Accreditation and the Development of Process Performance Measures

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by

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PhD Thesis

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Declaration of Originality

I certify that this thesis does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Signed: _____ On: 6/12/2016

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Thesis Papers

Paper I

Bogh SB, Falstie-Jensen AM, Bartels P, Hollnagel E, Johnsen SP. Accreditation and improvement in process quality of care: a nationwide study. Int J Qual Health Care. 2015 Oct; 27(5):336-43

Paper II

Bogh SB, Falstie-Jensen AM, Hollnagel E, Holst R, Braithwaite J, Johnsen SP. Improvement in quality of hospital care during accreditation: A nationwide stepped-wedge study. Int J Qual Health Care. 2016

Paper III

Bogh SB, Falstie-Jensen AM, Hollnagel E, Holst R, Braithwaite J, Raben DC, Johnsen SP. Predictors of the effectiveness of accreditation on hospital performance: A nationwide stepped-wedge study. Submitted

Paper IV

Bogh SB, Blom A, Raben CD, Braithwaite J, Thude B, Hollnagel Erik, Plessen Cv. Voices from the front lines: healthcare staff's experiences and perceptions of hospital accreditation. Submitted

List of Abbreviations

CI:	Confidence intervals
DDKM:	The Danish Healthcare Quality Programme (Den Danske Kvalitetsmodel)
HQS:	Health Quality Service
JCI:	Joint Commission International
JCAHO:	Joint Commission Accreditation of Healthcare Organisations
OR:	Odds ratio
PDSA:	Plan-Do-Study-Act
PR:	Principal Researcher

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Summary

Accreditation is an external review process used to assess how well an organisation performs relative to established standards. Accreditation provides a framework for continuous quality improvement, and health services worldwide embrace accreditation and use it as a strategy to improve quality in organisations. The scientific literature is sparse and consists of inconsistent results. Therefore, it is not possible to draw a clear conclusion regarding whether accreditation serves as a framework for improvement. In Denmark, hospital accreditation was first adopted in 2002 by hospitals in the capital, which were voluntarily accredited. These hospitals were followed two years later by hospitals from the Southern Jutland County, which were also voluntarily accredited. In 2009, a mandatory accreditation programme was launched for all public hospitals.

This thesis examined the effect of hospital accreditation on quality of care using nationwide quantitative designs aimed at detecting changes over time in hospital performance in relation to both voluntary (Study 1) and mandatory accreditation (Study 2). Further, a qualitative study (Study 3) was conducted to complement the findings in Study 2.

To examine the voluntary accreditation programme, we used a controlled pre- and post-design with difference-in-differences analysis based on process data from patients admitted for acute stroke, heart failure or ulcer. The primary outcome was a change in the opportunity-based composite score, and the secondary outcome was a change in all-or-none scores. The opportunity-based composite score improved significantly more for non-accredited hospitals. The absolute difference between improvements in the all-or-none score for non-accredited and accredited hospitals was not significant.

A mixed-method sequential explanatory design was used to examine the mandatory accreditation programme. The quantitative study was a multilevel, longitudinal, stepped-wedge, nationwide study of process performance measures based on data from patients admitted for acute stroke, heart failure, ulcer, diabetes, breast cancer and lung cancer. The qualitative study was based on eight semi-structured interviews conducted at a Danish hospital. Overall, mandatory accreditation did not contribute to improvement process measures, but development began to plateau when the external survey was conducted. Staff argued that these processes were already well implemented before the mandatory accreditation and were not considered to have contributed to anything new in that respect. The quantitative analyses showed that heart failure and breast cancer were overall negatively affected by DDKM, but for processes below target values, diabetes and diagnostics were positively affected. Staff reported that accreditation affected management's priorities. In favour of DDKM, other improvement initiatives were neglected, and staff spent less time with patients, which might explain why performance measures in some cases were negatively affected. The quantitative analysis showed that mandatory accreditation affected quality development to a similar extent across all types of

hospitals. Finally, process measures below best-practice target values were positively affected by accreditation to a greater extent than processes above the target values. Mandatory accreditation was perceived by staff to have created a foundation for how hospital staff work with quality improvement in the future.

Dansk Resume

Akkreditering er en kvalitetsvurderings proces til at undersøge, hvor godt en organisation lever op til et sæt fælles standarder. Akkreditering er bredt anvendt af sundhedsorganisationer rundt omkring i verden, hvor det danner rammen for kvalitetsforbedringsarbejde. Den videnskabelige litteratur om akkreditering og dens effekt er mangelfuld og inkonsistent og giver ikke mulighed for at drage en entydig konklusion. Akkreditering af hospitaler i Danmark blev introduceret i 2002, da hovedstadens hospitaler blev frivilligt akkrediteret. To år efter valgte hospitaler i Sønderjylland ligeledes at blive akkrediteret. I 2009 blev et obligatorisk akkrediteringsprogram indført for alle offentlige hospitaler i Danmark.

Denne afhandling undersøger hvilken indflydelse akkreditering af de danske hospitaler har haft på sygdomsbehandlingen. Landsdækkende kvantitative studie designs blev anvendt til at undersøge ændringer i klinisk proces kvalitet i relation til både frivillig (Studie 1) og obligatorisk akkreditering (Studie 2). Endvidere blev et kvalitative studie (Studie 3) gennemført for at komplementere resultaterne fra studie 2.

Effekten af den frivillige akkreditering blev undersøgt ved brug af et kontrolleret før og efter design, hvor analyserne var baseret på klinisk proces data fra patientindlæggelser relateret til apopleksi, hjertesvigt og mavesår. Det primære effektmål var ændring i sandsynligheden for at modtage en behandling og det sekundære effektmål var ændring i sandsynligheden for at modtage alle de anbefalede behandlinger. Sandsynligheden for at modtage en behandling forbedrede sig signifikant mere for ikke-akkrediterede hospitaler sammenlignet med akkrediteret hospitaler, mens der ikke var forskel grupperne imellem når ændring i sandsynligheden for at modtage alle de anbefalede behandlinger blev sammenlignet.

Den obligatorisk akkreditering af samtlige danske hospitaler blev undersøgt både kvantitativt og kvalitativt. Den kvantitative del bestod af et longitudinelt design, baseret på klinisk proces data relateret til apopleksi, hjertesvigt, mavesår, diabetes, brystkræft og lungekræft. Den kvalitative del var baseret på otte semi-strukturerede interviews med ansatte fra et dansk hospital. Studiet viste at akkreditering generelt ikke bidrog med forbedret proceskvalitet, tværtimod blev udviklingen over tid reduceret i perioden efter det eksterne besøg. Personalet forklarede at disse kliniske processer var godt implementeret allerede inden den obligatoriske akkreditering, og personalet anså derfor ikke akkreditering til at have bidraget med noget nyt i den henseende. Stratificerede kvantitative analyser viste, at hjertesvigt og brystkræft overordnet var negativt påvirket af akkreditering, og at diabetes og diagnostik var positivt påvirket når kun processer under grænseværdien var inkluderet. Personalet oplevede at akkreditering påvirkede hvordan ledelsen prioriterede. På grund at akkreditering blev andre forbedringsprojekter tilsidesat og personalet oplevede at have mindre tid hos patienterne. Kvantitative analyser viste endvidere, at den obligatorisk akkreditering påvirkede udviklingen i kliniskproceskvalitet på samme måde uanset hospitalskaratiristik. Generelt var processer under grænseværdien i højere grad positivt påvirket end processer over grænseværdien.

Personalet havde generelt oplevelsen af, at den obligatorisk akkreditering havde bidraget til et fundament for, hvordan hospital vil arbejde med kvalitetsudvikling i fremtiden.

Chapter 1: Introduction

1.1 Focus of the Research

The objective of this thesis was to investigate the effect of hospital accreditation on quality of care in Danish public hospitals. In Denmark, accreditation began in 2002 and was implemented voluntarily by a few hospitals. This was followed by a nationwide mandatory accreditation programme in 2009 that included all public hospitals. A clear understanding of the effectiveness of accreditation, in terms of improved hospital performance, is critical to ensure that accreditation programmes achieve their aims.

Healthcare systems in developed countries consume a significant amount of resources (1), and the prospects of an ageing population and scientific and technological advances leading to more advanced and possibly more expensive treatments do not give hope for a less expensive healthcare system in the future. Without the provision of additional resources, healthcare managers must expect pressure on their organisation to be more efficient and simultaneously provide better quality of care for patients. The presence of many different stakeholders, subsectors, equipment and technologies make it difficult to navigate modern healthcare organisations such as hospitals (2). Accreditation of healthcare systems is increasingly used as an approach to ensure standards of healthcare (3, 4). Accreditation is proposed as an objective method for verifying health service providers (e.g., hospitals) through compliance with accepted standards (3, 5). Accreditation is influenced by contextual factors (6), which may explain some of the variations and inconsistencies of effects reported in the literature (4, 7–10).

The studies included in this thesis represent the first empirical investigation designed to assess how accreditation has affected the development of process quality of care at the national level in the Danish context. This thesis uses quantitative and qualitative methods to provide insights into the effects of both voluntary and mandatory accreditation in Denmark.

1.2 Framework of the Thesis

This thesis consists of three studies that contribute to the understanding of how hospital accreditation has affected quality of care.

Chapter 2 introduces accreditation, the scientific literature and the Danish context. This is followed by a description of the methods used and a chronological presentation of the three studies to guide the reader through the history of accreditation in Denmark.

The first study examines the effect of voluntary accreditation by comparing accredited and non-accredited hospitals. This study is reported in Paper I: ‘Accreditation and improvement in process quality of care: a nationwide study’.

The second study examines the effect of mandatory accreditation on hospital performance measures using a longitudinal design. The study is reported in Paper II: 'Improvement in quality of hospital care during accreditation: a nationwide stepped-wedge study' and Paper III: 'Predictors of the effectiveness of accreditation on hospital performance: A nationwide stepped-wedge study'.

The third study examines staff members' views and understanding of accreditation using qualitative methods. The study is reported in Paper IV: 'Voices from the front lines: healthcare staff's experiences and perceptions of hospital accreditation'.

Figure 1.1 presents an overview of the four papers presented in this thesis.

