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Title

Implementation of a politically initiated national clinical guideline for cardiac rehabilitation in hospitals and municipalities in Denmark

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Conflict of interest

The authors declare that there are no conflicts of interests.

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Authors' contributions

CLE drafted the manuscript, and together with HKR and ADZ conducted the survey and analyzed data. All authors contributed to the design of the study and the content of the manuscript. The final version of the manuscript was approved by all authors.

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Highlights

- A politically initiated clinical guideline was launched in Denmark to improve cardiac rehabilitation.
- Hospital and community based care was surveyed before and two years after implementation.
- The results indicated improvement in hospital care but not at community level.
- This suggests a different impact in the two settings, widening the gap between services.
- More research is needed to better understand barriers to implementation of guidelines in different settings.

1 Title

2 **Implementation of a politically initiated national clinical guideline for cardiac**
3 **rehabilitation in hospitals and municipalities in Denmark**
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9 Abstract

10 A politically initiated national clinical guideline was launched in Denmark in 2013 to improve quality
11 and equality of cardiac rehabilitation (CR) services. The guideline is to be implemented in both
12 hospital and community (municipality) settings due to shared responsibility for provision of CR
13 services. Little is known about implementation outcomes of a guideline in these two settings. We
14 aimed to study this by determining the extent to which Danish CR services in hospitals and
15 municipalities adhered to national recommendations following the launch of the guideline.
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22 The study employed an observational, longitudinal design. Data were gathered by a questionnaire
23 survey to compare CR services at baseline, measured in 2013 immediately before the guideline was
24 launched, with CR services at a two-year follow up in 2015. All Danish hospital departments offering
25 CR services (N=36) and all municipalities (N=98) were included. Data were analysed using inferential
26 statistics.
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Hospitals reported improvement of both content and quality of CR services. Municipalities reported
no change in content of services, and lower level of fulfilment of one quality aspect. The results
suggest that the guideline had different impact in hospitals and municipalities and that the
differences in content and quality of services between the two settings increased in the study period,
thus contradicting the guideline's aim of uniform, evidence-based content of CR services across
settings.

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Cardiac rehabilitation; implementation; clinical guideline; quality improvement; hospital;
municipality

1. Introduction

Ischemic heart disease (IHD) is a leading cause of mortality and morbidity worldwide [1,2], and is thus extremely costly to health care systems. It is forecasted that the prevalence of IHD and the costs due to the disease will increase substantially in the coming decade calling for immediate health political action [3]. Cardiac rehabilitation (CR) is a structured set of post-treatment services intended to facilitate optimal physical, mental and social recovery, decrease re-hospitalization rates and improve lifestyle and wellbeing in patients recovering from IHD [4–6]. CR interventions have documented beneficial effects [7,8], are considered cost-effective [7], and are recommended by European and American medical societies as part of secondary prevention programs [4,5]. CR is highlighted as one of the important focus areas to reduce cost when IHD is present [3]. Despite this, implementation of CR into practice has often been limited, and CR services as described in evidence-based recommendations remain underutilized [9,10], with marked differences in content and duration of the provided services [10–14].

The provision of CR in Denmark has been similar to that in other western countries. Although local clinical CR practices have existed in Denmark since the 1970s and recommendations since the 1990s, the progression and uptake of CR has been slow [15]. National surveys from 1999 and 2007 report discrepancies between CR recommendations and the services provided in hospital settings in Denmark [15,16].

In 2007, the responsibility for CR services in Denmark shifted from solely resting with the regional level (responsible for hospital management) to a shared responsibility between regional and local community level (administrative entities called municipalities) [17]. Whereas hospitals still provide specialized services, the main responsibility for rehabilitation lies with the municipalities, with the possibility of outsourcing the services to e.g. regional level. This shift was a consequence of a politically initiated major reform of the public sector in Denmark [18], reflecting the global trend of moving care from hospitals to the local community level [19–21]. However, four years after the Danish reform only half of the municipalities had established CR services [22], and patients in hospitals still experienced incomplete CR services and suboptimal equality of care [23].

In response to the insufficient provision and quality of CR, a national clinical guideline was developed in 2013 by the National Health and Medicines Authority. The guideline was the result of a national political agreement aimed at improving the quality and equality of care [24]. The political involvement represented a contrast to previous recommendations, which were produced by professional associations and regional agencies. The guideline was systematically developed and based on best available evidence. It is targeted at clinicians and local administrators, and

1 encompasses recommendations on nine core components of non-pharmacological elements of CR at
2 both patient and programme level [25] (**Table 1**). The guideline is restricted to outpatient Phase II
3 rehabilitation, which according to national guidance can be provided by both hospitals and
4 municipalities as a result of the shared responsibility for CR delivery [25,26]. Adherence to the
5 guideline is not mandatory [25], but is recommended by the National Health and Medicines
6 Authority.
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11 Unfortunately, launch of a guideline does not mean that it is actually implemented. It is well
12 documented that even high-quality guidelines may be difficult to implement [8,27,28]. While setting
13 is a recognized factor affecting implementation [29,30], the majority of guideline implementation
14 studies have focused on the use of guidelines in hospital and primary care (GP) settings [30,31].
15 Although it has been highlighted that the use of guidelines and similar evidence-based
16 recommendations in community settings may be challenging and varying [32–35], and generally at a
17 lower level than that of hospitals [36], in general less appear to be documented about the
18 implementation of guidelines in community settings or implementation outcomes at regional or
19 community level [31]. Considering this knowledge gap in guideline implementation research, in
20 combination with the hitherto suboptimal provision and inequality of CR services in Denmark, it is
21 highly relevant to investigate whether the new guideline has influenced CR provision in both
22 hospitals and municipalities. Hence, the aim of this study was to determine the extent to which
23 Danish CR services in hospitals and municipalities adhere to national recommendations just prior to
24 and two years after the publication of the national clinical guideline.
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37 2. Methods

38 2.1. General design

39 The study is an observational, longitudinal study. Data were gathered by survey to compare CR
40 services at baseline, measured in 2013 immediately before the guideline was launched, with the CR
41 services at a two-year follow up in 2015. All Danish hospital departments offering CR services (N=36)
42 and all Danish municipalities (N=98) were included.
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48 2.2. Hospital-level questionnaire and participants

49 Data regarding the hospitals' CR services were derived from the Danish Cardiac Rehabilitation
50 Database (DHRD), which collects programme-level CR data routinely, using a web-based
51 questionnaire [37]. The questionnaire is based on a previously tested and applied version [15,16],
52 although it has been modified to cover provision of the nine core components of programme-level
53 recommendations in the new national clinical guideline, listed in **Table 1**. When indicated by
54 evidence-based recommendations in the guideline, the questionnaire also incorporates questions
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1 regarding the quality of the services (**Table 1**). Furthermore, questions regarding the organization of
2 CR services are included. The questionnaire is divided into four areas of professional responsibility
3 relevant to the multidisciplinary CR team: physician, nurse, dietitian and physiotherapist.
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6 DHRD identified relevant respondents by contacting each hospital department by telephone. A
7 representative with managing or coordinating responsibility from each of four professional groups in
8 the multidisciplinary teams (physician, nurse, dietitian and physiotherapist) was identified for each
9 hospital department.
10

11 2.3. Municipality-level questionnaire and participants

12 National data regarding programme-level CR services are not routinely collected at the municipality
13 level. Therefore, a separate, parallel web-based survey was undertaken by the research group of the
14 present study, covering all Danish municipalities (N=98). We applied a slightly modified version of the
15 DHRD survey to allow for comparisons between hospitals and municipalities. In the survey questions,
16 the word 'hospital' was replaced by 'municipality' and a few response options were modified to fit
17 the municipality context. Content validity of the municipality questionnaire was pilot-tested, with
18 minor revisions regarding question phrasing and response categories being applied before use.
19

20 Based on experience from practice within the research team, we recognized that there would be
21 organizational differences between hospitals and municipalities regarding staffing in the CR teams.
22 For instance, physicians are rarely part of the team at municipality level. Therefore, we chose to
23 have only one respondent in each municipality, employed in a leading or coordination position
24 relevant to CR, assuming they would have an overview over the local CR services. The municipalities
25 were contacted by telephone and each asked to select one employee to represent them in the
26 survey. These respondents received the four professionally divided (described above) questionnaires
27 merged into one. However, response times and verbal feedback indicated that the burden on the
28 individual respondent was considerable, and thus, at follow-up two years later the DHRD approach
29 with professionally themed questionnaires was used, with the aim of increasing the response
30 proportions (for distribution of questionnaire items pr. professional group, see **Appendix, Table 1**). A
31 slightly different approach was used to identify respondents at follow-up. We identified local
32 rehabilitation team contact persons through the Danish national website sundhed.dk, and they were
33 subsequently contacted by e-mail and asked to select respondents. When not all four professional
34 groups were present in a municipality, it was decided locally who would answer any remaining
35 questionnaires.
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2.4. Data collection process

At both baseline and follow-up, an invitation to fill out the web-based questionnaire was sent by e-mail to the respondents identified at the hospitals and municipalities. Two e-mail reminders were sent. Remaining non-responders were contacted by telephone. The cover letter to the hospital-level respondents included a sentence about mandatory responses because the questionnaire emanated from the DHRD, and hospital participation in DHRD is required according to Danish law. Contrarily, participation for the municipalities was voluntary. The web-based surveys were conducted using Enalyzer Survey Solutions (www.enalyzer.com).

Since adherence to national CR recommendations in two different health care sectors were the focus of the study, additional organizational information was collected to assess possible associations between provision of CR services and different subcategories of hospitals and municipalities. For hospitals, we searched regional information websites for information regarding health care region (a total of five regions), population size in hospital catchment area and degree of specialization (cardiology specialist department yes/no). For municipalities, data regarding organizational aspects included health care region, classification according to geography (urban/suburban/rural), population size and socioeconomic index, which was obtained from the Ministry of Social Affairs and the Interior (www.noegletal.dk).

2.5. Ethics

The study was approved by The Danish Data Protection Agency, Region Zealand, regional approval number REG-149-2015. Approval from The Scientific Ethical Committee was not necessary in this study according to Danish law, since it does not include patient data and is not biomedical with inclusion of human material [38]. Use of hospital survey data was approved by the steering committee for the Danish Cardiac Rehabilitation Database. The names of the survey respondents were kept confidential.

