six patient outcomes for which exactly one study group received feedback. First we evaluated improvement per indicator at patient level; additionally we compared, at centre level, overall performance (number of processes and outcomes at or above benchmark level) and data completeness (number of processes and outcomes for which centres recorded complete data) at baseline and one year of follow-up.

Secondary outcome measure was the difference in change in guideline concordance with respect to prescribing the four main CR therapies. Concordant prescribing was defined as prescribing a therapy for patients who were indicated to receive it, and not prescribing a therapy for patients who were not indicated to receive it according to the Dutch clinical CR guidelines [23, 24]. Additionally we measured change in concordance with respect to actual attendance of these four therapies by patients.

Data collection and validation
We used routinely collected patient data from centres’ EPRs. At the time we conducted our study, two commercial vendors of EPR systems for CR were available in the Netherlands. Both systems incorporated the Dutch CR guidelines [23, 24] and followed the same data model. Data collection was structured as part of the needs assessment procedure, and fed into the CDS module providing prescription recommendations for each of the four CR therapies [28].

Centres participated for a minimum of one year, with data collection ending in December 2014. At the end of the trial, we performed an audit to assess data quality and completeness by comparing our study database to an independent data source (typically the centres’ local patient clinic schedules). From the analyses for each of the four CR therapies, we omitted centres with more than 25% percent discrepancies between the study database and the independent data source for prescribing that therapy. For further details we refer to the study protocol [20].
Sample size
To calculate the minimally required number of centres participating in the trial, we used data from a previous trial [7]. Calculations were based on the normal approximation to the binomial distribution, using a Type I error risk (alpha) of 5%, and 80% power. Based on the results we aimed to include at least nineteen centres that would treat 350 CR patients, on average, during the study period of one year. Further details can be found in [20].

Cluster randomisation and allocation
Randomisation of centres was stratified by size (more/less than 30 patients starting treatment per month). Per stratum, we generated a randomisation scheme with randomly assigned block sizes of either two or four centres using dedicated software. This scheme was concealed to those enrolling and allocating centres [20]. Due to the nature of the intervention, it was not possible to blind participants, or those involved in providing the intervention, to allocation.

Statistical analysis
To assess the effect of the intervention we performed separate mixed-effects logistic regression analyses [13, 29] for each of the care processes and patient outcomes (primary outcome) and four therapies (secondary outcome) for which exactly one study group received feedback. To this end we included covariates ‘study group’, ‘time’, and ‘study group × time’. We focused on the interaction term to assess the difference in change over one year study follow-up between the two groups—that is, the effect of the intervention—because we expected clinical performance to improve gradually as a result of our intervention. We used random effects to adjust for the variation in baseline performance between centres (random intercept for each centre) and the variation in effect over time (random slope for time). To adjust for differences in case mix, we included age, gender, and indication for CR at patient level, and size (average weekly patient volume) and type (specialized rehabilitation centre or part of a university or teaching hospital versus part of a non-teaching hospital) at centre level as covariates.

To assess the effects on the overall performance (number of processes and outcomes at or above benchmark level) and data completeness (number of processes and outcomes for which centres recorded complete data) we used mixed-effects linear regression. Per clinic we assessed for both the change in percentage between baseline and at one year study follow-up. Additionally, we explored secular trends in the four patient-level general processes, that were shown to both groups, by performing mixed-effects logistic analyses while withholding ‘study group’ and ‘study group × time’ as covariates. Changes in the five centre-level processes were assessed by counting the number of such processes that were in place at baseline and follow-up. Finally we performed separate mixed-effect logistic regression analyses to assess concordance with guideline recommendations for attendance of each of the four CR therapies as measured at the end of the program.

We used Multiple Imputation by Chained Equations (MICE) to handle missing data on outcomes and confounders [30]. To verify the robustness of our findings, we performed a
sensitivity analysis with complete cases only. All analyses were performed using R version 3.1.2 (R Foundation for Statistical Computing; Vienna, Austria).

RESULTS

Participants
Eighteen of 22 eligible CR centres accepted our invitation to participate in the trial. Our randomisation scheme assigned ten centres to group A (receiving feedback with respect to psychosocial rehabilitation), and eight to group B (receiving feedback with respect to physical rehabilitation). However, due to an algorithmic error in our software two centres in group B received the intervention associated with group A, leading to an eventual distribution of twelve centres in group A and six in group B (see Figure 1). Table 1 shows the baseline characteristics of centres and patients. The distribution of all characteristics, except for centre type, was equal between the groups. During the study period a total of 14,847 patients started CR in the participating centres.

Implementation of the intervention
Table 2 shows detailed information on how, and to what extent, the main components of the A&F intervention were implemented in the participating centres. There were no differences in team size, number of indicators selected as QI goal and number of actions per goal in the QI plan, attendance to the visits, and mean study period between the two study groups. On average, the time between randomization and the first educational visit was 3.5 months (standard deviation [SD], 0.7). The average time between subsequent visits was 4.0 months (SD 1.4). One centre in group A completed only three A&F iterations instead of the per protocol minimum of four iterations. The mean number of selected QI goals in each QI plan decreased from 8.0 (SD 2.4) during the initial A&F iteration to 5.0 (SD 3.2) in the final iteration. Multidisciplinary teams reportedly achieved 1.8 of these QI goals per A&F iteration, on average. Overall 21.0% (49/233) QI goals were achieved within the study period. The percentage of resolved goals across all iterations for group A was 15.6% (24/154) compared to 31.6% (25/79) of group B ($\chi^2 = 8.110$, df = 1, p = 0.004).

Effects on clinical performance
Table 3 shows the effect on clinical performance as measured by the eleven care processes and six patient outcomes. For none of the care processes nor patient outcomes in our study, the intervention led to significant differences in performance between study groups. We observed a positive secular trend for indicator 14 ‘Patients receive a discharge letter with remaining lifestyle goals’ in both the control (OR: 5.39; 95% CI 2.14 to 13.56) and intervention group (OR: 4.61; 95% CI 2.29 to 9.30). In the control group, we observed positive secular trends for indicator 6c ‘Completion of stress management and relaxation therapy’ (OR: 2.47; 95% CI 1.25 to 4.88 per year), 9 ‘Improvement in exercise capacity’ (OR: 1.28; 95% CI 1.11 to 1.47), and 13b ‘Vigorously
active lifestyle norm met at discharge’ (OR: 1.29; 95% CI 1.15 to 1.45). We found negative trends for indicator 6b ‘Exercise training completed’ in the control (OR: 0.44; 95% CI 0.27 to 0.74) and for indicator 6a ‘Disease specific education completed’ in the intervention (OR: 0.44; 95% CI 0.29 to 0.67) group. Our sensitivity analysis for clinical performance showed similar results (see Appendix I); we found a positive secular trend in the control group for indicator 13b and a negative trend for indicator 6a in both the control and intervention group and no significant differences in performance between groups.

Overall clinical performance did not significantly improve in centres (effect 4.1% per year; 95% CI -1.13 to 8.53). Data completeness improved by 4.5% per year (95% CI 0.65 to 8.36). Appendix II shows the secular trends in the five general processes that were shown to both groups. We found a positive effect for indicator 15 ‘Cardiologist and GP receive a report after CR’ (OR: 3.42; 95% CI 2.24 to 5.24) and a negative effect for indicator 1a ‘Median time between hospital discharge and needs assessment procedure’ (OR: 0.7; 95% CI 0.54 to 0.91) and 7 ‘Rehabilitation evaluated at discharge’ (OR: 0.43; 95% CI 0.28 to 0.64). In the complete case analysis (Appendix IV) we did not find any significant effect.

Table 4 shows the effects on guideline concordance with respect to each of the four therapies. In the control group, we observed a positive concordance trend for prescribing exercise therapy (OR: 2.52; 95% CI 1.03 to 6.16). We found negative trends for prescribing disease-specific education (OR: 0.62; 95% CI 0.43 to 0.89) and lifestyle modification (OR: 0.37; 95% CI 0.15 to 0.92) in the intervention group. Concerning concordance with respect to therapy attendance we found a negative trend in the control group for relaxation and stress management (OR: 0.44; 95% CI 0.23 to 0.83) and in the intervention group for disease-specific education (OR: 0.51; 95% CI 0.32 to 0.81). For none of the therapies the intervention led to significant differences in concordance trends, neither for prescription or attendance. Overall, concordance rates for prescription of all four therapies were higher compared to attendance rates. Concordance rates were highest for prescribing Relaxation and stress management (85.1%) followed by education (77.8%). The lifestyle modification showed the lowest concordance rates, both for prescription (44.4%) and attendance (37.4%). Our sensitivity analysis for guideline concordance showed a concordance improvement for attendance of education (OR: 2.83; 95% CI 1.1 to 7.27) and a negative concordance trend in the control group for attendance of both the lifestyle modification (OR: 0.72; 95% CI 0.53 to 0.97) and relaxation and stress management therapy (OR: 0.42; 95% CI 0.17 to 0.99) (Appendix III).
Figure 1 – Example feedback report for a centre in study group A. Group A received feedback on performance in the psychosocial rehabilitation (indicator 2b, 2c, 2e, 5, 6a, 6d, 10, 12 and 14) and on general processes (indicator 1b, 3, 7 and 15) and structures (indicator 4, 5, 16, 17 and 18). The indicator scores in this report are fictitious but representative for the scores seen in real reports. Abbreviations: CR= cardiac rehabilitation, GP= general practitioner.

Figure 2 – Flow of centres through the trial.
Table 1 – Baseline characteristics of centres (N=18) and patients (N=14,847) per study group; values are numbers (%), unless indicated otherwise.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group A (feedback on psychosocial rehabilitation)</th>
<th>Group B (feedback on physical rehabilitation)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Centres</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number participating</td>
<td>12 (66.6)</td>
<td>6 (33.3)</td>
</tr>
<tr>
<td>Median (min-max) number of patients per year</td>
<td>431 (183–1,156)</td>
<td>370 (256–988)</td>
</tr>
<tr>
<td>Large centre (&gt;30 patients per month)</td>
<td>6 (50.0)</td>
<td>3 (50.0)</td>
</tr>
<tr>
<td>Centre type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-teaching hospital</td>
<td>7 (58.3)</td>
<td>3 (50.0)</td>
</tr>
<tr>
<td>Teaching hospital</td>
<td>2 (16.7)</td>
<td>3 (50.0)</td>
</tr>
<tr>
<td>University hospital or specialized rehabilitation centre</td>
<td>3 (25.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Patients</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number included in analyses</td>
<td>9,353</td>
<td>5,494</td>
</tr>
<tr>
<td>Mean (SD) age in years</td>
<td>65.0 (11.5)</td>
<td>65.9 (11.8)</td>
</tr>
<tr>
<td>Male gender</td>
<td>6,650 (71.1)</td>
<td>3,900 (71.0)</td>
</tr>
<tr>
<td>Indications for CR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACS with revascularization</td>
<td>4,689 (50.1)</td>
<td>2,620 (47.7)</td>
</tr>
<tr>
<td>ACS without revascularization</td>
<td>469 (5.0)</td>
<td>401 (7.3)</td>
</tr>
<tr>
<td>Elective CABG or valvular surgery</td>
<td>1,346 (14.4)</td>
<td>637 (11.6)</td>
</tr>
<tr>
<td>Elective PCI</td>
<td>536 (5.7)</td>
<td>341 (6.2)</td>
</tr>
<tr>
<td>Other elective interventions</td>
<td>360 (3.8)</td>
<td>119 (2.2)</td>
</tr>
<tr>
<td>CHF or stable AP, no intervention</td>
<td>262 (2.8)</td>
<td>194 (3.5)</td>
</tr>
<tr>
<td>Other diagnosis, no intervention</td>
<td>456 (4.9)</td>
<td>163 (3.0)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1,235 (13.2)</td>
<td>1,019 (18.5)</td>
</tr>
</tbody>
</table>

Abbreviations: ACS= acute coronary syndrome, AP= angina pectoris, CABG= coronary artery bypass graft surgery, CHF= chronic heart failure, PCI= percutaneous coronary intervention, SD= standard deviation.
Table 2 – Implementation of the multifaceted A&F intervention, separately per study group; values are mean (SD) unless indicated otherwise

<table>
<thead>
<tr>
<th>Implementation of the A&amp;F intervention</th>
<th>Group A (feedback on psychosocial rehabilitation)</th>
<th>Group B (feedback on physical rehabilitation)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Range</td>
<td>Range</td>
</tr>
<tr>
<td>Multidisciplinary teams</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of study period per centre in months</td>
<td>19.8 (6.0) 12 – 30</td>
<td>22.5 (4.1) 14 – 27</td>
</tr>
<tr>
<td>Number of A&amp;F iterations</td>
<td>4.6 (1.0) 3 – 6</td>
<td>5.7 (0.7) 4 – 6</td>
</tr>
<tr>
<td>Size of local multidisciplinary team</td>
<td>7.5 (2.8) 3 – 13</td>
<td>6.3 (1.3) 4 – 8</td>
</tr>
<tr>
<td>Number of team members attending outreach visits</td>
<td>5.4 (1.9) 1 – 11</td>
<td>4.7 (1.8) 2 – 8</td>
</tr>
<tr>
<td>Number (%) of teams receiving first telephone follow-up</td>
<td>5 (41.7) n.a.</td>
<td>5 (83.3) n.a.</td>
</tr>
<tr>
<td>Number (%) of teams receiving second telephone follow-up</td>
<td>3 (25.0) n.a.</td>
<td>5 (83.3) n.a.</td>
</tr>
<tr>
<td>QI action planning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of indicators selected as QI goal in QI plan</td>
<td>6.9 (3.1) 1 – 14</td>
<td>6.3 (2.5) 0 – 10</td>
</tr>
<tr>
<td>Mean number of actions per QI goal in QI plan</td>
<td>1.9 (0.5) 1.0 – 3.3</td>
<td>1.6 (0.4) 1.0 – 2.6</td>
</tr>
<tr>
<td>Number of achieved QI goals per follow-up A&amp;F iteration</td>
<td>1.7 (1.5) 0 – 5</td>
<td>1.9 (1.5) 0 – 6</td>
</tr>
<tr>
<td>Number of unachieved QI goals in final A&amp;F iteration</td>
<td>5.9 (3.5) 1 – 13</td>
<td>3.5 (2.2) 0 – 7</td>
</tr>
</tbody>
</table>

Abbreviations: A&F= audit and feedback, n.a. = not applicable, QI= quality improvement, SD= standard deviation.
Table 3 – Effects on clinical performance measured by eleven care processes and six patient outcomes (primary outcome) (n=14,874)

<table>
<thead>
<tr>
<th>Care processes and patient outcomes</th>
<th>Type</th>
<th>Control group</th>
<th>Intervention group</th>
<th>Adjusted performance trend; OR (95% CI)</th>
<th>Adjusted performance trend; OR (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Crude baseline performance</td>
<td>Crude follow-up performance</td>
<td>Crude baseline performance</td>
<td>Crude follow-up performance</td>
<td></td>
</tr>
<tr>
<td>Psychosocial rehabilitation (study group A)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Complete data on psychological functioning</td>
<td>Process</td>
<td>69.0% (623/903)</td>
<td>68.3% (3,134/4,591)</td>
<td>0.64 (0.32 to 1.28)</td>
<td>86.1% (1,733/2,012)</td>
<td>84.7% (6,217/7,341)</td>
</tr>
<tr>
<td>2. Complete data on social functioning</td>
<td>Process</td>
<td>16.1% (145/903)</td>
<td>15.5% (712/4,591)</td>
<td>0.17 (0.01 to 2.06)</td>
<td>53.2% (1,071/2,012)</td>
<td>56.4% (4,142/7,341)</td>
</tr>
<tr>
<td>3. Complete data on lifestyle factors</td>
<td>Process</td>
<td>82.8% (748/903)</td>
<td>84.6% (3,885/4,591)</td>
<td>0.92 (0.46 to 1.85)</td>
<td>86.1% (1,733/2,012)</td>
<td>80.2% (5,884/7,341)</td>
</tr>
<tr>
<td>4. Disease specific education completed *</td>
<td>Process</td>
<td>51.3% (424/827)</td>
<td>44.1% (1,796/4,071)</td>
<td>0.76 (0.48 to 1.20)</td>
<td>62.7% (842/1,342)</td>
<td>61.7% (3,046/4,934)</td>
</tr>
<tr>
<td>5. Lifestyle modification programme completed *</td>
<td>Process</td>
<td>41.3% (373/903)</td>
<td>40.8% (1,874/4,591)</td>
<td>1.08 (0.63 to 1.85)</td>
<td>55.7% (877/1,575)</td>
<td>58.3% (3,255/5,580)</td>
</tr>
<tr>
<td>6. Improved quality of life after CR</td>
<td>Outcome</td>
<td>44.6% (403/903)</td>
<td>46.5% (2,133/4,591)</td>
<td>0.99 (0.86 to 1.13)</td>
<td>41.0% (826/2,012)</td>
<td>43.5% (3,193/7,341)</td>
</tr>
<tr>
<td>7. Successful smoking cessation</td>
<td>Outcome</td>
<td>56.0% (506/903)</td>
<td>54.2% (2,489/4,591)</td>
<td>0.96 (0.84 to 1.09)</td>
<td>49.5% (996/2,012)</td>
<td>51.1% (3,752/7,341)</td>
</tr>
<tr>
<td>8. Patients receive a discharge letter with remaining lifestyle goals</td>
<td>Process</td>
<td>13.1% (118/903)</td>
<td>19.9% (914/4,591)</td>
<td>5.39 (2.14 to 13.56)</td>
<td>27.3% (549/2,012)</td>
<td>28.9% (2,120/7,341)</td>
</tr>
<tr>
<td>Physical rehabilitation (study group B)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Complete data on physical functioning</td>
<td>Process</td>
<td>54.5% (1,097/2,012)</td>
<td>61.8% (4,534/7,341)</td>
<td>1.35 (0.72 to 2.54)</td>
<td>52.6% (475/903)</td>
<td>65.6% (3,010/4,591)</td>
</tr>
<tr>
<td>10. Complete data concerning cardiovascular risk factors</td>
<td>Process</td>
<td>55.3% (1,112/2,012)</td>
<td>49.8% (3,656/7,341)</td>
<td>1.12 (0.76 to 1.65)</td>
<td>54.4% (491/903)</td>
<td>60.4% (2,775/4,591)</td>
</tr>
</tbody>
</table>
11. Exercise training completed *  
<table>
<thead>
<tr>
<th>Process</th>
<th>53.4%</th>
<th>45.9%</th>
<th>0.44</th>
<th>65.8%</th>
<th>60.9%</th>
<th>0.8</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(1,074/2,012)</td>
<td>(3,366/7,341)</td>
<td>(0.27 to 0.74)</td>
<td>(421/640)</td>
<td>(1,780/2,922)</td>
<td>(0.29 to 2.21)</td>
</tr>
</tbody>
</table>

12. Relaxation and stress management training completed *  
<table>
<thead>
<tr>
<th>Process</th>
<th>43.6%</th>
<th>48.3%</th>
<th>2.47</th>
<th>44.7%</th>
<th>45.8%</th>
<th>1.04</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(666/1,528)</td>
<td>(2,367/4,898)</td>
<td>(1.25 to 4.88)</td>
<td>(370/827)</td>
<td>(1,863/4,071)</td>
<td>(0.40 to 2.71)</td>
</tr>
</tbody>
</table>

13. Cardiovascular risk factors evaluated at discharge  
<table>
<thead>
<tr>
<th>Process</th>
<th>10.3%</th>
<th>7.4%</th>
<th>0.87</th>
<th>32.7%</th>
<th>29.9%</th>
<th>1.01</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(208/2,012)</td>
<td>(541/7,341)</td>
<td>(0.41 to 1.83)</td>
<td>(295/903)</td>
<td>(1,373/4,591)</td>
<td>(0.43 to 2.37)</td>
</tr>
</tbody>
</table>

14. Improvement in exercise capacity  
<table>
<thead>
<tr>
<th>Outcome</th>
<th>46.5%</th>
<th>51.3%</th>
<th>1.28</th>
<th>50.2%</th>
<th>49.7%</th>
<th>1.12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(936/2,012)</td>
<td>(3,769/7,341)</td>
<td>(1.11 to 1.47)</td>
<td>(453/903)</td>
<td>(2,280/4,591)</td>
<td>(0.91 to 1.38)</td>
</tr>
</tbody>
</table>

15. Successful work resumption  
<table>
<thead>
<tr>
<th>Outcome</th>
<th>53.3%</th>
<th>52.4%</th>
<th>0.93</th>
<th>65.7%</th>
<th>68.5%</th>
<th>0.97</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(1,072/2,012)</td>
<td>(3,848/7,341)</td>
<td>(0.83 to 1.05)</td>
<td>(593/903)</td>
<td>(3,146/4,591)</td>
<td>(0.84 to 1.12)</td>
</tr>
</tbody>
</table>

16. Moderately active lifestyle norm met at discharge  
<table>
<thead>
<tr>
<th>Outcome</th>
<th>37.1%</th>
<th>35.7%</th>
<th>0.96</th>
<th>71.8%</th>
<th>72.8%</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(747/2,012)</td>
<td>(2,621/7,341)</td>
<td>(0.83 to 1.11)</td>
<td>(648/903)</td>
<td>(3,340/4,591)</td>
<td>(0.85 to 1.17)</td>
</tr>
</tbody>
</table>

17. Vigorously active lifestyle norm met at discharge  
<table>
<thead>
<tr>
<th>Outcome</th>
<th>22.1%</th>
<th>30.8%</th>
<th>1.29</th>
<th>26.8%</th>
<th>28.1%</th>
<th>1.13</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(444/2,012)</td>
<td>(2,263/7,341)</td>
<td>(1.15 to 1.45)</td>
<td>(242/903)</td>
<td>(1,292/4,591)</td>
<td>(0.99 to 1.30)</td>
</tr>
</tbody>
</table>

We used Multiple Imputation by Chained Equations to handle missing data. Baseline period: first three months of study period; follow-up period: complete study period minus the baseline period. Performance trends: odds ratios associated with a one year study follow-up, adjusted for patients’ age, gender, indication for CR, and centres’ type and size. P-value: probability of trends being similar in intervention and control group.