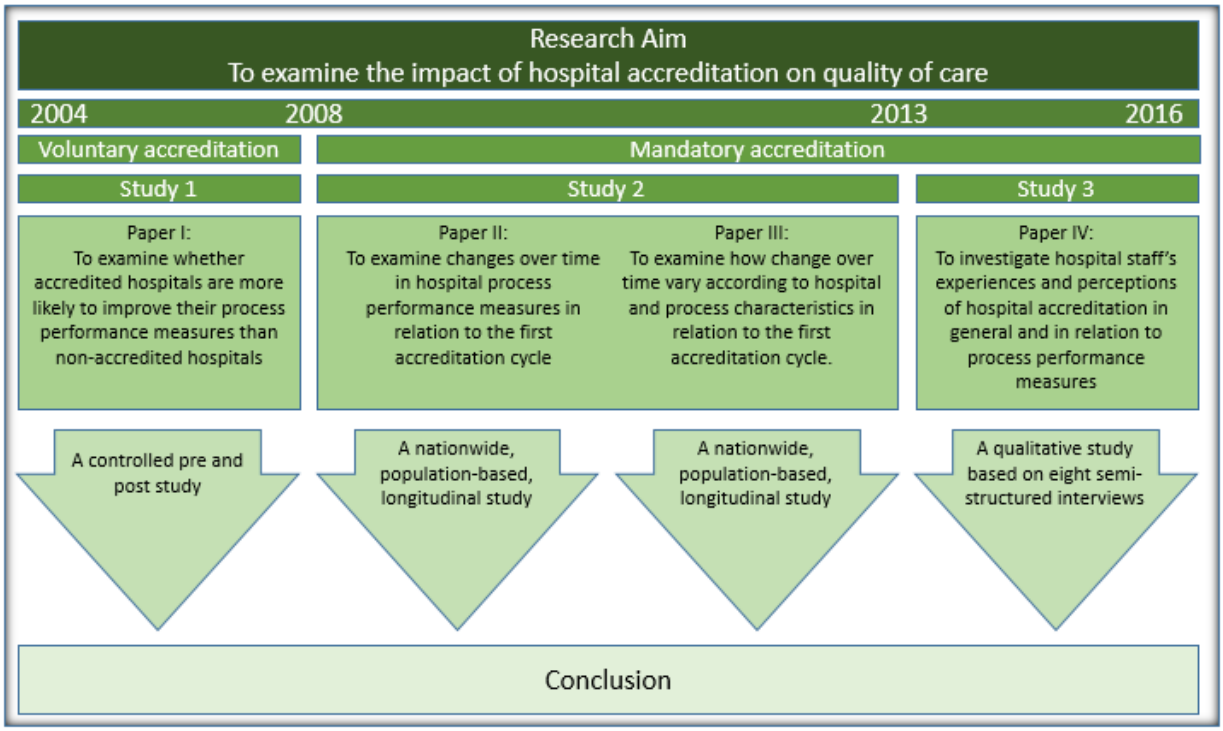

Figure 1.1: Overview of papers included in the thesis

Chapter 2: Background

2.1 Danish Healthcare System

In Denmark, all citizens are provided with tax-supported healthcare, including free access to hospital care, by the national healthcare system. In 2008, Denmark had a population of 5.5 million people and was classified as a high-income country (11). Further, it had 38 hospital beds per 10,000 inhabitants (12, 13). Denmark is organised into five regions that are responsible for providing secondary healthcare.

In 2013, the Organisation for Economic Co-operation and Development (OECD) published a review of the quality of healthcare in Denmark and concluded that:

> Denmark is ahead of most OECD countries in efforts to monitor and improve clinical health care quality. Central, regional and municipality government all share responsibility for quality monitoring depending on the services they deliver or oversee. Over time, Denmark has set up strong institutions for tracking and improvement the quality of health care, ranging from accreditation to clinical guidelines, quality registries and quality indicators (14).

In 2002, five hospitals in Copenhagen were accredited for the first time by the Joint Commission International (JCI) (15), whereas the Health Quality Service (HQS) accredited hospitals in the County of Southern Jutland for the first time in 2004 (16). Both programmes were later replaced by a nationwide mandatory programme called the Danish Healthcare Quality Programme (*Den Danske Kvalitetsmodel* [DDKM]), which was implemented by the Board of Health, Ministry of Health, Association of County Councils and the Copenhagen Hospital Corporation (17). All public hospitals in Denmark were required to implement DDKM. The first version of DDKM was used from 2010 to 2012, and the second and last version followed from 2013 to 2015. Since 2016, Danish hospitals have not been required to be accredited according to DDKM.

2.2 What is Accreditation?

Accreditation is an external review process designed to assess how well an organisation performs relative to predefined standards (5). Accreditation aims to be a framework for high quality of care and continuous improvement of care (18). The outcome of the external review determines whether an organisation is awarded with an accredited status. Accreditation is usually voluntary (19), but it is used as an extension of statutory licensing in an increasing number of countries (20). In these cases, accreditation is a visible component of the mechanism through which politicians and administrators ensure accountability and value for the resources spent on health services (21). The perception of the role of accreditation varies from a badge of achievements to a management tool and an instrument of self-development and self-investment (22, 23). However, there is an element of control because accreditation bodies can withhold accreditation from hospitals if standards are not sufficiently met (23).

2.3 Accreditation Standards

Accreditation is the formulation of standards and the control of adherence to them (24). An independent accreditation body is responsible for developing the standards, which are generic and built around essential features that are common to hospitals. Each standard describes good practice in areas that have been found to be important for ensuring organisational performance, quality of care and safety standards in hospitals. Common themes in accreditation programmes include management in general, documentation, data management, quality management, patient safety and personnel qualifications and training.

2.4 External Survey

The control of adherence to standards is typically called the external survey or review (hereafter referred to as external survey).

A set of surveyors conducts the external survey. The dates of the survey are usually announced 6–12 months in advance to ensure there is time for preparation and self-assessment (5). The main task of the external survey is to evaluate organisations' compliance with the predefined standards. Depending on the size of the organisation, the survey can vary from a day or two with a few surveyors to several days with a large team. The external survey consists of several data collection methods, including interviews with managers, staff and patients, as well as reviews of local guidelines and observations of practice (3, 25). Based on the survey, a report is prepared for the accreditation bodies, which evaluate whether organisations should be given accreditation. The frequency of visits varies between accreditation programmes, but visits are typically made every third to fourth year and include a midterm visit to maintain momentum.

2.5 Structure, Process and Outcome

Traditionally, accreditation standards have focused on organisational policies and procedures rather than the organisation of specific clinical activities (26). During the 1980s and 1990s, accreditation evolved through the adoption of principles of continuous quality improvement inspired by quality management in industries (26). Continuous quality improvement is based on the principle that every process has opportunities for improvement (27). With the evolution of accreditation, the emphasis of the external survey is now not only on structures and processes, but also on meeting the performance objectives of the standards and on the outcome. If surveyors observe serious underlying weaknesses in the organisational structure or work processes, they make recommendations for improvement (28). At the same time, indicator-based monitoring systems are often developed to stimulate continuous improvement of hospital performance throughout the entire accreditation cycle. The assumption behind benchmarking is that it will stimulate continuous improvement, thereby helping hospitals to better serve their patients (29).

Due to the goal of ensuring that high-quality and continuous quality improvement driven by standards for structures, processes and outcomes, accreditation considers causal linkages between them. These relationships were first described by Donabedian (30), who argued that good structure increases the likelihood of good processes, and good processes increase the likelihood of a good outcome. According to Donabedian:

- Structure denotes the attributes (material resources, human resources and organisational structure) of the settings in which care occurs (30).
- Process denotes what is actually done in giving and receiving care, including both patients' and practitioners' activities (30).
- Outcome denotes the effect of care on the health status of patients and populations (30).

With a focus on structures and processes to secure good outcomes, accreditation emphasises that the system and the organisation of care, rather than the staff themselves, are responsible for delivering good-quality care for patients.

2.6 Logic Model

The logic model presented in Figure 2.1 illustrates the linear link between the intentions of accreditation and continuous improvement in quality of care. The logic model is not exhaustive and should be seen only as a graphical device used to outline the underlying assumption of cause-and-effect relationships (31).

The presented model outlines the assumptions that accreditation relies on and the inputs and activities planned by hospitals. Output and outcome are the intended results of accreditation and the planned work:

- Assumptions are the hypothesised underlying cause-and-effect relationships that accreditation is based on.
- Inputs are the resources that enable compliance with accreditation standards.
- Activities are the actions and events that hospitals set in motion to comply with the standards. Employees at all levels can be included in these activities.
- Outputs are the intended results of the activities and reflect the requirements of the standards.
- Outcomes are the goals of accreditation.

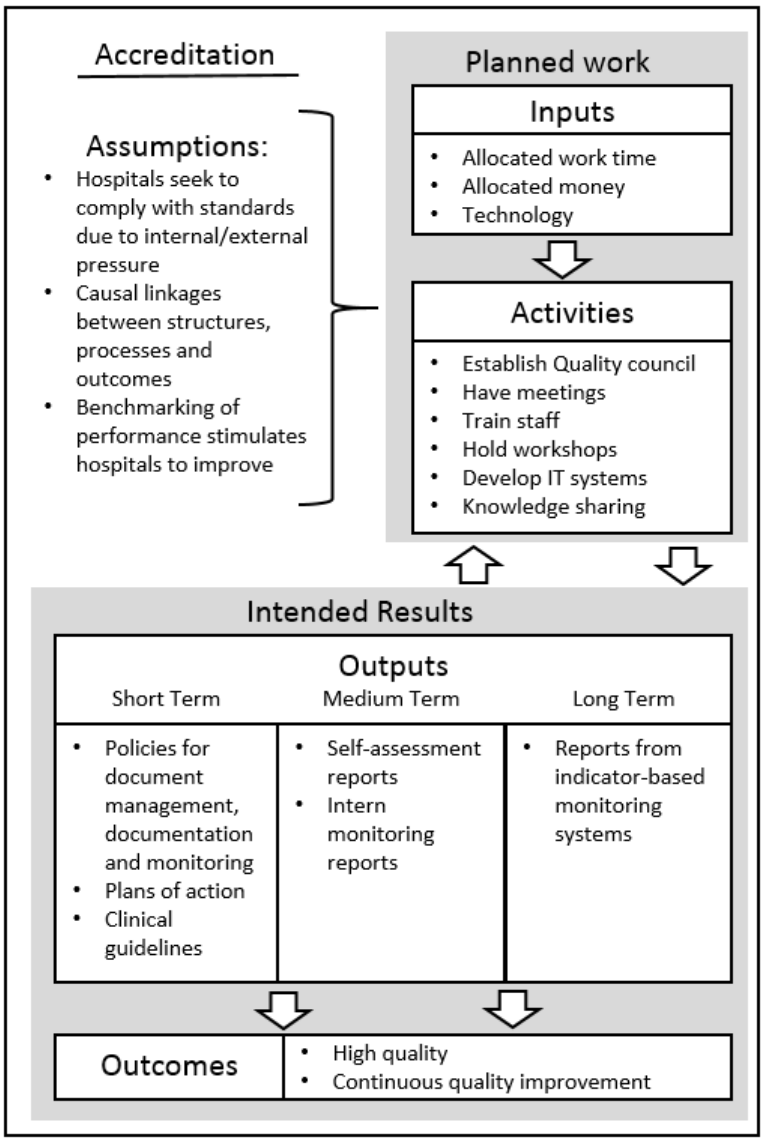

Figure 2.1: Logic model showing link between accreditation and continuous quality improvement

2.7 Challenges When Examining the Effect of Accreditation

Accreditation covers a cluster of activities at multiple levels that interact to produce organisational changes, making it difficult to draw links between specific activities and outcomes (20). Further, accreditation is an intervention with no specific endpoint, which makes it difficult to evaluate (32). Entering an accreditation programme is usually a political decision, making it intrinsically difficult to investigate. As the researcher does not have an opportunity to manipulate the intervention, it can be categorised as a natural experiment. Natural experiments are susceptible to bias and confounding, which should be taken into account (33). However, mixed methods, stepped-wedge designs and other quasi-experimental designs, such as controlled studies and interrupted times series, can be powerful designs for evaluating a

complex intervention, and they can be used in natural experiments (e.g., evaluation of an accreditation programme) (34, 35).

2.8 Research on Hospital Accreditation and Quality of Care

This section reviews the existing literature on hospital accreditation and the effect on development in quality of care to provide supporting information to the thesis.

2.8.1 Search strategy

A literature search was performed in PubMed and included literature published in the English and Scandinavian language. The literature search included three blocks. The first block consisted of 'accreditation, accredited, non-accredited and unaccredited [Title and abstracts]'. The second block consisted of 'impact, effect, improv* and causality [Title and abstracts]'. The third block consisted of 'hospital and hospitals [Title and abstracts]'. These blocks were used in combination with 'NOT education' to exclude literature on educational accreditation. All research that assessed the effect of hospital accreditation on relation process measures was included, irrespective of methodological design and how the processes were measured. Thus, studies using outcomes that were not necessarily termed as processes of care or performance measures were also included. Further, reference lists of the included publications were searched for additional relevant references.