We used the SQUIRE 2.0 recommendations to guide writing of the manuscript (<http://squire.citysoft.org/>).

2.6. Data analysis

Inferential statistical analysis of responses was conducted with mean and standard deviations used where appropriate. We classified adherence to the core CR recommendations at hospitals and municipalities in 2013 and 2015 as either 'fulfilled' (i.e. the service is available) or 'not fulfilled' (the service is not available) for each of the guideline recommendations. Adherence on a national level was calculated as n ('fulfilled') / N . Municipalities indicating that they had no Phase II CR services

1 were not included in the analyses. As there were very few instances of missing data on single items,
2 this was not adjusted for in the analyses.
3

4 Based on the total numbers of fulfilled core CR recommendations and quality aspects, differences
5 between baseline and follow-up adherence were analysed using Fisher's Exact Test. Significance
6 tests for difference between baseline and follow-up at municipality level was calculated only for
7 municipalities responding to the questionnaire both years, and who reported provision of Phase II CR
8 both years (N=49).
9

10 The total number of core CR recommendations fulfilled at each hospital and municipality was
11 calculated as a sum (min 0, max 7) for baseline and follow-up respectively, and mean scores
12 (Standard Deviations) were calculated. We analysed fulfilment of the six quality aspects in a
13 corresponding manner.
14

15 Finally, we analysed the association between the different organizational aspects of hospitals and
16 municipalities and the number of core recommendations and quality aspects fulfilled at each unit
17 (categorized into low, fair, and high fulfilment) using Fisher's Exact Test due to low numbers. The
18 organizational aspects were categorized for the purpose of these analyses. (For a description, see
19 overview of variables displayed in **Appendix, Table 4.**)
20

21 A significance level of 0.05 was applied. SAS version 9.3 was used for the statistical analyses.
22

23 3. Results

24 3.1. Questionnaire responses

25 Participation in the survey is illustrated in **Figure 1**. The DHRD hospital survey reached 100%
26 response proportion at both baseline and follow-up, and all (n=36) hospitals reported provision of
27 Phase II CR services. Among municipalities, 82% (n=80) responded in the baseline survey and 96%
28 (n=94) in the follow-up. In 2013, 75% (n=60) of the municipalities participating in the survey reported
29 provision of Phase II CR services, whereas the proportion had increased to 93% (n=87) by 2015,
30 which suggests a significant improvement (p=0.02).
31

32 3.2. Provision of core components of CR according to guideline recommendations

33 Reported provision of each of the core CR recommendations in the national clinical guideline at
34 baseline (in 2013) and at follow-up (in 2015) is shown in **Table 2**. According to responses at hospital
35 level, overall fulfilment of the core guideline recommendations was high, except for the
36 recommendations 'anxiety and depression screening' and 'vocational advice'. A significant change
37 was observed from 2013 to 2015 for one of the recommendations, 'screening for anxiety and
38 depression', which increased from 61% (n=22) to 97% (n=35) (p<0.001). Other changes were not
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1 statistically significant. At the municipality level, baseline fulfilment of the 'exercise training'
2 recommendation was reported high at 98% (n=59), whereas adherence to the remaining
3 recommendations was reported to be below 90% and lower than hospital levels. Although some
4 changes were indicated in municipalities in the follow-up, none of these were statistically significant.
5 Sample size (N) differed across the components for municipalities in 2015 due to varying numbers of
6 respondents to the four professionally themed questionnaires.
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12 The data for the total number of core CR components fulfilled at the individual hospital and
13 municipality suggested that none of the hospitals provided all of the measured core CR components
14 in 2013, while two out of the 60 municipalities that reported provision of Phase II rehabilitation did.
15 Interestingly, at follow-up two years later the picture had changed, as two out of the 36 hospitals and
16 none of the participating municipalities reported provision of all of the recommended services
17 (**Figure 2a**). Overall, an increased number of hospitals seemed to offer more core components at the
18 programme level in 2015 (mean 5.9, Standard Deviation (SD) 0.9) compared to 2013 (mean 5.5, SD
19 0.7) (p=0.05). In municipalities, the responses indicate that the overall provision of core components
20 remained the same in the two-year period, with mean 4.6 (SD 1.5) in 2013 and mean 4.3 (SD 1.3) in
21 2015 (p=0.35). Importantly, the data indicate large inter-site/local variability within both sectors, and
22 suggest that both improvement and cutback of CR services could take place at the local level.
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34 3.3. Quality of the provided services

35 The respondents' reports of the quality aspects of services according to national recommendations is
36 shown in **Table 2**, for hospitals and municipalities respectively. Similar to the provision of core CR
37 components, the quality of the provided services seemed to improve at the hospital level. Screening
38 for anxiety and depression using the Hospital Anxiety and Depression Scale (HADS) increased from
39 25% (n=9) to 72% (n=26) (p<0.001) (**Table 2**). Mean scores of the number of quality aspects fulfilled
40 at individual hospital level indicate that more hospitals fulfilled more quality aspects at follow-up
41 (mean 3.9, SD 1.1) compared to baseline (mean 3.4, SD 1.2) (p=0.001) (**Figure 2b**). In municipalities
42 on the other hand, fewer respondents reported fulfilling 'all components of patient education' at
43 follow-up than at baseline, decreasing from 51% (n=25) to 29% (n=14) (p=0.04) among municipalities
44 participating in the survey in both 2013 and 2015 (N=49) (**Appendix table 3**). For the remaining
45 quality aspects, the reported data suggest no significant changes on an overall level in municipalities
46 in the two-year follow-up period. Similarly, there were no indication of significant changes in the
47 mean number of quality aspects fulfilled at municipality level (mean 2.2, SD 1.2 in 2013, and mean
48 1.9, SD 1.1 in 2015, p=0.35). As seen for the core CR components, there was considerable inter-
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1 | ~~site~~local variability of the quality in both hospitals (1-6 quality aspects fulfilled) and municipalities (0-
2 | 4 quality aspects fulfilled) (**Figure 2b**).
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5 | No associations were found between reported provision of CR and hospitals' specialization or the
6 | population size in catchment area, and the same applied for population size, geography or
7 | socioeconomic factors in municipalities (data displayed in **Appendix, Table 4**). Data did suggest
8 | regional differences regarding provision of core components in municipalities in 2013 (p=0.04) as
9 | well as regional differences in fulfilment of quality aspects in hospitals in 2013 (p=0.005). These
10 | differences were not evident in 2015.
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18 | 4. Discussion

19 | This longitudinal, real-life study concerning provision of CR services according to national guideline
20 | recommendations in hospital and municipality settings in Denmark, ~~r~~ points towards some
21 | improvements at hospital level in the first years following the launch of the guideline, ~~but~~ ~~and~~ no
22 | ~~overall~~ improvements at municipality level. This finding is important, as it suggests that the guideline
23 | ~~did~~ ~~has~~ not ~~broadly~~ influenced practice at the municipality level, and implies that the gap between
24 | the two sectors ~~is~~ ~~widened~~ ing in the study period. This is in contrast to the intended goals of
25 | national guidelines: to achieve high-quality, evidence-based care and reduce unwanted practice
26 | variations [39].
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34 | Our findings are not surprising, adding to the body of previous research indicating that guidelines
35 | often are unsuccessful in influencing practice [27,28] unless they are properly disseminated and
36 | implemented [40]. While the reported improvements in hospitals indicate that they might have
37 | implemented the guideline to some extent, the lack of change in municipalities suggests that the
38 | guideline was not implemented in this setting, or at least not sufficiently to track any improvements
39 | at an overall level. The causes ~~offer~~ the differences in implementation between the two settings
40 | were not investigated in this study, but with reference to implementation theories and determinant
41 | frameworks, possible explanations may be differences in knowledge, competencies, culture, and
42 | resources for quality improvement work [41,42]. Previous evaluations of the Danish healthcare
43 | system has pointed to such sector differences, arguing that there has been a strong focus on quality
44 | improvement and quality management in hospitals, whereas other healthcare sectors have not
45 | engaged in this movement until recently [43,44]. Likewise, a Danish guideline project concluded that
46 | while clinical guidelines are well established tools in hospital settings, the use of guidelines in
47 | municipality settings is relatively new and generally at a ~~af~~ lower level [36].
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1 Although our study indicates possible effectiveness of the guideline in hospital settings, the design
2 was observational, and thus, factors other than the guideline may have influenced the results. Hence,
3 it may be useful to view results from this study in light of previous Danish studies conducted in 1999
4 and 2007 investigating the provision of CR services at hospital level [15,16], from which
5 questionnaires were utilized in an adapted form in the present study. Our findings indicate a
6 continuation of a positive trend for hospital-level content of services according to recommendations,
7 e.g. for smoking cessation counselling, which was provided by 71% of the hospitals in 1999 and has
8 now reached >90%. Screening for anxiety and depression was established in 24% of the hospitals in
9 2007 compared to reports of 97% in our 2015 survey (data displayed in **Appendix, Table 5**). These
10 findings suggest that a persistent, long-term political and professional focus advances practice, and
11 that the improvements seen in our study may be the result of continuous quality improvement
12 efforts influenced by a number of initiatives. Furthermore, the findings highlight that improvements
13 may take an unexpected long time, and thus, the two-year follow-up period of the present study may
14 have been too short a period to expect improvements. On the other hand, this study does
15 demonstrate some changes, indicating that relatively rapid improvements are possible, assuming
16 these changes were not already under way.

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29 Another possible factor influencing the reported improvements in hospitals could be the introduction
30 of a national clinical quality database for CR. It was launched alongside the publication of the
31 national guideline in 2013, with mandatory reporting for hospitals providing CR services [37]. It has
32 been suggested that routine monitoring of CR service provisions could improve quality and reduce
33 programme variations [11,15,45]. The Danish Cardiac Rehabilitation Database monitors and gives
34 feedback on CR programme and patient level services on selected indicators, mirroring the
35 recommendations in the CR guideline [37]. The results are available to the public through a national
36 website (www.sundhed.dk) and are also part of a national indicator monitoring healthcare quality
37 [46]. Although use of the database thus may have played a role as a quality improvement driver
38 [31,47] for the positive hospital-level development in the present study, further research is
39 warranted to establish this connection. Notably, the database could potentially also explain the some
40 of the difference between hospitals and municipalities, as the municipalities are denied access due to
41 legislation in relation to patient data security.