Abbreviations: CI = confidence interval, CR = cardiac rehabilitation, OR = odds ratio

* We excluded centres with incomplete data for this indicator. The number of centres and patients included in the analyses were therefore as follows: indicator 4: 12 centers, 11,174 patients; indicator 5: 15 centres, 12,649 patients; indicator 11: 16 centres, 12,915 patients; indicator 12: 15 centres, 11,324 patients.
Table 4 – Concordance rates and difference in concordance between study groups for the four CR therapies (both prescribed and attended therapies) (secondary outcome) (n=14,874).

<table>
<thead>
<tr>
<th>CR therapies</th>
<th>Control group</th>
<th>Intervention group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Crude baseline concordance</td>
<td>Crude follow-up concordance</td>
<td>Adjusted concordance trend [OR (95% CI)]</td>
</tr>
<tr>
<td>Psychosocial rehabilitation (study group A)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education (prescribed)</td>
<td>73.4% (663/903)</td>
<td>66.0% (3,031/4,591)</td>
<td>0.66 (0.43 to 1.01)</td>
</tr>
<tr>
<td>Lifestyle (prescribed)</td>
<td>28.9% (261/903)</td>
<td>24.9% (1,145/4,591)</td>
<td>0.49 (0.14 to 1.80)</td>
</tr>
<tr>
<td>Education (attended)*</td>
<td>74.6% (617/827)</td>
<td>68.3% (2,780/4,071)</td>
<td>0.98 (0.55 to 1.74)</td>
</tr>
<tr>
<td>Lifestyle (attended)*</td>
<td>26.3% (168/640)</td>
<td>28.2% (824/2,922)</td>
<td>1.19 (0.74 to 1.91)</td>
</tr>
<tr>
<td>Physical rehabilitation (study group B)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise (prescribed)</td>
<td>72.1% (1,450/2,012)</td>
<td>80.0% (5,869/7,341)</td>
<td>2.52 (1.03 to 6.16)</td>
</tr>
<tr>
<td>Relaxation (prescribed)</td>
<td>88.9% (1,789/2,012)</td>
<td>92.8% (6,811/7,341)</td>
<td>0.91 (0.70 to 1.17)</td>
</tr>
<tr>
<td>Exercise (attended)*</td>
<td>61.2% (935/1,528)</td>
<td>61.3% (3,003/4,898)</td>
<td>0.82 (0.61 to 1.09)</td>
</tr>
<tr>
<td>Relaxation (attended)*</td>
<td>57.0% (898/1,575)</td>
<td>48.3% (2,695/5,580)</td>
<td>0.44 (0.23 to 0.83)</td>
</tr>
</tbody>
</table>

We used Multiple Imputation by Chained Equations to handle missing data. Baseline period: first three months of study period; follow-up period: complete study period minus the baseline period. Performance trends: odds ratios associated with a one year study follow-up, adjusted for patients’ age, gender, indication for CR, and centres’ type and size. P-value: probability of trends being similar in intervention and control group.

Abbreviations: CI= confidence interval, CR= cardiac rehabilitation, OR = odds ratio

* We excluded centres with incomplete data for this therapy. The number of centres and patients included in the analyses were therefore as follows: Education: 12 centres, 11,174 patients; Lifestyle modification: 15 centres, 12,649 patients; Exercise training: 16 centres, 12,915 patients; and Relaxation and stress management training: 15 centres, 11,324 patients.
DISCUSSION

We evaluated an A&F intervention in a large cluster–randomised trial among 18 CR centres and 14,847 patients. Our intervention modestly increased data completeness and engaged teams to set improvement goals, but it yielded no improvement of clinical performance of multidisciplinary CR teams.

A Cochrane review of 140 randomized A&F trials revealed a median of 4.3% improvement in quality of care, with a minority of studies showing a strong positive effect [15]. In the review, the authors identified characteristics that may enhance A&F effectiveness, such as: the use of educational outreach visits, providing feedback multiple times, and involving the entire team in action-planning and goal-setting activities [15-19]. In addition to incorporating these characteristics in our intervention, we built on the findings of an extensive barrier analysis which identified the need to target decision making by multidisciplinary teams in order to increase guideline concordance in the field of CR [14]. The resulting intervention encouraged multidisciplinary teams to develop and revise (up to five times) improvement plans based on indicator-based performance that was provided in quarterly feedback reports. Less than 20% of similar studies use iterative cycles of change, and only 14% of them repeatedly use data over time [31]. However, despite our efforts to design a successful intervention containing all of these characteristics, the intervention did not improve clinical performance. Apparently there are other, unidentified factors that are equally or more important to achieve change in clinical practice.

The electronic nature of our intervention enabled us to monitor and measure improvement processes at the centre-level: teams recorded and managed their QI plans within the same web-based system through which they were provided with performance feedback. We found that our intervention successfully encouraged teams to define local performance improvement goals, but it largely failed to support them with actually completing the actions needed to achieve those goals: 79% of planned improvement actions remained uncompleted until the end of the study. Previous research in the field of intensive care [32, 33] and general practice [34, 35] suggested that failures to complete improvement actions may be due to a lack of organizational support, e.g. competing priorities, or due to a shortage of individual skills or knowledge, e.g. to translate population-level quality targets into effective improvement actions in local clinical practice. Although not assessed, we assume that also our A&F intervention did completely solve these organizational and professional barriers. As proposed by others [16, 32], extending our intervention with ready-to-use improvement tools might have addressed the professional barrier. The few A&F studies that incorporated such support did so in different ways. For instance, through facilitated group discussions to reflect upon the feedback and identify improvement strategies [36], or by including suggestions in the feedback reports for how to address deficiencies in practice [37]. As the surplus value of adding supportive improvement tools to A&F interventions has not yet been investigated, this should be a focus of future research.
The authors of the Cochrane review recommended explicit use of theory when developing and evaluating A&F interventions [15]. Although we designed our study before this recommendation, our intervention is well-founded in the Model for Improvement [26]. The model encourages teams improving their practice following plan-do-study-act (PDSA) cycles. This also fits within Control Theory [38], which poses that A&F effects are achieved through a mechanism of two steps: (i) performance feedback convinces health professionals that change is necessary and to set improvement intentions, and (ii) intentions are translated into action [38]. We recently evaluated the first of these two steps, and found that the performance scores and benchmark comparisons presented in the feedback convinced professionals that change was necessary [39]. However, improvement intentions appeared to vary substantially between professionals because they disagreed with benchmarks, deemed improvement unfeasible, or did not consider the indicator an essential aspect of care quality [39]. This likely diluted the effect of our A&F intervention, and may thus partially explain the lack of impact reported in our current study.

Examples of persisting organisational barriers within our study context might have been related to lack of resources of centres (e.g. budget ceilings imposed by insurers), competing interests between managers from different disciplines, and poor attendance of cardiologists and managers at outreach visits. Recently, other theoretical, more socio-technical frameworks have been proposed to design and evaluate A&F interventions, such as the Triangle Model [40], Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) framework [41], the Systems Engineering Initiative for Patient Safety (SEIPS) model [42] and the 8-dimension socio-technical model [43]. Such socio-technical models typically approach the implementation process as consisting of multiple components that continuously interact with and change each other; including people, teams, tasks, tools and technologies, underlying organizational conditions, and the surrounding context. To address this complexity, future studies could consider using socio-technical models as the underlying theoretical framework to guide the development, implementation and evaluation of A&F interventions.

A limitation of our study is that we implemented our A&F intervention shortly after centres had started working with a new EPR. Although exporting routinely collected EPR data minimized centre’s data collection efforts for the study, the EPR implementation may have conflicted with the time and resources available for working on actual performance improvement. Second, some outcome measures showed little room for improvement (i.e., ceiling effects), making them less likely to change significantly over the course of the study, and as such less suitable for assessing the effectiveness of our intervention. Other outcome measures might have been difficult to improve because they relied on patients’ compliance with prescribed therapies, which is a well-known barrier to guideline concordance [44]. Third, there may have contamination between groups due to an overall increase of awareness of clinical performance and quality improvement. This may have resulted in professionals working on other aspects of CR care, even though they had been randomised to target only psychosocial (group A) or physical rehabilitation (group B). Fourth, we included one centre less in our study sample than estimated
in our sample calculations. Although we exceeded the estimated required number of patients per centre per year, we cannot rule out lack of statistical power as a potential explanation for finding no significant effect in our study. Finally, two centres were incorrectly assigned to group A due to an algorithmic error in our software. However, since there were no differences in baseline characteristics between study groups, we believe the unequal distribution of centres did not influence our final results.

CONCLUSION

We designed a web-based A&F intervention in the field of CR guided by an extensive analysis of barriers in the field and by incorporating characteristics proven successful in the A&F literature. The intervention had no impact on the measured care processes, patient outcomes, or guideline concordance. Our intervention did modestly increase data completeness and engaged teams to define local performance improvement goals, but failed to support them in actually completing the improvement actions that were needed to achieve those goals. Future studies should focus on improving A&F interventions and their evaluation, for instance by improving the actionability of feedback on clinical performance and by addressing the socio-technical perspective of implementation processes more extensively.

CONTRIBUTORS

Both MvE en WG contributed equally to the writing of this paper. NP, MvE and NdK had the basic idea for this study and were involved in the development of the protocol, with additional support form SvdV and HK. MvE collected all data and WG analysed the data with support form NP. All authors were involved in data interpretation. MvE and WG wrote the draft of the manuscript. All authors were involved in the critical revision of the paper for intellectual content and its final approval before submission.

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- Albert Schweitzer Hospital, Dordrecht (MA Groenewegen)
- BovenIJ Hospital, Amsterdam (A Venema and A Oor)
- Diaconessen/ Noorderboog Hospital Meppel (W Baas and H Hooijer)
- Hospital Gelderse Vallei, Ede (A Meissner-Vogel and M van Steenbergen)
- Hospital Group Twente, Almelo and Hengelo (E Rodijk)
- Hospital NijSmellinghe (M van Aalsum and M Oosting)
- Ikazia Hospital, Rotterdam (Y Snijder and E van Alphen)
- Laurentius Hospital, Roermond (H Kleinen)
- Kennemer Hospital, Haarlem (M Vesters and R Greuter)
- Maxima Medical Centre, Veldhoven (HMC Kemps and M Donkers)
- Rijnland Hospital, Leiderdorp (D Kok and M van der Werve)
- Rijnlands Rehabilitation Centre, Leiden (HJ van Exel)
- Rijnstate Hospital, Arnhem (M Zootjes-Mes)
- Sophia Rehabilitation, Delft (J Wiegel and A Kouwenhoven)
- St. Jans Hospital, Weert (FMG Verkennis and EA van der Sande)
- Tergooi Hospital, Hilversum (S van der Voort and J Bomhof)
- Zaans Medical Centre, Zaandam (H Mirck)
APPENDIX

Overview

Table I. Effect on clinical performance measured by eleven care processes and six patient outcomes (primary outcome): complete case analysis including correction for case mix

Table II. Results and secular trend on five general CR processes all centres received feedback upon: using MICE including correction for case mix and results on availability of five organisational structures (additional analysis)

Table III. Concordance rates and difference in concordance between study groups for the four CR therapies (both prescribed and attended therapies) (secondary outcome): complete case analysis including correction for case mix

Table IV. Results and secular trend on ten quality indicators all centres received feedback upon (additional analysis): complete case analysis including correction for case mix
Table I  Effect on clinical performance measured by eleven care processes and six patient outcomes (primary outcome): complete case analysis including correction for case mix

<table>
<thead>
<tr>
<th>Care processes and patient outcomes</th>
<th>Type</th>
<th>Control group</th>
<th>Intervention group</th>
<th>P-value</th>
<th>N (centres)</th>
<th>Missing values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Crude baseline performance</td>
<td>Crude follow-up performance</td>
<td>Crude baseline performance</td>
<td>Crude follow-up performance</td>
<td>Adjusted performance trend; [OR (95% CI)]</td>
</tr>
<tr>
<td><strong>Psychosocial rehabilitation (study group A)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Complete data on psychological functioning</td>
<td>Process</td>
<td>67.1% (425/633)</td>
<td>70.4% (2,703/3,842)</td>
<td>0.56 (0.25 to 1.25)</td>
<td>86.8% (1,474/1,698)</td>
<td>85.6% (5,495/6,420)</td>
</tr>
<tr>
<td>2. Complete data on social functioning</td>
<td>Process</td>
<td>20.2% (128/633)</td>
<td>17.3% (666/3,842)</td>
<td>0.14 (0.01 to 1.91)</td>
<td>56.2% (955/1,698)</td>
<td>56.2% (3,608/6,420)</td>
</tr>
<tr>
<td>3. Complete data on lifestyle factors</td>
<td>Process</td>
<td>83.3% (527/633)</td>
<td>86.0% (3,304/3,842)</td>
<td>0.90 (0.45 to 1.83)</td>
<td>86.3% (1,465/1,698)</td>
<td>80.7% (5,180/6,420)</td>
</tr>
<tr>
<td>4. Disease specific education completed *</td>
<td>Process</td>
<td>36.3% (61/168)</td>
<td>46.5% (451/970)</td>
<td>0.59 (0.44 to 0.77)</td>
<td>48.9% (149/305)</td>
<td>69.4% (738/1,064)</td>
</tr>
<tr>
<td>5. Lifestyle modification programme completed *</td>
<td>Process</td>
<td>51.4% (19/37)</td>
<td>42.7% (108/253)</td>
<td>0.63 (0.17 to 2.42)</td>
<td>21.3% (612/286)</td>
<td>33.3% (235/706)</td>
</tr>
<tr>
<td>6. Improved quality of life after CR</td>
<td>Outcome</td>
<td>47.0% (70/149)</td>
<td>48.8% (471/966)</td>
<td>1 (0.76 to 1.33)</td>
<td>46.6% (275/590)</td>
<td>49.0% (1,182/2,412)</td>
</tr>
<tr>
<td>7. Successful smoking cessation</td>
<td>Outcome</td>
<td>63.0% (63/100)</td>
<td>58.3% (277/475)</td>
<td>0.91 (0.65 to 1.29)</td>
<td>54.1% (119/220)</td>
<td>58.5% (424/725)</td>
</tr>
<tr>
<td>8. Patients receive a discharge letter with remaining lifestyle goals</td>
<td>Process</td>
<td>9.1% (242/263)</td>
<td>17.8% (209/1,173)</td>
<td>5.35 (0.58 to 49.38)</td>
<td>15.5% (161/1,037)</td>
<td>26.7% (1,004/3,755)</td>
</tr>
<tr>
<td>Event</td>
<td>Process</td>
<td>Outcome</td>
<td>Baseline</td>
<td>Follow-up</td>
<td>Odds Ratio</td>
<td>95% CI</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>---------</td>
<td>---------</td>
<td>----------</td>
<td>-----------</td>
<td>------------</td>
<td>--------</td>
</tr>
<tr>
<td>9. Complete data on physical functioning</td>
<td>56.0%</td>
<td>64.1%</td>
<td>(950/1698)</td>
<td>(4,118/6,420)</td>
<td>1.66</td>
<td>(0.90 to 3.05)</td>
</tr>
<tr>
<td>10. Complete data concerning cardiovascular risk factors</td>
<td>53.5%</td>
<td>48.6%</td>
<td>(909/1698)</td>
<td>(3,123/6,420)</td>
<td>1.13</td>
<td>(0.76 to 1.70)</td>
</tr>
<tr>
<td>11. Exercise training completed *</td>
<td>55.0%</td>
<td>50.2%</td>
<td>(364/662)</td>
<td>(1,124/2,399)</td>
<td>1.17</td>
<td>(0.49 to 2.77)</td>
</tr>
<tr>
<td>12. Relaxation and stress management training completed *</td>
<td>35.0%</td>
<td>51.4%</td>
<td>(143/409)</td>
<td>(721/1,404)</td>
<td>0.40</td>
<td>(0.09 to 1.72)</td>
</tr>
<tr>
<td>13. Cardiovascular risk factors evaluated at discharge</td>
<td>12.1%</td>
<td>8.8%</td>
<td>(156/1,286)</td>
<td>(360/4,085)</td>
<td>0.51</td>
<td>(0.10 to 2.66)</td>
</tr>
<tr>
<td>14. Improvement in exercise capacity</td>
<td>50.8%</td>
<td>59.5%</td>
<td>(199932)</td>
<td>(966/1,624)</td>
<td>1.14</td>
<td>(0.95 to 1.36)</td>
</tr>
<tr>
<td>15. Successful work resumption</td>
<td>65.2%</td>
<td>59.8%</td>
<td>(204/313)</td>
<td>(539/901)</td>
<td>1.07</td>
<td>(0.80 to 1.44)</td>
</tr>
<tr>
<td>16. Moderately active lifestyle norm met at discharge</td>
<td>27.3%</td>
<td>32.0%</td>
<td>(229/833)</td>
<td>(781/2,439)</td>
<td>1.45</td>
<td>(0.98 to 2.13)</td>
</tr>
<tr>
<td>17. Vigorously active lifestyle norm met at discharge</td>
<td>9.2%</td>
<td>19.2%</td>
<td>(77/834)</td>
<td>(467/2,438)</td>
<td>1.36</td>
<td>(1.04 to 1.79)</td>
</tr>
</tbody>
</table>

Baseline period: first three months of study period; follow-up period: complete study period minus the baseline period. Performance trends: odds ratios associated with a one year study follow-up, adjusted for patients’ age, gender, indication for CR, and centres’ type and size. p-value: probability of trends being similar in intervention and control group.

Abbreviations: CI = confidence interval, CR = cardiac rehabilitation, OR = odds ratio, NA= not applicable
### Table II  Results and secular trend on five general CR processes all centres received feedback upon: using MICE including correction for case mix and results on availability of five organisational structures

<table>
<thead>
<tr>
<th>Care processes and organisational structures</th>
<th>Type</th>
<th>Crude baseline performance</th>
<th>Crude follow-up performance</th>
<th>Performance trend; [OR (95% CI)]</th>
<th>N (centres)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicators referring to general practises (both study groups)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Median time between hospital discharge and needs assessment procedure</td>
<td>Process</td>
<td>68.0% (1,983/2,915)</td>
<td>61.6% (7,355/11,932)</td>
<td>0.7 (0.54 to 0.91)</td>
<td>14,847 (18)</td>
</tr>
<tr>
<td>19. Patients are offered a rehabilitation plan tailored to their needs</td>
<td>Process</td>
<td>85.0% (2,479/2,915)</td>
<td>85.4% (10,191/11,932)</td>
<td>0.89 (0.72 to 1.09)</td>
<td>14,847 (18)</td>
</tr>
<tr>
<td>20. Rehabilitation evaluated at discharge</td>
<td>Process</td>
<td>39.0% (1,137/2,915)</td>
<td>34.0% (4,059/11,932)</td>
<td>0.43 (0.28 to 0.64)</td>
<td>14,847 (18)</td>
</tr>
<tr>
<td>21. Cardiologist and GP receive a report after CR</td>
<td>Process</td>
<td>42.5% (1,239/2,915)</td>
<td>57.7% (6,879/11,932)</td>
<td>3.42 (2.24 to 5.24)</td>
<td>14,847 (18)</td>
</tr>
<tr>
<td>Availability of five organisational structures (both study groups)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. Professionals work with a multidisciplinary patient record</td>
<td>Yes/no</td>
<td>94.4% (17/18)</td>
<td>100% (18/18)</td>
<td>n.a.</td>
<td>18</td>
</tr>
<tr>
<td>23. Availability of specialized education for patients with chronic heart failure</td>
<td>Yes/no</td>
<td>55.6% (10/18)</td>
<td>61.1% (11/18)</td>
<td>n.a.</td>
<td>18</td>
</tr>
<tr>
<td>24. Assessment of long-term patients outcomes</td>
<td>Yes/no</td>
<td>33.3% (6/18)</td>
<td>33.3% (6/18)</td>
<td>n.a.</td>
<td>18</td>
</tr>
<tr>
<td>25. Performing internal evaluation and quality improvement</td>
<td>Yes/no</td>
<td>83.3% (15/18)</td>
<td>94.4% (17/18)</td>
<td>n.a.</td>
<td>18</td>
</tr>
<tr>
<td>26. Performing patient satisfactory research</td>
<td>Yes/no</td>
<td>44.4% (8/18)</td>
<td>55.6% (10/18)</td>
<td>n.a.</td>
<td>18</td>
</tr>
</tbody>
</table>

We used Multiple Imputation by Chained Equations to handle missing data. Baseline period: first three months of study period; follow-up period: complete study period minus the baseline period. Performance trends: odds ratios associated with a one year study follow-up, adjusted for patients’ age, gender, indication for CR, and centres’ type and size.