2.8.2 Effect of hospital accreditations on processes of care

The literature search identified 16 relevant studies on the effect of accreditation after 986 abstracts were screened. The research design employed in the identified studies varied considerably. Table 2.1 outlines the included publications by publication year and first author. Only one study (36) used a randomised control trial design. Three studies used a longitudinal design: the first one used an interrupted time-series design on data from one hospital (37), the second study had a control group (38) and the third did not have a control group (39)). Two studies used pre- and post-design with control groups (40, 41), and ten studies used a cross-sectional design—eight with controls (42–49) and two without controls (50, 51).

All cross-sectional studies with control groups examined the process performance measures used, except for one Philippine study that used vignettes (case scenarios) (47). In this cross-sectional survey, 145 physicians were asked to answer three vignettes: one for diarrhoea, one for pneumonia and one on common dermatologic conditions. The vignettes were independently scored by two trained physician abstractors who were blinded to the physicians' identity and each other's scores. Analysis showed that the quality of care was higher among accredited physicians than non-accredited. However, it was not possible to isolate the accreditation effect from the effect of insurance payments (47).

Five cross-sectional studies with control groups investigated the effect of accreditation while focusing on a single condition. Chen et al. conducted a cross-sectional study of 4,221 hospitals

and found that patients treated at accredited hospitals were more likely to receive a higher quality of care related to acute myocardial infarction than patients at non-accredited hospitals. Two other cross-sectional studies reached a similar conclusion, finding a positive association in seven out of eight (43) and three out of four (46) performance measures. Chandra et al. found a more inconsistent result, with accredited hospitals performing better on only two out of six quality measures (44). Wells et al. also found inconsistent results in investigating the association between accreditation and drug abuse treatment. The authors analysed the association between accreditation and six measures of treatment comprehensiveness and two measures of treatment sufficiency. They found that accreditation was positively associated with three measures. Treatment duration was the only measure with a negative association, meaning that accredited hospitals treated patients for an inadequate period (48).

Two cross-sectional studies with control groups evaluated accreditation across several conditions. Lutfiyya et al. (45) examined the correlation between accreditation on 16 process performance measures and found that accredited hospitals performed modestly better. Shaw et al. used composite scores to explore whether accreditation influenced quality management activities at four clinical service levels (acute myocardial infarction, deliveries, hip fracture and stroke). Accreditation appeared to promote processes that supported patient safety and clinical organisation, but it had a limited effect on the delivery of evidence-based practice. The authors argued that it might be expected accreditation first to stimulate quality management at the level of care processes before it improves clinical outcomes. They found that some elements of quality management at the clinical level were associated with accreditation, but others were not (49).

Table 2.1: Identified literature on the effect of accreditation on process performance

Author and year	Objective and design	Population and setting	Exposure and outcome	Results and comments
Almasabi M and Thomas S (50), 2016	To develop an understanding of the effect of accreditation on quality of care. Mixed-method (survey and interview) cross-sectional design.	Three accredited public hospitals in Saudi Arabia. Accreditation was mandatory for all hospitals.	Accredited by the Central Board for Accreditation of Healthcare Institutions. Staff perceptions measured on a five-point Likert scale and codes based on interviews.	58.8% (n = 394) of the staff agreed that the hospital had shown steady, measurable improvements in the quality of care provided to patients over the past few years, but only 10% of the variation was explained by accreditation benefits. Accreditation was considered a temporary improvement rather than continuous.
Devkaran S and O'Farrell P (37), 2015	To examine the effect of accreditation over a 4-year period (before and after accreditation). Interrupted time-series analysis.	All patients at a 150-bed hospital in Abu Dhabi. 2009–2012.	Accredited by Joint Commission International. 27 quality measures. All measures were applicable to all patients in the hospital.	Thirteen of the 27 measures had a positive pre-accreditation slope. The accreditation survey was associated with a significant negative change in slope in 13 measures. A single hospital and lack of baseline data made it difficult to ascertain whether accreditation contributes to improvements pre-accreditation.
Kilsdonk MJ et al. (38), 2014	To examine the effect of external peer review for multidisciplinary cancer care for breast cancer patients. A longitudinal comparative study: external assessment v. control.	Patients with breast cancer between 1990 and 2011 from hospitals in the Northern Netherlands and the Rotterdam region.	External peer review programme. Intervention group was categorised by the implementation proportion. Six measures of breast cancer treatments.	No relationship was found between participating in the external peer review programme and variation in treatment. External programmes were not described. It is not known whether the implementation proportion reflects how well hospitals participated in the programme.

Author and year	Objective and design	Population and setting	Exposure and outcome	Results and comments
Merkow RP et al. (46), 2014	To assess the association between performance indicators and cancer centre accreditation status. A comparative cross-sectional study: accredited v. non-accredited.	Patients with cancer at 3,563 centres in US.	National Cancer Institute and Commission on Cancer. Four process measures.	Accreditation was associated with a decreased likelihood of poor performance for 3 of the 4 measures. Accreditation programmes were not described. They controlled for state-level clustering.
Shaw CD et al. (49), 2014	To explore whether certification and/or accreditation influences quality management activities at four clinical service levels. A mixed-method multilevel cross-sectional design.	210 hospital from the Czech Republic, France, Germany, Poland, Portugal, Spain and Turkey. Disease area: acute myocardial infarction, stroke, hip fracture and delivery. 2011–2012.	Health service accreditation or certificated for a hospital-wide quality management system under ISO 9001. Four composite measures of quality and safety: specialised expertise and responsibility, evidence-based organisation of pathways, patient safety strategies and clinical review.	Accreditation showed benefits in acute myocardial infarction and stroke care. Accreditation appeared to promote structures and processes that support patient safety and clinical organisation, but had limited effect on the delivery of evidence-based practice. Effect of accreditation was likely to be inconsistent between countries. Combination of both accreditation and certification was superior to accreditation alone.
Peacock FW et al. (52), 2013	To describe the association between accreditation and hospital quality performance. One to two matched follow-up design. Accredited v. non-accredited.	Acute myocardial infarction patients enrolled in the ACTION Registry–GWTG improvement programme.	Accredited by the Society of Cardiovascular Patient Care. 13 process measures and one composite score.	Although non-accredited sites started slightly lower, all sites finished with similar overall acute myocardial infarction performance composite scores after 1 year (92.1% v. 92.2%). As all hospitals were part of the ACTION Registry–GWTG improvement programme,

Author and year	Objective and design	Population and setting	Exposure and outcome	Results and comments
		487 US hospitals with data from 2007–2010.		results cannot be expected to be similar for non-ACTION Registry–GWTG hospitals.
Schmalz SP et al. (40), 2011	To examine the association between accreditation status and quality measures. A historical follow-up study: accredited v. non-accredited.	Patients with acute myocardial infarction, heart failure and pneumonia from 3,891 hospitals in the US. 2004–2008.	Accredited by Joint Commission. 16 quality measures.	Accredited hospitals outperformed non-accredited hospitals on quality measures and the gap between groups increased over the five years of the study. Accreditation programmes were not described. Hospitals accredited for part of the study period were excluded. Analyses were adjusted for hospital characteristics.
Chandra et al. (44), 2009	To evaluate the association between accreditation and adherence to evidence-based guidelines for myocardial infarction. Cross-sectional study: accredited v. non-accredited.	Patients with non-ST-segment elevation myocardial infarction and acute coronary syndrome from 344 hospitals in the US were included. 2005.	Accredited by Society of Chest Pain Center Accreditation. Six core measures of care for acute myocardial infarction.	Accreditation was associated with improved adherence to two of the six measures. Description of accreditation programme was limited. Excluded patients who died within the first 24 hours of admission.
Lutfiyya et al. (45), 2009	To determine whether quality measures differed for critical access hospitals based on accreditation status. Cross-sectional: accredited v. non-accredited.	Patients with acute myocardial infarction, heart failure, pneumonia and surgical infection. 2006.	Accredited by Joint Commission on Accreditation of Healthcare Organizations (JCAHO). 16 quality care indicators.	Accredited hospitals performed better in four of 16 quality indicators. No difference in the remaining 12 quality indicators. A composite score showed that accredited hospitals were more likely to score in the top half (OR 1.39, 95% CI 1.09–1.76).

Author and year	Objective and design	Population and setting	Exposure and outcome	Results and comments
				Voluntary reporting of data and only a 56% participation rate. Accreditation programmes were not described.
EL-Jardali F. et al. (51), 2008	To assess the perceived effect of accreditation on quality of care. Cross-sectional survey study.	1,058 nurses from 59 hospitals in Lebanon. All hospitals should have passed through both accreditation surveys I and II.	Ministry of Public Health implemented accreditation in 2011. Staff perception measured on a five-point Likert scale.	Accreditation seems to have improved perceived quality of care, where results were better in small- and medium-sized hospitals. Accreditation programmes were not described.
Pollack HA and D'Aunno T (39), 2008	To examine the extent to which US methadone maintenance facilities meet established standards for minimum dosages, 1988–2005. Longitudinal analysis using random effects multiple regressions.	Sampling facilities consisted of the Food and Drug Administration's 1988 list of US methadone maintenance treatment units (n = 587). Facilities included: 1988, n = 172 1990, n = 140 1995, n = 116 2000, n = 150 2005, n = 146.	Accredited by JCAHO and the Commission on Accreditation of Recovery Facilities. Used percentages of patients in each treatment unit who received dosages that were below 40, 60 or 80 mg/day.	JCAHO-accredited units were more likely to adhere to the recommended 60 mg/day minimum dosage guideline and were significantly more likely to provide doses exceeding 80 mg/day. The association declined markedly in the 2005 wave and was no longer statistically significant. Accreditation programmes were not described. Accreditation became mandated after 2000, which might explain why the association faded.

Author and year	Objective and design	Population and setting	Exposure and outcome	Results and comments
Ross et al. (43), 2008	To determine if adherence to core measures for acute myocardial infarction is correlated with accreditation. Cross-sectional study: accredited v. non-accredited.	Patients with acute myocardial infarction from 4,197 hospitals were included. 2006.	Accredited by Society of Chest Pain Center Accreditation. Eight core measures of care for acute myocardial infarction.	Accredited hospitals had higher rates of compliance with all core measures, except for time to thrombolytic. Accreditation programme was not described. Accredited hospitals were larger and more actively involved in cardiac interventions than non-accredited hospitals.
Quimbo SA et al. (47), 2008	To examine the correlation of accreditation of physicians with the quality of inpatient paediatric care. Using written case scenarios designed to measure the quality of clinical care by measuring a doctor's ability to diagnose properly and treat patients. Range of scores was 0–100%.	145 physicians from the Philippines were included.	Accredited by Philippine Health Insurance Corporation. Each physician answered three vignettes (cases): one for diarrhoea, one for pneumonia and one on common dermatologic condition. Each vignette was scored by two blinded and trained abstractors.	With 5.9% higher score was accredited physicians significantly associated with quality of care. Description of accreditation programme was limited. It is not possible to isolate the accreditation effect from the effect of insurance payments.
Wells R et al. (48), 2006	To examine the association between accreditation/licensure and treatment. Cross-sectional survey.	Drug abuse treatment Units included: 1999/2000, n = 571 (response rate 89%) 2005, n = 566 (response rate 88%).	Accredited by JCAHO. Six measures of treatment comprehensiveness and two measures of treatment sufficiency.	Accreditation was positively associated with percentage of clients receiving physical examinations and mental healthcare. Also, positively associated with percentage of clients for whom agencies were preparing written after-treatment plans, and negatively associated with treatment duration.