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53 In our analysis of the distribution of CR services across types and sizes of hospitals and municipalities,
54 we found some regional differences in 2013 but not in 2015. This might be an indication of a growing
55 homogeneity in the content of CR services across the Danish health care regions. With regards to the
56 other studied context variables, the provision of core CR components was evenly distributed at both
57 baseline and at follow-up, corresponding to previous Danish findings [15]. The association between
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1 contextual factors and quality of CR has not previously been studied in Denmark. Contextual aspects
2 are considered important in the implementation of change in healthcare [41,48], and it is likely that
3 other factors in the context contributed to an explanation of the observed differences.
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7 Our findings regarding CR provision at hospital level can be compared to those of studies in other
8 countries where clinical guidelines provide recommendations. A recent study of Phase II CR services
9 in New Zealand showed that 94% of hospitals provided CR services, although with variations in
10 delivery and content [11]. An Irish national study [13] and British audits [14,49] also show overall
11 improved programmes with considerable inter-site variations. While the overall picture is similar
12 across countries, direct comparisons of the services are difficult to make due to differences in the
13 health care systems. Nonetheless, these studies reflects our findings of improvement but with
14 varying adherence within a country.
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22 4.1. Strengths and limitations

23 In this study, we have focused on the implementation outcomes of a new national clinical guideline
24 in both hospitals and municipalities. This is important, as the guideline was part of a larger national
25 political initiative in Denmark, and the documented differences between settings regarding
26 adherence to guideline recommendations may have implications for the future implementation
27 strategies for guidelines targeting multiple settings. At the same time, our study was the first, to our
28 knowledge, to study the nationwide programme level provision of CR covering both regional and
29 community sectors, which is significant in order to provide a complete status of CR services. It is a
30 major strength of the present study that it is based on data from all hospitals providing CR in
31 Denmark. We also reached high response proportions at municipality level (82% and 96% in 2013
32 and 2015, respectively). The high response proportions make the results representative of CR
33 provision in Denmark. Moreover, the design with continuous follow-up makes it possible to follow
34 the development over time.
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45 Nonetheless, the study also has limitations, which must be considered when interpreting the
46 findings. Firstly, the study was of observational design, meaning that uncontrolled factors may have
47 influenced the results. Although the analysis did account for some of these factors (e.g. population,
48 geography and socioeconomy), and we suggest other possible explanations such as the national
49 quality database, other unknown factors may exist. Because the guideline was disseminated widely
50 across the country by national authorities and professional organizations, it was not regarded
51 feasible to define a control group. Secondly, it was not possible to determine whether the self-
52 reported CR services reflected actual practice, even though content validity of the questionnaires
53 was pilot-tested presenting good inter-rater correlation between respondents from the same
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1 institutions (data not shown). Thirdly, as with other subjectively reported data, social desirability bias
2 may be present, meaning that respondents were likely aware of the recommendations and therefore
3 inclined to be overly optimistic when reporting local programme content. Fourthly, in the
4 municipality data collection, the use of only one respondent at baseline and one to four respondents
5 with different professional backgrounds at follow-up may well have affected the quality of the
6 answers [50,51]. A possible consequence of this split to professionally themed questionnaires could
7 be more accurate answers due to access to knowledge, compared to responses provided by a single
8 respondent with coordinating or managing responsibilities. Yet, the overlapping of respondents at
9 baseline and follow-up and, furthermore, the encouragement of respondents to ask colleagues when
10 in doubt, is likely to have minimized the possible bias. Finally, when searching the literature about
11 community-based implementation, we recognized that the term is used with different meanings,
12 thus challenging a thorough overview of studies focusing on administrative healthcare entities that
13 resemble municipalities.
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24 **4.2. Perspectives**

25 Although research has documented that imperfect adherence to clinical guidelines is common, the
26 relatively poor implementation outcomes of the national clinical guideline suggested by this study, in
27 particular at community level delivered by municipalities, is important knowledge for the
28 policymakers initiating the guideline, but also for guideline developers and local managements. The
29 guideline studied in the present project was part of a political initiative, developing and launching 50
30 national clinical guidelines under the auspices of the National Health and Medicines Authority over a
31 4-year period to the cost of 80 million DKK (10.7 million Euro) [24]. The funding was recently
32 extended until 2020 with another 38 million DKK (5.1 million Euro) [52]. It seems highly relevant that
33 this investment is fruitful beyond producing high-quality guidelines, and the national authorities
34 emphasizes that implementation is crucial to their effectiveness. A qualitative mid-way evaluation
35 report of this large-scale initiative however suggests varying implementation successes, with the
36 least positive effects in the municipalities and primary care sector [53]. The evaluation thus supports
37 findings of the present study, and strengthens the impression that implementation outcomes in
38 different settings may vary. This seems particularly important to note, as one of the main objectives
39 with the national guideline is to contribute to uniform, evidence-based content of services across
40 settings. As pointed out in previous studies [54], it seems necessary to supplement the dissemination
41 of national guidelines by applying supportive implementation strategies tailored to meet the
42 different contexts of hospitals and municipalities. For the national CR guideline, specific barriers for
43 implementation in both hospitals and municipalities could be further investigated [36,55], and
44 particular attention to ‘what works’ in the high-performing settings may be worthwhile [31].
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1 While this study was performed in Denmark, the trend of moving care to the communities is
2 international [19] and also encompasses rehabilitation services. The World Health Organization
3 recommends rehabilitation services to be provided in both hospital and communities to ensure
4 timely interventions, access to services and possibly improved patient satisfaction [56]. The need for
5 ensuring availability of evidence-based, equitable CR services in multiple settings thus seems a
6 contemporary worldwide challenge [56]. The present study suggests that use of clinical guidelines to
7 support this endeavour requires careful consideration of the challenges that may present when
8 implementing them, as they may otherwise prove not to be the expected drivers of change.
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15 In Denmark, the movement of CR services from hospital to municipalities recently got a push forward
16 by the launch of national recommendations regarding how to organize CR cross-sectorial patient
17 pathways, which emphasizes that CR services increasingly should be carried out in the municipalities
18 [26]. This has fuelled the ongoing debate of where services are best provided, since not all
19 professionals agree and are calling for evidence of the quality and equality of municipal CR services
20 [57]. The results of the present study could be regarded as an argument against moving CR services
21 to the municipalities. However, while sparsely documented, the development of quality
22 improvement initiatives in the municipalities seem to be moving fast forward [34]. For instance, local
23 databases mirroring the national CR database were implemented in 2017 by some municipalities,
24 documenting levels of performance equal to those of hospitals [58]. The fact that more
25 municipalities reported provision of CR services in our follow-up survey strengthens this picture of
26 increased focus and activity in municipalities, a trend also documented in a British community health
27 services context [59]. Results should be interpreted in the light of this rapid development, and the
28 present study places emphasis on continuous monitoring of the content and quality of CR services
29 across sectors.
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42 In the Danish context, our results contribute to improved understanding of the current deficiencies in
43 core components of CR programmes, which may aid the design of specific national improvement
44 initiatives. In a wider perspective, measuring structural components is important as part of
45 prognostic data necessary to make analyses of patient level outcomes [60], and this study has
46 demonstrated a cheap and feasible way to collect data on structural aspects of care that can serve as
47 an inspiration for rehabilitation programmes across countries and CR registries, which have achieved
48 growing international interest during the recent years [61,62].
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5. Conclusion

This follow-up study investigating adherence to Danish national clinical guideline recommendations, specifically content and quality of CR services in both hospital and community (municipality) settings, indicates overall improved adherence in hospitals, whereas no such general improvement was seen in municipalities. Our results thus suggest that this politically initiated guideline possibly has affected CR services in hospital settings, while to a lesser extent the municipality settings. Although data indicate considerable inter-site~~local~~ variation, overall, there seemed to be a widening gap in content and quality of provided services in these two health care sectors sharing responsibility for CR provision in Denmark. This contradicts the guideline's aim of uniform, evidence-based content of CR services across settings. Even though national clinical guidelines are important in summarizing best evidence and providing recommendations, it seems necessary to supplement their dissemination by applying setting-specific initiatives to support the implementation, and thus generate improved CR services in both hospitals and municipalities.

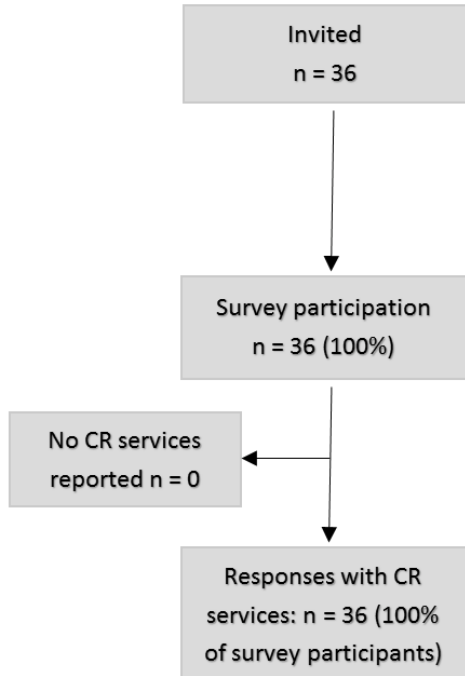
Table 1. Overview of core components of cardiac rehabilitation and related quality aspects according to the Danish national clinical guideline

Core component	Quality aspect of core component
1.a. Systematic referral	-
1.b. Management of barriers to patient attendance	-
2. Exercise training	<ul style="list-style-type: none">• Training twice a week for 12 weeks• Test before and after exercise training period• Valid test method
3. Patient education	All sub-components of patient education included *
4. Psychosocial support	-
5. Anxiety and depression screening	Screening with HADS**
6. Nutritional counselling	Screening for need of counselling
7. Smoking cessation counselling	Integrated part of services***
8. Vocational advice	-
* Sub-components include: cardiac disease and medical treatment; lifestyle, motivation and lifestyle change; psychological reactions; social relations; sexuality and cardiac disease	
** HADS=the Hospital Anxiety and Depression Scale	
*** Only relevant at hospital level, and therefore not included in the analyses	