Abbreviations: CI = confidence interval, CR = cardiac rehabilitation, GP= general practitioner, OR = odds ratio.
### Table II
Results and secular trend on five general CR processes all centres received feedback upon: using MICE including correction for case mix and results on availability of five organisational structures

<table>
<thead>
<tr>
<th>Type</th>
<th>Baseline performance</th>
<th>Follow-up performance</th>
<th>Performance trend</th>
<th>OR (95% CI)</th>
<th>p-value</th>
<th>N (centres)</th>
<th>Missing (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.</td>
<td>Median time between hospital discharge and needs assessment procedure</td>
<td>68.0%</td>
<td>61.6%</td>
<td>0.7</td>
<td>14,847 (18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19.</td>
<td>Patients are offered a rehabilitation plan tailored to their needs</td>
<td>85.0%</td>
<td>85.4%</td>
<td>0.89</td>
<td>14,847 (18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20.</td>
<td>Rehabilitation evaluated at discharge</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>21.</td>
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<td>57.7%</td>
<td>3.42</td>
<td>14,847 (18)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

We used Multiple Imputation by Chained Equations to handle missing data. Baseline period: first three months of study period; follow-up period: complete study period minus the baseline period. Performance trends: odds ratios associated with a one year increase in the exposure, adjusted for patients’ age, gender, indication for CR, and centres’ type and size. P-value: probability of trends being similar in intervention and control group.

### Table III
Concordance rates and difference in concordance between study groups for the four CR therapies (both prescribed and attended therapies) (secondary outcome): complete case analysis including correction for case mix

<table>
<thead>
<tr>
<th>CR therapies</th>
<th>Control group</th>
<th>Intervention group</th>
<th>P-value</th>
<th>N (centres)</th>
<th>Missing (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychosocial rehabilitation (study group A)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education (prescribed)</td>
<td>81.2% (375/462)</td>
<td>71.1% (2,292/3,222)</td>
<td>0.69 (1,411/1,612)</td>
<td>0.662</td>
<td>11,247 (18)</td>
</tr>
<tr>
<td>Lifestyle (prescribed)</td>
<td>34.3% (155/452)</td>
<td>25.6% (830/3,240)</td>
<td>0.45 (1,023/1,624)</td>
<td>0.682</td>
<td>11,294 (18)</td>
</tr>
<tr>
<td>Education (attended)</td>
<td>83.8% (150/179)</td>
<td>77.8% (782/1,005)</td>
<td>1.19 (185/298)</td>
<td>0.031</td>
<td>4,804 (11)</td>
</tr>
<tr>
<td>Lifestyle (attended)</td>
<td>21.8% (27/124)</td>
<td>21.8% (157/722)</td>
<td>0.72 (125/445)</td>
<td>0.243</td>
<td>3,834 (9)</td>
</tr>
<tr>
<td>Physical rehabilitation (study group B)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise (prescribed)</td>
<td>72.6% (976/1,345)</td>
<td>82.8% (4,211/5,088)</td>
<td>2.66 (124/320)</td>
<td>0.310</td>
<td>9,204 (18)</td>
</tr>
<tr>
<td>Relaxation (prescribed)</td>
<td>89.9% (1,460/1,625)</td>
<td>95.0% (5,724/6,026)</td>
<td>1.49 (399/483)</td>
<td>0.378</td>
<td>11,482 (18)</td>
</tr>
<tr>
<td>Exercise (attended)</td>
<td>75.2% (279/371)</td>
<td>64.1% (667/1,040)</td>
<td>0.69 (12/16)</td>
<td>0.326</td>
<td>3,976 (14)</td>
</tr>
<tr>
<td>Relaxation (attended)</td>
<td>76.7% (227/296)</td>
<td>81.2% (574/707)</td>
<td>0.42 (46/46)</td>
<td>0.203</td>
<td>5,514 (12)</td>
</tr>
</tbody>
</table>

Baseline period: first three months of study period; follow-up period: complete study period minus the baseline period. Performance trends: odds ratios associated with a one year increase in the exposure, adjusted for patients’ age, gender, indication for CR, and centres’ type and size. P-value: probability of trends being similar in intervention and control group.

Abbreviations: CI = confidence interval, CR = cardiac rehabilitation, OR = odds ratio.
Table IV  Results and secular trend on five general CR processes all centres received feedback upon (additional analysis): complete case analysis including correction for case mix

<table>
<thead>
<tr>
<th>Care processes</th>
<th>Type</th>
<th>Crude baseline performance</th>
<th>Crude follow-up performance</th>
<th>Performance trend; [OR (95% CI)]</th>
<th>N  (centres)</th>
<th>Missing values (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicators referring to general processes (both study groups)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Median time between hospital discharge and needs assessment procedure</td>
<td>Process</td>
<td>64.0% (1,137/1,778)</td>
<td>60.3% (5,212/8,646)</td>
<td>0.77 (0.57 to 1.05)</td>
<td>10,424 (18)</td>
<td>2169 (17.2%)</td>
</tr>
<tr>
<td>19. Patients who are offered a rehabilitation plan tailored to their needs</td>
<td>Process</td>
<td>87.3% (2,034/2,331)</td>
<td>88.4% (9,073/10,262)</td>
<td>0.92 (0.74 to 1.13)</td>
<td>12,593 (18)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>20. Patients who had their rehabilitation goals evaluated after CR</td>
<td>Process</td>
<td>41.1% (957/2,331)</td>
<td>34.7% (3,565/10,262)</td>
<td>1.25 (0.90 to 1.74)</td>
<td>8,178 (18)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>21. Patients for whom their cardiologist and GP receive a report after CR</td>
<td>Process</td>
<td>38.4% (444/1,156)</td>
<td>51.2% (1,978/3,861)</td>
<td>1.63 (0.89 to 2.98)</td>
<td>5,017 (18)</td>
<td>7576 (60.2%)</td>
</tr>
</tbody>
</table>

Baseline period: first three months of study period; follow-up period: complete study period minus the baseline period. Performance trends: odds ratios associated with a one year study follow-up, adjusted for patients’ age, gender, indication for CR, and centres’ type and size.

Abbreviations: CI = confidence interval, CR = cardiac rehabilitation, GP = general practitioner, OR = odds ratio.
REFERENCES


WHAT IS NEEDED TO IMPLEMENT A WEB-BASED AUDIT AND FEEDBACK INTERVENTION WITH OUTREACH VISITS TO IMPROVE CARE QUALITY: A CONCEPT MAPPING STUDY AMONG CARDIAC REHABILITATION TEAMS

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ABSTRACT

**Introduction:** Evidence on successful quality improvement (QI) in health care requires quantitative information from randomized clinical trials (RCTs) on the effectiveness of QI interventions, but also qualitative information from professionals to understand factors influencing QI implementation.

**Objective:** Using a structured qualitative approach, concept mapping, this study determines factors identified by cardiac rehabilitation (CR) teams on what is needed to successfully implement a web-based audit and feedback (A&F) intervention with outreach visits to improve the quality of CR care.

**Methods:** Participants included 49 CR professionals from 18 Dutch CR centres who had worked with the A&F system during a RCT. In three focus group sessions participants formulated statements on factors needed to implement QI successfully. Subsequently, participants rated all statements for importance and feasibility and grouped them thematically. Multi dimensional scaling was used to produce a final concept map.

**Results:** Forty-two unique statements were formulated and grouped into five thematic clusters in the concept map. The cluster with the highest importance was QI team commitment, followed by organisational readiness, presence of an adequate A&F system, access to an external quality assessor, and future use and functionalities of the A&F system.

**Conclusion.** CR professionals identified five thematic clusters with factors for successful implementation of a QI intervention in a multidisciplinary setting. While presence of a web-based A&F system and external quality assessor were seen as instrumental for gaining insight into performance and formulating QI actions, QI team commitment and organizational readiness were perceived as essential to actually implement and carry out these actions. Future research to evaluate QI interventions should focus on addressing these socio-technical factors during the design and execution of the study.

**Key words:** Quality of health care; Concept mapping; Cardiac Rehabilitation.
INTRODUCTION

There is persistent room for quality improvement (QI) in health care, but the complexity of health care systems makes it difficult to achieve change [1]. The field of cardiac rehabilitation (CR), a multidisciplinary therapy to support patients with cardiovascular disease in restoring their physical and psychosocial condition [2], also faces challenges in improving care quality. The efficacy of CR has been studied in at least 47 separate randomized controlled trials [3, 4] and in a population based cohort study showing a substantial survival benefit [5]. Despite this documented efficacy, CR is still not implemented in a standardized way [6, 7] and CR uptake remains low [8, 9]. Example challenges for QI in the field of CR are a lack of awareness of CR benefits among consultant cardiologists, limited use of CR performance measures, and limitations in capacity, and reimbursement constraints [10].

A common approach to changing complex health systems is systematic QI, which focuses on improving a system’s underlying processes rather than on correcting mistakes of individuals. It relies on data from professionals’ own setting and encourages them to work in multidisciplinary QI teams [11]. Data about the organization’s performance should guide them in improving their practice by the Plan-Do-Study-Act (PDSA) cycle, which is part of the Model for Improvement [11]. Within the Plan and the Study steps in the PDSA cycle, audit and feedback (A&F) is a crucial element. A&F consists of providing health care professionals with an objective summary of their clinical performance over a specified period of time [12]. Clinical performance is typically measured by a set of quality indicators derived from clinical guidelines or expert opinion, each indicator representing a quality aspect of care. A&F interventions assume that professionals are prompted to plan QI actions for their practice when observing a discrepancy between their own performance and a target (e.g. national or benchmark) value [13]. A recent Cochrane review concluded that A&F interventions may be more effective when they include both an action plan and explicit goals [12]. Furthermore, the effect of indicator-based performance feedback is likely to be stronger when it is combined with educational meetings, directed towards actively involving professionals in the improvement process [12]. Through such meetings, professionals can be supported to use presented feedback to select targets for improvement and to plan concrete actions.

Many current QI interventions are based on the PDSA cycle and use A&F, often complemented with other elements, to implement QI in different health care settings [14, 15]. We developed a multifaceted A&F intervention for the field of CR that both incorporates successful characteristics described in the literature [12, 14, 16-18] and also specifically addresses multidisciplinary teams rather than individual professionals only [19, 20].

To gain insight in the effectiveness of QI interventions we need evidence from randomized clinical trials (RCTs). However, many context specific factors may influence the uptake of interventions in daily practice, and information on these factors is usually not provided by an RCT [21]. Yet, information on such contextual factors, e.g. organization-professional processes such as culture and workflow, is essential both to interpret RCT results and to facilitate future
implementation of a QI intervention. Commonly used qualitative research methods (e.g. individual or focus group interviews and observations) can provide these insights but typically involve only a limited group of respondents against sufficient time and resources (e.g. to collect, analyse and report on data) [22]. Concept mapping is a research methodology that overcomes some of these drawbacks. This mixed-methods approach collects qualitative data from larger groups of stakeholders with different content expertise or interests in a certain domain. The generated ideas are analysed and structured by statistical techniques to represent them visually on maps [23]. As the method is designed to investigate ideas from larger groups of participants in an efficient way and short time frame, we assumed this method can be appropriate to evaluate QI interventions. The aim of this study was to determine factors identified by CR teams on what is needed to successfully implement a web-based A&F intervention with outreach visits to improve the quality of CR care in the Netherlands.

BACKGROUND

Clinical setting: Improving CR in the Netherlands
CR programmes offer a cost-effective, multidisciplinary, comprehensive approach to address cardiovascular risk factors, regain physical capacity, improve psychosocial condition, and achieve lifestyle changes [2, 4, 24]. CR is offered by multidisciplinary teams which generally include a cardiologist, specialized nurses (of whom one acts as rehabilitation coordinator), physical therapists, a psychologist, dietician and social worker. A recent meta-analysis of RCTs shows evidence of the effectiveness of CR with regard to mortality and cardiac events (relative-risk reduction: 21-47%) [25].

To improve CR services we previously developed and evaluated an electronic patient record (EPR) with clinical decision support (CDS) facilities [26]. We found that that CDS considerably improved the concordance of CR teams’ clinical decisions with prevailing clinical practice guidelines. However, the trial also revealed persisting organisational barriers to full guideline implementation [26]. The CDS was not effective when changes were required, related to e.g. lack of time, reimbursement or capacity, that users considered to be beyond their tasks and responsibilities. Therefore we hypothesized that guideline implementation with CDS might be more powerful if used in conjunction with other interventions directed at the decision-making processes at the organizational level [19]. As systematic QI is increasingly used to achieve changes at this level in health care, we developed a multifaceted QI intervention including a web-based A&F system with outreach visits [19, 20].

The QI intervention: a web-based A&F system with outreach visits
The web-based A&F system, called CARDSS Online, was designed in 2011 for CR centres in the Netherlands that were using an EPR with CDS [20]. Centres that started to use the system (n=18) all participated in the CARDSS-II RCT [19, 27]. This RCT evaluated the effect of system use in combination with educational outreach visits on clinical performance between July 2012
and December 2014 [19]. Currently we are analysing the RCT results on improved professional performance (change in performance in eleven care processes and six patient outcomes and on guideline concordance for the four main CR therapies).

The system was designed to be primarily employed during four quarterly outreach visits within the RCT period. During the visits an external quality assessor (MvEV) met the centre’s local QI team to support them continuing all steps of the PDSA cycle. Each QI team consisted of at least the coordinating nurse, a caregiver from one other discipline, a cardiologist, and the centre’s manager. The system supports (i) monitoring of indicator-based performance, (ii) selecting aspects of care that need improvement, (iii) developing a QI plan, and (iv) periodically adjusting the plan [20]. During the visits the quality assessor actively engaged the team in the QI effort by means of the system, without them needing to have extensive knowledge of the underlying concepts on systematic QI.

**METHODS**

Concept mapping is a structured qualitative research method that is used to collect, aggregate and analyse ideas from different individuals, with respect to a certain focus question. The method results in a graphical map, called ‘concept map’, that displays interrelationships between ideas expressed by participants [28, 29]. We followed the five steps of the structured group conceptualization method as described by Trochim and Kane [28, 29] (see Figure 1).

![Figure 1 - Five steps of the concept mapping method](image-url)
Participants
During the project planning, we identified the focus for the project, selected participants and
determined the schedule and logistics. The eligible participants were all 116 professionals that
took part in the QI teams of the 18 centres using the web-based A&F system (range 3–10
professionals per centre). Most professionals concerned nurses (n=30), physiotherapists (n=20),
managers (n=18) and cardiologists (n=15). Not all centres had started working with the system
at the same time. We only invited professionals from centres which had worked with this system
for at least one year. During the first round of data collection (focus group sessions), there were
11 centres that fulfilled this criterion, and during the second round (online structuring of ideas),
all 18 centres fulfilled this criterion.

Data collection
In the first round of data collection we used brainstorming by the participants during three
focus group sessions to generate ideas and articulate the relationships between the ideas.
We expected that during live interaction participants would recognize and complement each
others’ ideas, resulting in a more comprehensive set of statements addressing all factors relating
to QI (compared to online brainstorming). In the winter of 2013/2014 we asked one or two
representatives per centre to take part in one of the focus groups. This could be each discipline(s)
from the team. The sessions, maximal 1.5 hour, were organized during national CR meetings in
different regions in the country to minimise travel time for participants and maximise response
rate. Participants were asked to formulate as many statements as they wished in response to
the focus question “To successfully implement QI in a CR centre by means of a web-based
A&F system with outreach visits, it is necessary that...”. To support participants in discussing
multiple factors related to QI and to make them share their own experiences with the A&F
system during the RCT, a topic list was used by the chairman (TV or NP) (see Appendix I). After
the focus groups, the list of statements was reviewed by three researchers (TV, NP and NdK)
based on consensus, to eliminate duplicates and reformulate remaining statements to minimize
any confusion or ambiguity in meaning during interpretation outside the focus group context.
The goal was to compose a set of mutually exclusive statements that expressed only one idea
without loss of their original content.

During the second round, we asked participants to synthesize and structure ideas individually.
We used an online concept mapping tool for sorting and rating [30]. Participants were asked to
sort the statements into thematically related groups (clusters) which made sense to them, using
at least 2 –but no more than 10– clusters, and to provided a name for each cluster that covers
its thematic content. During the rating subtask participants rated each individual statement on
a Likert scale from 1 (not at all) to 5 (very) for two dimensions: its importance during QI in their
own CR centre; and its feasibility, defined as the possibility to be accomplished within one year
in their own CR centre. In addition, all participants were requested to fill out a questionnaire
with five questions concerning their background (gender, age, disciplinary background, area
of residence and computer experience). Data for this round were collected during the eight
months following the last focus group session (spring and summer 2014); participants who did not respond received up to four reminders.

**Data analysis**
A sequence of multivariate statistical analyses was performed to analyse and compute the maps [28]. We used the Concept Systems Global Max package for this step [30]. The analyses which started with the construction of a similarity matrix from the sorted data. This matrix showed the number of participants who sorted each pair of statements together. Thereafter multidimensional scaling was used to position each statement as a separate point on a two-dimensional map (i.e., the point map) showing all statements in relation to each other. To measure the degree to which the distances on the map were discrepant from the values in the input similarity matrix a stress value was calculated (a number between 0 and 1 where 0 is a perfect map). A meta-analysis of multiple concept mapping studies estimates an average stress of 0.285 (SD 0.04) [31].

As statements that are more often sorted together appear closer to each other on the point map, the ideas can be organized into clusters. Hierarchical cluster analysis was used to group points reflecting similar concepts together. To compute a map with optimal balance between sufficient detail and meaningful interpretation, iteratively separating or merging clusters is needed to adequately represent the data [28]. After reviewing different configurations the final cluster map was determined by the research team based on a consideration of its content and meaningfulness for the research question. In addition we used the Go-Zones graph to compare ratings on importance and feasibility. Within this graph quadrants were constructed by dividing above or below the mean rating for importance and feasibility [28].

To interpret and utilize the maps, the research team proposed thematic labels for the clusters based on the titles generated by the study participants. We discussed the results within the team and, when needed, with other stakeholders (e.g. national societies or future users of the system) to determine strategies and tactics for future QI implementation actions.

**Ethics**
All eligible participants were informed about the purpose, the procedures and implications of participating in the study through an invitation mail. From those who decided to participate, written informed consent was acquired prior to participation, both for joining the focus group sessions, the sorting and rating procedure and publication of the results. Participants were given the opportunity to withdraw their contribution at any time. The Institutional Review Board of the Academic Medical Centre of the University of Amsterdam waived the necessity to obtain ethical approval for this study.
RESULTS

Focus group sessions
To generate ideas during the focus group sessions, the QI teams of all 11 invited CR centres responded by sending one or two representatives, resulting in 18 participants (3–8 per session) (see Table 1). The sessions ended with lists of 27, 28, and 30 statements respectively (total 85 statements). The formulated statements included local and general experiences with, essential elements of, and improvements for, performing QI by means of the web-based A&F intervention with outreach visits; such as “A cardiologist actively participates in the QI team [meaning not only attending the outreach visit but also executing their actions from the QI plan]” and “Feedback in CARDSS Online confronts you with your own shortcomings”.

Online sorting and rating
Before the 116 members of the QI teams started to structure ideas online, the 85 statements were consolidated into 42 unique statements (see Table 2). The online sorting and rating tasks were performed by respectively 36 (31%) and 49 (42%) of the invited participants representing all 18 centres (see Table 1). The online sessions had a mean duration of 45-minutes and were performed at the time and place participants preferred. Participant characteristics were quite similar between the groups that generated and structured the ideas and representative for the overall CR professional population. The sorting task yielded different amount and names of clusters per participant. For example, the previously mentioned statement about participation of the cardiologist was sorted by one participant together with the statement “There is equivalence and an open culture within the QI team” in a cluster labelled as “Work situation in QI team”. By another participant this statement was sorted together with “There is a clear division of tasks within the QI plan” in a cluster labelled as “Implementation of QI actions”.

The mean ratings of the statements on importance and feasibility are shown in Table 2 and Figure 4. The average rating on importance ranged from 4.68 for statement 6 (“Multidisciplinary meetings and informal clinician agreement take place on a regular basis”) to 2.68 for statement 23 (“Participating in the CARDSS Online QI intervention is obliged”). For feasibility the average rating ranged from 4.10 for statement 6 again to 1.36 for statement 3 (“There are no overarching issues in the organisation like a merger with another organisation or austerity measures”).
Table 1 – Characteristics of participants.

<table>
<thead>
<tr>
<th></th>
<th>GENERATE IDEAS</th>
<th>STRUCTURE IDEAS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Focus group sessions</td>
<td>Online sorting</td>
</tr>
<tr>
<td></td>
<td>Importance</td>
<td>Feasibility</td>
</tr>
<tr>
<td>Participants (%)</td>
<td>18/66 (27.3)</td>
<td>36/116 (31.0)</td>
</tr>
<tr>
<td>Centres represented (%)</td>
<td>11/11 (100.0)</td>
<td>17/18 (94.4)</td>
</tr>
<tr>
<td>Mean age (SD)</td>
<td>44.6 (8.8)</td>
<td>45.2 (9.9)</td>
</tr>
<tr>
<td>Female gender (%)</td>
<td>16 (88.9)</td>
<td>24 (66.7)</td>
</tr>
<tr>
<td>Discipline (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specialist nurse</td>
<td>13 (72.2)</td>
<td>17 (47.2)</td>
</tr>
<tr>
<td>Physiotherapist</td>
<td>2 (11.1)</td>
<td>8 (22.2)</td>
</tr>
<tr>
<td>Manager</td>
<td>1 (5.6)</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>Cardiologist</td>
<td>0 (0.0)</td>
<td>2 (5.6)</td>
</tr>
<tr>
<td>Psychologist or social worker</td>
<td>2 (11.1)</td>
<td>5 (13.9)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0.0)</td>
<td>3 (8.3)</td>
</tr>
</tbody>
</table>
Table 2 – Statements per cluster. Clusters are sorted on rank of importance and statements within clusters are sorted on importance.