Author and year	Objective and design	Population and setting	Exposure and outcome	Results and comments
				Accreditation programme was not described. Units that did not respond tended to be private, for-profit, small and young.
Chen J. et al. (42), 2003	To examine the association between accreditation and quality of care. Cross-sectional: accredited v. non-accredited.	4,221 US hospitals treating 134,579 patients with acute myocardial infarction.	Accredited by JCAHO. Five processes of care measures for acute myocardial infarction.	Patients admitted to accredited hospitals were more likely to receive the five process measures than patients admitted to non-accredited hospitals. No 95% CI on the estimates.
Salmon JW (36), 2003	To assess the effects of an accreditation programme on hospital quality of care. Randomised control trial.	20 public hospitals in South Africa were included. Baseline data collected from Dec. 1998 to Feb. 1999 for intervention hospitals and for control hospitals from May to June 1999. Follow-up was conducted from May to October 2000.	Accredited by the Council for Health Services Accreditation of Southern Africa. Nurses' perception.	Nurses' perception of quality at accredited hospitals increased during the study compared to non-accredited hospitals. Baseline data were collected too late to be true baseline, and only nine months on average elapsed between the two data collection rounds.

Two cross-sectional studies without controls used surveys to evaluate nurses' perceptions of the effect of accreditation on quality of care. El-Jardali et al. surveyed nurses at 59 hospitals in Lebanon to assess their perception of improvements in the quality of care as a result of hospital accreditation. The authors found that nurses perceived an improvement in the quality of care in relation to accreditation; however, the improvement appeared to depend on hospital size. Better results were observed in small- and medium-sized hospitals compared with large hospitals, except for the leadership, commitment and support subscales (51). In a recent study, Almasabi and Thomas (2016) used the same survey at three accredited public hospitals in Saudi Arabia. A little over half of the staff agreed that the hospitals had shown steady and measurable improvements in the quality of care, but analysis showed that only 10% of the variation was due to accreditation benefits. The researchers complemented this survey with 12 semi-structured interviews with senior managers. Thematic analysis showed that managers perceived that accreditation facilitated greater unity among members of hospital staff, encouraged the leadership of the hospitals to promote a positive culture of accountability and encouraged better policies and procedures at the hospitals (50).

In a longitudinal design, Kilsdonk et al. examined the possible effects of external peer reviews on multidisciplinary cancer care for breast cancer patients (38). They did not find a relationship between participation in an external peer review programme and patterns in cancer treatment. Results indicated that regional factors were of greater importance than participating in an external peer review programme. Pollack et al. (39) conducted a longitudinal study to examine the association between accreditation and methadone dosages. They showed that JCAHO-accredited units were more likely to adhere to the recommended dosage. However, this correlation declined markedly in the last data wave. The weaker correlation may be because accreditation became mandatory five years earlier, thereby removing a possible selection bias. The authors argued that accredited units in the earlier waves were more motivated to improve quality of care and were relatively resource-rich compared with non-accredited units. Devkaran and O'Farrell conducted an interrupted time-series design based on 27 quality measures from a single hospital in Abu Dhabi. Using segmented regression, they examined the effect of accreditation over a four-year period (one-year pre-accreditation and three years post-accreditation). Despite the slope began to plateau post-accreditation, the improvement achieved in the pre-accreditation period was maintained during the three-year accreditation cycle. However, it is uncertain whether accreditation contributed to the improvement pre-accreditation; the authors only demonstrated that the development of quality measures decreased post-accreditation (37). Two US studies used a follow-up design and found contradictory results. Peacock et al. (41) found that a composite score for non-accredited hospitals improved more over time than that of accredited hospitals. This was in contrast to the findings of Schmaltz et al., who found that accredited hospitals outperformed non-accredited hospitals at baseline with a composite score based on 16 quality measures. Further, they found that the gap between the groups increased further doing the five-year study period (40).

In the systematic search, one study was identified as using a randomised control trial design. In the study, 20 randomly selected public hospitals in South Africa were included, of which ten hospitals were randomised to an accreditation programme. The aim was to assess the effects of accreditation on hospital quality of care. Effects were measured by survey data and quality indicator data collected by an independent research team composed of South African and US investigators. Nurses' perceptions of quality of care at accredited hospitals increased during the study period compared to nurses at non-accredited hospitals. The other measures were not found to improve during the study period compared with the controls (36).

The identified studies used two general types of measures for the process of care: 'objective measures' and 'provider's perception'. Neither measure covers the whole picture of hospital performance regarding process of care; thus, a multifaceted approach is needed. Provider's perception of quality of care provides a dimension of how accreditation affects quality of care, but it can be criticised as being superficial and influenced by people's prejudices. The advantage of this approach is that it allows staff to share their interpretation of the effect of accreditation so they can have a more comprehensive view of the quality of care compared to 'objective measures' and so they can share their experience of how accreditation works.

2.8.3 Summary of the review of empirical research

To summarise, the review showed a mixed and inconsistent picture of the effect of accreditation on quality of care. Further, methodological limitations are prominent in most of the existing studies. The studies are generally characterised by selected samples of hospitals, and most of the reviewed studies used a cross-sectional design, which is not suitable for detecting changes over time in quality of care related to accreditation (42–51). The fact that only six relevant studies were identified in relation to the effect of hospital accreditation on the development of process performance measures is not impressive, particularly when taking into account the comprehensive use of accreditation worldwide (36–41). The two studies with a follow-up design (40, 41) examined associations between accreditation and changes in processes of care. However, the changes were only based on two time points and did not consider the possibility of an underlying secular time trend in the quality of care, which, if present, is prone to generate false positive findings on the effect of accreditation (53). The study that used an interrupted time series (37), which accounted for the secular trend by design, included only one hospital, thereby making it difficult to generalise the findings. Of the two remaining longitudinal studies (38, 39), only one used a control group (38).

Due to the sparse literature, the inconsistency in results and the important methodological limitations, it is not possible to draw a clear conclusion regarding whether accreditation serves as a framework for improvement in processes of care. This thesis attempts to reduce this gap in knowledge by using both qualitative and quantitative study designs to detect changes in hospital performance over time.

2.9 Research Objectives

The overall aim of this thesis is to examine the effect of hospital accreditation on quality of care. Study 1 investigates the effect of voluntary accreditation, while Study 2 and Study 3 investigate the effect of mandatory accreditation. The studies are based on the following objectives:

Study 1: To examine whether process performance measures improve more in accredited hospitals than in non-accredited hospitals.

Study 2: To assess changes over time in process performance measures in relation to the first mandatory accreditation cycle in Denmark and how they vary according to hospital, disease and process characteristics.

Study 3: To investigate hospital staff's experience and perception of hospital accreditation in general and in relation to process performance measures.

Chapter 3: Overall Methods

3.1 Definition of quality of care

Quality of care can, as previously mentioned, be evaluated based on structure, process or outcome (54). In the past couple of decades, there has been a recurring debate on the merits of process versus outcome measures (55). Process measures have been criticised for their lack of robust and consistent relationships with outcomes (55). However, process measures have several advantages over outcome measures: (i) they do not generally require risk adjustment because the treatment should, in theory, always adhere to recommended care if the inclusion and exclusion criteria are well specified and followed (55); (ii) they are directly actionable; and (iii) they can generally be linked to evidence-based guidelines. This thesis addresses the process domain of quality of care.

3.2 Materials

Study 1 and Study 2 obtained data from national clinical quality registries. According to Danish law, participation is mandatory for all hospitals. National clinical quality registries have been established in Denmark with the aim to document, monitor and improve quality of care at the national level (56, 57). Each clinical quality registry has a multidisciplinary board with representation by relevant medical specialities. The board is responsible for identifying evidence-based performance measures that reflect recommendations in national clinical guidelines. For each process performance measure, a timeframe and a target value is set that reflects best practice for each process. Data are prospectively collected using a standardised registration form. Data from each registry are used for an annual report to evaluate the disease-specific quality of care within and between hospitals. Each process of care is coded as 1 or 0, corresponding to whether an eligible patient received a given process of care within the recommended timeframe or not. However, patients can be classified as not eligible for the process of care, which consequently causes variations in the number of eligible patients between the individual processes within a disease area. The completeness of the patient registration in the registries is regularly cross-checked with other registries. The proportion of patients with missing data is generally low (i.e., < 10%) (57–59).

Chapter 4: Voluntary Accreditation—Study 1

4.1 Background

Accreditation formally began when JCAHO was created in 1951. In the 1960s and 1970s, accreditation was introduced in Canada and Australia, and it was implemented in Europe in the 1980s (19, 60). Accreditation reached Denmark in 1999, where hospitals in the capital area made an agreement with JCI. JCI is an international branch of the Joint Commission, formerly called the JCAHO. Hospitals in the capital were accredited by JCI in 2002, 2005, 2008 and 2011.

In 2004, four hospitals in Southern Jutland County were accredited for the first time by the British HQS. The four HQS-accredited hospitals merged in 2006 and were accredited as one hospital in 2007. The HQS is now part of the CHKS Healthcare Accreditation & Quality Unit, which provides healthcare intelligence and quality services such as benchmarking, performance management solutions and international accreditation programmes (61).

Both JCI and HQS programmes aimed to cover the entire hospital and all aspects of healthcare provision and organisational development. Both programmes included an assessment process that led to external surveys by peers. All hospitals achieved accreditation. Both accreditation programmes required that hospitals document quality improvement work and management involvement. Further, data relating to the work of the hospitals in both programmes were collected and analysed as part of their improvement efforts according to guidelines. Both JCI and HQS standards established a framework for quality work at the hospitals, including systematically evaluating their process performance (15, 16).

4.2 Hypothesis

Accredited hospitals were more likely to have improved performance in process measures than non-accredited hospitals.

4.3 Method

4.3.1 Design

The Effective Practice and Organisation of Care Group of the Cochrane Collaboration identified four study designs to address questions about the effects of health system interventions such as accreditation programmes. The recommended designs include randomised and non-randomised control trials, controlled pre-post studies and interrupted time-series studies (62).

In Study 1, accredited and non-accredited hospitals were compared using a controlled pre- and post-design with difference-in-differences analysis based on process performance data from Danish public hospitals. The difference-in-differences analysis controls for unobserved individual differences and common trends based on the assumption that the unobserved characteristics are fixed.

4.3.2 Groups

Included hospitals were divided into two groups: accredited and non-accredited. Hospitals accredited by the HQS were treated as one hospital due to the merging in 2006. Several other hospitals merged during the study period; therefore, the hospital's status from 2008 was used.

4.3.3 Data

Process performance measures from four diseases were included, comprising seven process measures related to stroke (Danish Stroke Registry (63)), six process measures related to heart failure (Danish Heart Failure Registry (64)), four to bleeding ulcer and four to perforated ulcer (Danish Register of Emergency Surgery). The study period for stroke and heart failure took place from 2004 to 2008, while the study period for perforated and bleeding ulcer took place from 2006 to 2008.