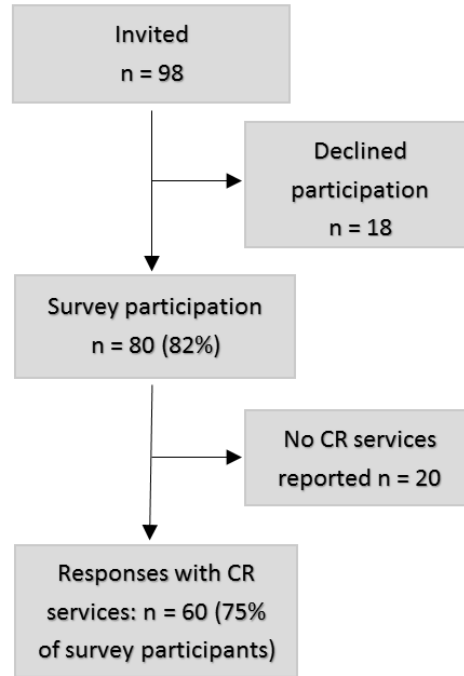
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Figure 1. Survey participation in hospitals and municipalities at baseline (2013) and follow-up (2015)

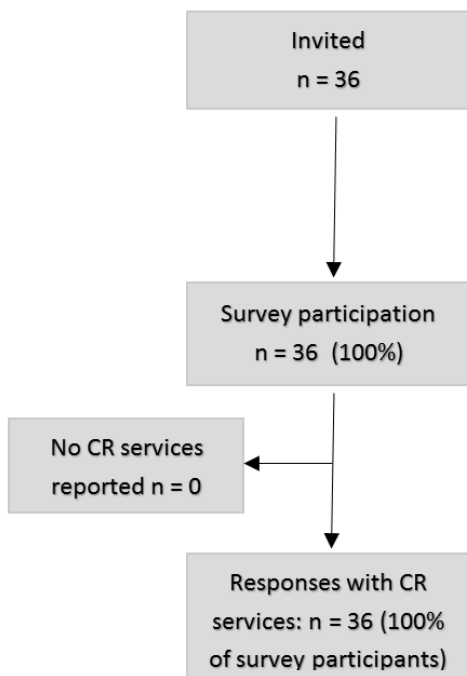
Hospitals 2013



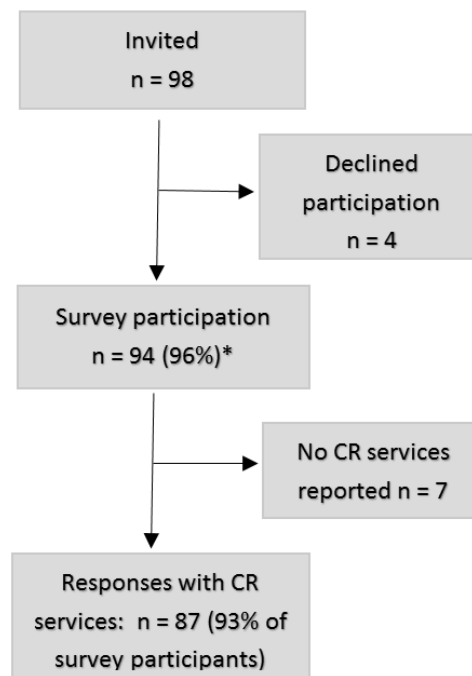
Municipalities 2013



Hospitals 2015



Municipalities 2015



* In the 2015 survey of municipalities, 4 thematic questionnaires were applied – see also Methods section. A detailed overview of responses for each thematic questionnaire is reported in **Appendix, Flowchart and Table 2**.

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Table 2. Provision and quality of core components of cardiac rehabilitation in Danish hospitals and municipalities in 2013 and 2015

	Hospitals 2013 N=36	Hospitals 2015 N=36	p-value*	Municipalities 2013 N=60	Municipalities 2015	p-value* #	
<i>Core components at programme level</i>	n (%)	n (%)		n (%)	n (%)	N***	
Exercise training	36 (100 %)	35 (97 %)	1.00	59 (98 %)	64 (96 %)	67	0.20
Patient education	35 (97 %)	35 (97 %)	1.00	45 (75 %)	56 (84 %)	67	1.00
Psychosocial support	32 (89 %)	32 (89 %)	1.00	38 (63 %)	42 (63 %)	67	0.83
Anxiety and depression screening	22 (61 %)	35 (97 %)	<0.001	12 (20 %)	13 (19 %)	67	0.45
Nutritional counselling	35 (97 %)	34 (94 %)	1.00	50 (83 %)	52 (78 %)	67	0.79
Smoking cessation counselling	34 (94 %)	33 (92 %)	1.00	53 (88 %)	58 (82 %)	71	0.39
Vocational advice	4 (11 %)	8 (22 %)	0.34	6 (10 %)	9 (13 %)	71	1.00
<i>Quality aspects of core components</i>							
Exercise training 2 days/week for 12 weeks	22 (61 %)	23 (64 %)	1.00	25 (42 %)	24 (36 %)	67	0.68
Test before and after exercise training	33 (92 %)	34 (94 %)	1.00	53 (88 %)	59 (88 %)	67	0.58
Valid test method for exercise training	10 (28 %)	12 (33 %)	0.80	4 (7 %)	5 (7 %)	67	0.68
All components of patient education	25 (69 %)	25 (69 %)	1.00	28 (47 %)	25 (37 %)	67	0.04
Screening with HADS**	9 (25 %)	26 (72 %)	<0.001	5 (8 %)	8 (12 %)	67	1.00
Dietary counselling screening	9 (25 %)	11 (31 %)	0.79	13 (22 %)	15 (22 %)	67	1.00
Smoking cessation integrated in hospital CR services	14 (39 %)	11 (31 %)	0.62	N/A	N/A	-	-

* Calculated using Fisher's Exact Test.
 ** HADS = the Hospital Anxiety and Depression Scale
 *** N varies for components due to varying number of responses to different professionally themed questionnaires (see Appendix flowchart). Only hospitals reporting overall provision of Phase II services are included in the calculations.
 # p-values for municipalities are calculated for those municipalities who have responded to the questionnaire in both 2013 and 2015 and who have reported Phase II services in both years (n=49). Provision and quality of core components of CR for these 49 municipalities are displayed in Appendix, Table 3.

Figure 2a. Provision of core components of cardiac rehabilitation at hospital and municipality level at baseline and follow-up (%)

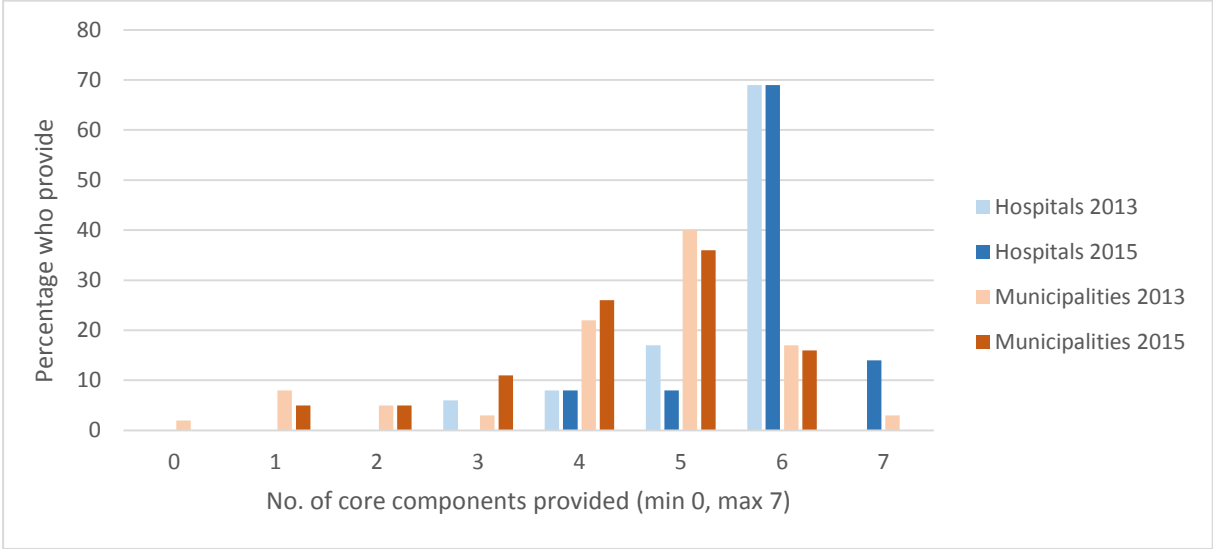
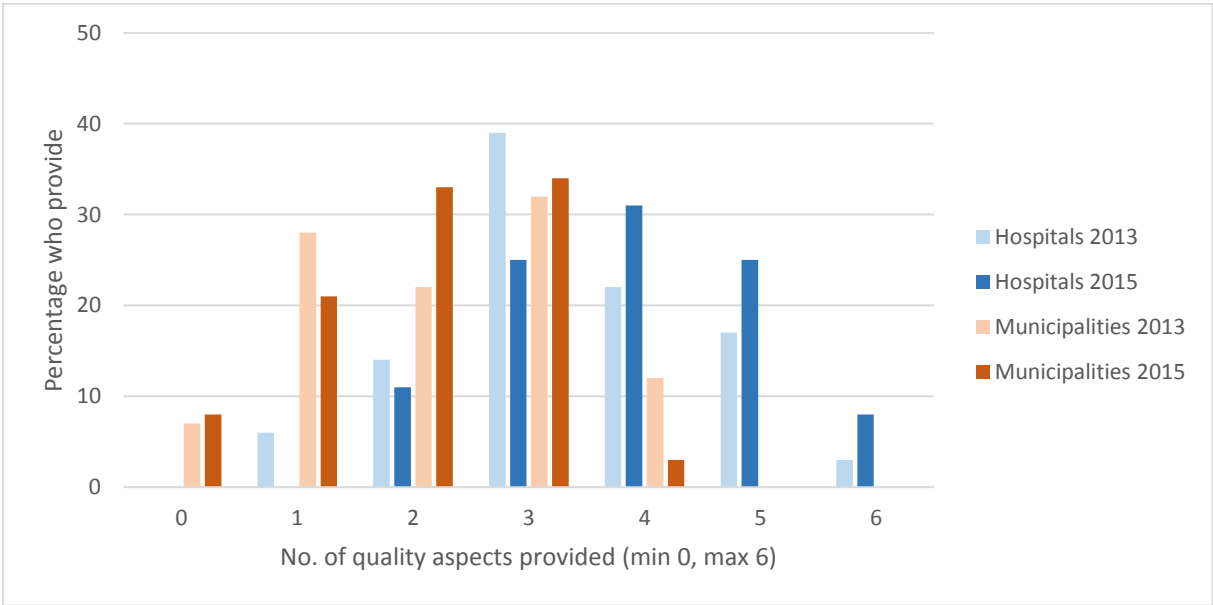