<table>
<thead>
<tr>
<th>Cluster</th>
<th>Nr*</th>
<th>Statement</th>
<th>Importance</th>
<th>SD Importance</th>
<th>Feasibility</th>
<th>SD Feasibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. QI team commitment</td>
<td></td>
<td>There is equivalence and an open culture within the QI team; making the QI effort a mutual responsibility of all disciplines, including the cardiologist and manager.</td>
<td>4.30</td>
<td>0.74</td>
<td>3.53</td>
<td>1.12</td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td>Multidisciplinary meetings and informal clinician agreement take place on a regular basis.</td>
<td>4.68</td>
<td>0.51</td>
<td>4.10</td>
<td>1.06</td>
</tr>
<tr>
<td>7.</td>
<td></td>
<td>There is equivalence and an open culture within the care team.</td>
<td>4.64</td>
<td>0.52</td>
<td>3.74</td>
<td>1.00</td>
</tr>
<tr>
<td>8.</td>
<td></td>
<td>Each discipline properly carries out their own actions from the QI plan.</td>
<td>4.58</td>
<td>0.49</td>
<td>3.10</td>
<td>1.06</td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td>A cardiologist actively participates in the QI team.</td>
<td>4.47</td>
<td>0.88</td>
<td>3.28</td>
<td>1.48</td>
</tr>
<tr>
<td>9.</td>
<td></td>
<td>There is a clear division of tasks within the QI plan.</td>
<td>4.42</td>
<td>0.60</td>
<td>4.00</td>
<td>0.89</td>
</tr>
<tr>
<td>30.</td>
<td></td>
<td>The centre has a leader who can drive continuation of QI after the study.</td>
<td>4.42</td>
<td>0.71</td>
<td>3.42</td>
<td>1.18</td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td>A manager actively participates in the QI team.</td>
<td>4.36</td>
<td>0.85</td>
<td>3.36</td>
<td>1.37</td>
</tr>
<tr>
<td>27.</td>
<td></td>
<td>Everyone within the QI team takes time to discuss QI actions.</td>
<td>4.30</td>
<td>0.53</td>
<td>3.50</td>
<td>0.98</td>
</tr>
<tr>
<td>31.</td>
<td></td>
<td>People really work as a team and involve new employees in the QI effort.</td>
<td>4.26</td>
<td>0.62</td>
<td>3.78</td>
<td>1.06</td>
</tr>
<tr>
<td>16.</td>
<td></td>
<td>The QI team has a clear mandate to carry out QI plans from the very first beginning.</td>
<td>4.21</td>
<td>0.83</td>
<td>3.08</td>
<td>1.07</td>
</tr>
<tr>
<td>25.</td>
<td></td>
<td>The nurse acting as rehabilitation coordinator is willing to share responsibilities with colleagues and does not try to solve everything on her own.</td>
<td>4.08</td>
<td>1.01</td>
<td>3.68</td>
<td>1.09</td>
</tr>
<tr>
<td>18.</td>
<td></td>
<td>There is a central coordinator of QI in multiple disciplines within the centre.</td>
<td>3.85</td>
<td>1.04</td>
<td>3.00</td>
<td>1.28</td>
</tr>
<tr>
<td>36.</td>
<td></td>
<td>The QI plan is printed on paper and used during QI meetings in between the outreach visits.</td>
<td>3.60</td>
<td>1.07</td>
<td>3.90</td>
<td>0.96</td>
</tr>
</tbody>
</table>

Nr of statements: 13
Rank on importance: 1
Rank on feasibility: 1
### Organisational readiness

<table>
<thead>
<tr>
<th>Nr of statements: 5</th>
<th>Rank on importance: 2</th>
<th>Rank on feasibility: 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>41. Every discipline accurately records patient data, preferably in the same system.</td>
<td>4.51</td>
<td>0.77</td>
</tr>
<tr>
<td>10. There is enough time to finish all actions in the QI plan.</td>
<td>4.43</td>
<td>0.63</td>
</tr>
<tr>
<td>14. The EPR for CR is already in use for a longer time period to ensure that data recording issues are solved.</td>
<td>4.08</td>
<td>0.89</td>
</tr>
<tr>
<td>3. There are no overarching issues in the organisation like a merger with another organisation or austerity measures.</td>
<td>3.62</td>
<td>1.20</td>
</tr>
<tr>
<td>26. There exists pressure from external governing bodies (e.g. the health care inspectorate) on the hospital board to support QI actions.</td>
<td>3.60</td>
<td>0.98</td>
</tr>
</tbody>
</table>

### Presence of an adequate A&F system

<table>
<thead>
<tr>
<th>Nr of statements: 9</th>
<th>Rank on importance: 3</th>
<th>Rank on feasibility: 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. It is clear how to record all patient data within the EPR for CR, in order to avoid unpleasant surprises in the feedback.</td>
<td>4.57</td>
<td>0.53</td>
</tr>
<tr>
<td>42. CARDSS Online presents an unambiguous workflow, which creates a learning effect.</td>
<td>4.25</td>
<td>0.77</td>
</tr>
<tr>
<td>5. Feedback in CARDSS Online convinces the QI team about the necessity of change.</td>
<td>4.21</td>
<td>0.65</td>
</tr>
<tr>
<td>28. A QI plan is defined with CARDSS Online.</td>
<td>4.06</td>
<td>0.76</td>
</tr>
<tr>
<td>4. Feedback in CARDSS Online confronts you with your own shortcomings.</td>
<td>3.94</td>
<td>0.83</td>
</tr>
<tr>
<td>34. CARDSS Online supports you in defining priorities.</td>
<td>3.85</td>
<td>0.98</td>
</tr>
<tr>
<td>29. The QI plan defined in CARDSS Online is also consulted on a regular basis in between the outreach visits.</td>
<td>3.79</td>
<td>0.63</td>
</tr>
<tr>
<td>32. The feedback in CARDSS Online is used intensively.</td>
<td>3.66</td>
<td>0.85</td>
</tr>
<tr>
<td>40. CARDSS is a national project, participating makes you being heard.</td>
<td>3.43</td>
<td>1.02</td>
</tr>
</tbody>
</table>
### 2. Access to an external quality assessor

<table>
<thead>
<tr>
<th>Nr of statements: 9</th>
<th>Rank on importance: 4</th>
<th>Rank on feasibility: 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>37. The external quality assessor supports the QI team during the outreach visits with clear explanations and examples.</td>
<td>4.13</td>
<td>0.67</td>
</tr>
<tr>
<td>39. The external quality assessor is active within national societies and therefore has thorough knowledge of the field.</td>
<td>4.13</td>
<td>0.73</td>
</tr>
<tr>
<td>13. The outreach visits are performed by an external quality assessor who is engaged and who knows how to motivate people.</td>
<td>4.08</td>
<td>0.89</td>
</tr>
<tr>
<td>22. During the year with support from the external quality assessor the message should be: What do you need in order to work independently on QI in the future?</td>
<td>3.92</td>
<td>0.93</td>
</tr>
<tr>
<td>35. The external quality assessor shares experiences and solutions from other centres with us.</td>
<td>3.92</td>
<td>0.89</td>
</tr>
<tr>
<td>21. Outreach visits do not occur more often than once within three months, otherwise there is not enough time to work on the QI actions.</td>
<td>3.83</td>
<td>1.02</td>
</tr>
<tr>
<td>11. A quality assessor from outside the organisation, without a professional relation with the QI team, performs the outreach visits.</td>
<td>3.66</td>
<td>0.89</td>
</tr>
<tr>
<td>17. The centre receives regular outreach visits from an external quality assessor.</td>
<td>3.55</td>
<td>0.96</td>
</tr>
<tr>
<td>12. There is an induction period during which everyone has time to get to know the external quality assessor.</td>
<td>2.96</td>
<td>0.97</td>
</tr>
</tbody>
</table>

### 5. Future use and functionalities of the A&F system

<table>
<thead>
<tr>
<th>Nr of statements: 6</th>
<th>Rank on importance: 5</th>
<th>Rank on feasibility: 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>38. Reasons for low participation rates in certain CR therapies can be recorded in CARDSS Online.</td>
<td>4.08</td>
<td>0.99</td>
</tr>
<tr>
<td>33. Questionnaires are also considered ‘completed’ when only a few items are missing.</td>
<td>3.83</td>
<td>1.18</td>
</tr>
<tr>
<td>19. Feedback relating to insurmountable barriers is not shown over and again.</td>
<td>3.36</td>
<td>0.75</td>
</tr>
<tr>
<td>24. Participating in the CARDSS Online QI intervention is not obliged.</td>
<td>3.21</td>
<td>1.20</td>
</tr>
<tr>
<td>20. In the future feedback in CARDSS Online will differentiate between different locations of a single centre.</td>
<td>2.89</td>
<td>1.25</td>
</tr>
<tr>
<td>23. Participating in the CARDSS Online QI intervention is obliged.</td>
<td>2.68</td>
<td>1.18</td>
</tr>
</tbody>
</table>

Abbreviations: A&F= audit and feedback; CR=cardiac rehabilitation; QI= quality improvement

* Nr= number of statement; also used in Figure 2 and Figure 3
Cluster maps and content

All responses were included in the analysis to compute maps. Based on the sorting data of the participants a point map was calculated with a stress value of 0.2615. Clustering the points led to the final cluster map as shown in Figure 2. The map consisted of five thematic clusters, with a range of 5 – 13 statements per cluster. Table 2 presents the descriptions of the clusters, including all statements per cluster and the mean ratings on importance and feasibility which were used to rank the clusters. Mean importance ratings of the clusters ranged from 4.30 (“QI team commitment”) to 3.34 (“Future use and functionalities of the A&F system”). Mean feasibility ratings ranged from 3.53 to 2.36 for the same two clusters.

When comparing the ratings on importance and feasibility, 18/42 (42.9%) of the statements were rated above average for both and ended up in the upper right quadrant of the Go-Zone graph (Figure 3). Out of these, 11 (61.1%) statements (6, 7, 8, 1, 9, 30, 2, 27, 31, 16 and 25) were sorted into the cluster on “QI team commitment” (13 statements in total), all of which describing different factors of a QI team dedicated to improve care quality.

Figure 2 – Final Concept Map showing the five clusters.

Abbreviations: A&F= audit and feedback; QI= quality improvement.
Figure 3 – Go-Zones showing the scores on feasibility and importance for each statement. Horizontal line represents mean feasibility rating; vertical line represents mean importance rating. Scoring was on a 5 point Likert scale (1 = not important/feasible, 5 = very important/feasible). See Table 2 for a complete description of all statements.

Interpretation and utilization
During the final step of concept mapping, we discussed the results within our research team to get a comprehensive overview of the five thematic clusters, that influenced the effectiveness of our QI intervention on care quality. Obtained insights will support the interpretation of our RCT results on improved professional performance. Both the role of the QI team and organisation were rated more important than those of the developed A&F system and the external QI assessor. This means that differences in organizational readiness and QI team commitment to formulate and actually implement QI interventions might explain differences in the effectiveness of the A&F system in the different CR centres.

Moreover, we currently use the results to define improvements for our A&F system together with representatives of the Committee on Cardiovascular Prevention and Rehabilitation of the Netherlands Society of Cardiology and CR centres which aim to use the system in the future. During further national dissemination of the system we will need to take into account team commitment for working on QI and organizational readiness more explicitly before a centre actually starts working on QI by using the A&F system and getting support from an external quality assessor.
DISCUSSION

This paper describes how we used concept mapping to qualitatively gain insight into factors to successfully implement a web-based A&F intervention with outreach visits to improve quality of CR care in the Netherlands. In order of decreasing importance, the following five thematic clusters were deemed important and feasible for implementing the QI intervention: QI team commitment, organisational readiness, presence of an adequate A&F system, access to an external quality assessor (performing the outreach visits), and future use and functionalities of the A&F system. The thematic clusters, and especially high rated statements as “1. A cardiologist actively participates in the QI team”, “41. Every discipline accurately records patient data, preferably in the same system” and “42. CARDSS Online presents an unambiguous workflow, which creates a learning effect”, are currently used as reference to interpret and contextualize the quantitative results from an RCT on the QI interventions’ effectiveness. Furthermore we work on a strategy for national dissemination of our intervention which better takes into account the importance and feasibility of team commitment and organizational readiness for successful QI.

When we compare our results revealing the importance of external factors to successful implementation of a QI intervention with other qualitative evaluations of QI, outcomes are quite similar. During a focus group to evaluate a multifaceted QI intervention within 30 intensive care units, De Vos et al found e.g. that, characteristics of the environment (comparable to our cluster organisational readiness) were the second most reported category of barriers (after characteristics of the indicators) [32]. Marshall et al also emphasized the importance of the context within which QI projects take place in a GP setting. These included shared values, experiences, and leadership capabilities of the participants, the constraints under which they operate, and the infrastructure supporting them [33]. In addition, a systematic review towards the influence of context on QI success in health care concludes that leadership from top management, organizational culture, data infrastructure and information systems, and years involved in QI efforts are important to QI success [34]. Other potentially important factors identified in the review included: physician involvement in QI, resources for QI, and QI team leadership [34]. As we found in our study several important factors related to team commitment (e.g. “7. There is equivalence and an open culture within the care team”) and organisational readiness (e.g. “10. There is enough time to finish all actions in the QI plan”), we suggest to determine both before initiating QI with a thorough needs analysis as e.g. proposed by the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) framework [35]. This may uncover many underlying issues within a team (e.g. absence of support of leadership, varying perceptions and attitudes about the existing culture towards QI) and institution (e.g. equipment problems, staffing shortage) which need to be addressed before participating in a QI intervention to improve success of the intervention. Also the Triangle Model [36] and the Systems Engineering Initiative for Patient Safety (SEIPS) model [37] present a broader sociotechnical approach in which the emphasis is on a characterizing the many interactions between healthcare professional teams, technology, their environment and the organization.
in a concise and coherent manner to identify points for improvement or intervention. These models can be useful during the design and execution of future studies to evaluate (A&F-based) QI interventions.

To evaluate QI interventions from this broad approach it is essential to include diverse stakeholders and disciplines from multiple levels of the health care system. At the same time contemporary health care resources are under continuous pressure with an increasing consciousness on the importance of continuous monitoring and working on systematic QI. These challenges require processes and methods that can address the complexity and demanding requirements [23]. In this study concept mapping proved to be a useful and efficient tool to gain an understanding of stakeholder experiences on the implementation of a QI intervention in the field of CR. In our study we did experience three advantages of concept mapping over traditional interviews or focus groups for both the participants and research team. First we gained both face-to-face (18 participants to generate ideas) and online (49 participants to structure ideas) input from all invited CR clinics and disciplines. Second, both data collection and analysis were performed in an efficient way and short time frame with support of an online tool, resulting in a minimum investment of time and resources for this study. Finally the resulting maps that visually depict the composite thinking of the participants are now used for both the interpretation of RCT data on outcomes of the QI intervention and for designing future QI interventions. The thematic clusters and their content appeared a convenient framework which can easily be shared and discussed with other relevant stakeholders. Using other qualitative study designs, it would have been less likely to receive input from such a large amounts of representative participants within the same resources. Other designs often also result in a more diffuse overview of results and recommendations compared to the thematic clusters.

Our study has also some limitations. Although we received input from all CR disciplines, the number of cardiologists and managers (together representing the managerial level) appeared low, especially during the focus group sessions. This hindered a comparison of their responses with the other disciplines (e.g. nurses and physiotherapists). At the same time it is illustrative for one of the main conclusions from the cluster on QI team commitment: the importance of active participation of both the cardiologist and manager is explicitly named as success factor for QI. The low participation rates in our study demonstrate how hard it is to actually involve them. The concept mapping methodology itself has also some limitations. There is a restriction in the number of statements that can reasonably be processed by the participants. However, it is possible to reduce the list by combining (near-)redundant statements (from 85 to 42 in this study). In addition the focus statement should be formulated well and specific, as double-barrelled focus statements may result in incoherent results.
CONCLUSION

This concept mapping study found five thematic clusters with factors that, according to CR professionals, are necessary to successfully implement a multifaceted QI intervention in a multidisciplinary setting. By enabling professionals to interact with each other’s views in an efficient way the concept mapping method gives an overview of relevant concepts and their rating by different stakeholders in a relatively short time frame. We conclude that a web-based A&F system and external quality assessor are instrumental to gain insight into team performances and to formulate QI actions. However, QI team commitment and organizational readiness are considered essential to actually implement and finish these actions. Future research to evaluate (A&F-based) QI interventions in health care should focus on addressing these socio-technical factors during the design and execution of the study.

ACKNOWLEDGEMENTS

The authors would like to thank all the members from QI teams of the CR centres, who invested their time to participate in our research to evaluate our QI intervention, for their contribution.

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CONTRIBUTORS

MvEV, NdK and NP had the basic idea for this study and were, together with JH, involved in the development of the protocol. NP and TV performed data collection during the focus group sessions and MvEV for the online sorting and rating part. MvEV and EJ performed the analyses. MvEV and NdK drafted the manuscript. All authors were involved in the critical revision of the paper for intellectual content. All authors read and approved the final manuscript.
APPENDIX I: TOPIC LIST FOCUS GROUP SESSIONS

Focus question: “To successfully implement quality improvement in a cardiac rehabilitation centre by means of a web-based audit and feedback system with outreach visits, it is necessary that …?”

Introduction question (shortly answered by all participants)
Think about factors which might influence successful implementation of a web-based quality improvement application in your CR centre and name, according to your experience and opinion, the most important one?

Topic list
- Which things in your CR centre successfully changed when you compare the situation before and after working with CARDSS Online?
  • What was needed to receive the change (reduced barriers)?
  • And which things did not change? Why not (persisting barriers for change)?
- What are your experiences with the different elements of systematic quality improvement during the trial?
  • CARDSS Online system: What were your experiences with the system? Which parts can be improved?
  • Quality indicator set: What were good and worse indicators?
  • Outreach visits: What do you think of the role of the external quality assessor during the educational outreach visits?
- How would you describe the role of your manager and cardiologist when working with CARDSS Online? Where the stimulating or hindering quality improvement changes?
- How would you evaluate the time you have put into working with CARDSS Online during the trial? Not much or on the contrary a lot?
- What is your biggest wish for a new quality improvement change in your CR centre for the next year (independent if it can be reached)?
  • Do you think you can implement this change? How?
  • If not, why do you think you cannot implement this change?

Closing questions
- What factors should be in place within your CR centre to facilitate a continuous systematic quality improvement process with CARDSS Online?
  • What factors should be in place to keep working with CARDSS Online after participation in the trial on a voluntary base?
  • What are your ideas about a national cardiac rehabilitation registry?
    • Voluntary/ obligated? Costs? Number of feedback reports?
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SUMMARY AND GENERAL DISCUSSION
INTRODUCTION

The overall aim of this thesis was to use the principles of the Learning Health System (LHS) to realise an infrastructure to connect physicians, other health professionals, managers, professional associations, electronic patient record (EPR) developers, patients and researchers to continuously improve professional performance in the field of cardiac rehabilitation (CR) in the Netherlands. The infrastructure integrates both technical and organisational components. The technical components allow the co-use of data collected in the EPR with clinical decision support (CDS), and realise an audit and feedback (A&F) system. The organisational components concern the active involvement of all stakeholders to receive their necessary input and commitment for the optimal functioning of the technical infrastructure, and support services for multidisciplinary CR teams during outreach visits to actually use the A&F system and improve their performance by executing the LHS learning cycle (see Figure 1 in Chapter 1).

In the introduction in Chapter 1 we addressed three research aims; in this concluding chapter we will present a summary and discussion of the main findings for each research aim followed by our recommendations for researchers, decision-makers and other stakeholders from both inside and outside the field of CR.

RESULTS PER AIM

1) To assess current improvement challenges in the field of CR

Summary of main findings
Within the field of CR an EPR system with computerized clinical decision support (CDS) functionalities was previously developed to stimulate concordance with guideline recommendations for CR. In Chapter 2 we described the results of a qualitative study after the implementation of this system to assess reduced and persistent barriers for improvement [1]. We found that the CDS system improved guideline implementation by increasing its users’ familiarity with the recommendations and decision logic of the guidelines. Furthermore, by overcoming users’ inertia to previous practice, and reducing guideline complexity by for example facilitating assessment result calculation and interpretation, guideline adherence was improved. However, although the CDS has proven to be effective, implementation barriers related to a lack of time or resources, organisational constraints, and a lack of reimbursement in combination with guideline related barriers (e.g., ambiguities, omissions, and contradictions) were not solved by the CDS system implementation [1].