4.3.4 Outcome

Two aggregated performance measures were calculated of underlying individual performance measures to summarise the changes over time. An opportunity-based composite score was calculated and served as the primary outcome:

$$\text{Primary outcome} = \frac{\text{Fulfilled process measures}}{\text{All eligible process measures}}$$

The secondary outcome was the all-or-none score:

$$\text{Secondary outcome} = \frac{\begin{array}{c}\text{Patients receiving care, which fullfills 100\%} \\ \text{of relevant process performance measures}\end{array}}{\text{Patients who were eligible for treatment}}$$

Both the primary and the secondary outcomes are presented as a composite score for each disease and combined into an overall composite score.

4.3.5 Statistical analysis

Chi^2 tests were used to assess the relationship between groups and hospital characteristics. Proportions and the relative changes of eligible patients receiving care within the timeframe were calculated. Linear regression was used to estimate changes in the opportunity-based

composite score for each disease area. All composite scores were adjusted for cluster effects at the hospital level to take into account that other and unmeasured characteristics at the hospital level could be associated with participation in an accreditation programme. Sub-analysis was performed to assess differences in performance between JCI- and HQS-accredited hospitals.

4.4 Results

A total of 27,274 patients were included in the analyses of recommended hospital care, corresponding to 130,423 processes of care in the three clinical registries. Patients were treated at 33 hospitals, of which six were accredited and 27 were non-accredited. As shown in Table 4.1, when compared with non-accredited hospitals, accredited hospitals were more often a teaching hospital and they were only represented in two of the five geographical regions (Capital Region of Denmark and Region of Southern Denmark), but they did not differ in size in terms of number of beds.

Table 4.1: Hospital characteristics by group

Characteristic	Non-accredited (n = 27)	Accredited (n = 6)	p-value[1]
Teaching hospital			0.09
Yes	12	5	
No	15	1	
Census region			0.03
Capital Region of Denmark	5	5	
Region Zealand	4	0	
Region of Southern Denmark	5	1	
Central Denmark Region	9	0	
North Denmark Region	4	0	
Bed size			0.62
< 200	4	1	
200–399	10	1	
400+	13	4	

[1] p-values are based on Chi^2.

4.4.1 Performance at baseline and follow-up

4.4.1.1 *Opportunity-based*

As shown in Table 4.2, there were no differences in opportunity-based composite scores when non-accredited and accredited hospitals were compared at baseline. At follow-up, non-accredited hospitals had significantly higher performance in the overall opportunity-based composite scores than accredited hospitals (non-accredited 67.6% [64.5; 70.8] v. accredited 62.0% [56.4; 67.5]). At the disease level, non-accredited and accredited hospitals performed at a comparable level in 2008 for stroke and bleeding ulcer, whereas performance for perforated ulcer was higher for patients admitted to an accredited hospital (non-accredited 59.2% [51.5;

66.9] v. accredited 71.9% [57.3; 86.5]). In contrast, accredited patients with heart failure had a lower opportunity-based composite score than non-accredited patients (non-accredited 67.8% [62.2; 73.3] v. accredited 60.1% [57.6; 62.5]).

Table 4.2: Opportunity-based composite score for received process of care by accreditation status

	2004/2006		2008	
Disease area	**Non-accredited**	**Accredited**	**Non-accredited**	**Accredited**
Opportunity-based [95% CI[1]]				
Stroke[3]	59.4 [54.5;64.2]	57.9 [47.5:68.8]	73.1 [69.6;76.6]	67.8 [58.8;76.9]
Hearth failure[3]	50.8 [44.0;57.6]	51.4 [36.9;65.8]	67.8 [62.2;73.3]	60.1 [57.6;62.5]
Perforated ulcer[4]	52.1 [44.5;59.7]	61.7 [37.5;85.9]	59.2 [51.5;66.9]	71.9 [57.3;86.5]
Bleeding ulcer[4]	37.1 [34.9;39.3]	34.5 [29.8;39.2]	36.2 [34.6;37.8]	35.8 [31.8;39.8]
Overall	54.9 [51.3;58.7]	54.2 [45.6;62.7]	67.6 [64.5;70.8]	62.0 [56.4:67;5]

[1] CI, confidence interval. [2] Based on linear regression adjusted for cluster effect at hospital level. [3] Based on processes of care from 2004. [4] Based on processes of care from 2006.

4.4.1.2 *All-or-none*

As shown in Table 4.3, no differences were found between non-accredited and accredited hospitals in the all-or-none scores, either at baseline or follow-up. This was the case both at the disease level and for the overall score.

Table 4.3: Processes of care for patients admitted to non-accredited and accredited Danish hospitals in 2004/2006 and 2008 by accreditation status

	2004			2008		
Process of care[2]	**Non-accredited**	**Accredited**	**RR3 [95%CI[1]]**	**Non-accredited**	**Accredited**	**RR3 [95%CI[1]]**
Stroke	1.169/6.015 (19.4%)	199/1.110 (17.9%)	0.92 [0.68–1.25]	2.478/8.425 (29.4%)	305/1.252 (24.4%)	0.82 [0.57–1.19]
Heart failure	364/3.451 (10.6%)	93/738 (12.6%)	1.19 [0.78–1.82]	570/2.809 (20.3%)	79/467 (16.9%)	0.83 [0.58–1.19]
	2006			**2008**		
Perforated ulcer	14/143 (9.8%)	3/22 (13.6%)	1.39 [0.33–5.85]	74/335 (22.0%)	19/73 (26.0%)	1.18 [0.63–2.20]
Bleeding ulcer	277/650 (42.6%)	45/115 (39.1%)	0.92 [0.79–1.07]	544/1.395 (39.0%)	93/274 (33.9%)	0.87 [0.68–1.12]
Overall all-or-none	1.823/10.259 (17.8%)	340/1.985 (17.1%)	0.96 [0.80–1.15]	3.527/12.964 (27.2%)	483/2.066 (23.4%)	0.85 [0.66–1.12]

[1] CI, confidence interval. [2] Calculated as the proportion of all eligible patients who received the indicated care. [3] Relative risk estimated based on binomial regression adjusting for cluster effect at hospital level.

4.4.2 Changes in composite scores

4.4.2.1 *Opportunity-based*

As illustrated in Figure 4.1, both groups improved their overall opportunity-based composite score throughout the study period.

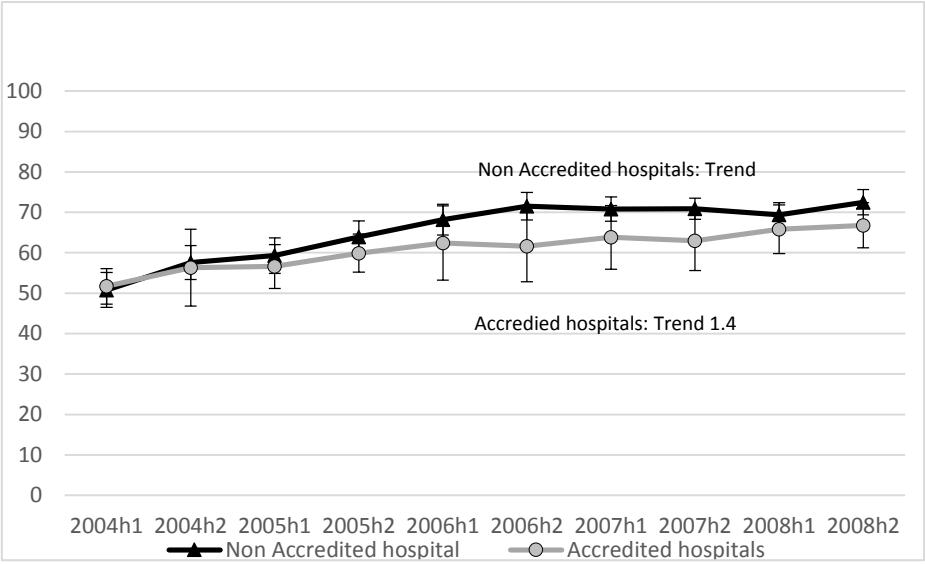

Figure 4.1: Development in opportunity-based composite score

Table 4.4 presents changes in opportunity-based composite scores. At the disease level, none of the improvements differed between groups. In the overall opportunity-based composite scores, non-accredited hospitals improved significantly more than accredited hospitals (absolute difference: 3.8 percentage points [95% CI 0.8; 14.4]).

Table 4.4: Change in opportunity-based composite score for received process of care by accreditation status

Disease area	Non-accredited	Accredited	Absolute difference
Opportunity-based [95% CI[1]]			
Stroke	13.8 [9.7;17.8]	9.8 [4.6;15.1]	3,9 [−1.4;9.2]
Heart failure	16.8 [11.5;22.5]	8.7 [−5.9;23.3]	8.3 [−3.3;19.9]
Perforated ulcer	7.1 [−1.3;15.6]	10.2 [−20.4;40.8]	−3.0 [−23.5;17.4]
Bleeding ulcer	−0.3 [−2.3;1.7]	−0.1 [−4.8;4.7]	−0.2 [−3.7;3.3]
Overall	13.7 [10.6;16.8]	9.9 [5.4:14.4]	3.8 [0.8;8.3]
All-or-none			
Stroke	9.9 [3.9;16.0]	6.4 [−4.8;17.7]	3.6 [−3.8;10.9]
Heart failure	9.7 [5.4;14.1]	4.3 [−1.8;10.4]	5.4 [−0.1;14.4]
Perforated ulcer	12.3 [0,4;24.2]	12.4 [−19.3;44.1]	−0,1 [−22.6;22.4]
Bleeding ulcer	−3.6 [−7.9;−0.3]	−5.2 [−11.7;1.3]	1,6 [−1.8;8.2]
Overall	9.4 [5.0;13.9]	6.3 [−0.6;13.2]	3.2 [−3.6:9.9]

[1] CI, confidence interval. [2] Based on linear regression adjusted for cluster effect at the hospital level.

4.4.2.2 *All-or-none*

At the disease level, non-accredited hospitals improved their all-or-none scores for stroke, heart failure and perforated ulcer, as well as the overall all-or-none score. Accredited hospitals did not improve for any of the four diseases, or in the overall all-or-none score. However, no significant absolute differences occurred at the disease level or in the overall all-or-none score.

Chapter 5: Mandatory Accreditation

5.1 Background

5.1.1 Establishing the first version of DDKM for hospitals

In 2001, the Danish National Council for Quality in Healthcare published recommendations on the use of hospital accreditation. Based on these recommendations, the Danish government and the Association of County Councils agreed by mid-2002 to establish DDKM. It was decided that DDKM should include standards for structure, equipment, patient care, the performance of processes and results, and that participation was mandatory for all public hospitals (67).

In 2005, the Danish Institute for Quality and Accreditation in Healthcare was established to develop and manage DDKM. In the subsequent preparation period, healthcare professionals were involved in developing standards to ensure ownership. The initial phase of developing DDKM was supported by HQS (68). Version 1 of DDKM for hospitals comprised 104 accreditation standards and was accredited by the International Society for Quality in Healthcare (69).

5.1.2 Objectives of DDKM

DDKM aimed to facilitate learning and quality development in the healthcare system through ongoing assessment of each institution's results (70). The specific objectives were:

- to improve the quality of patient pathways
- to improve the development of the clinical, organisation and patient perceived quality
- to make quality in the healthcare system visible.

The intention for DDKM was to become a complete, integrated and joint system for the improvement and assessment of quality in the Danish healthcare system. This goal could be achieved by introducing a programme that fosters learning and quality improvement within the participating organisations through ongoing assessments (68, 70). However, at first, only hospitals were assessed, followed by accreditation programmes for other services (e.g., pharmacies, general practitioners and practising specialists).