Figure 2b. Provision of quality aspects of cardiac rehabilitation at hospital and municipality level at baseline and follow-up (%)



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1 Title

2 **Implementation of a politically initiated national clinical guideline for cardiac**
3 **rehabilitation in hospitals and municipalities in Denmark**
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9 Abstract

10 A politically initiated national clinical guideline was launched in Denmark in 2013 to improve quality
11 and equality of cardiac rehabilitation (CR) services. The guideline is to be implemented in both
12 hospital and community (municipality) settings due to shared responsibility for provision of CR
13 services. Little is known about implementation outcomes of a guideline in these two settings. We
14 aimed to study this by determining the extent to which Danish CR services in hospitals and
15 municipalities adhered to national recommendations following the launch of the guideline.
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18 The study employed an observational, longitudinal design. Data were gathered by a questionnaire
19 survey to compare CR services at baseline, measured in 2013 immediately before the guideline was
20 launched, with CR services at a two-year follow up in 2015. All Danish hospital departments offering
21 CR services (N=36) and all municipalities (N=98) were included. Data were analysed using inferential
22 statistics.
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25 Hospitals reported improvement of both content and quality of CR services. Municipalities reported
26 no change in content of services, and lower level of fulfilment of one quality aspect. The results
27 suggest that the guideline had different impact in hospitals and municipalities and that the
28 differences in content and quality of services between the two settings increased in the study period,
29 thus contradicting the guideline's aim of uniform, evidence-based content of CR services across
30 settings.
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45 Keywords

46 Cardiac rehabilitation; implementation; clinical guideline; quality improvement; hospital;
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1. Introduction

Ischemic heart disease (IHD) is a leading cause of mortality and morbidity worldwide [1,2], and is thus extremely costly to health care systems. It is forecasted that the prevalence of IHD and the costs due to the disease will increase substantially in the coming decade calling for immediate health political action [3]. Cardiac rehabilitation (CR) is a structured set of post-treatment services intended to facilitate optimal physical, mental and social recovery, decrease re-hospitalization rates and improve lifestyle and wellbeing in patients recovering from IHD [4–6]. CR interventions have documented beneficial effects [7,8], are considered cost-effective [7], and are recommended by European and American medical societies as part of secondary prevention programs [4,5]. CR is highlighted as one of the important focus areas to reduce cost when IHD is present [3]. Despite this, implementation of CR into practice has often been limited, and CR services as described in evidence-based recommendations remain underutilized [9,10], with marked differences in content and duration of the provided services [10–14].

The provision of CR in Denmark has been similar to that in other western countries. Although local clinical CR practices have existed in Denmark since the 1970s and recommendations since the 1990s, the progression and uptake of CR has been slow [15]. National surveys from 1999 and 2007 report discrepancies between CR recommendations and the services provided in hospital settings in Denmark [15,16].

In 2007, the responsibility for CR services in Denmark shifted from solely resting with the regional level (responsible for hospital management) to a shared responsibility between regional and local community level (administrative entities called municipalities) [17]. Whereas hospitals still provide specialized services, the main responsibility for rehabilitation lies with the municipalities, with the possibility of outsourcing the services to e.g. regional level. This shift was a consequence of a politically initiated major reform of the public sector in Denmark [18], reflecting the global trend of moving care from hospitals to the local community level [19–21]. However, four years after the Danish reform only half of the municipalities had established CR services [22], and patients in hospitals still experienced incomplete CR services and suboptimal equality of care [23].

In response to the insufficient provision and quality of CR, a national clinical guideline was developed in 2013 by the National Health and Medicines Authority. The guideline was the result of a national political agreement aimed at improving the quality and equality of care [24]. The political involvement represented a contrast to previous recommendations, which were produced by professional associations and regional agencies. The guideline was systematically developed and based on best available evidence. It is targeted at clinicians and local administrators, and

1 encompasses recommendations on nine core components of non-pharmacological elements of CR at
2 both patient and programme level [25] (**Table 1**). The guideline is restricted to outpatient Phase II
3 rehabilitation, which according to national guidance can be provided by both hospitals and
4 municipalities as a result of the shared responsibility for CR delivery [25,26]. Adherence to the
5 guideline is not mandatory [25], but is recommended by the National Health and Medicines
6 Authority.
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11 Unfortunately, launch of a guideline does not mean that it is actually implemented. It is well
12 documented that even high-quality guidelines may be difficult to implement [8,27,28]. While setting
13 is a recognized factor affecting implementation [29,30], the majority of guideline implementation
14 studies have focused on the use of guidelines in hospital and primary care (GP) settings [30,31].
15 Although it has been highlighted that the use of guidelines and similar evidence-based
16 recommendations in community settings may be challenging and varying [32–35], and generally at a
17 lower level than that of hospitals [36], in general less appear to be documented about the
18 implementation of guidelines in community settings or implementation outcomes at regional or
19 community level [31]. Considering this knowledge gap in guideline implementation research, in
20 combination with the hitherto suboptimal provision and inequality of CR services in Denmark, it is
21 highly relevant to investigate whether the new guideline has influenced CR provision in both
22 hospitals and municipalities. Hence, the aim of this study was to determine the extent to which
23 Danish CR services in hospitals and municipalities adhere to national recommendations just prior to
24 and two years after the publication of the national clinical guideline.
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37 2. Methods

38 2.1. General design

39 The study is an observational, longitudinal study. Data were gathered by survey to compare CR
40 services at baseline, measured in 2013 immediately before the guideline was launched, with the CR
41 services at a two-year follow up in 2015. All Danish hospital departments offering CR services (N=36)
42 and all Danish municipalities (N=98) were included.
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48 2.2. Hospital-level questionnaire and participants

49 Data regarding the hospitals' CR services were derived from the Danish Cardiac Rehabilitation
50 Database (DHRD), which collects programme-level CR data routinely, using a web-based
51 questionnaire [37]. The questionnaire is based on a previously tested and applied version [15,16],
52 although it has been modified to cover provision of the nine core components of programme-level
53 recommendations in the new national clinical guideline, listed in **Table 1**. When indicated by
54 evidence-based recommendations in the guideline, the questionnaire also incorporates questions
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1 regarding the quality of the services (**Table 1**). Furthermore, questions regarding the organization of
2 CR services are included. The questionnaire is divided into four areas of professional responsibility
3 relevant to the multidisciplinary CR team: physician, nurse, dietitian and physiotherapist.
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6 DHRD identified relevant respondents by contacting each hospital department by telephone. A
7 representative with managing or coordinating responsibility from each of four professional groups in
8 the multidisciplinary teams (physician, nurse, dietitian and physiotherapist) was identified for each
9 hospital department.
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11 2.3. Municipality-level questionnaire and participants

12 National data regarding programme-level CR services are not routinely collected at the municipality
13 level. Therefore, a separate, parallel web-based survey was undertaken by the research group of the
14 present study, covering all Danish municipalities (N=98). We applied a slightly modified version of the
15 DHRD survey to allow for comparisons between hospitals and municipalities. In the survey questions,
16 the word 'hospital' was replaced by 'municipality' and a few response options were modified to fit
17 the municipality context. Content validity of the municipality questionnaire was pilot-tested, with
18 minor revisions regarding question phrasing and response categories being applied before use.
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20 Based on experience from practice within the research team, we recognized that there would be
21 organizational differences between hospitals and municipalities regarding staffing in the CR teams.
22 For instance, physicians are rarely part of the team at municipality level. Therefore, we chose to
23 have only one respondent in each municipality, employed in a leading or coordination position
24 relevant to CR, assuming they would have an overview over the local CR services. The municipalities
25 were contacted by telephone and each asked to select one employee to represent them in the
26 survey. These respondents received the four professionally divided (described above) questionnaires
27 merged into one. However, response times and verbal feedback indicated that the burden on the
28 individual respondent was considerable, and thus, at follow-up two years later the DHRD approach
29 with professionally themed questionnaires was used, with the aim of increasing the response
30 proportions (for distribution of questionnaire items pr. professional group, see **Appendix, Table 1**). A
31 slightly different approach was used to identify respondents at follow-up. We identified local
32 rehabilitation team contact persons through the Danish national website sundhed.dk, and they were
33 subsequently contacted by e-mail and asked to select respondents. When not all four professional
34 groups were present in a municipality, it was decided locally who would answer any remaining
35 questionnaires.
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2.4. Data collection process

At both baseline and follow-up, an invitation to fill out the web-based questionnaire was sent by e-mail to the respondents identified at the hospitals and municipalities. Two e-mail reminders were sent. Remaining non-responders were contacted by telephone. The cover letter to the hospital-level respondents included a sentence about mandatory responses because the questionnaire emanated from the DHRD, and hospital participation in DHRD is required according to Danish law. Contrarily, participation for the municipalities was voluntary. The web-based surveys were conducted using Enalyzer Survey Solutions (www.enalyzer.com).

Since adherence to national CR recommendations in two different health care sectors were the focus of the study, additional organizational information was collected to assess possible associations between provision of CR services and different subcategories of hospitals and municipalities. For hospitals, we searched regional information websites for information regarding health care region (a total of five regions), population size in hospital catchment area and degree of specialization (cardiology specialist department yes/no). For municipalities, data regarding organizational aspects included health care region, classification according to geography (urban/suburban/rural), population size and socioeconomic index, which was obtained from the Ministry of Social Affairs and the Interior (www.noegletal.dk).

2.5. Ethics

The study was approved by The Danish Data Protection Agency, Region Zealand, regional approval number REG-149-2015. Approval from The Scientific Ethical Committee was not necessary in this study according to Danish law, since it does not include patient data and is not biomedical with inclusion of human material [38]. Use of hospital survey data was approved by the steering committee for the Danish Cardiac Rehabilitation Database. The names of the survey respondents were kept confidential.

We used the SQUIRE 2.0 recommendations to guide writing of the manuscript (<http://squire.citysoft.org/>).