In Chapter 3 we designed a continuous improvement strategy directed at both organisational barriers and guideline related barriers identified in Chapter 2 [2]. Two learning cycles were designed to be embedded within computerized CDS in a continuous improvement strategy. First, to address barriers related to practicability of the underlying guidelines, a guideline-maintenance cycle was proposed. This cycle used routinely collected EPR data to serve as input for a guideline
SUMMARY AND GENERAL DISCUSSION

revision process. Second, barriers within teams and organisations were addressed by a benchmark-feedback cycle. Within this cycle, the EPR data was used to periodically aggregate performance feedback for professionals and their managers. A case study with 21 CR teams receiving one feedback iteration on their performance resulted in positive responses. Several centres reported that viewing personal performance within a context of peer performance together with their manager, was effective to create necessary facilities to improve their CR program. However, many centres found it difficult to make time to discuss the report [2].

Chapter 4 demonstrates that, among patients who were diagnosed with an acute coronary syndrome (ACS: myocardial infarction [MI] and unstable angina pectoris [AP]) and/or therapeutic intervention (coronary artery bypass graft surgery [CABG], percutaneous coronary interventions [PCI] or valve surgery), only 28.5% received CR within the following year [3]. Factors associated with low CR uptake included female gender, older age (>70), elective PCI as compared to acute PCI or CABG, unstable AP as compared to MI, long travelling distances to the nearest CR provider (>15 km), and comorbidities [3].

Discussion of main findings – continuously improving care by combining multiple interventions

The results of Chapter 2 suggest that a CDS system implementation alone is insufficient to realise changes in clinical practice that users consider beyond their tasks, influence, and responsibilities. This is in line with other studies, emphasising that many different types of barriers to guideline implementation exist and suggesting that improvement is possible, but generally requires comprehensive approaches at different levels (professional, team, organisation, wider environment), tailored to specific settings and target groups [4-6]. After the implementation of the CDS system tailored to improve knowledge and behaviour of the individual professional, we identified remaining barriers related to teams and organisations and the underlying guidelines (wider environment). However, there is limited evidence concerning which combination of strategies is effective under which circumstances [5, 6]. As the LHS principles emphasise the need of implementing simultaneous learning cycles across all levels in a health system, we developed two learning cycles (see Figure 1) which extend beyond the level of learning from the individual professional using CDS at the point of care. First, with the guideline-maintenance cycle (inner cycle in Figure 1) we aimed to implement a learning cycle for revising clinical guidelines by collecting EPR data from multiple centres (step 1), in a central data registry (step 2) to analyse compliance levels (step 3), which are combined with knowledge from professionals and domain experts (step 4), to formulate the revisions (step 5), and implement them through the knowledge base of the CDS system (step 6). Second, the benchmark-feedback cycle, focuses on improving an organisation’s underlying processes to overcome the identified barriers at the decision-making level of the team and organisation (outer cycle in Figure 1). Here the collected EPR data from multiple centres (step 1), that is available in the data registry (2), provides input for feedback reports with benchmark information (step 3), to steer discussions in team meetings, including managers (step 4), to formulate (step 5) and implement actions to improve care process and patient outcomes (step 6). A caveat of such a feedback approach,
revealed in the case study, was the assumption that a conferring structure with regular team meetings is present or realised at participating centres, to discuss the feedback and decide how to act upon it. Since such an organisational structure did not exist in several CR centres, these reports were simply not discussed, and as such, did not affect the clinical practice. To stimulate actual execution of the efferent steps from the LHS learning cycle, we proposed to extend our strategy with educational meetings as they are known to improve feedback effectiveness [7]. Furthermore, in our case study we only applied one feedback iteration; ongoing data collection and analyses are required for long-term efficacy assessment of our strategy, and guarantee continuous performance improvement over time.

Finally, Chapter 4 underlines the need for such instant improvement strategies, since we showed that only a minority of Dutch patients that are eligible for CR actually received it. These results were the reason for the Dutch Health Care Inspectorate to force CR centres to improve their performance by stimulating them to work with an EPR with CDS instead of paper-based records [10]. They emphasised the necessity of collecting digital EPR data from multiple centres as input for learning cycles and also to make e.g. CDS for automatic referral at discharge possible [10]. In addition, several CR professional associations, especially the Netherlands Society of Cardiology, recognized the need to update the guidelines and actively participated in the revision process [11]. They also stimulated their members to take part in the guideline-maintenance and benchmark-feedback learning cycles as we proposed. The collaboration with these national organisations appeared to be essential to convince CR centres to start working on improving their performance. Although not yet facilitated by a technical infrastructure, the data analysis and publication on CR uptake rates did in fact result in a first iteration of the CR uptake learning cycle (see Figure 2).
Figure 1 – Learning cycle of continuous improvement [8, 9] completed with the technical and organisational components of the infrastructure we developed for the guideline-maintenance cycle (inner cycle) and benchmark-feedback cycle (outer cycle) in the field of CR.
Figure 2 – Learning cycle of continuous improvement [8, 9] completed with the technical and organisational components of the infrastructure we developed to improve CR uptake rates.
Recommendations – to address multiple improvement challenges in the field of CR

We defined the following recommendations for national organisations, researchers and other stakeholders in the field of CR to address the improvement challenges from the first part of this thesis. The recommendations are based on the findings from Chapter 2, 3 and 4, their discussion within a wider context of the LHS principles, and our experiences during and after performing these studies. The recommendations might also serve as input to assess and start improvement upon challenges in other domains of health care.

- Based on the effect of computerized CDS on guideline concordance [12] by optimizing the knowledge and attitude of CR professionals [1], the use of CDS in the CR EPR should be continued and stimulated. As underlying guidelines and work processes of professionals may change over time, the EPR with CDS should regularly be updated by the developers, together with the users, to guarantee optimal use during daily care data collection and effect on care processes and patient outcomes in the future.

- After implementation of a guideline, regular analysis of implementation barriers should be performed, serving as input for a guideline-maintenance cycle to optimize concordance [2]. According to this learning cycle, CR guidelines should be regularly updated, using recent evidence from the literature, and experience from daily practice to overcome ambiguities, omissions and contradictions.

- An intervention with a continuous character [2] to engage CR teams, their managers and organisation in the learning cycle is expected to support them to understand and reduce persistent organisational barriers [1, 4] to improve professional performance.

- To overcome barriers for improvements within each domain of health care, collaboration with national organisations, like professional associations or the Health Care Inspectorate, can assist in gaining national attention. Data collection, analyses and publication is required to inform those organisations about current challenges, like our publication indicating low CR uptake rates [3]. Regular provision of information to, and communication with, national organisations should be performed to receive their commitment to collaborate in a learning cycle to solve the challenge.
2) To develop an infrastructure to facilitate continuous improvement

Summary of main findings
To facilitate continuous improvement in the field of CR we developed a multiple-component infrastructure which connects the stakeholders and fragmented repositories of data and knowledge. The four chapters in this part of the thesis each address a different component of the infrastructure, either technical, organisational or both, necessary to implement the guideline-maintenance cycle and benchmark-feedback cycle as designed in the previous part. According to the LHS principles, both cycles start with, and rely on routinely collected EPR data to generate new knowledge as an ongoing, natural by-product of the daily care process. This indicates complete and high quality EPR data on CR care processes and patient outcomes as an essential starting point.

In Chapter 5 we assessed and developed recommendations to improve the usability of the data entry interface in the current EPR for CR to optimize the data collection [13]. Figure 3 gives an overview of this separate learning cycle. Based on our results, the EPR developers organised the data entry navigational structure in the redesigned system version in a flexible way around an overview screen. This better mimics users’ former paper-based daily routines of collecting patient data. In the redesign we assessed that the changes had resulted in an increased number of completed data register tasks and a decrease in navigation actions. Remaining problems concerned flexibility (e.g. lack of customization options) and consistency (mainly with layout and position of items on the screen), indicating room for further improvement to minimize the data collection effort of professionals [13].

In Chapter 6 we implemented the guideline-maintenance cycle as proposed in Chapter 3. We revised the Dutch clinical CR algorithm, a practical procedure for assessing patient needs, to further improve guideline implementation [14]. We used a combination of the routinely collected EPR data, knowledge from academic experts and experience from field experts. A large variation in assessment of patient needs was observed between CR centres. The algorithm was extended with assessment instruments for anxiety and depression, cardiovascular risk factors, stress, absence of partner and lifestyle parameters (smoking, physical activity and alcohol consumption), and limits the option of using only clinical judgement to assess CRSP needs (e.g. only when a patient encounters language or cognition problems) [14].

To enable implementation of the benchmark-feedback cycle from Chapter 3, we developed a set of indicators to monitor and evaluate the quality of CR care in Chapter 7 [15]. These indicators were needed to support the data analysis and interpretation steps from the learning cycle, and had not yet been developed for CR care in the Netherlands. As we aimed to receive input from multiple sources and stakeholders, we combined strengths from multiple development methods. Using this comprehensive method, referred to as a modified Rand method [15], we combined results from a literature and guideline review with knowledge of an expert and patient panel in an extensive rating and consensus procedure. All sources contributed to the final set of 18 quality indicators for CR (e.g. including processes indicators like ‘Complete data collection during needs assessment’ and outcome indicators as ‘Successful smoking cessation’) [15].
Figure 3 – Learning cycle of continuous improvement [8, 9] completed with the technical and organisational components of the infrastructure we developed to improve data registration in CR EPR.
In Chapter 8 we developed an A&F system to implement the entire benchmark-feedback cycle from Chapter 3 to improve decision-making at the team and organisational level [16]. To facilitate all learning cycle steps, we developed a back-end system, which collects CR EPR data, to calculate results on the indicators from Chapter 7 and present them in an A&F system to deliver tailored messages and support action to change. In more detail, the A&F system, named CARDSS Online, promoted four tasks:

1) Monitoring clinical performance,
2) Selecting specific care processes and patient outcomes for improvement,
3) Goal setting and action planning, and
4) Revising selected processes and outcomes, goals and actions in the plan during follow-up iterations to guarantee a continuous character.

The system was designed to be primarily employed during quarterly outreach visits during where an external quality assessor met the centre's local multidisciplinary team to support them continuing all steps of the learning cycle [16].

Discussion of main findings – the challenge of building an LHS infrastructure by involving multiple stakeholders

To develop an infrastructure which connects multiple stakeholders for continuous improvement of healthcare system, all of them should be willing to get involved, committed to the same goals and able to allocate dedicated resources. Unfortunately there is no handbook on how to recruit stakeholders with different interests and make them cooperate. To improve usability of data collection in the EPR for CR, which is essential to start a learning cycle, cooperation between the EPR developers, usability researchers and the first end-users from CR centres was required. Even after explicit commitment of the EPR team, due to unexpected technical difficulties as well as resource and time constraints, software iterations based on observed usability issues and final system implementation exceeded two years. After implementation of the redesigned EPR, we found that usability issues were solved but also that new usability issues were introduced. This indicates that the effort needed from CR professionals for data collection can still be further decreased during future iterations of the EPR usability learning cycle (see Figure 3). Using human centred design processes from the requirements phase on, is generally advised for development of all health information systems, including EPRs, but also applies to development of CDS and A&F systems [17].

During the revision of the CR guidelines, getting input of representatives of all professional associations involved in CR was also more time-consuming than anticipated. Although we tried to address as many barriers as we could identify from the compliance data and field experts, unavoidable compromises were necessary to complete the interpretation step of the learning cycle and reach consensus within the expert group. Furthermore, when the update of the guideline was finished, within a year new issues arose related to measures for the psychosocial assessment of the patient (e.g. to determine anxiety and depression, social support and expected problems during work resumption). In addition to a second iteration of
the guideline-maintenance cycle, resulting in the release of a second update, we underlined the need for a continuous guideline-maintenance cycle. However, as guideline updates in the field of CR are commonly financed by incidental grants, a continuous update process is difficult to achieve. When developing an LHS infrastructure it is essential to not only support national data collection, but also identify responsible organisations who have the funds to analyse the data and translate the results into clinical practice guidelines on a routine basis.

For the development of the indicator set to monitor and evaluate the quality of CR care, again we collaborated with an expert panel, complemented with a patient panel. Although we received detailed input from both stakeholders’ with respect to characteristics of quality of CR, not all characteristics could be included in our indicator set. For instance, indicators of long-term outcomes were not included simply because data of these outcomes was unavailable. For optimal use and interpretation of the results on a quality indicator set, professionals should be aware that indicators do not cover all aspects of the quality of health care. And, similarly to the guideline-maintenance cycle, preferably one organisation is responsible for regularly updating the indicator set in a indicator-maintenance cycle. Only then can up-to-date measures, which adequately represent care quality according to the latest guideline and knowledge from experts in the field, be guaranteed.

The developed A&F intervention, includes both technical (e.g. the data registry and web-based A&F system) and organisational components (e.g. outreach visits) to support all six steps of the iterative learning cycle. Although the first experiences with the system presented in Chapter 8 were promising, wider implementation and evaluation is required to assess whether actual improvements of clinical performance in a national setting can be realised (as we did in Chapter 11). Besides this quantitative information, the evaluation of A&F systems, like ours, should also take qualitative information into account (Chapter 12). Many context specific factors may influence the uptake of interventions in daily practice, e.g. organisation-professional processes such as culture and workflow. Information on these factors is usually not provided by quantitative studies [18]. Yet, information on such contextual factors, is essential both to interpret RCT results and to facilitate future implementation of improvement interventions.

A limitation of our A&F intervention is that improvement of CR uptake is not specifically addressed. In Chapter 4 we found this to be an important improvement challenge. However, although CR professionals recognized the importance of improving CR uptake, CR uptake was not adopted in the final quality indicator set. To gain insight into CR uptake at individual patient levels, information from departments outside the CR (e.g. the cardiology department) should be collected and analysed. The burden of gathering this necessary data to be included in our data registry was found too high within available resources of local CR teams. In addition, professional CR associations prepared other measures to increase CR uptake rates: a change in the national finance and declaration structure for CR and improving patient’s awareness on CR benefits (see Figure 3). The Netherlands Society of Cardiology (NVVC) actively contacted involved financial organisations to realise this reimbursement change. In 2014 the updated financial structure was introduced. The Cardiovascular Patients Organisation (H&V) developed new educational
materials to inform patients. Also these two associations, together with the Dutch Health Care Inspectorate, discussed the problem and possible solutions in national publications for both CR professionals (and patients), and on national meetings and congresses. As a result of this national awareness, CR teams often discussed improving CR uptake in their own institution during the outreach visits. Although not being part of presented feedback, goals and actions to improve uptake regularly ended up in the improvement plans. The current situation is that CR uptake rates are progressing steadily [19]. However, the issue needs ongoing national awareness to reach acceptable levels in the near future [20]. A future technical infrastructure including patient data on CR uptake in the EPR export to a central data registry can optimize the learning cycle to improve CR uptake (see the additions to step 2 and 3 in Figure 2).

Recommendations – to build an infrastructure which stimulates improvement in continuous learning cycles

We defined the following recommendations for researchers and decision-makers within the field of CR for instituting an infrastructure to stimulate improvement by continuous learning cycles. The recommendations can also be used within other fields of health care to build such an infrastructure. The recommendations are based on the findings from Chapter 5, 6, 7 and 8, their discussion within the wider context of the LHS principles and our experiences during and after performing these studies.

- Data collection is an essential first step of each learning cycle [9, 21]. To support high quality data collection as an ongoing, natural by-product of the care experience, the usability of EPR’s should be continuously optimized [13]. Therefore, collaboration between EPR developers, usability experts and end users should be organised in a learning cycle (see Figure 3). This process starts with the requirement phase and lasts until regular updates to solve remaining or new issues after implementation [13]. This recommendation can also be applied in a broader context towards optimizing the usability of other health information systems, e.g. CDS and A&F systems [17].

- When developing an LHS infrastructure it is essential to not only support national data collection but also to identify responsible organisation(s) who have the funds to analyse the data, interpret the results into knowledge and translate that knowledge into tailored messages in e.g. clinical practice guidelines [14] and accompanying quality indicators [15] on a routine base. The organisation should explicitly be capable to invite, motivate and collaborate with all stakeholders in this process [14, 15]. Without data analyses and tailored messages, the step to take action to improve practice is a difficult task for professionals collecting the data during their daily care routine [9, 21].

- To optimize the learning cycle to improve CR uptake, efforts from other stakeholders are needed since it is not specifically addressed in our A&F intervention. To obtain the necessary patient level data for analysis, collaboration between EPR developers, CR centres and the organisations they work within, and an analysing organisation is needed (see Figure 2). As long as patient level information is lacking, other national
sources (e.g. health insurance databases) can be used to provide realistic results on CR uptake in population based cohort studies to inform the CR uptake learning cycle [3, 19, 22].

3) To assess the effect of a web-based audit and feedback system with outreach visits on professional performance

Summary of main findings

The efferent side of our infrastructure supports the decision-making and taking action to change practice by multidisciplinary teams. To assess the effectiveness, we conducted a cluster-randomized trial in 18 CR centres with the web-based A&F system in combination with educational outreach visits. Chapter 9 describes the study protocol for this RCT [23] with details on the intervention and its rationale. The intervention is based on a combination of the framework of Cabana et al., defining internal and external barriers for guideline adherence [4], and the learning cycle from the Model for Improvement from Langley et al. [24]. All CR centres working with an EPR for CR with CDS during the needs assessment were able to participate in the study. Outcome measures of the study included improvement of professional performance; both measured as change on care processes and patient outcomes in the quality indicator set, and changes in concordance of the four CR therapies with guideline recommendations [23].

In Chapter 10 our preliminary results focus solely on the concordance with guideline recommendations [25]. No significant differences were found for any of the four CR therapies (education, physical exercise, lifestyle modification and relaxation) [25].

The final results in Chapter 11 describe all outcome measures [26]. During the trial a total of 233 quality improvement goals were identified by participating teams, of which 49 (21%) were achieved during the study period. Our intervention modestly increased data completeness in the CR EPR (4.5% improvement per year; 95% CI 0.65 to 8.36) and engaged teams to set improvement goals, but it yielded no improvement of clinical performance of multidisciplinary CR teams. No significant differences were found for any of the measured care processes and patient outcomes from the indicator set, or for concordance for the four CR therapies [26].

In Chapter 12 a concept mapping study among CR professionals, who participated in the trial, identified five thematic clusters with factors for successful implementation of an improvement intervention in a multidisciplinary setting [27]. While presence of a web-based A&F system and external quality assessor as used in the trial of Chapter 10, were seen as instrumental for gaining insight into clinical performance and formulating improvement actions, team commitment and organisational readiness were perceived as essential to actually implement and carry these actions out. Identified barriers relating to feasibility of the team commitment included: lack of mandate to carry out defined improvement actions; lack of an improvement coordinator who can motivate the team; and lack of commitment of all involved disciplines to carry out their own actions (especially the manager and cardiologist). Identified barriers related to feasibility of the own organisation included: lack of time and expertise with
data recording in recently implemented new CR EPR; lack of perceived commitment to improve CR from the hospital board and lack of time caused by e.g. a merger with another organisation or austerity measures [27].

Discussion of main findings – from setting improvement goals to completing the required actions

We found that our intervention successfully encouraged teams to define local performance improvement goals, but it largely failed to support them with actually completing the actions needed to achieve those goals: 79% of planned improvement actions remained uncompleted until the end of the study [26]. These results can be interpreted using Control Theory; an increasingly recognised theory in A&F literature that offers an explanation of how this feedback mechanism works [28]. This theory reveals two steps in the feedback mechanism essential to improve upon indicator results:

1) Healthcare professionals must recognise achievable room for improvement before setting improvement goals (e.g. develop intentions to change), and

2) They must formulate and actually perform effective improvement actions (e.g. translate intentions into actions) [28].

Combining Control Theory with the LHS learning cycle results in a specification of the ‘Take action to change practice’ step, in two separate steps: intention and actual action to change. Recently, we investigated the first step using data from our trial [29], showing that care processes and patient outcomes with more room for improvement (yellow or red icons) were more likely to be selected. Yet, in more than 25% of the cases professionals did not select indicators with obvious improvement opportunities, or selected indicators without apparent improvement opportunity (green icon) because they disagreed with benchmarks, deemed improvement unfeasible, or did not consider the indicator an essential aspect of care quality. These phenomena impede intentions to improve practice, and are thus likely to have diluted our A&F intervention.

To improve the translation of intention to change into effective actions, previous research [30-33] suggest that failures to complete improvement actions may be due to a lack of organisational support, e.g. competing priorities, or due to a shortage of individual skills or knowledge, e.g. to translate population-level quality targets into effective improvement actions in local clinical practice. These suggestions are reinforced with the results of our concept mapping study [27], indicating organisational readiness and team commitment as most important factors to actual achieve change; however indicating low feasibility of especially organisational readiness in the participating centres during our trial. As proposed by other authors [30, 34], extending our intervention with ready-to-use improvement tools could likely have addressed some of the barriers. The few A&F studies that incorporated such support did this in various ways. For instance, through facilitated group discussions to reflect upon the feedback and identify improvement strategies [35], or by including suggestions in the feedback reports for how to address deficiencies in practice [36]. Specific suggestions and practical tools for improvement might have assisted the improvement teams in effectively translating
their improvement intentions into action. However, as the surplus value of adding supportive improvement tools to A&F interventions has not yet been investigated, this should be a focus of future research.