5.1.3 Accreditation cycle

Hospitals received DDKM Version 1 on 17 August 2009. Several recommendations were provided on how to implement the model. In addition to baseline assessments and self-assessments, hospitals were recommended to carry out an internal survey approximately six months before the external survey. Employees from other units at the hospital were asked to carry out the internal survey as an assessment of the compliance of the accreditation standards.

In that way, the internal survey could serve as a test run of the external survey and show relevant initiatives that should be settled before the external survey (71).

5.1.4 Accreditation standards

All accreditation standards were based on a template (see Appendix 1). The basis for all accreditation standards in DDKM was Deming's quality circle, which is also known as the Plan-Do-Study-Act (PDSA) cycle (70). This method is used to ensure continuous improvements (8). The four steps in the PDSA cycle were incorporated into each standard:

- Step 1 (Plan): Ensure that guiding documents exist that describe how the quality goal in the given accreditation standard is met.
- Step 2 (Do): Ensure the implementation of the guiding documents.
- Step 3 (Study): Survey the quality of structures, processes and the services delivered.
- Step 4 (Act): Assess the results of the surveillance and prioritise and make initiations where there are flaws in quality.

The 104 standards were developed based on 37 themes relating to the entire hospital service. They were organised into three categories:

- organisational accreditation standards
- general patient pathway accreditation standards
- disease-specific accreditation standards.

Figure 5.1 outlines the content of DDKM Version 1.

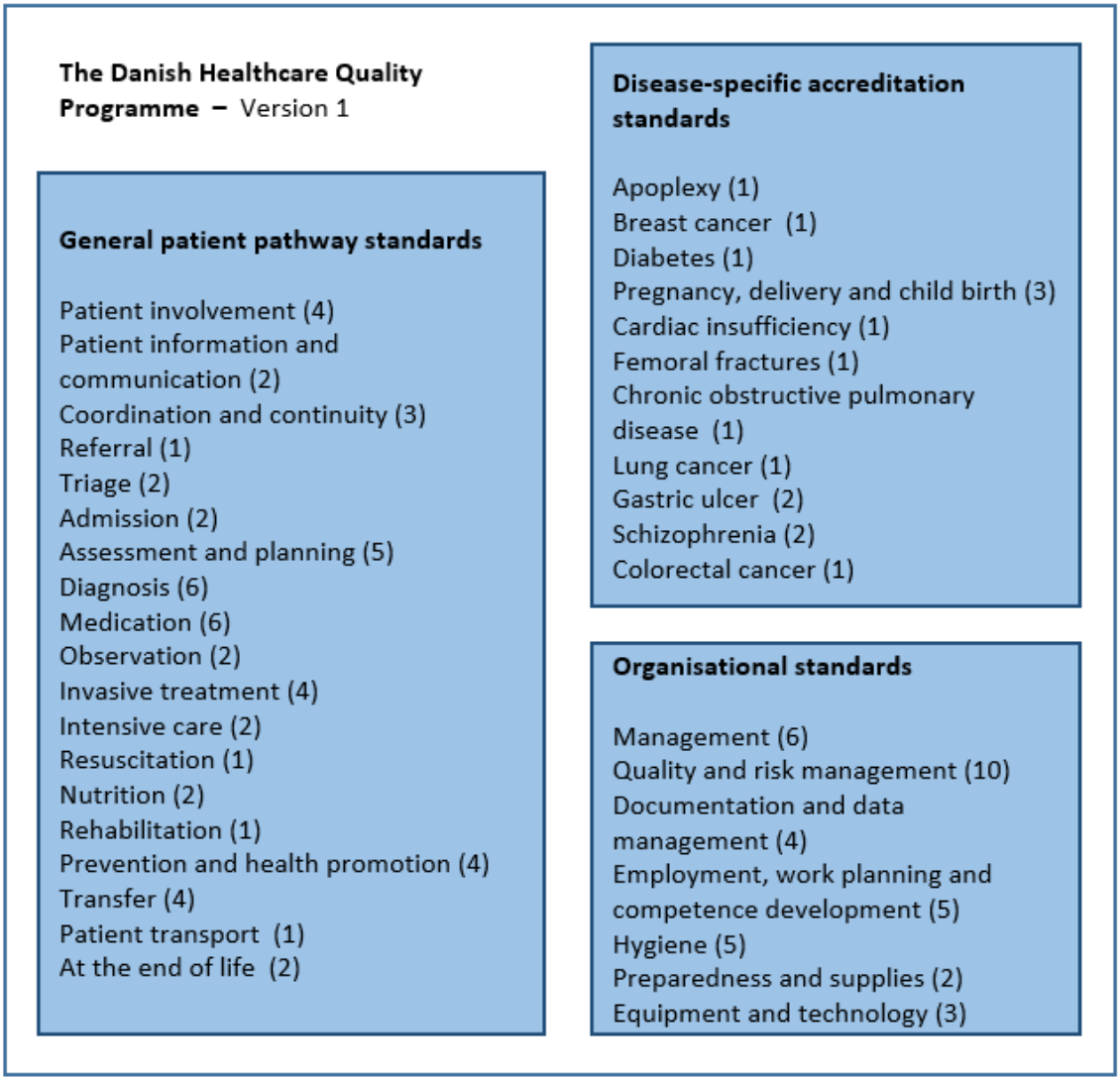

Figure 5.1: Overview of standards included in the Danish Healthcare Quality Programme

Disease-specific standards targeted a specific group of patients and aimed to have a direct clinical effect on the patients involved. Diseases included were selected based on frequency, seriousness and complexity of the patient pathway. Disease-specific standards aimed to ensure that all patients with the specific disease were assessed, treated, cared for and rehabilitated in accordance with clinical, evidence-based practices. Disease-specific standards required hospitals to document quality improvements in measures that failed to comply with the stipulated target value (step 4) set by the national clinical quality registries (see Appendix 2 for an example of a disease-specific standard). If a hospital reached a target value, that level was to be maintained at a minimum, and no further action was required (71).

DDKM identifies five organisational standards as framework standards—that is, central elements for the institutions' forward quality development. These framework standards describe basic requirements for data quality, guiding documents and quality improvements that

are not repeated in the other accreditation standards (71). This concerns the following accreditation standards:

1. Policy for quality management and risk management, which describes the framework for working with quality development in the individual organisation (71).
2. Organisation of quality management and risk management, which describes who and how the institution works with quality development (71).
3. Documentation and data management, which describes the requirements for database quality and data validity (71).
4. Quality improvement, which describes how management, based on quality surveillance of all accreditation standards. Management ensures the preparation of action plans (71).
5. Document management, which describes the requirements for the policies and guidelines that will be prepared as part of the implementation of DDKM (71).

These standards focus on quality development in general. Nine experts with extensive knowledge of DDKM and/or the Danish healthcare system identified the standards with the greatest perceived effect on processes of care (68, 72). Ranked in order, they are:

1. quality and risk management: use of clinical guidelines
2. quality and risk management: documentation and monitoring of quality and patient safety
3. quality and risk management: quality improvement
4. coordination and continuity: integrated care pathway
5. disease-specific standards: stroke
6. disease-specific standards: breast cancer
7. employment, work planning and competence development: training and competence development
8. documentation and data management: patient health record
9. disease-specific standards: diabetes
10. employment, work planning and competence development: work planning.

Research has found that a high level of compliance with DDKM Version 1 is associated with improved patient-related outcomes, higher probability of receiving the recommended hospital care (68), reduced 30-day mortality (68, 73), and reduced length of stay (68, 74). Nevertheless, it is not known whether these associations are a mark of high-quality organisations in general or whether the first version of DDKM contributed per se to quality improvement.

5.2 Design

The overall design in evaluating the mandatory accreditation programme was a sequential explanatory design, i.e. a two-phase mixed-method design, where qualitative findings helped to explain and understand the quantitative results (65, 66). The qualitative study, aim and themes investigated was influenced and formed by knowledge and findings from Study 2.

5.3 Quantitative phase—Study 2

5.3.1 Hypotheses

Hypothesis 1: The effect of DDKM would be reflected in an improved trend in fulfilment of process performance measures during accreditation compared to prior to accreditation.

Hypothesis 2: The external pressure as a result of the accreditation would subsequently play a less dominant role once the external survey was completed. Therefore, the trend in improvement in process performance measures would decrease post-accreditation.

Hypothesis 3: The improvement effect would be more evident for process performance measures where hospitals delivered quality of care at an unsatisfactory level prior to accreditation.

Aggregated measures are at risk of neglecting important information about more specific measures of quality of care. Therefore, we also wanted to assess how process measures vary according to hospital characteristics and type of care.

5.3.2 Method

5.3.2.1 Design

To examine the effect of DDKM on process performance measures, we designed a nationwide, population-based longitudinal study covering the period from 1 November 2008 to 31 December 2013. The five-year study period was due to the longitudinal design and the gradual rollout of the external survey at the individual hospitals; the first hospital was accredited in May 2010 and the last was accredited in June 2012.

The longitudinal design makes it possible to use segmented analysis, which requires data to be regularly collected over time and organised at equally spaced intervals. This design strengthens causal inferences from natural experimental studies such as the present study. Segmented analysis makes it possible to show a gradual shift in data due to DDKM not accounted for if a simpler regression model was used (75). The applied model has the advantage of using data from all 25 hospitals as part of the estimation procedure for each parameter presented, and it is more resistant to bias than other non-randomised designs (76). As was the case in Study 1, this approach is most appropriate when the variables (process performance measures) of interest change over time and the unmeasured variables are stable. Like the pre- and post-design, segmented analysis is vulnerable for other interventions that have occurred at the same time as the intervention (75). To reduce the likelihood of this scenario, we used a stepped-wedge inclusion of the hospitals, thereby making it very unlikely that other interventions would affect the results (34).

The study period for each hospital was divided into three periods: prior to accreditation, during accreditation and post-accreditation. The during accreditation period was defined as a six-month period starting from the date at which DDKM recommended an internal survey to the time of the external survey.

5.3.2.2 Data included

Forty-three process performance measures were included, covering acute stroke (63), heart failure (64), ulcer (perforated and bleeding), diabetes (77), breast cancer (78) and lung cancer (79). Appendix 3 presents the process performance measures and related target values.

All public hospitals in Denmark with admissions related to the six conditions were identified. Twelve hospitals were merged to six units during the study period. Therefore, a census of 25 hospitals was included.

5.3.2.3 Statistical analysis

Analysis to determine the effect of DDKM involved a comparison of trends based on weekly time points (study period = 269 weeks). To take the clustering of data (processes measures nested within hospitals) into account, analysis was conducted as mixed-effect logistic regressions to allow adjustments for heterogeneity between hospitals (80). Further, this study allowed for random slopes at each of the three periods, in that way had all hospitals individual intercept and trends through the study period.

The model is described as follows:

$$\text{logit}(p_{it}) = \beta_0 + \beta_1 \text{time}_t + \beta_2 \text{during\_time}_{it} + \beta_3 \text{post\_time}_{it} + b_{0i} + b_{1i}\text{time}_t + b_{2i}\text{during\_time}_{it} + b_{3j}\text{post\_time}_{it}$$

Where t is a continuous variable representing time in weeks at time_t; during_time is a variable counting time in weeks after the beginning of the during accreditation period at time_t; post_time is a variable counting time in weeks after the beginning of the post-accreditation period at time_t; i is the index of hospitals; b_{0i} is the hospital-level random effects and is the difference between hospital i's mean and the overall mean (β_0); b_{1i} is the hospital-level random slope in the prior to accreditation period; b_{2i} is the hospital-level random slope in the during accreditation period; b_{3i} is the hospital-level random slope in the post-accreditation period.