2.6. Data analysis

Inferential statistical analysis of responses was conducted with mean and standard deviations used where appropriate. We classified adherence to the core CR recommendations at hospitals and municipalities in 2013 and 2015 as either 'fulfilled' (i.e. the service is available) or 'not fulfilled' (the service is not available) for each of the guideline recommendations. Adherence on a national level was calculated as n ('fulfilled') / N . Municipalities indicating that they had no Phase II CR services

1 were not included in the analyses. As there were very few instances of missing data on single items,
2 this was not adjusted for in the analyses.
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4 Based on the total numbers of fulfilled core CR recommendations and quality aspects, differences
5 between baseline and follow-up adherence were analysed using Fisher's Exact Test. Significance
6 tests for difference between baseline and follow-up at municipality level was calculated only for
7 municipalities responding to the questionnaire both years, and who reported provision of Phase II CR
8 both years (N=49).
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10 The total number of core CR recommendations fulfilled at each hospital and municipality was
11 calculated as a sum (min 0, max 7) for baseline and follow-up respectively, and mean scores
12 (Standard Deviations) were calculated. We analysed fulfilment of the six quality aspects in a
13 corresponding manner.
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15 Finally, we analysed the association between the different organizational aspects of hospitals and
16 municipalities and the number of core recommendations and quality aspects fulfilled at each unit
17 (categorized into low, fair, and high fulfilment) using Fisher's Exact Test due to low numbers. The
18 organizational aspects were categorized for the purpose of these analyses. (For a description, see
19 overview of variables displayed in **Appendix, Table 4.**)
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21 A significance level of 0.05 was applied. SAS version 9.3 was used for the statistical analyses.
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23 3. Results

24 3.1. Questionnaire responses

25 Participation in the survey is illustrated in **Figure 1**. The DHRD hospital survey reached 100%
26 response proportion at both baseline and follow-up, and all (n=36) hospitals reported provision of
27 Phase II CR services. Among municipalities, 82% (n=80) responded in the baseline survey and 96%
28 (n=94) in the follow-up. In 2013, 75% (n=60) of the municipalities participating in the survey reported
29 provision of Phase II CR services, whereas the proportion had increased to 93% (n=87) by 2015,
30 which suggests a significant improvement (p=0.02).
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32 3.2. Provision of core components of CR according to guideline recommendations

33 Reported provision of each of the core CR recommendations in the national clinical guideline at
34 baseline (in 2013) and at follow-up (in 2015) is shown in **Table 2**. According to responses at hospital
35 level, overall fulfilment of the core guideline recommendations was high, except for the
36 recommendations 'anxiety and depression screening' and 'vocational advice'. A significant change
37 was observed from 2013 to 2015 for one of the recommendations, 'screening for anxiety and
38 depression', which increased from 61% (n=22) to 97% (n=35) (p<0.001). Other changes were not
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1 statistically significant. At the municipality level, baseline fulfilment of the 'exercise training'
2 recommendation was reported high at 98% (n=59), whereas adherence to the remaining
3 recommendations was reported to be below 90% and lower than hospital levels. Although some
4 changes were indicated in municipalities in the follow-up, none of these were statistically significant.
5 Sample size (N) differed across the components for municipalities in 2015 due to varying numbers of
6 respondents to the four professionally themed questionnaires.
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12 The data for the total number of core CR components fulfilled at the individual hospital and
13 municipality suggested that none of the hospitals provided all of the measured core CR components
14 in 2013, while two out of the 60 municipalities that reported provision of Phase II rehabilitation did.
15 Interestingly, at follow-up two years later the picture had changed, as two out of the 36 hospitals and
16 none of the participating municipalities reported provision of all of the recommended services
17 (**Figure 2a**). Overall, an increased number of hospitals seemed to offer more core components at the
18 programme level in 2015 (mean 5.9, Standard Deviation (SD) 0.9) compared to 2013 (mean 5.5, SD
19 0.7) (p=0.05). In municipalities, the responses indicate that the overall provision of core components
20 remained the same in the two-year period, with mean 4.6 (SD 1.5) in 2013 and mean 4.3 (SD 1.3) in
21 2015 (p=0.35). Importantly, the data indicate large inter-site variability within both sectors, and
22 suggest that both improvement and cutback of CR services could take place at the local level.
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34 3.3. Quality of the provided services

35 The respondents' reports of the quality aspects of services according to national recommendations is
36 shown in **Table 2**, for hospitals and municipalities respectively. Similar to the provision of core CR
37 components, the quality of the provided services seemed to improve at the hospital level. Screening
38 for anxiety and depression using the Hospital Anxiety and Depression Scale (HADS) increased from
39 25% (n=9) to 72% (n=26) (p<0.001) (**Table 2**). Mean scores of the number of quality aspects fulfilled
40 at individual hospital level indicate that more hospitals fulfilled more quality aspects at follow-up
41 (mean 3.9, SD 1.1) compared to baseline (mean 3.4, SD 1.2) (p=0.001) (**Figure 2b**). In municipalities
42 on the other hand, fewer respondents reported fulfilling 'all components of patient education' at
43 follow-up than at baseline, decreasing from 51% (n=25) to 29% (n=14) (p=0.04) among municipalities
44 participating in the survey in both 2013 and 2015 (N=49) (**Appendix table 3**). For the remaining
45 quality aspects, the reported data suggest no significant changes on an overall level in municipalities
46 in the two-year follow-up period. Similarly, there were no indication of significant changes in the
47 mean number of quality aspects fulfilled at municipality level (mean 2.2, SD 1.2 in 2013, and mean
48 1.9, SD 1.1 in 2015, p=0.35). As seen for the core CR components, there was considerable inter-site
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1 variability of the quality in both hospitals (1-6 quality aspects fulfilled) and municipalities (0-4 quality
2 aspects fulfilled) (**Figure 2b**).
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5 No associations were found between reported provision of CR and hospitals' specialization or the
6 population size in catchment area, and the same applied for population size, geography or
7 socioeconomic factors in municipalities (data displayed in **Appendix, Table 4**). Data did suggest
8 regional differences regarding provision of core components in municipalities in 2013 ($p=0.04$) as
9 well as regional differences in fulfilment of quality aspects in hospitals in 2013 ($p=0.005$). These
10 differences were not evident in 2015.
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18 4. Discussion

19 This longitudinal, real-life study concerning provision of CR services according to national guideline
20 recommendations in hospital and municipality settings in Denmark points towards some
21 improvements at hospital level in the first years following the launch of the guideline, but no overall
22 improvements at municipality level. This finding is important, as it suggests that the guideline did not
23 broadly influence practice at the municipality level, and implies that the gap between the two sectors
24 widened in the study period. This is in contrast to the intended goals of national guidelines: to
25 achieve high-quality, evidence-based care and reduce unwanted practice variations [39].
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32 Our findings are not surprising, adding to the body of previous research indicating that guidelines
33 often are unsuccessful in influencing practice [27,28] unless they are properly disseminated and
34 implemented [40]. While the reported improvements in hospitals indicate that they might have
35 implemented the guideline to some extent, the lack of change in municipalities suggests that the
36 guideline was not implemented in this setting, or at least not sufficiently to track any improvements
37 at an overall level. The causes of the differences in implementation between the two settings were
38 not investigated in this study, but with reference to implementation theories and determinant
39 frameworks, possible explanations may be differences in knowledge, competencies, culture, and
40 resources for quality improvement work [41,42]. Previous evaluations of the Danish healthcare
41 system has pointed to such sector differences, arguing that there has been a strong focus on quality
42 improvement and quality management in hospitals, whereas other healthcare sectors have not
43 engaged in this movement until recently [43,44]. Likewise, a Danish guideline project concluded that
44 while clinical guidelines are well established tools in hospital settings, the use of guidelines in
45 municipality settings is relatively new and generally at a lower level [36].
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58 Although our study indicates possible effectiveness of the guideline in hospital settings, the design
59 was observational, and thus, factors other than the guideline may have influenced the results. Hence,
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1 it may be useful to view results from this study in light of previous Danish studies conducted in 1999
2 and 2007 investigating the provision of CR services at hospital level [15,16], from which
3 questionnaires were utilized in an adapted form in the present study. Our findings indicate a
4 continuation of a positive trend for hospital-level content of services according to recommendations,
5 e.g. for smoking cessation counselling, which was provided by 71% of the hospitals in 1999 and has
6 now reached >90%. Screening for anxiety and depression was established in 24% of the hospitals in
7 2007 compared to reports of 97% in our 2015 survey (data displayed in **Appendix, Table 5**). These
8 findings suggest that a persistent, long-term political and professional focus advances practice, and
9 that the improvements seen in our study may be the result of continuous quality improvement
10 efforts influenced by a number of initiatives. Furthermore, the findings highlight that improvements
11 may take an unexpected long time, and thus, the two-year follow-up period of the present study may
12 have been too short a period to expect improvements. On the other hand, this study does
13 demonstrate some changes, indicating that relatively rapid improvements are possible, assuming
14 these changes were not already under way.

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16 Another possible factor influencing the reported improvements in hospitals could be the introduction
17 of a national clinical quality database for CR. It was launched alongside the publication of the
18 national guideline in 2013, with mandatory reporting for hospitals providing CR services [37]. It has
19 been suggested that routine monitoring of CR service provisions could improve quality and reduce
20 programme variations [11,15,45]. The Danish Cardiac Rehabilitation Database monitors and gives
21 feedback on CR programme and patient level services on selected indicators, mirroring the
22 recommendations in the CR guideline [37]. The results are available to the public through a national
23 website (www.sundhed.dk) and are also part of a national indicator monitoring healthcare quality
24 [46]. Although use of the database thus may have played a role as a quality improvement driver
25 [31,47] for the positive hospital-level development in the present study, further research is
26 warranted to establish this connection. Notably, the database could potentially also explain the some
27 of the difference between hospitals and municipalities, as the municipalities are denied access due to
28 legislation in relation to patient data security.