In addition, other theoretical, more socio-technical frameworks have recently been proposed to design and evaluate A&F interventions, such as the Triangle Model [37], Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) framework [38], the Systems Engineering Initiative for Patient Safety (SEIPS) model [39] and the 8-dimension socio-technical model [40]. Such socio-technical models typically approach the implementation process as consisting of multiple components that continuously interact with and change each other, including people, teams, tasks, tools and technologies, underlying organisational conditions, and the surrounding context. For example, the TeamSTEPPS framework [38] emphasises that a thorough needs analysis should be performed to determine organisational readiness before initiating change. This might uncover underlying issues within the institution (e.g. equipment problems or staffing shortages) which first should be resolved to make the improvement effort succeed [38]. In addition, the SEIPS model [39] focusses on system design and its impact on processes and outcomes. This model describes how all the interacting components should be addressed to understand how they are related to each other and affect both work (e.g. maintenance and supply chain management) and clinical (e.g. direct patient care) processes; as these two processes in turn influence the patient, employee, and organisational outcomes of care [39]. To address the socio-technical complexity of an implementation process and its effectiveness, future studies could consider using the suggested models as the underlying theoretical framework to guide the development, implementation and evaluation of A&F interventions.

**Recommendations – to increase the impact of A&F interventions on professional performance**

We defined the following recommendations for researchers within the field on A&F on how the impact A&F interventions on professional performance might be improved in future research. The recommendations are based on the findings from Chapter 9, 10, 11 and 12, our experiences during these studies and the discussion of the results within the broader context of both the principles from the LHS and Control Theory. Researchers, decision-makers and other stakeholders from the field of CR can use the recommendations to stimulate further improvement of CR professionals’ performance.

- Future A&F studies should focus on individually addressing the ‘Develop intention to change’ and ‘Translate intentions into actions’ steps as revealed by Control Theory [28], during the ‘Take action to change practice’ step from the LHS learning cycle (specification of step 6). When doing so in both the design and evaluation of their interventions, further insights can be gained into which interventions influence each step of the feedback mechanism.

- As the surplus value of adding supportive improvement tools to A&F interventions on improving professionals skills and knowledge on how to translate intentions
into effective actions has not yet been investigated, this should be a focus of future research.

- To address complexity within an implementation process consisting of multiple components that continuously interact with and change each other, future studies could consider using socio-technical models [37-40] as the underlying theoretical framework to guide the development, implementation and evaluation of A&F interventions.

CONCLUSION

The work in this thesis shows how we build a LHS principles based infrastructure to improve professional performance in multiple continuous learning cycles. In our conclusion we state that in order to be effective such an infrastructure needs to successfully:

a) Aid professionals to collect (step 1 of the learning cycle) and assemble (step 2) data as an ongoing, natural by-product of the care experience, to gain knowledge (step 3) and make accurate self-assessments of their clinical performance (step 4),

b) Deliver tailored messages (step 5) to create adequate intentions among professionals to improve their practice where it does not meet the standard (first step feedback mechanism, specification of step 6), and

c) Provide professionals with the necessary skills and knowledge to start and actual achieve effective improvement actions (second step feedback mechanism, specification of step 6).

For each of these steps all involved stakeholders should be willing to get involved, committed to the same goals, and be able to allocate dedicated resources to guarantee continuous improvement by the infrastructure over time. Such an infrastructure must be systematically planned, unanimously governed, and reciprocal for all involved stakeholders.

During the development of our infrastructure to improve professional performance in the field of CR, we successfully assembled routinely collected EPR in a central data registry. We also succeeded in connecting with multiple stakeholders to translate the data into knowledge and tailored messages. We did so both on a national level in a guideline-maintenance cycle, and on a centre level with the web-based A&F system and the educational outreach visits. Concerning the final step of the learning cycle, our A&F intervention engaged teams to define local performance improvement goals, but failed to support them in actually completing the improvement actions required to achieve those goals. Future research should therefore focus on improving the actionability of feedback on clinical performance, and on more extensively addressing the socio-technical context during the development, implementation and evaluation of A&F interventions.
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SAMENVATTING
INTRODUCTIE

Het bouwen van een infrastructuur

De titel van dit proefschrift is ‘Het bouwen van een infrastructuur ter verbetering van hartrevalidatie: van richtlijnen naar audit en feedback’. De introductie geeft een toelichting bij elk van de begrippen uit deze titel. Bij het bouwen van de infrastructuur hebben we gebruik gemaakt van het concept ‘Learning Health Systems’ (LHS; lerend gezondheidssysteem). Het LHS concept benadrukt het belang van data en analyse om te leren van iedere patiënt. Om vervolgens verkregen kennis over ‘wat het beste werkt’ terug te leveren aan zorgprofessionals en andere belanghebbende partijen. De gebouwde infrastructuur omvat zowel technische als organisatorische onderdelen voor het met elkaar in verbinding brengen van artsen, andere zorgprofessionals, managers, beroepsverenigingen, ontwikkelaars van elektronische patiënten dossiers (EPDs), patiënten en onderzoekers. Dit zodat alle partijen met elkaar kunnen samenwerken, van elkaar kunnen leren en opgedane kennis direct kunnen toepassen in concrete acties ter verbetering van de zorgprestaties in de dagelijkse zorg.

Ter verbetering van

Om volgens het LHS concept te komen tot een lerend gezondheidssysteem – op ieder niveau of schaal – is continue zelfstudie en verbetering nodig. Na het vaststellen van een relevant probleem kan dit worden bereikt door het doorlopen van een zogeheten ‘continue leercyclus’ bestaande uit zes stappen:

1) Data verzamelen,
2) Data bij elkaar brengen en
3) Data analyseren, gevolgd door
4) Interpretatie van de resultaten, als input voor
5) Concrete verbetersuggesties en
6) Uiteindelijke verbeteracties (zie Figuur 1 in de Introductie).

Binnen een complexe gezondheidsorganisatie is de kans groot dat iedere belanghebbende partij zijn eigen relevante problemen definieert, wat zorgt voor meerdere, naast elkaar lopende leercycli. Dit is niet optimaal omdat iedere cyclus dan zijn eigen technologie, analisten, kosten enz. met zich meebrengt. Een LHS infrastructuur kan als platform dienen om meerdere cycli tegelijk te ondersteunen; bijvoorbeeld door het verzamelen van data in één database die beschikbaar is voor meerdere partijen om de eigen onderzoeksvragen te analyseren en beantwoorden.

Het gebruik van het LHS concept houdt in dat de resultaten uit dit proefschrift steeds zullen worden gelinkt aan een of meerdere stappen van de leercyclus. Op deze manier dragen de resultaten bij aan het verbeteren van het hartrevalidatie veld in het algemeen maar ook in een toename van de kennis over succesfactoren voor het implementeren van een continue leerproces, met bijbehorende infrastructuur, ter verbetering van zorgprestaties. Deze kennis kan zowel worden toegepast binnen het hartrevalidatie veld als ter verbetering van andere domeinen binnen de gezondheidszorg.
Hartrevalidatie

Hartrevalidatie is voor iedereen die behandeld is vanwege zijn hart. Uit onderzoek blijkt dat hartrevalidatie veel kan opleveren: 50% minder kans op nieuwe hartproblemen; 30% minder kans op sterfte door hartproblemen; verbetering lichamelijke fitheid; vertraging snelheid slagaderverkalking; betere stemming, weer plezier hebben in leven; meer vertrouwen in toekomst en minder zorgen; weer deel kunnen nemen aan sociale leven. Hartrevalidatie wordt gegeven door een multidisciplinair team bestaande uit o.a. een cardioloog, fysiotherapeut, verpleegkundige, psycholoog, maatschappelijk werker en een diëtist. Het programma start na een uitgebreid intake gesprek met de coördinator (meestal de verpleegkundige), duurt gemiddeld 6 tot 12 weken en wordt afgesloten met een evaluatie. Tijdens het intake en evaluatie gesprek worden gegevens verzameld over de patiënt zijn medische, fysieke en psychosociale conditie en over zijn leefstijl. Gebaseerd op de intake resultaten en het gesprek met de patiënt wordt een revalidatieprogramma vastgesteld. Dit bestaat uit een aantal persoonlijke doelen (bijvoorbeeld 'Verbeteren van lichamelijke fitheid' of 'Herstel emotionele balans') en maximaal vier groepstherapieën: educatie, fysieke training, leefstijlverandering en ontspanning. Wanneer nodig wordt er ook nog individuele begeleiding geboden (bijvoorbeeld door de psycholoog of diëtist). Tijdens de evaluatie worden behaalde resultaten en blijvende aandachtspunten besproken, waar na terug verwijzing naar de huisarts en eventueel nog andere zorgverleners, plaatsvindt.

Door de toenemende vergrijzing en de stijging in het aantal patiënten met hart- en vaatziekten heeft het begeleiden van patiënten bij gedragsverandering ter preventie van een nieuw hart incident de laatste jaren aan belang gewonnen. Na ontslag uit het ziekenhuis is het volgen van hartrevalidatie een essentiële eerste stap voor patiënten om de hartaandoening een plek te geven, de bezigheden of werk weer op te pakken, te werken aan een gezonde leefstijl en omgang met eventuele angst om te bewegen. Het revalidatieprogramma leert mensen weer grip te krijgen op hun levens. Uit een recent Nederlandse studie van onze onderzoeksgroep blijkt dat het volgen van hartrevalidatie geassocieerd is met 35% vermindering van de mortaliteit over een follow-up periode van vier jaar. Ondanks alle bewezen voordelen laten grote Europese en Amerikaanse studies echter zien dat doorverwijzing naar hartrevalidatie nog steeds laag is en dat hartrevalidatie instellingen vaak niet werken volgens de laatste wetenschappelijke inzichten.

Van richtlijnen

Richtlijnen in de gezondheidszorg geven concrete aanbevelingen voor welke zorg dient te worden toegepast onder welke omstandigheden. Ze zijn gebaseerd op evidentie uit de literatuur, aangevuld met kennis van experts. Er zijn echter verschillende barrières waarom hartrevalidatie en andere zorgprofessionals richtlijnen niet altijd opvolgen. Bijvoorbeeld omdat ze een richtlijn niet kennen of ondersteunen (individuele barrières) of omdat ze beperkingen ondervinden binnen hun team, organisatie of verdere omgeving (externe barrières). Het gebruik van elektronische beslissingsondersteuning door professionals is effectief voor het verminderen van individuele barrières, omdat gericht advies wordt gegeven op de tijd en plaats waar hij of
Zij zijn beslissingen neemt.

Ter ondersteuning van hartrevalidatie professionals, is tijdens eerder onderzoek het CARDSS (CArdiac Rehabilitation Decision Support System) systeem ontwikkeld. Dit systeem is gebaseerd op de Multidisciplinaire Richtlijn voor Hartrevalidatie. Het ondersteund bij het uitvoeren van de dataverzameling tijdens de intake voor en evaluatie van de hartrevalidatie; het identificeert de geïndiceerde doelstellingen en bijbehorende therapieën voor het revalidatietraject van een patiënt (de beslissingsondersteuning), en voorziet in een EPD en aanverwante functionaliteit. Uit het voorgaande onderzoek blijkt dat het werken met het systeem effectief is voor het beter werken volgens de richtlijnen. Maar ook dat niet alle aanbevelingen uit de richtlijnen beter worden opgevolgd. Zo bleef er sprake van onder behandeling voor het verbeteren van leefstijl en was er grote praktijkvariatie in het aanbod van de hartrevalidatie.

Naar audit en feedback

Binnen het LHS concept kan een EPD met beslissingsondersteuning worden gezien als de afferente (aanvoerende) kant van de leerclculus: hiermee wordt de data verzameld die nodig is voor analyse en het verkrijgen van kennis. De A&F kan worden gezien als de efferente (afvoerende) kant: hiermee wordt verkregen kennis en advies voor verbetering terug geleverd aan zorgprofessionals en andere belanghebbende partijen zodat zij gerichte acties kunnen nemen ter verbetering van de prestaties.
DOELSTELLING VAN HET PROEFSCHRIFT

Het doel van dit proefschrift was het bouwen van een infrastructuur, gebaseerd op het LHS concept, om de prestaties van zorgprofessionals in het hartrevalidatie veld te verbeteren in een continue leerproces. De infrastructuur omvat zowel technische als organisatorische onderdelen voor het in verbinding brengen van alle belanghebbende partijen. De technische onderdelen maken het hergebruik van EPD data mogelijk als input voor een A&F systeem. De organisatorische onderdelen zijn in eerste instantie gericht op het actief betrekken van alle belanghebbende partijen voor input en betrokkenheid bij het optimaal laten functioneren van de technische infrastructuur. Daarnaast hebben we een structuur opgezet met educatieve bezoeken aan multidisciplinaire hartrevalidatie teams ter ondersteuning van het daadwerkelijk gebruik van het A&F systeem in een leercyclus voor het verbeteren van de prestaties.

Bij het bouwen van de infrastructuur hebben we ons gericht op drie thema’s: uitdagingen voor het verbeteren van het hartrevalidatie veld; het ontwikkelen van de infrastructuur en het effect van onze aanpak op de prestaties. Hieronder vindt u voor elk van deze drie thema’s de belangrijkste bevindingen en onze aanbevelingen voor onderzoekers, besluitvormers en ander belanghebbende partijen van zowel binnen als buiten het hartrevalidatieveld, zoals geformuleerd naar aanleiding van de discussie in Hoofdstuk 13.

RESULTATEN PER THEME

1) Uitdagingen voor het verbeteren van het hartrevalidatie veld

Samenvatting van de belangrijkste bevindingen

In Hoofdstuk 2 beschrijven we de resultaten van een kwalitatieve studie na afloop van de implementatie van het EPD voor hartrevalidatie met beslissingsondersteuning (het CARDSS systeem) ter verbetering van het werken volgens de richtlijn. We waren geïnteresseerd in welke barrières voor verbetering door het systeem verminderd waren en welke barrières er nog steeds aanwezig waren. We vonden dat het systeem richtlijn implementatie verbeterden door het vergroten van bekendheid van de gebruikers met de aanbevelingen en beslissystematiek uit de richtlijnen. Verder door het verminderen van vasthoudendheid aan de bekende manier van werken en het verwijderen van richtlijncomplexiteit; bijvoorbeeld door het automatisch berekenen en interpreteren van resultaten op vragenlijsten. Ondanks de bewezen effectiviteit van het systeem vonden we echter ook een aantal onopgeloste barrières na implementatie van het systeem. Deze barrières waren ten eerste gerelateerd aan gebrek aan tijdsbeharing na implementatie, andere organisatorische beperkingen of een gebrek aan vergoedingen. Ten tweede waren ze gerelateerd aan de onderliggende richtlijnen van het systeem, bijvoorbeeld onduidelijkheden in de richtlijn, onderwerpen die misten of aanbevelingen die elkaar tegenspraken.

In Hoofdstuk 3 hebben we een continue verbeterstrategie ontwikkeld die gericht is op het verminderen van zowel de nog aanwezige organisatorische als richtlijn gerelateerde
barrières uit Hoofdstuk 2. Deze continue verbeterstrategie omvat twee verschillende leercycli die in aanvulling op de beslissingsondersteuning in het EPD worden toegepast (zie Figuur 1 in Hoofdstuk 13). Ten eerste stellen we een richtlijn-onderhoud cyclus voor, gericht op het verbeteren van de toepasbaarheid van de richtlijnen in de dagelijkse praktijk (de binnen cyclus in Figuur 1 in Hoofdstuk 13). Deze cyclus gebruikt de routinematig verzamelde EPD data vanuit het hartrevalidatiedossier als input voor een richtlijn revisie proces. Ten tweede stellen we een benchmark-feedback cyclus voor, gericht op het verbeteren van de samenwerking binnen teams en de omstandigheden in de organisatie (de buiten cyclus in Figuur 1 in Hoofdstuk 13). In deze cyclus wordt dezelfde EPD data gebruikt voor het periodiek opstellen van feedback rapporten voor de hartrevalidatieteams en hun managers. We ontvingen veel positieve reacties op deze rapporten tijdens een case studie, waarin 21 hartrevalidatieteams eenmalig een rapport met resultaten op hun prestaties ontvingen. Naast de eigen resultaten werd er ook een benchmark score gegeven: het gemiddelde van alle centra. Een aantal centra gaven aan dat het bespreken van deze feedback, samen met de manager, effectief was voor bijvoorbeeld het verkrijgen van middelen om het hartrevalidatieprogramma te verbeteren. Echter, veel centra vonden het moeilijk om voldoende tijd vrij te maken om het rapport te bespreken.

Hoofdstuk 4 beschrijft een studie naar het aantal patiënten wat in Nederland hartrevalidatie krijgt en onderzoekt welke factoren samen gaan met het wel of niet volgen van hartrevalidatie. Uit een grote Europese studie kwam eerder een schatting naar voren dat minder dan de helft van de patiënten die ervoor in aanmerking komen, daadwerkelijk hartrevalidatie krijgt. Om dit voor de Nederlandse situatie exact inzichtelijk te maken hebben we samengewerkt met een grote zorgverzekeraar. Door gebruik te maken van hun database met declaratiegegevens konden we zowel bepalen welke mensen in aanmerking kwamen (bijv. declaratie voor een hartoperatie) als welke mensen ook echt hartrevalidatie gevolgd hebben (bijv. declaratie voor een fysiek trainingsprogramma). De resultaten laten zien dat, onder patiënten met een diagnose van ofwel een acuut coronair syndroom (ACS, zowel een myocard infarct [MI, hartaanval] als instabiele angina pectoris [AP, pijn op de borst]) en/of een hartoperatie (CABG [omleidingsoperatie], klepoperatie of PCI [dotterprocedure]), slechts 28,5% hartrevalidatie volgt in het jaar na hun ziekenhuisopname. Groepen die minder vaak deelnemen aan hartrevalidatie zijn vrouwen, ouderen patiënten (70+), patiënten na een geplande PCI in vergelijking met patiënten na een acute PCI of CABG, patiënten met instabiele AP klachten in vergelijking met een MI, een langere reisafstand naar de dichtstbijzijnde aanbieder van hartrevalidatie (>15 km) en patiënten die ook nog andere ziekten onder de leden hebben (co-morbiditeit).

Deze resultaten waren voor de Nederlandse Vereniging voor Cardiologie (NVVC), de Inspectie voor de Gezondheidszorg (IGZ) en de Hart&Vaatgroep (H&V, patiëntenorganisatie) aanleiding om samenwerking en een aantal concrete verbeter initiatieven te starten. Onder ander het verbeteren van de declaratiestructuur, twee landelijke enquêtes voor de Staat van de Gezondheidszorg van de IGZ, het stimuleren van het gebruik van een digitaal EPD (i.p.v. papier) ten behoeve van data verzameling, nieuw informatiemateriaal over de voordelen voor patiënten
en aandacht tijdens landelijke bijeenkomsten en congressen. Al deze nationale aandacht zorgde mede voor een toenemende interesse vanuit het veld voor uitvoer van de door ons voorgestelde benchmark-feedback cyclus ter verbetering van processen en uitkomsten van de hartrevalidatiezorg in Nederland.

**Aanbevelingen gericht op de verschillende uitdagingen in het hartrevalidatieveld**

We hebben de volgende aanbevelingen gedefinieerd voor nationale organisaties, onderzoekers en andere belanghebbende partijen in het hartrevalidatieveld. De aanbevelingen zijn gebaseerd op de resultaten uit de Hoofdstukken 2, 3 en 4, de discussie daarvan in Hoofdstuk 13 in de bredere context van het LHS concept en onze eigen ervaringen tijdens, maar ook na afloop van de studies. De aanbevelingen kunnen ook gebruikt worden als input voor het aantonen en verbeteren van uitdagingen in andere domeinen van de gezondheidszorg.

- Gezien het effect van het hartrevalidatie EPD op het navolgen van de richtlijnen door het verbeteren van kennis en attitude van hartrevalidatieprofessionals, raden we aan om het gebruik hiervan voort te zetten en te stimuleren. Omdat onderliggende richtlijnen en werkprocessen van professionals over de tijd veranderen, zou het EPD met de beslissingsondersteuning regelmatig moeten worden ge-update door de ontwikkelaars, samen met de gebruikers. Op deze manier kan optimaal gebruik voor het registreren van data en het effect op het werken volgens de richtlijnen en op uitkomsten voor patiënten, gegarandeerd worden in de toekomst.

- Na de implementatie van een richtlijn zou er regelmatig onderzoek moeten plaatsvinden naar nog aanwezige barrières voor het werken volgens de richtlijn. Deze informatie kan als input dienen voor een richtlijn-onderhoud cyclus om het werken met de richtlijn te optimaliseren. Ook de hartrevalidatierichtlijnen zouden regelmatig ge-update moeten worden volgens deze continue leercyclus. Hierbij zou gebruik gemaakt moeten worden van zowel recente evidente uit wetenschappelijk literatuur als ervaringen van professionals uit de dagelijkse praktijk om onduidelijkheden, missende onderwerpen of aanbevelingen die elkaar tegenspreken, op te lossen.

- Een interventie met een continue karakter zou moeten worden opgezet om hartrevalidatieteam, inclusief hun managers en organisaties, te betrekken in een leercyclus voor het verbeteren van hun prestaties. Zo kunnen ze inzicht verkrijgen in, en werken aan, het verminderen van aanwezige barrières voor verbetering van prestaties binnen de eigen organisatie.