All random effects were assumed to be normally distributed with zero mean and constant variances. A mixed-effect model consists of a fixed and a random part. In this model, the fixed part specifies the mean-delivered care at specific periods, while the random part contains the residuals due to unobserved random variations at the hospital level.

This segmented model reports the following estimates and is illustrated in Figure 5.2:

- β_0 is the base level of the outcome at the beginning of the study period.

- β_1 is the base trend—is the b the change in outcome from week to week in the prior to accreditation period.
- β_2 is the change in trend between prior to and during accreditation.
- β_3 is the change in trend from during to post-accreditation. The sum of $\beta_1 + \beta_2 + \beta_3$ is the post accreditation trend.

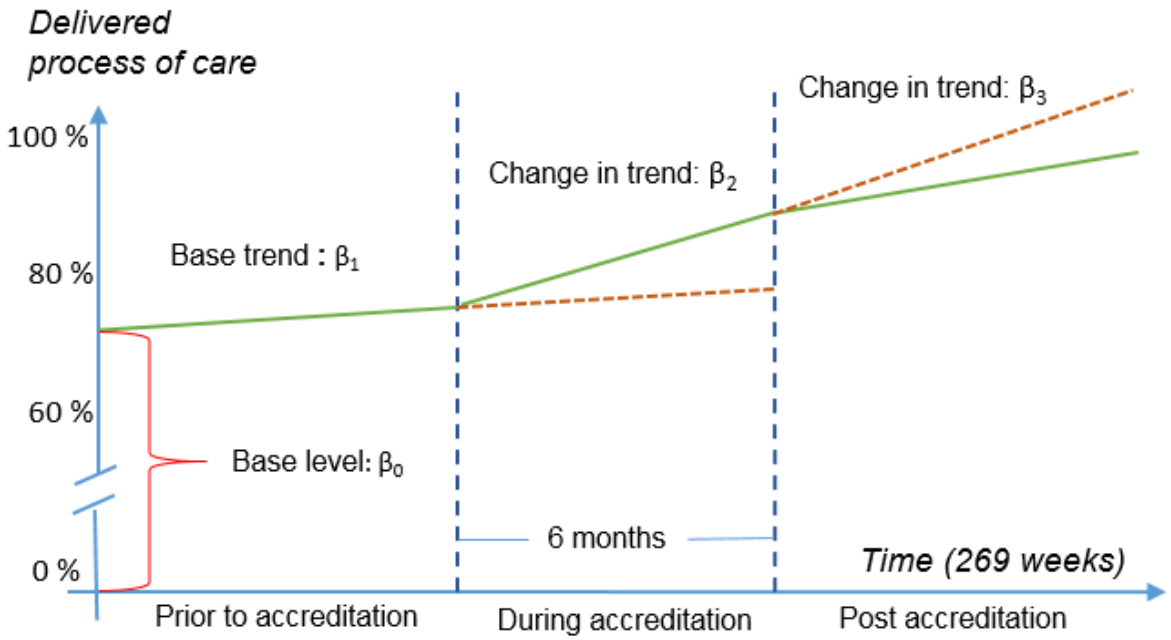

Figure 5.2: Segmented model with changes in trends between the three periods related to accreditation

5.3.2.4 Outcome

The outcome was expressed as a difference between trends in prior to accreditation (β1) and during accreditation (β2) and between trends during accreditation and post-accreditation (β3).

5.3.2.5 Sub-analyses

As DDKM specifically addressed process measures where the performance at the hospital level did not meet the pre-specified target value for best practice, we conducted sub-analyses in which only processes of care below the target values were included. A process performance measure beneath the target values was defined as a measure, where a hospital did not reach the target value within the six months prior to the during accreditation period.

Stratified by characteristics

Nationwide analyses are at risk of hiding underlying patterns for subgroups of hospitals or processes, thus leaving out important details on how accreditation affects hospital performance

in different settings and for different types of care. To explore this, we conducted stratified analysis at two levels: process and hospital.

Process level

Two divisions were made at this level: one related to the disease and one related to the type of care. Table 5.1 shows the distribution of process performance measures between the two divisions.

- Disease: The 43 processes of care were stratified in relation to their illness (stroke (n = 8), heart failure (n = 6), breast cancer (n = 6), lung cancer (n = 9), ulcer (n = 7) and diabetes (n = 7)).
- Type of care: The division in types of care was consensus-based and carried out by two experts who agreed to divide processes of care into four groups: primary treatment (n = 16), diagnostics (n = 7), secondary prophylaxis (n = 6) and patient monitoring (n = 14).

Table 5.1: Distribution of process performance measures according to condition and type of care

	Primary treatment	Diagnostics	Secondary prophylaxis	Patient monitoring	Total
Stroke	2	1	1	4	8
Heart failure	2	2	3	0	7
Breast cancer	0	3	2	0	5
Lung cancer	8	1	0	0	9
Ulcer	4	0	0	3	7
Diabetes	0	0	0	7	7
Total	16	7	6	14	43

Hospital level

To detect variations in the effect of accreditation, the analysis was stratified by hospital characteristic: hospital size, university affiliation, geographical location, previously accredited by an international accreditation body (Study 1) and whether hospitals were fully or partially accredited.

5.3.3 Results

In this study, 1,624,518 processes of care were included in the main analysis and 759,713 in the sub-analysis. Table 5.2 presents the characteristics of the hospitals included.

Table 5.2: Hospital characteristics

	Hospitals (n = 25)	Processes of care (n = 1,624,518)
Teaching hospital		
Yes	14	998,459 (61,5%)
No	11	626.059 (38,5%)
Census region		
Capital Region of Denmark	8	416,082 (26.1%)
Region Zealand	4	203,199 (12.8%)
Region of Southern Denmark	4	493,945 (31%)
Central Denmark Region	5	336,683 (21.1%)
North Denmark Region	4	144,352 (9.1%)
Bed size		
< 300	7	145,217 (8.9%)
300–599	7	409,140 (25.2%)
600–899	8	705,333 (43.4%)
900+	3	364,828 (22.5%)
Part of a merger		
Yes	6	690,511 (42.5%)
No	19	934,007 (57.5%)

5.3.3.1 Main analysis

Figure 5.3 illustrates the hospitals' improved process performance measures throughout the study period.

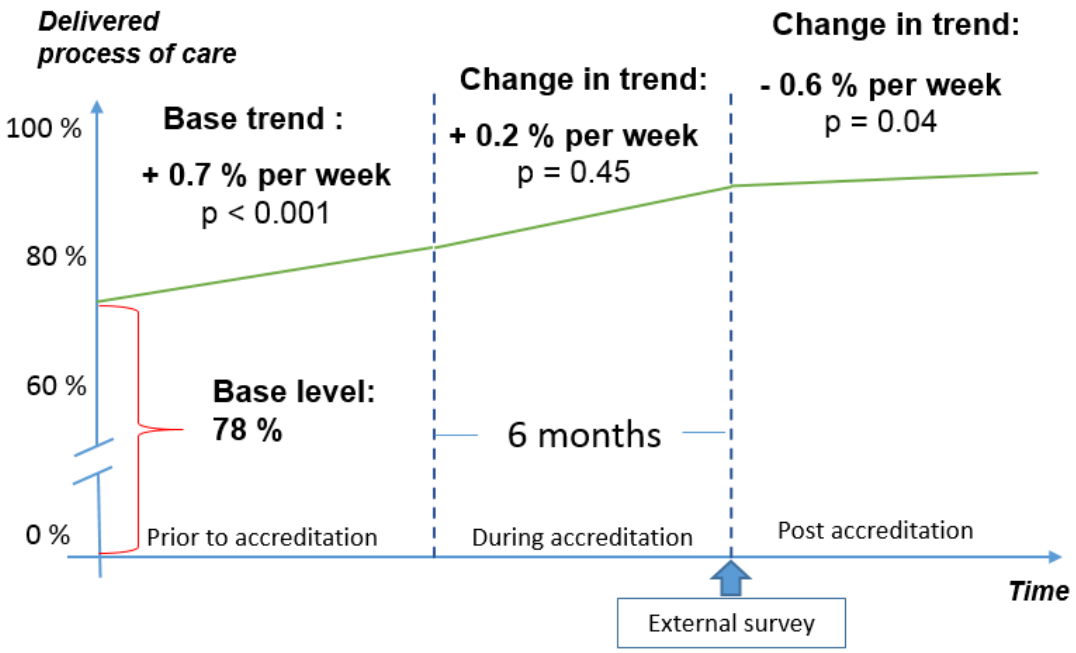

Figure 5.3: Development in hospitals process performance measures at Danish public hospitals according to the first accreditation cycle

The base level was 78% probability for patients to receive treatment according to clinical guidelines. With that level as the starting point, hospital performance improved further, with a

positive weekly trend prior to accreditation (OR = 1.007; 95% CI: 1.005–1.008). The positive trend did not significantly change in the during accreditation period (OR = 1.002; 95% CI: 0.997–1.006), but it significantly decreased in the post-accreditation period (OR = 0.994; 95% CI: 0.988–0.999).

When the main analysis was stratified according to diseases, the effects of DDKM differed (see Table 5.3). Changes in trends during accreditation differed significantly for breast cancer (OR = 0.991; 95% CI: 0.984–0.9) when compared with the change in lung cancer ($p = 0.03$), ulcer ($p < 0.01$) and diabetes ($p = 0.03$). Heart failure (OR = 0.996; 95% CI: 0.994–0.999) only differed significantly from ulcer ($p = 0.01$). Heart failure (OR = 1.003; 95% CI: 1.0–1.006) significantly increased its trend of improvement post-accreditation, which differed significantly from the change in ulcer ($p = 0.02$) and diabetes ($p = 0.04$). Trends for stroke, diabetes, lung cancer and ulcer were unchanged throughout the study period.

When the main analysis was stratified according to types of care, the effects of DDKM differed. Changes in trends during accreditation differed significantly for diagnostics (OR = 0.993; 95% CI: 0.99–0.996) from the change in trend for patient monitoring ($p < 0.01$) and patient treatment ($p = 0.03$). Post-accreditation decreased the patient monitoring trend significantly (OR = 0.989; 95% CI: 0.98–0.998), which was significantly different compared with changes in diagnostics ($p < 0.01$), primary treatment ($p = 0.04$) and secondary prophylaxis ($p = 0.02$).