29
30 In our analysis of the distribution of CR services across types and sizes of hospitals and municipalities,
31 we found some regional differences in 2013 but not in 2015. This might be an indication of a growing
32 homogeneity in the content of CR services across the Danish health care regions. With regards to the
33 other studied context variables, the provision of core CR components was evenly distributed at both
34 baseline and at follow-up, corresponding to previous Danish findings [15]. The association between
35 contextual factors and quality of CR has not previously been studied in Denmark. Contextual aspects

1 are considered important in the implementation of change in healthcare [41,48], and it is likely that
2 other factors in the context contributed to an explanation of the observed differences.
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5 Our findings regarding CR provision at hospital level can be compared to those of studies in other
6 countries where clinical guidelines provide recommendations. A recent study of Phase II CR services
7 in New Zealand showed that 94% of hospitals provided CR services, although with variations in
8 delivery and content [11]. An Irish national study [13] and British audits [14,49] also show overall
9 improved programmes with considerable inter-site variations. While the overall picture is similar
10 across countries, direct comparisons of the services are difficult to make due to differences in the
11 health care systems. Nonetheless, these studies reflect our findings of improvement but with varying
12 adherence within a country.
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19 4.1. Strengths and limitations

20 In this study, we have focused on the implementation outcomes of a new national clinical guideline
21 in both hospitals and municipalities. This is important, as the guideline was part of a larger national
22 political initiative in Denmark, and the documented differences between settings regarding
23 adherence to guideline recommendations may have implications for the future implementation
24 strategies for guidelines targeting multiple settings. At the same time, our study was the first, to our
25 knowledge, to study the nationwide programme level provision of CR covering both regional and
26 community sectors, which is significant in order to provide a complete status of CR services. It is a
27 major strength of the present study that it is based on data from all hospitals providing CR in
28 Denmark. We also reached high response proportions at municipality level (82% and 96% in 2013
29 and 2015, respectively). The high response proportions make the results representative of CR
30 provision in Denmark. Moreover, the design with continuous follow-up makes it possible to follow
31 the development over time.
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43 Nonetheless, the study also has limitations, which must be considered when interpreting the
44 findings. Firstly, the study was of observational design, meaning that uncontrolled factors may have
45 influenced the results. Although the analysis did account for some of these factors (e.g. population,
46 geography and socioeconomy), and we suggest other possible explanations such as the national
47 quality database, other unknown factors may exist. Because the guideline was disseminated widely
48 across the country by national authorities and professional organizations, it was not regarded
49 feasible to define a control group. Secondly, it was not possible to determine whether the self-
50 reported CR services reflected actual practice, even though content validity of the questionnaires
51 was pilot-tested presenting good inter-rater correlation between respondents from the same
52 institutions (data not shown). Thirdly, as with other subjectively reported data, social desirability bias
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1 may be present, meaning that respondents were likely aware of the recommendations and therefore
2 inclined to be overly optimistic when reporting local programme content. Fourthly, in the
3 municipality data collection, the use of only one respondent at baseline and one to four respondents
4 with different professional backgrounds at follow-up may well have affected the quality of the
5 answers [50,51]. A possible consequence of this split to professionally themed questionnaires could
6 be more accurate answers due to access to knowledge, compared to responses provided by a single
7 respondent with coordinating or managing responsibilities. Yet, the overlapping of respondents at
8 baseline and follow-up and, furthermore, the encouragement of respondents to ask colleagues when
9 in doubt, is likely to have minimized the possible bias. Finally, when searching the literature about
10 community-based implementation, we recognized that the term is used with different meanings,
11 thus challenging a thorough overview of studies focusing on administrative healthcare entities that
12 resemble municipalities.
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22 4.2. Perspectives

23 Although research has documented that imperfect adherence to clinical guidelines is common, the
24 relatively poor implementation outcomes of the national clinical guideline suggested by this study, in
25 particular at community level delivered by municipalities, is important knowledge for the
26 policymakers initiating the guideline, but also for guideline developers and local managements. The
27 guideline studied in the present project was part of a political initiative, developing and launching 50
28 national clinical guidelines under the auspices of the National Health and Medicines Authority over a
29 4-year period to the cost of 80 million DKK (10.7 million Euro) [24]. The funding was recently
30 extended until 2020 with another 38 million DKK (5.1 million Euro) [52]. It seems highly relevant that
31 this investment is fruitful beyond producing high-quality guidelines, and the national authorities
32 emphasize that implementation is crucial to their effectiveness. A qualitative mid-way evaluation
33 report of this large-scale initiative however suggests varying implementation successes, with the
34 least positive effects in the municipalities and primary care sector [53]. The evaluation thus supports
35 findings of the present study, and strengthens the impression that implementation outcomes in
36 different settings may vary. This seems particularly important to note, as one of the main objectives
37 with the national guideline is to contribute to uniform, evidence-based content of services across
38 settings. As pointed out in previous studies [54], it seems necessary to supplement the dissemination
39 of national guidelines by applying supportive implementation strategies tailored to meet the
40 different contexts of hospitals and municipalities. For the national CR guideline, specific barriers for
41 implementation in both hospitals and municipalities could be further investigated [36,55], and
42 particular attention to ‘what works’ in the high-performing settings may be worthwhile [31].
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1 While this study was performed in Denmark, the trend of moving care to the communities is
2 international [19] and also encompasses rehabilitation services. The World Health Organization
3 recommends rehabilitation services to be provided in both hospital and communities to ensure
4 timely interventions, access to services and possibly improved patient satisfaction [56]. The need for
5 ensuring availability of evidence-based, equitable CR services in multiple settings thus seems a
6 contemporary worldwide challenge [56]. The present study suggests that use of clinical guidelines to
7 support this endeavour requires careful consideration of the challenges that may present when
8 implementing them, as they may otherwise prove not to be the expected drivers of change.

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15 In Denmark, the movement of CR services from hospital to municipalities recently got a push forward
16 by the launch of national recommendations regarding how to organize CR cross-sectorial patient
17 pathways, which emphasizes that CR services increasingly should be carried out in the municipalities
18 [26]. This has fuelled the ongoing debate of where services are best provided, since not all
19 professionals agree and are calling for evidence of the quality and equality of municipal CR services
20 [57]. The results of the present study could be regarded as an argument against moving CR services
21 to the municipalities. However, while sparsely documented, the development of quality
22 improvement initiatives in the municipalities seem to be moving fast forward [34]. For instance, local
23 databases mirroring the national CR database were implemented in 2017 by some municipalities,
24 documenting levels of performance equal to those of hospitals [58]. The fact that more
25 municipalities reported provision of CR services in our follow-up survey strengthens this picture of
26 increased focus and activity in municipalities, a trend also documented in a British community health
27 services context [59]. Results should be interpreted in the light of this rapid development, and the
28 present study places emphasis on continuous monitoring of the content and quality of CR services
29 across sectors.
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42 In the Danish context, our results contribute to improved understanding of the current deficiencies in
43 core components of CR programmes, which may aid the design of specific national improvement
44 initiatives. In a wider perspective, measuring structural components is important as part of
45 prognostic data necessary to make analyses of patient level outcomes [60], and this study has
46 demonstrated a cheap and feasible way to collect data on structural aspects of care that can serve as
47 an inspiration for rehabilitation programmes across countries and CR registries, which have achieved
48 growing international interest during the recent years [61,62].
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5. Conclusion

This follow-up study investigating adherence to Danish national clinical guideline recommendations, specifically content and quality of CR services in both hospital and community (municipality) settings, indicates overall improved adherence in hospitals, whereas no such general improvement was seen in municipalities. Our results thus suggest that this politically initiated guideline possibly has affected CR services in hospital settings, while to a lesser extent the municipality settings. Although data indicate considerable inter-sitevariation, overall, there seemed to be a widening gap in content and quality of provided services in these two health care sectors sharing responsibility for CR provision in Denmark. This contradicts the guideline's aim of uniform, evidence-based content of CR services across settings. Even though national clinical guidelines are important in summarizing best evidence and providing recommendations, it seems necessary to supplement their dissemination by applying setting-specific initiatives to support the implementation, and thus generate improved CR services in both hospitals and municipalities.

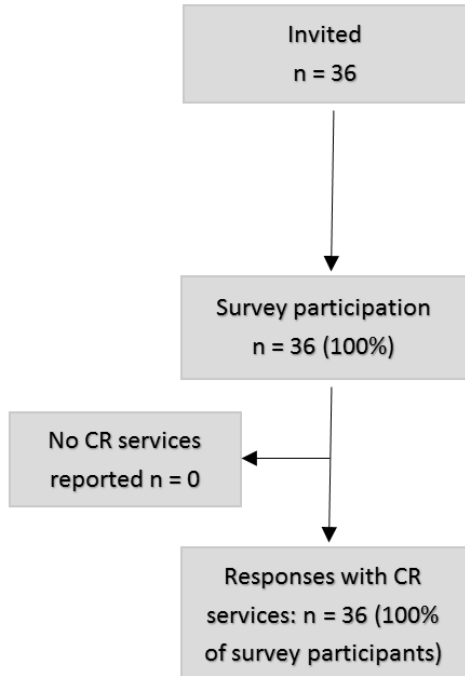
Table 1. Overview of core components of cardiac rehabilitation and related quality aspects according to the Danish national clinical guideline

Core component	Quality aspect of core component
1.a. Systematic referral	-
1.b. Management of barriers to patient attendance	-
2. Exercise training	<ul style="list-style-type: none">• Training twice a week for 12 weeks• Test before and after exercise training period• Valid test method
3. Patient education	All sub-components of patient education included *
4. Psychosocial support	-
5. Anxiety and depression screening	Screening with HADS**
6. Nutritional counselling	Screening for need of counselling
7. Smoking cessation counselling	Integrated part of services***
8. Vocational advice	-
* Sub-components include: cardiac disease and medical treatment; lifestyle, motivation and lifestyle change; psychological reactions; social relations; sexuality and cardiac disease	
** HADS=the Hospital Anxiety and Depression Scale	
*** Only relevant at hospital level, and therefore not included in the analyses	

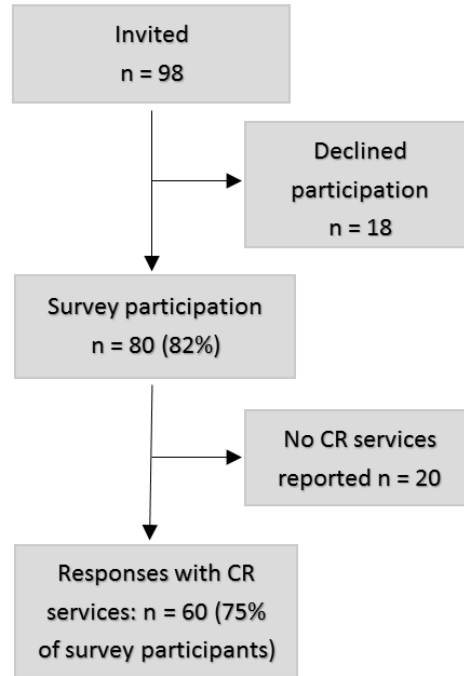
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Figure 1. Survey participation in hospitals and municipalities at baseline (2013) and follow-up (2015)