- Binnen ieder domein van de gezondheidszorg is samenwerking met nationale organisaties zoals beroepsverenigingen en de IGZ, van belang voor het verkrijgen van nationale aandacht voor aanwezige uitdagingen. Data verzameling, analyse en publicaties zijn noodzakelijk om deze organisaties te informeren over de huidige uitdagingen in het veld, zoals bijvoorbeeld onze publicatie met de lage deelname percentages aan hartrevalidatie. Aanlevering van, en communicatie met, deze nationale organisaties zou regelmatig moeten worden uitgevoerd om zo hun betrokkenheid en samenwerking te verkrijgen binnen een leercyclus om de uitdaging op te lossen.
2) Het ontwikkelen van een infrastructuur voor continue verbetering

Samenvatting van de belangrijkste bevindingen

Ter ondersteuning van een continue leerproces binnen de hartrevalidatie, hebben we een infrastructuur ontwikkeld die bestaat uit meerdere componenten om de verschillende belanghebbende partijen, en de verspreid aanwezige data met elkaar in verbinding te brengen. De vier hoofdstukken in dit deel van het proefschrift gaan elk over een ander onderdeel van deze infrastructuur (zowel technisch en/of organisatorisch), wat nodig is voor de uitvoer van de richtlijn-onderhoud cyclus en de benchmark-feedback cyclus zoals beschreven in het eerste deel. Volgens het LHS concept starten beide cycli met, en zijn ze afhankelijk van, routinematig verzamelde EPD data om kennis te generen vanuit de dagelijkse zorg (met minimale dataregistratie last). Dit maakt EPD data over zorgprocessen en patiënten uitkomsten die compleet en van hoge kwaliteit is, een essentieel start punt.

In Hoofdstuk 5 hebben we een usability (vrij vertaald als ‘gebruikersgemak’) studie uitgevoerd naar de data registratie in het hartrevalidatie EPD. Figuur 3 in Hoofdstuk 13 geeft een overzicht van de bijbehorende leercyclus. Tijdens de studie hebben we aanbevelingen gedaan aan de software ontwikkelaars om de usability te verbeteren. De data invoer in het vernieuwde design is flexibeler georganiseerd rond een overzichtsscherm. Dit sluit beter aan bij hoe gebruikers eerder met resultaten op vragenlijsten werkten in hun papieren dossier. Bij het opnieuw vaststellen van de usability in het vernieuwde design zagen we dat de veranderingen resulteerden in een toename van het aantal compleet uitgevoerde data registratie taken en een afname in het aantal benodigde navigatie acties. Nog aanwezige problemen betroffen met name flexibiliteit (bijv. gebruik aan op maat instellingen per centrum) en consistentie (vooral over lay-out en positie van items op het scherm. Dit laat zien dat er nog meer ruimte is voor het verminderen van de data registratie last voor hartrevalidatie professionals.

In Hoofdstuk 6 hebben we de richtlijn-onderhoud cyclus uitgevoerd zoals voorgesteld in Hoofdstuk 3. Om de implementatie verder te verbeteren hebben we de Beslisboom Hartrevalidatie herzien. Deze beslisboom beschrijft de stappen voor het vaststellen van een revalidatieprogramma op maat tijdens het intake gesprek. Hierbij hebben we gebruik gemaakt van een combinatie van routinematig verzamelde EPD data, kennis van academische experts en praktijkervaring van hartrevalidatie professionals. In de data zagen we een grote variatie in het vaststellen van het revalidatieprogramma tussen de verschillende centra. De Beslisboom Hartrevalidatie werd daarom uitgebreid met meetinstrumenten (vragenlijsten) voor het vaststellen van angst en depressie, cardiovasculaire risicofactoren, stress, aanwezigheid van de partner en kenmerken van de leefstijl (roken, fysieke activiteit en alcoholgebruik). Het vaststellen van het programma op basis van enkel klinische ervaring werd beperkt; bijvoorbeeld alleen wanneer een patiënt de Nederlandse taal onvoldoende beheerst voor het invullen van vragenlijsten of cognitie problemen heeft. Een jaar na het verschijnen van de update bleken er nieuwe inzichten te zijn over een aantal meetinstrumenten, deze inzichten resulteerden in een tweede rondgang van de richtlijn-update cyclus en een tweede update. De aanpassingen gingen over het vaststellen van
angst en depressie, sociale steun en eventuele problemen met werkhervatting. Deze tweede herziening benadrukt het belang van een organisatie die verantwoordelijk is en de middelen heeft voor data verzameling en analyse als input voor regelmatige updates van de richtlijnen.

Om de uitvoer van de benchmark-feedback cyclus zoals beschreven in Hoofdstuk 3, mogelijk te maken, hebben we in Hoofdstuk 7 een set met indicatoren ontwikkeld voor het monitoren en evalueren van de kwaliteit van hartrevalidatie zorg. Deze indicatoren waren nodig ter ondersteuning van de data analyse en interpretatie stappen in de leercyclus en bestonden nog niet voor de Nederlandse hartrevalidatie. Tijdens de ontwikkeling hebben we een combinatie gebruikt van verschillende ontwikkelmethoden om input te krijgen uit verschillende bronnen en van verschillende belanghebbende partijen. Door het gebruik van deze zogeheten samengestelde Rand methode, konden we resultaten van een literatuurstudie en richtlijn overzicht combineren met kennis van een expert- en een patiëntenpanel, in een uitgebreide beoordeling en consensus procedure. Alle verschillende bronnen hebben bijgedragen aan de uiteindelijke set van 18 kwaliteitsindicatoren voor hartrevalidatie. De set omvat bijvoorbeeld proces indicatoren zoals ‘Complete data verzameling tijdens het intake gesprek’ en uitkomst indicatoren zoals ‘Percentage patiënten wat stopt met roken tijdens de hartrevalidatie’.

In Hoofdstuk 8 hebben we een A&F system ontwikkeld die de implementatie van de gehele benchmark-feedback cyclus uit Hoofdstuk 3 mogelijk maakt als input voor het verbeteren van de beslissingen binnen het team en de organisatie. Om alle stappen uit de leercyclus uit te voeren hebben we een back-end systeem gemaakt die de data uit het hartrevalidatie EPD verzameld in een database voor het automatisch berekenen van de scores op de indicatoren uit Hoofdstuk 7 en deze vervolgens presenteert op een door ons ontwikkelde A&F website. De A&F wordt aangeboden inclusief benchmark informatie, suggesties voor verbetering (volgens stoplichtkleuren: groene en oranje vinkjes of een rood uitroepteken) en ondersteuning bij het opstellen van verbeteracties. In meer detail ondersteund het A&F systeem, genaamd CARDSS Online, vier taken:

1) Monitoren van zorg prestaties (resultaten op indicatoren),
2) Selecteren van specifieke zorgprocessen en patiënten uitkomsten die verbetering behoeven (ondersteuning door de stoplichticonen),
3) Het stellen van doelen en plannen van verbeteracties (invullen verbeterplan),
4) Aanpassen van de geselecteerde processen, uitkomsten, doelen en acties in het plan tijdens herhaald gebruik van het systeem om zo een continue karakter te garanderen.

Het systeem is in eerste instantie ontwikkeld om gebruikt te worden tijdens educatieve bezoeken door een externe onderzoeker met kennis van kwaliteitsverbetering, aan het multidisciplinaire hartrevalidatieteam. Tijdens deze bezoeken krijgt het team uitleg en ondersteuning bij het werken met het systeem om alle stappen van de leercyclus uit te voeren en worden best practices uit andere instellingen gedeeld. In het begin is deze ondersteuning intensief, na verloop van tijd kan er zelfstandig met het systeem gewerkt worden.
Een beperking van onze A&F interventie is dat verbetering van het deelnamepercentage aan hartrevalidatie geen specifiek onderdeel is. In Hoofdstuk 4 vonden we echter dat dit een belangrijk verbeter uitdaging is. De last voor dataverzameling hierover vanuit meerdere afdelingen in een ziekenhuis werd echter te hoog ervaren voor opname in de indicatoren set en onze data registratie. Echter, als gevolg van samenwerking met, en de genoemde nationale aandacht door o.a. de NVVC, IGZ en H&V kwam het vaak voor dat het verbeteren van deelname besproken werd tijdens onze educatieve bezoeken en er doelen en verbeteracties voor gesteld werden. Het cijferboek van de Hartstichting laat zien dat het deelnamepercentage aan hartrevalidatie inmiddels gestaag gestegen is tot zo’n 40% in de groep na een ACS of hartoperatie. Ondanks dat dit nog niet gefaciliteerd wordt door een complete technische infrastructuur, heeft de data analyse en publicatie van de deelnamepercentages in feite dus wel geresulteerd in een eerste rondgang van de leercyclus ter verbetering van de deelname (zie Figuur 2 in Hoofdstuk 13). Tijdens aandacht voor het deelnamepercentage op het landelijke hartrevalidatiecongres afgelopen jaar, werd echter benadrukt dat blijvende aandacht voor dit onderwerp van belang is voor het bereiken van een acceptabel deelnamepercentage in de nabije toekomst.

**Aanbevelingen voor het bouwen van een infrastructuur ter ondersteuning van verbetering in een continue leerproces**

We hebben de volgende aanbevelingen opgesteld voor onderzoekers en besluitnemers in het hartrevalidatie veld voor het instellen van een infrastructuur, die verbetering in een continue leerproces mogelijk maakt. De aanbevelingen kunnen ook worden gebruikt bij het bouwen van een vergelijkbare infrastructuur in andere domeinen van de gezondheidszorg. De aanbevelingen zijn gebaseerd op de resultaten uit de Hoofdstukken 5, 6, 7 en 8, de discussie daarvan in Hoofdstuk 13 in de bredere context van het LHS concept en onze eigen ervaringen tijdens, maar ook na afloop van de studies.

- Data verzameling is een essentiële eerste stap in iedere leercyclus. Om hoge kwaliteit data verzameling vanuit de dagelijkse zorg mogelijk te maken met minimale dataregistratie last, is optimalisatie van de usability van het EPD noodzakelijk. Hiervoor is organisatie nodig van de samenwerking tussen EPD ontwikkelaars, usability experts en eindgebruikers in een continue optimalisatie proces. Dit proces begint bij het opstellen van de voorwaarden tot en met regelmatige updates na implementatie voor het oplossen van blijvende of nieuwe usability problemen. Deze aanbeveling kan ook breder worden toegepast voor het optimaliseren van andere systemen binnen de gezondheidszorg, bijvoorbeeld beslissingsondersteunende systemen of A&F systemen.

- Bij het ontwikkelen van een LHS infrastructuur is het essentieel om niet alleen nationale data verzameling te ondersteunen, maar ook om organisaties aan te stellen die verantwoordelijk zijn en de middelen hebben om routinematig, data te analyseren, resultaten in kennis te interpreteren en deze kennis te vertalen naar concrete aanbevelingen voor de praktijk, bijvoorbeeld in richtlijnen en bijbehorende kwaliteitsindicatoren. Deze organisatie(s) moet expliciet in de gelegenheid zijn voor
het uitnodigen, motiveren van en samenwerken met alle belanghebbende partijen in dit proces. Zonder data analyse en concrete aanbevelingen, is de stap naar actie voor verbetering in de praktijk een moeilijke opgave voor de professionals die de data verzamelen tijdens de dagelijkse zorg.

- Voor het optimaliseren van de leercyclus ter verbetering van de deelname percentage aan hartrevalidatie is er input van andere belanghebbende partijen nodig omdat dit geen onderdeel is wat aan bod komt in onze A&F interventie. Om de benodigde patiënten data beschikbaar te krijgen voor analyse, is samenwerking tussen EPD ontwikkelaars, hartrevalidatiecentra en een analyserende partij noodzakelijk (zie Figuur 2 in Hoofdstuk 13). Zolang deze data op patiëntniveau nog niet beschikbaar is, blijven andere nationale bronnen (zoals de database van een zorgverzekeraar) nodig om realistische resultaten over deelname aan hartrevalidatie te verkrijgen als input voor de leercyclus ter verbetering van dit percentage.

3) Effect van een online audit en feedback systeem in combinatie met educatieve bezoeken op de prestaties van zorgprofessionals

**Samenvatting van de belangrijkste bevindingen**

De efferente (afvoerende) kant van de infrastructuur ondersteunt het maken van beslissingen en het uitvoeren van verbeteracties door multidisciplinaire teams. Om de effectiviteit hiervan te meten hebben we een cluster gerandomiseerd onderzoek uitgevoerd in 18 hartrevalidatie instellingen met het A&F systeem in combinatie met de educatieve bezoeken. *Hoofdstuk 9* beschrijft het studieprotocol voor dit onderzoek met details over de interventie en de achterliggende rationale. De interventie is gebaseerd op een combinatie van het raamwerk van Cabana en collega’s die het onderscheid in interne en externe barrières voor richtlijnimplementatie maken, en de leercyclus zoals omschreven in het Model voor Verbetering van Langley en collega’s. Alle hartrevalidatiecentra die met een EPD voor hartrevalidatie met beslissingsondersteuning tijdens het intake gesprek werkten, konden deelnemen aan onze studie. De uitkomstmaten van de studie hadden betrekking op het verbeteren van de prestaties van zorgprofessionals, zowel gemeten als verandering in zorgprocessen en patiënten uitkomsten uit de indicatoren set en verandering in het voorschrijven van de vier hartrevalidatie therapieën volgens de richtlijn.

In *Hoofdstuk 10* worden onze voorlopige resultaten beschreven met betrekking op enkel werken volgens de richtlijnen zoals gepresenteerd op een internationaal congres. Er werden geen significante verschillen gevonden voor het voorschrijven van een of meer van de vier hartrevalidatie therapieën.

De uiteindelijke resultaten in *Hoofdstuk 11* beschrijven alle uitkomstmaten. Tijdens het onderzoek werden er in totaal 233 verbeterdoelen gesteld door de deelnemende hartrevalidatieteams. Van deze doelen werden er 49 (21%) behaald tijdens de studie periode. Onze A&F interventie zorgde voor een bescheiden verbetering in data compleetheid in het hartrevalidatie EPD (4.5% verbetering per jaar; 95% betrouwbaarheidsinterval 0.65 tot 8.36)
en motiveerde teams tot het stellen van doelen ter verbetering van hun prestaties. Onze interventie zorgde echter niet voor verbetering in de klinische prestaties van de multidisciplinaire heartrevalidatietams. We vonden geen significante verandering in de gemeten zorgprocessen, patiënten uitkomsten of het werken volgens de richtlijn.

In Hoofdstuk 12 hebben we een gestructureerde kwalitatieve methode gebruikt, genaamd concept mapping, om ervaringen vast te stellen van hartrevalidatie teams die aan het onderzoek met de A&F interventie hebben meegedaan. In deze studie hebben 49 professionals in totaal vijf thematische clusters geïdentificeerd die nodig zijn voor succesvolle implementatie van een verbeterinterventie in een multidisciplinaire setting. De beschikbaarheid van een online A&F systeem en een externe onderzoeker met kennis van kwaliteitsverbetering werden zeker als behulpzaam ervaren voor het verkrijgen van inzicht in de eigen prestaties en het formuleren van verbeteracties. Echter team ‘commitment’ (vrij vertaald in ‘overtuiging en betrokkenheid’) en organisatie ‘readiness’ (‘bereidwilligheid’) werden gezien als essentieel voor het daadwerkelijk implementeren en uitvoeren van de verbeteracties. Aanwezige barrières tijdens de studie met betrekking tot de commitment van de eigen teams waren: gebrek aan mandaat voor het uitvoeren van verbeteracties; gebruik aan een coördinator voor het blijvend motiveren van de teamleden; gebrek aan betrokkenheid van alle disciplines bij het uitvoeren van hun eigen acties (met name de manager en cardioloog). Aanwezige barrières tijdens de studie met betrekking tot de eigen organisatie waren: gebruik aan tijd en expertise bij het registreren van de data in het recent nieuw geïmplementeerde hartrevalidatie EPD; gebrek aan ervaren steun voor verbetering vanuit de raad van bestuur van het centrum; en gebrek aan beschikbare tijd voor verbetering in verband met bijvoorbeeld een fusie of ingevoerde bezuinigingsmaatregelen.

Aanbevelingen voor het vergroten van het effect van A&F interventies op de prestaties van zorgprofessionals: van het stellen van doelen naar het afronden van acties

We hebben de volgende aanbevelingen opgesteld voor onderzoekers in het veld van A&F over hoe het effect van A&F interventies op prestaties van zorgprofessionals verbeterd kan worden met toekomstig onderzoek. De aanbevelingen zijn gebaseerd op de resultaten uit de Hoofdstukken 9, 10, 11 en 12, onze eigen ervaringen tijdens deze studies en de discussie daarvan in Hoofdstuk 13 in de bredere context van zowel het LHS concept als de Control Theory. Onderzoekers, besluitvormers en andere belanghebbende partijen in het hartrevalidatieveld kunnen deze aanbevelingen ook gebruiken voor het verder verbeteren van de prestaties van hartrevalidatie professionals.

- Toekomstige A&F studies zouden zich apart moeten richten op de ‘Ontwikkel intentie voor verandering’ en ‘Vertaal intentie naar effectieve actie’ stappen waarin door Control Theory onderscheid wordt gemaakt tijdens de laatste ‘Maak actie voor verbetering’ stap in de LHS leercyclus (een specificatie van stap 6 in twee delen). Wanneer dit wordt gedaan tijdens zowel het ontwerp als de evaluatie van nieuwe interventies, dan kunnen er nieuwe inzichten worden gekregen over welke interventies effect hebben op beide aparte onderdelen van het feedback mechanisme (intentie vs. actie).
- Omdat de toegevoegde waarde van aanbieden van ondersteunende, praktische verbeter ‘tools’ (‘hulpmiddelen’) binnen een A&F interventie, op het verbeteren van de vaardigheden en kennis van professionals voor het vertalen van verbeterintenties naar effectieve acties, nog niet onderzocht is, zou dit een goed onderwerp voor toekomstig onderzoek zijn.

- Om beter rekening te houden met de complexiteit van een implementatie proces wat bestaat uit verschillende componenten (professional, team, taken, systemen en technologieën, onderliggende organisatie en bredere context) die continue met elkaar in contact staan en elkaar veranderen, zouden toekomstige studies kunnen overwegen om gebruik te maken socio-technische modellen als onderliggend theoretisch raamwerk bij de ontwikkeling, implementatie en evaluatie van A&F interventies.

CONCLUSIE

Het onderzoek in dit proefschrift laat zien hoe we een infrastructuur gebouwd hebben, gebaseerd op het LHS concept, ter verbetering van prestaties van zorgprofessionals in meerdere continue leercycli. Om effectief te zijn stellen we in onze conclusie dat zo een infrastructuur succesvol zou moeten:

a) Ondersteunen bij data registratie (stap 1 van de leercyclus) en verzameling (stap 2) door professionals vanuit de dagelijkse zorg met minimale dataregistratie last, om accurate kennis (stap 3) en interpretatie van de eigen zorgprestaties te verkrijgen (stap 4),

b) Aanleveren van concrete verbetersuggesties (stap 5) voor het stimuleren van adequate intenties bij zorgprofessionals voor het verbeteren van hun prestaties wanneer die niet aan de standaard voldoen (eerste stap van het feedback mechanisme, specificatie van stap 6), en

c) Professionals voorzien van de noodzakelijke vaardigheden en kennis voor het uitvoeren en daadwerkelijk afronden van effectieve verbeteracties (tweede stap van het feedback mechanisme, specificatie van stap 6).

Voor elk van deze stappen dienen alle belanghebbende partijen bereid te zijn om betrokken te worden, overtuiging te hebben voor het bereiken van dezelfde doelen en in de gelegenheid om voldoende middelen te vrij te maken voor het bereiken van deze doelen, om zo continue verbetering met de infrastructuur over de tijd te kunnen garanderen. Zo een infrastructuur moet systematisch worden gepland, eenduidig worden beheerd en evenwichtig in de kosten en baten zijn voor alle betrokken belanghebbende partijen.