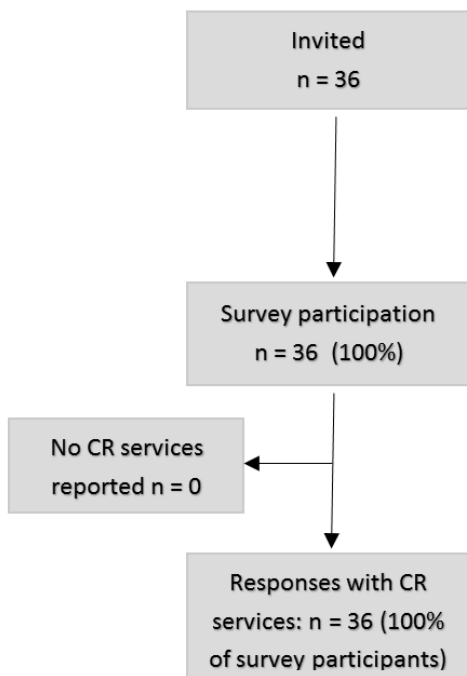
Hospitals 2013



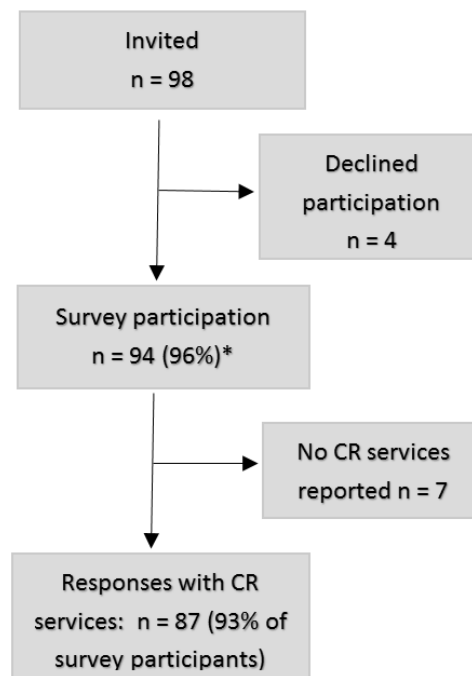
Municipalities 2013



Hospitals 2015



Municipalities 2015



* In the 2015 survey of municipalities, 4 thematic questionnaires were applied – see also Methods section. A detailed overview of responses for each thematic questionnaire is reported in **Appendix, Flowchart and Table 2**.

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Table 2. Provision and quality of core components of cardiac rehabilitation in Danish hospitals and municipalities in 2013 and 2015

	Hospitals 2013 N=36	Hospitals 2015 N=36	p-value*	Municipalities 2013 N=60	Municipalities 2015	N***	p-value* #
Core components at programme level	n (%)	n (%)		n (%)	n (%)		
Exercise training	36 (100 %)	35 (97 %)	1.00	59 (98 %)	64 (96 %)	67	0.20
Patient education	35 (97 %)	35 (97 %)	1.00	45 (75 %)	56 (84 %)	67	1.00
Psychosocial support	32 (89 %)	32 (89 %)	1.00	38 (63 %)	42 (63 %)	67	0.83
Anxiety and depression screening	22 (61 %)	35 (97 %)	<0.001	12 (20 %)	13 (19 %)	67	0.45
Nutritional counselling	35 (97 %)	34 (94 %)	1.00	50 (83 %)	52 (78 %)	67	0.79
Smoking cessation counselling	34 (94 %)	33 (92 %)	1.00	53 (88 %)	58 (82 %)	71	0.39
Vocational advice	4 (11 %)	8 (22 %)	0.34	6 (10 %)	9 (13 %)	71	1.00
Quality aspects of core components							
Exercise training 2 days/week for 12 weeks	22 (61 %)	23 (64 %)	1.00	25 (42 %)	24 (36 %)	67	0.68
Test before and after exercise training	33 (92 %)	34 (94 %)	1.00	53 (88 %)	59 (88 %)	67	0.58
Valid test method for exercise training	10 (28 %)	12 (33 %)	0.80	4 (7 %)	5 (7 %)	67	0.68
All components of patient education	25 (69 %)	25 (69 %)	1.00	28 (47 %)	25 (37 %)	67	0.04
Screening with HADS**	9 (25 %)	26 (72 %)	<0.001	5 (8 %)	8 (12 %)	67	1.00
Dietary counselling screening	9 (25 %)	11 (31 %)	0.79	13 (22 %)	15 (22 %)	67	1.00
Smoking cessation integrated in hospital CR services	14 (39 %)	11 (31 %)	0.62	N/A	N/A	-	-

* Calculated using Fisher's Exact Test.
 ** HADS = the Hospital Anxiety and Depression Scale
 *** N varies for components due to varying number of responses to different professionally themed questionnaires (see Appendix flowchart). Only hospitals reporting overall provision of Phase II services are included in the calculations.
 # p-values for municipalities are calculated for those municipalities who have responded to the questionnaire in both 2013 and 2015 and who have reported Phase II services in both years (n=49). Provision and quality of core components of CR for these 49 municipalities are displayed in Appendix, Table 3.

Figure 2a. Provision of core components of cardiac rehabilitation at hospital and municipality level at baseline and follow-up (%)

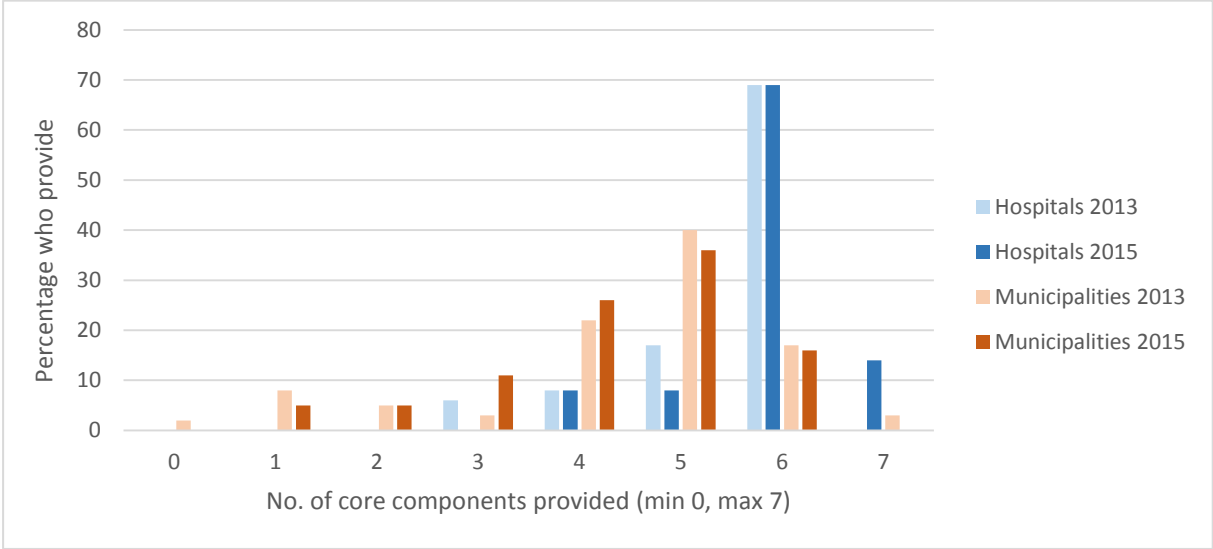
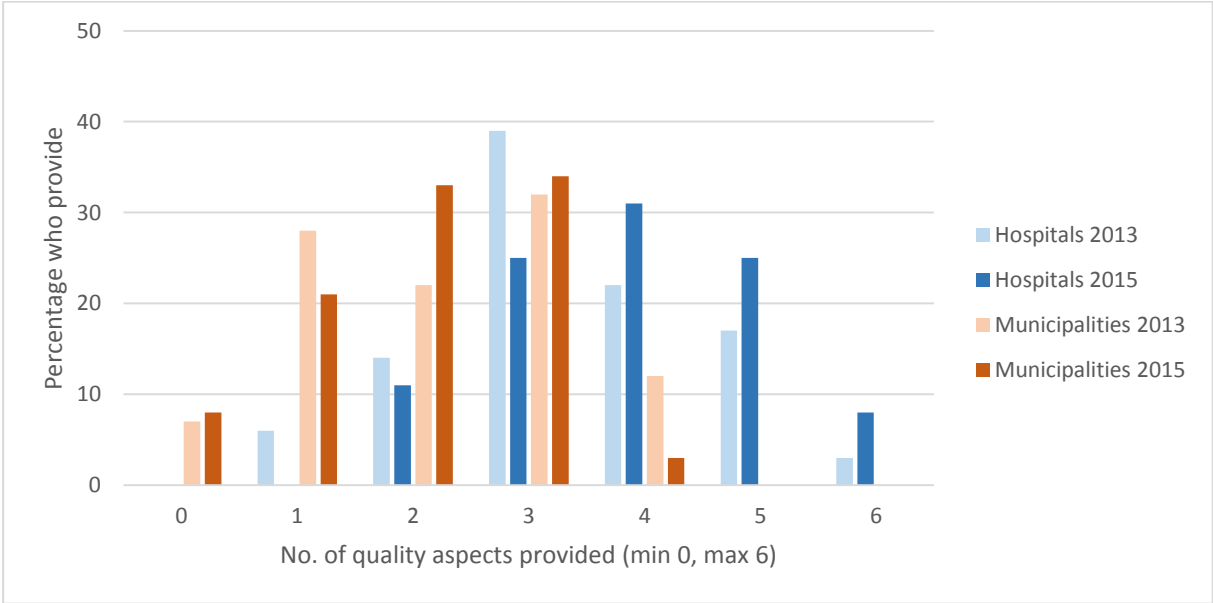


Figure 2b. Provision of quality aspects of cardiac rehabilitation at hospital and municipality level at baseline and follow-up (%)



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