Tijdens de ontwikkeling van onze infrastructuur voor het verbeteren van de prestaties van hartrevalidatie professionals zijn we geslaagd in het succesvol bijeenbrengen van routinematig verzamelde EPD data in een centrale database. We zijn ook succesvol geweest in het maken van connecties met de verschillende belanghebbende partijen om de verzamelde data te vertalen naar kennis en concrete verbetersuggesties. Dit hebben we gedaan zowel op een nationaal
niveau; tijdens de richtlijn-onderhoud cyclus, als op centrum niveau; tijdens de ontwikkeling en implementatie van het online A&F systeem en de educatieve bezoeken. Met betrekking tot de laatste stap van leercyclus, is onze A&F interventie er wel in geslaagd om teams actief te betrekken bij het opstellen van lokale doelen ter verbetering van de prestaties, maar is het niet gelukt om hen te ondersteunen bij het daadwerkelijk afronden van de verbeteracties noodzakelijk om de doelen te behalen. Toekomstig onderzoek zou zich kunnen focussen op het verbeteren van de actiegerichtheid van feedback op zorg prestaties en zou nadrukkelijk meer het socio-technische perspectief kunnen betrekken tijden de ontwikkeling, implementatie en evaluatie van A&F interventies.
PHD PORTFOLIO & PUBLICATIONS
# PHD PORTFOLIO

**Name PhD student:** Mariëtte M. van Engen-Verheul  
**PhD period:** September 2008 – March 2016  
**Promotores:** Prof. dr. N.F. de Keizer and Prof. dr. M.W.M. Jaspers  
**Co-promotores:** Dr. N.B. Peek and Dr. H.M.C. Kemps

## 1. PhD training

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<tr>
<td>Masterclass: ‘Uitkomstmeting in de revalidatie’.</td>
<td>2013 0.25</td>
<td></td>
</tr>
<tr>
<td>De Hoogstraat/ UMC Utrecht, Utrecht, Nederland.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Workshop Systematische reviews van meetinstrumenten.</td>
<td>2011 0.25</td>
<td></td>
</tr>
<tr>
<td>Kenniscentrum Meetinstrumenten, Afdeling Epidemiologie en Biostatistiek, VUMc, Amsterdam, Nederland.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VMBI lezing ‘Beslissingsondersteuning door IT’.</td>
<td>2009 0.1</td>
<td></td>
</tr>
<tr>
<td>VMBI, Oudaen Utrecht, Nederland.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expert meeting on ICT &amp; cardiovascular disease management.</td>
<td>2008 0.25</td>
<td></td>
</tr>
<tr>
<td>KIK AMC/ NIPED/ PHILIPS Research/ MEDECS BV, Amsterdam, Nederland.</td>
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<table>
<thead>
<tr>
<th>Oral presentations (international)</th>
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</thead>
<tbody>
<tr>
<td>Improving guideline concordance in multidisciplinary teams: preliminary results of a cluster-randomized trial evaluating the effect of a web-based audit and feedback intervention with outreach visits (full paper).</td>
<td>2015 1.5</td>
</tr>
<tr>
<td>AMIA Congress 2015, San Francisco, USA.</td>
<td></td>
</tr>
<tr>
<td>How to use concept mapping to identify barriers and facilitators of an electronic quality improvement intervention (full paper).</td>
<td>2015 1.5</td>
</tr>
<tr>
<td>MIE Congress 2015, Madrid, Spain.</td>
<td></td>
</tr>
<tr>
<td>Which factors influence implementation of quality improvement by means of a web-based application within the field of cardiac rehabilitation? An explanatory concept mapping study (abstract).</td>
<td>2014 0.5</td>
</tr>
<tr>
<td>Concept Systems’ 1st European Users Seminar, Heerlen, the Netherlands.</td>
<td></td>
</tr>
<tr>
<td>A Web-based System to Facilitate Local, Systematic Quality Improvement by Multidisciplinary Care Teams: Development and First Experiences of CARDSS Online (full paper).</td>
<td>2013 1.5</td>
</tr>
<tr>
<td>MedInfo Congress 2013, Copenhagen, Denmark.</td>
<td></td>
</tr>
<tr>
<td>Usability evaluation of a guideline implementation system for cardiac rehabilitation: think aloud study (full paper).</td>
<td>2012 1.5</td>
</tr>
<tr>
<td>MIE Congress 2012, Pisa, Italy.</td>
<td></td>
</tr>
<tr>
<td>Modified Rand method to derive quality indicators: a case study in cardiac rehabilitation (full paper).</td>
<td>2011 1</td>
</tr>
<tr>
<td>MIE Congress 2011, Oslo, Norway (presented by N.B. Peek).</td>
<td></td>
</tr>
<tr>
<td>Usability Evaluation of a Guideline Implementation System for Cardiac Rehabilitation: Think Aloud Study (abstract).</td>
<td>2011 0.5</td>
</tr>
<tr>
<td>Human Factors in Engineering in Health Informatics 2011, Trondheim, Norway (presented by N.B. Peek).</td>
<td></td>
</tr>
<tr>
<td>Design of a continuous multifaceted guideline-implementation strategy based on CDS (full paper).</td>
<td>2010 1.5</td>
</tr>
<tr>
<td>MedInfo Congress 2010, Cape Town, South Africa.</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Oral presentations (national)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nationaal Congres Hartrevalidatie</td>
<td></td>
</tr>
<tr>
<td>2015: ‘Kwaliteitsverbetering van de hartrevalidatie in Nederland’.</td>
<td>2015</td>
</tr>
<tr>
<td>2012: ‘CARDSS-II: Onderzoek naar kwaliteitsverbetering van de Hartrevalidatie’.</td>
<td>2012 1.5</td>
</tr>
<tr>
<td>2010: ‘Beslisboom Poliklinische Indicatiestelling Hartrevalidatie 2010’.</td>
<td>2010 0.5</td>
</tr>
<tr>
<td>Ede/Amersfoort, Nederland.</td>
<td></td>
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</tbody>
</table>
### Chapter 14

**MI PhD days**

<table>
<thead>
<tr>
<th>Year</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>‘Building the bridge: from guidelines towards improving clinical performance in cardiac rehabilitation’.</td>
</tr>
<tr>
<td>2012</td>
<td>‘CARDSS-II: Implementation of the cardiac rehabilitation guidelines by a multifaceted decision support, feedback and educational outreach visit intervention: Study protocol’.</td>
</tr>
<tr>
<td>2011</td>
<td>‘CARDSS-II trial: A multifaceted guideline implementation strategy based on computerized decision support’.</td>
</tr>
<tr>
<td>2010</td>
<td>‘CARDSS-II Project’.</td>
</tr>
<tr>
<td>2009</td>
<td>‘CARDSS-II: Standardized individual tailoring of multidisciplinary treatment in cardiac rehabilitation’.</td>
</tr>
</tbody>
</table>

Breukelen/Amsterdam/Renesse, the Netherlands.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>Hartrevalidatie en CARDSS: Kick-off bijeenkomst regio Twente en Oost-Achterhoek.</td>
</tr>
<tr>
<td></td>
<td>Kick Off NVVC Connect Netwerk Acute Zorg Euregio, Enschede, Nederland.</td>
</tr>
<tr>
<td></td>
<td>Presentatie Multidisciplinaire Richtlijn Hartrevalidatie 2011, Maastricht, Nederland.</td>
</tr>
<tr>
<td>2010</td>
<td>CARDSS-II project &amp; Implementatie Beslisboom Hartrevalidatie 2010.</td>
</tr>
<tr>
<td></td>
<td>CarVasZ Congres 2010, Utrecht, Nederland.</td>
</tr>
<tr>
<td>2010</td>
<td>Aanpassing Beslisboom Hartrevalidatie 2010 &amp; CARDSS-II project.</td>
</tr>
<tr>
<td></td>
<td>Regio overleg Revalidatie Centra Amsterdam, Amsterdam, Nederland.</td>
</tr>
<tr>
<td></td>
<td>Congres VHVL (op: FysioCongres 2009), RAI Amsterdam, Nederland.</td>
</tr>
<tr>
<td></td>
<td>Landelijk Overleg Werkgroep Cardiopsychologie, Bilthoven, Nederland.</td>
</tr>
<tr>
<td>2008</td>
<td>CARDSS Mediscore, CARDSS-II, beslisboom, nationale registratie hartrevalidatie.</td>
</tr>
<tr>
<td></td>
<td>Regio overleg Revalidatie Centra Amsterdam, Amsterdam, Nederland.</td>
</tr>
<tr>
<td>2008</td>
<td>Interventie CARDSS II project.</td>
</tr>
<tr>
<td></td>
<td>Regio overleg Hartrevalidatie Oost, Arnhem, Nederland.</td>
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</table>

**Poster presentations**

<table>
<thead>
<tr>
<th>Year</th>
<th>Title</th>
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<tbody>
<tr>
<td>2014</td>
<td>Influence of anxiety and depression symptoms on uptake of lifestyle change therapy during cardiac rehabilitation. EuroPRevent Congress 2014, Amsterdam, the Netherlands (presented by J.M.R. Wiggers).</td>
</tr>
<tr>
<td>2013</td>
<td>CARDSS Online: Elektronische ondersteuning bij lokale kwaliteitsverbetering op basis van indicatoren. CarVasZCongres 2013, Ede, Nederland.</td>
</tr>
<tr>
<td>2013</td>
<td>Comparison between different patient reported outcomes used to measure anxiety, depression and social support in cardiac rehabilitation. ISOQOL-NL Symposium 2013, Tilburg, Nederland.</td>
</tr>
<tr>
<td>International conferences</td>
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<td>--------------------------</td>
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<tr>
<td>MIE Congress 2015: ‘Digital healthcare empowering Europeans’. EFMI and SEIS, Madrid, Spain.</td>
<td>2015 1</td>
</tr>
<tr>
<td>MedInfo Congress 2013: ‘14th World Congress on Medical and Health Informatics’. IMIA and DSMI, Copenhagen, Denmark.</td>
<td>2013 1</td>
</tr>
<tr>
<td>EuroPRevent Congress 2013: ‘Universal approach to Preventive Cardiology’. EACPR and ESC, Rome, Italy.</td>
<td>2013 1</td>
</tr>
<tr>
<td>MIE Congress 2012: ‘Quality of Life through Quality of Information’. EFMI and AllM, Pisa, Italy.</td>
<td>2012 1</td>
</tr>
<tr>
<td>EuroPRevent Congress 2011: ‘From Knowledge to Practice’. EACPR and ESC, Geneva, Switzerland.</td>
<td>2011 1</td>
</tr>
<tr>
<td>MedInfo Congress 2010: ‘13th World Congress on Medical and Health Informatics’. IMIA and SAHIA, Cape Town, South Africa.</td>
<td>2010 1</td>
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<table>
<thead>
<tr>
<th>National conferences</th>
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<tbody>
<tr>
<td>Nationaal Congres Hartrevalidatie</td>
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<tr>
<td>2015: ‘Morgen is vandaag begonnen! Leefstijl en fysiek – praktijkvoorbeelden en innovaties’.</td>
<td>2015 0.75</td>
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<tr>
<td>CarVasZ Congres</td>
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<tr>
<td>2013: ‘Cardiovasculaire zorg(en), uitdagingen voor verpleegkundigen’.</td>
<td>2013 1</td>
</tr>
<tr>
<td>2010: ‘Verleg je grenzen’.</td>
<td>2010</td>
</tr>
<tr>
<td>MI PhD days</td>
<td></td>
</tr>
<tr>
<td>2015: ‘So you think you can PhD?’.</td>
<td>2015</td>
</tr>
<tr>
<td>2010 and 2009: ‘MI PhD days AMC and Erasmus MC’ KIK AMCA\VA, Breukelen/Amsterdam/Renesse, the Netherlands.</td>
<td>2010 2009</td>
</tr>
<tr>
<td>Kick Off NVVC Connect Netwerk Acute Zorg Euregio. NVVC Connect, Enschede, Nederland.</td>
<td>2015 0.2</td>
</tr>
<tr>
<td>Achmea congres 2014 ‘Zorguitkomsten: Het gaat om de klant!’. Achmea, NBC Nieuwegein, Nederland.</td>
<td>2014 0.2</td>
</tr>
<tr>
<td>ISOQOL-NL Symposium 2013: ‘Het gebruik van Patient Reported Outcome Measures (PROMs) als indicator voor kwaliteit van zorg en kwaliteit van leven in de dagelijkse praktijk. The do’s en dont’s’. ISOQOL-NL, Tilburg, Nederland.</td>
<td>2013 0.25</td>
</tr>
<tr>
<td>Presentatie Multidisciplinaire Richtlijn Hartrevalidatie 2011. NVVC/ Maastricht University/ CAPHRI, Maastricht, Nederland.</td>
<td>2011 0.2</td>
</tr>
<tr>
<td>Congres ‘Kennis Beter Delen’. KNMG, NBC Nieuwegein, Nederland.</td>
<td>2010 0.25</td>
</tr>
<tr>
<td>Congres VHVL: Vereniging voor Hart-, Vaat- en Longfysiotherapie (op: FysioCongres 2009). VHVL, RAI Amsterdam, Nederland.</td>
<td>2009 0.25</td>
</tr>
</tbody>
</table>
### Other

- **Guest member of the ‘Landelijk Multidisciplinair Overleg Hartrevaliatie (LMDO-H)’.** This assembly has quarterly meetings where I regularly presented updates on the CARDSS-II project.  
  LMDO-H/ NVVC, Utrecht/Hilversum, Nederland.  
  2008-2015 3.5

- **Guest member of the ‘Commissie cardiovasculaire Preventie en Hartrevalidatie (CCPH)’ van de NVVC.** This association has meetings twice a year where I regularly presented updates on the CARDSS-II project.  
  CCPH/ NVVC, Utrecht, Nederland.  
  2008-2015 1.5

- **Attending monthly research meetings.**  
  Department of Medical Informatics AMC, Amsterdam, Nederland.  
  2008-2015 3

- **Organiser of national congress on cardiac rehabilitation (350-450 participants).**  
  CCPH/CARDSS/CVOI, Ede/Amersfoort, Nederland.  
  2015 2012 2010 3

- **Organizer of regular meetings of both the executive committee and participating cardiac rehabilitation clinics of ‘Stichting CARDSS’ (foundation in formation).**  
  Stichting CARDSS, Amsterdam, Nederland.  
  2014-2015 2

- **Organiser of MI PhD days 2014: ‘No PhD is an island’ (40 participants).**  
  KIK AMC/UVA, Breukelen, the Netherlands.  
  2014 1

### Total PhD training

<p>| | | |</p>
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<tr>
<td>Total PhD training</td>
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### 2. Teaching

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<th>Lecture</th>
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<th>Hours/ECTS</th>
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<tbody>
<tr>
<td>College in Master course Medicine ‘Verbredend co-schaps binnen MI in GEN’.</td>
<td>2014</td>
<td>0.25</td>
</tr>
<tr>
<td>College in Master course MIK ‘Biomedical Research and evaluation methodology’.</td>
<td>2013</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>2012</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2011</td>
<td></td>
</tr>
<tr>
<td>Practicum teacher in Bachelor course MIK ‘Medische Kennistechnologie’.</td>
<td>2010</td>
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</table>

<table>
<thead>
<tr>
<th>Tutoring, Mentoring</th>
<th>Year</th>
<th>Hours/ECTS</th>
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</thead>
<tbody>
<tr>
<td>Tutor of workgroup evaluating the CARDSS Online system in Master course MIK ‘Biomedical Research and evaluation methodology’.</td>
<td>2013</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>2012</td>
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<tr>
<td></td>
<td>2011</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Supervising</th>
<th>Year</th>
<th>Hours/ECTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tsui-ling Man: ‘De financiering van Hartrevalidatie in Nederland’. Master Health Sciences, Specialization: Policy and Organisation, VU.</td>
<td>2010</td>
<td>1</td>
</tr>
<tr>
<td>Oussamma Bouhcine: ‘Design and Partial Execution of Usability Study on CARDSS-II.’ Bachelor Medical Informatics, AMC/UVA.</td>
<td>2010</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other</th>
<th>Year</th>
<th>Hours/ECTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guest lecture: ‘Richtlijnen en kwaliteitsverbetering binnen de hartrevalidatie: Update over de voortgang van de CARDSS-II studie.’ Continuing Nursing Education Hartrevalidatie 2012, Utrecht, Nederland.</td>
<td>2012</td>
<td>0.25</td>
</tr>
<tr>
<td>Guest lecture: ‘CARDSS-project: Richtlijnen en kwaliteitsverbetering binnen de hartrevalidatie.’ Cursus Hartrevalidatie 2010, NPI, Arnhem, Nederland.</td>
<td>2010</td>
<td>0.25</td>
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</tbody>
</table>

| Total Teaching |       | 5.2 |

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PUBLICATIONS

Peer reviewed (publications in this thesis)


10. van Engen-Verheul MM, Peek N, Haafkens J, Joukes E, Vromen T, Jaspers MWM, de Keizer NF. What is needed to implement a web-based audit and feedback intervention with outreach visits to improve care quality: a concept mapping study among cardiac rehabilitation teams. *(Submitted for publication).*

11. van Engen-Verheul MM, Gude WT, van der Veer SN, Kemps HMC, Jaspers MWM, de Keizer NF, Peek N. Effect of a web-based audit and feedback intervention with outreach visits on clinical performance of multidisciplinary teams: a cluster-randomized trial in cardiac rehabilitation. *(Submitted for publication).*

**Other peer reviewed publications**


24. Gude WT, van der Veer SN, van Engen-Verheul MM, de Keizer NF, Peek N. How do health care professionals select targets for quality improvement when confronted with feedback? A laboratory experiment and field study in cardiac rehabilitation. *(Re-sumitted for publication to BMJ Qual and Saf).*

**Other publications**


CURRICULUM VITAE
CURRICULUM VITAE


Op 29 augustus 2008 trouwde ze met Jan-Willem van Engen en begon daarna in september aan haar promotietraject bij het CARDSS (CArdiac Rehabilitation Decision Support System) project. Dit project maakt onderdeel uit van de afdeling KIK in het AMC en is gericht op het verbeteren van de kwaliteit van de hartrevalidatie in Nederland. Met haar onderzoek richtte Mariëtte zich specifiek op het bouwen van een infrastructuur, met zowel technische als organisatorische onderdelen, voor het met elkaar in verbinding brengen van artsen, andere zorgprofessionals, managers, beroepsverenigingen, ontwikkelaars van elektronische patiëntendossiers (EPDs), patiënten en onderzoekers binnen de hartrevalidatie. Naast het onderzoek bestond de functie voor een gedeelte uit het vertegenwoordigen van het CARDSS project binnen landelijke commissies zoals de Commissie Cardiovasculaire Preventie en Hartrevalidatie van de Nederlandse Vereniging voor Cardiologie (NVVC-CCPH) en het Landelijk Multidisciplinair Overleg Hartrevalidatie (LMDO-H). Daarnaast organiseerde zij, mede met deze commissies, het tweejaarlijkse landelijke hartrevalidatiecongres en begeleiden ze zowel bachelor als masterstages voor verschillende opleidingen. Het promotieonderzoek zoals beschreven staat in dit proefschrift is uitgevoerd onder leiding van Prof. dr. Nicolette F. de Keizer, Prof. dr. Monique M.W. Jaspers, Dr. Niels Peek en Dr. Hareld M.C. Kemps. De openbare verdediging vindt plaats op woensdag 30 maart 2016 in de Aula van de Universiteit van Amsterdam, Oude Lutherse Kerk op het Spui te Amsterdam.

Naast haar promotietraject betrokken Mariëtte parttime bij allerhande administratie, communicatie, verzekering- en personeelszaken voor hun steeds groeiende eigen bedrijf gespecialiseerd in duurzaam en ecologisch bouwen (Bouwbedrijf van Engen). Samen met Jan-Willem was ze erg gelukkig met de geboortes van zowel hun oudste zoon Julian (28 juli 2011) als tweede zoon Simon (20 maart 2014). Rond 11 mei 2016 verwachten ze hun derde kindje.
DANKWOORD
DE GOLDEN GATE BRIDGE EN HET PROMOTIETRAJECT

Tijdens congres bezoek aan San Francisco in november 2015 was ik in de gelegenheid om een wandeling over de Golden Gate Bridge te maken: een indrukwekkende ervaring! Vanaf deze rode, bijna drie kilometer lange brug uit 1937 heb je een prachtig uitzicht op het eiland Alcatraz, het omliggende natuurgebied en de stad aan de overkant. Ten minste, bij helder weer; de brug wordt regelmatig omgeven door grote mistflarden vanaf zee die het zicht op de omgeving onverwachts kunnen ontnemen. De overspanning tussen beide pijlers van de brug om de overkant te halen bedraagt 1400 meter zes-baans wegdek, welke 67 meter boven de waterspiegel hangt.

Deze aanzienlijke overspanning is alleen mogelijk door de grote hoogte van de beide pijlers waarop de brug gegrondvest ligt (bijna 250 meter, waarvan meer dan 20 meter uit het zicht onder water); dit in combinatie met de omvang van de twee staalkabels waaraan de brug stevig is opgehangen (een diameter van 90 cm, gevlochten uit 27.572 staaldraden met een totale lengte van drie keer de omtrek van de aarde). Ondanks het feit dat de Golden Gate Bridge de titel van hoogste en langste brug reeds lang heeft moeten afstaan, is het nog steeds een van de beroemdste infrastructurele bouwwerken ter wereld.

Aansluitend op het afronden van mijn masteropleiding 2008 was ik in de gelegenheid om als onderzoeker aan mijn promotietraject te gaan werken: een bijzondere ervaring! Dit ruim zeven en half durende traject had als prachtig uitzicht het beheersen van een ruime zet aan academische en communicatieve vaardigheden, uitmondend in een wetenschappelijk proefschrift aan de overkant. Ten minste, bij helder weer; het promotietraject werd regelmatig omgeven door tegenslagen, vertragingen en onverwachte wendingen die het vertrouwen in een goede afloop onverwachts ontnamen. De inspanning om de overkant te halen bedroeg het blijven zoeken naar kansen en mogelijkheden, en daarmee samenhangend vasthouden van moed en doorzettingsvermogen.

Deze aanzienlijke inspanning was alleen mogelijk door de hoge mate van steun vanuit mijn naaste omgeving voor het grondvesten van het promotietraject (de pijlers; te weten mijn man, gezin, moeder, broertje, [schoon-] familie, vriendinnen, vriendengroep, ons bedrijf en kerkelijke gemeente; deels zichtbaar in concrete activiteiten maar vaak ook ‘onder water’); dit in combinatie met de omvang van de betrokkenheid vanuit mijn werk omgeving om het promotietraject stevig op te hangen (de staalkabels; te weten mijn [co-]promotores, de CARDSS onderzoekers, al mijn co-auteurs, deelnemers aan het onderzoek, de KIK-collega’s en kamergenoten, de leden van de promotiecommissie, de coverdesigner, drukker en sponsors van het proefschrift en mijn paranimfen). Ondanks het feit dat ik, als ik van te voren alles had kunnen overzien, misschien niet aan dit promotietraject begonnen was, zal de verdediging van mijn proefschrift te midden van allen die als pijler of staalkabel gefungeerd hebben, een van de hoogtepunten van mijn leven zijn waar ik enorm trots op ben.
Start where you ARE
Use what you have
Do what you CAN