Table 5.3: Main analysis—development in hospital process performance measures at public Danish hospitals prior to, during and post-accreditation

		Processes of care (n=1,624,518)	Types of processes of care (n=43)	Prior to accreditation		During accreditation	Post accreditation
				Level	Trend	Change in trend	Change in trend
				OR [probability] (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Condition and care characteristics							
Condition:	Stroke	321,304 (19.8)	8	2.24 [69 %] (1.91-2.63)	**1.007** (1.005-1.009)	0.996 (0.990-1.001)	1.000 (0.993-1.006)
	Heart failure	107,804 (6.6)	6	2.05 [67 %] (1.75-2.39)	**1.003** (1.002-1.004)	**0.996 (**0.994-0.999)	**1.003 (**1.000-1.006)
	Breast cancer	31,251(1.9)	6	4.32 [81 %] (2.86-6.88)	**1.008** (1.004-1.011)	**0.991 (**0.984-0.997)	1.006 (0.999-1.014)
	Lung cancer	57,043 (3.5)	9	1.84 [65 %] (1.64-2.43)	**1.003** (1.001-1.006)	1.007 (0.995-1.019)	0.991 (0.977-1.004)
	Ulcer	23,076 (1.4)	7	0.83 [45 %] (0.75-0.90)	1.000 (0.999-1.001)	1.003 (0.999-1.008)	0.997 (0.992-1.001)
	Diabetes	1,084,040 (66.7)	7	7.21 [88 %] (4.83-10.76)	**1.009** (1.006-1.013)	1.010 (0.994-1.026)	0.984 (0.967-1.002)
Types of care:	Treatment	190,350 (11.7)	16	2.01 [66 %] (1.80-2.18)	**1.003** (1.002-1.005)	0.998 (0.995-1.004)	0.998 (0.994-1.002)
	Diagnostics	112,788 (6.9)	7	1.83 [55 %] (1.68-2.23)	**1.007** (1.006-1.008)	**0.993 (**0.990-0.996)	1.003 (1.000-1.006)
	Secondary prophylaxis	59,578 (3.7)	6	2.61[72 %] (2.38-3.16)	**1.003** (1.002-1.003)	0.998 (0.995-1.001)	1.001 (0.997-1.005)
	Patient monitoring	1,261,802 (77.7)	14	4.41 [82 %] (3.25-6.00)	**1.009** (1.006-1.012)	1.007 (0.998-1.015)	**0.989 (**0.980-0.998)
Hospital characteristics			**Hospitals (n=25)**				
University affiliation:	No	626,059 (38.5)	11	3.94 [80 %] (2.53-6.14)	**1.006 (**1.004-1.012)	1.002 (0.995-1.007)	0.994 (0.987-1.002)
	Yes	998,459 (61.5)	14	3.18[76 %] (2.54-3.99)	**1.006 (**1.004-1.008)	1.002 (0.995-1.009)	0.994 (0.986-1.003)
Region	Southern Denmark	493,971 (30.4)	4	3.87 [80 %] (2.73-5.53)	**1.008 (**1.005-1.011)	1.003 (0.998-1.009)	0.992 (0.984-1.000)
	Central Denmark	336,674 (20.7)	5	7.96 [89 %] (6.02-10.51)	**1.003 (**1.001-1.005)	1.000 (0.995-1.005)	0.998 (0.991-1.006)
	North Denmark	144,343 8 (8.9)	4	2.37 [70 %] (1.26-4.42)	**1.011 (**1.002-1.021)	0.995 (0.981-1.009)	0.999 (0.982-1.016)
	Zealand	233,442 (14.4)	4	2.63 [72 %] (1.58-4.35)	**1.007 (**1.002-1.013)	1.003 (0.989-1.016)	0.996 (0.990-1.002)
	Capital	416,088 (25.6)	8	2.76 [74 %] (2.28-3.38)	**1.006 (**1.005-1.007)	1.004 (0.993-1.015)	0.989 (0.978-1.001)
Number of hospital beds:	<300	145,217 (8.9)	7	3.37 [77 %] (1.82-6.28)	**1.007** (1.001-1.013)	0.998 (0.989-1.008)	0.998 (0.986-1.010)
	301-600	409,140 (25.2)	7	3.57 [78 %] (2.47-5.28)	**1.007** (1.002-1.012)	**1.007** (1.000-1.013)	**0.987 (**0.980-0.994)

		Processes of care (n=1,624,518)	Types of processes of care (n=43)	Prior to accreditation		During accreditation	Post accreditation
				Level	Trend	Change in trend	Change in trend
				OR [probability] (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
	601-900	705,333 (43.4)	8	3.62 [78 %] (2.54-5.10)	**1.007** (1.005-1.009)	1.003 (0.993-1.012)	0.993 (0.983-1.001)
	>900	364,828 (22.5)	3	3.28 [77 %] (1.77-6.01)	**1.006 (**1.005-1.008)	0.994 (0.988-1.000)	1.007 (0.990-1.024)
Experience with accreditation:	No	1,132,053 (69.7)	16	4.06 [80 %] (2.92-5.65)	**1.007 (**1.004-1.010)	1.000 (0.995-1.005)	0.997 (0.992-1.003)
	Yes	492,464 (30.3)	9	2.69 [73 %] (2.26-3.25)	**1.007 (**1.005-1.008)	1.005 (0.995-1.014)	0.988 (0.977-1.001)
Accreditation compliance: Partially		1,142,439 (70.3)	17	3.30 [77 %] (2.50-4.35)	**1.007 (**1.005-1.010)	1.002 (0.995-1.008)	0.994 (0.988-1.001)
	Fully	482,079 (29.7)	8	3.96 [80 %] (2.59-6.06)	**1.006 (**1.003-1.009)	1.002 (0.997-1.006)	0.993 (0.984-1.001)

OR=Odds Ratio; Bold = p<0.05

5.3.3.2 Sub-analysis

As shown in Figure 5.4, the base level was 68% when we only included process performance measures where the hospitals had not achieved the target values six months prior to the during accreditation period. The trend prior to accreditation was significantly positive (OR = 1.005; 95% CI: 1.003–1.006) and significantly increased in the during accreditation period (OR = 1.007; 95% CI: 1.002–1.012). The positive trend subsequently levelled off during the post-accreditation period (OR = 0.99; 95% CI: 0.984–0.996).

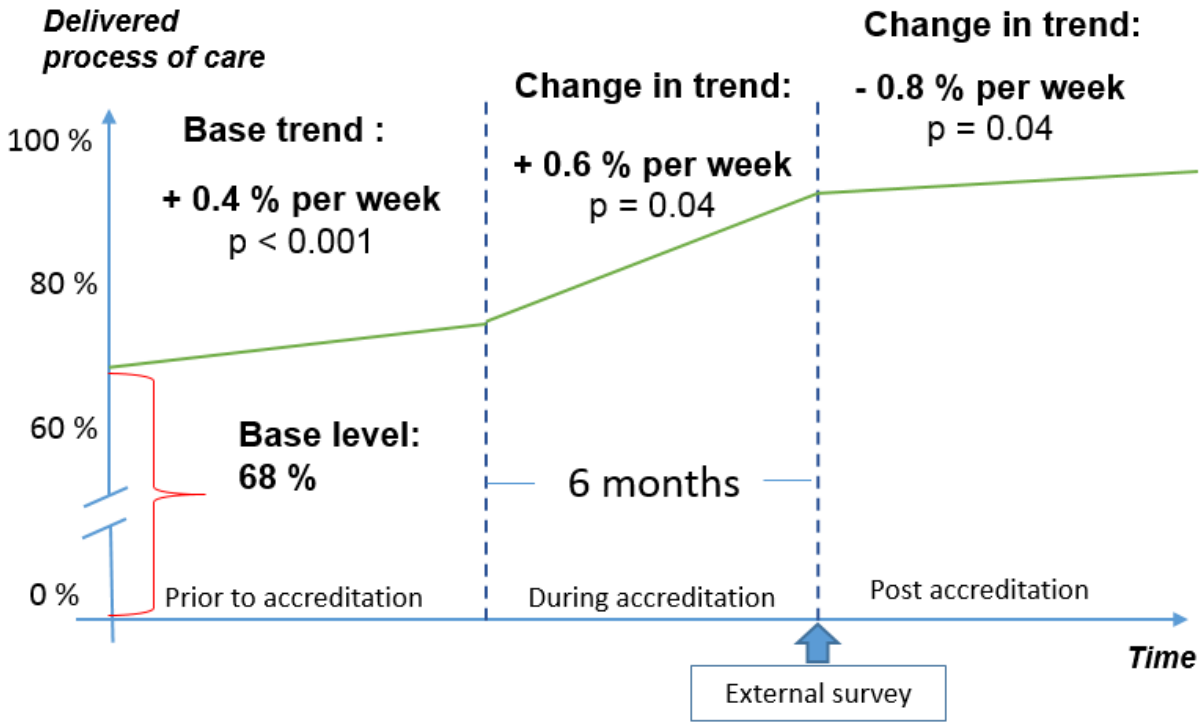

Figure 5.4: Development in hospital process performance measures at Danish public hospitals according to the first accreditation cycle; only process performance measures beneath the target values six months prior to the during accreditation period were included

When the sub-analysis was stratified according to diseases, the effects of DDKM differed (see Table 5.4). Diabetes was the only disease responding to DDKM with a significant change in the trend during accreditation (OR = 1.024; 95% CI: 1.007–1.04) and was significantly larger than changes in ulcer ($p = 0.04$), breast cancer ($p < 0.01$), stroke ($p < 0.01$) and heart failure ($p < 0.01$). Diabetes significantly decreased its trend post-accreditation (OR = 0.974; 95% CI: 0.954–0994) and differed significantly from changes in breast cancer ($p < 0.02$), stroke ($p < 0.02$) and heart failure ($p < 0.01$).

When the sub-analysis was stratified according to type of care, the effects of DDKM differed (see Table 5.4). The diagnostic performance measure significantly increased during accreditation (OR = 1.009; 95% CI: 1.004–1.014), followed by a significantly decreased trend

post-accreditation (OR = 0.988; 95% CI: 0.983–0.993). The patient monitoring performance measure significantly increased its trend during accreditation (OR = 1.012; 95% CI: 1.004–1.019) and significantly decreased its trend post-accreditation (OR = 0.988; 95% CI: 0.979–0.996). Development in both diagnostics and patient monitoring differed significantly from secondary prophylaxis during accreditation ($p < 0.01$ and $p < 0.01$, respectively) and post-accreditation ($p < 0.01$ and $p = 0.03$, respectively).

Table 5.4: Sub-analysis—development in hospital process performance measured at public Danish hospitals prior to, during and post-accreditation. Includes processes where the target values were not met in the six months prior to the during accreditation period for the individual hospitals

		Processes of care (n=759,713)	Types of processes of care (n=43)	Prior to accreditation		During accreditation	Post accreditation
				Level	Trend	Change in trend	Change in trend
				OR [probability] (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Condition and care characteristics							
Condition:	Stroke	190,967 (25)	8	1.90 [66 %] (1.619-2.235)	**1.007 (**1.005-1.008)	0.999 (0.993-1.005)	0.998 (0.991-1.005)
	Heart failure	22,403 (3)	6	0.81 [44 %] (0.576-1.139)	**1.002 (**1.000-1.003)	1.001 (0.997-1.005)	1.001 (0.997-1.005)
	Breast cancer	44,406 (5.9)	6	3.06 [75 %] (1.690-5.555)	**1.007 (**1.002-1.012)	0.997 (0.989-1.005)	0.999 (0.990-1.008)
	Lung cancer	48,191 (6.3)	9	1.70 [63 %] (1.413-2.045)	**1.003 (**1.001-1.004)	1.008 (0.995-1.022)	0.995 (0.980-1.010)
	Ulcer	6,828 (0.9)	7	0.38 [28 %] (0.305-0.617)	1.000 (0.999-1.002)	1.006 (1.000-1.012)	0.994 (0.988-1.000)
	Diabetes	446,918 (58.8)	7	3.42 [77 %] (2.079-5.624)	**1.009 (**1.003-1.014)	**1.024 (**1.007-1.040)	**0.974** (0.954-0.994)
Type of care:	Primary treatment	95,686 (12.6)	16	1.39 [55 %] (1.128-1.709)	**1.003 (**1.001-1.004)	1.001 (0.995-1.008)	0.995 (0.987-1.003)
	Diagnostics	40,399 (5.3)	7	1.48 [60 %] (1.201-1.817)	**1.006 (**1.004-1.008)	**1.009 (**1.004-1.014)	**0.988** (0.983-0.993)
	Secondary prophylaxis	41,027 (5.4)	6	1.47 [59 %] (1.142-1.885)	**1.002 (**1.000-1.004)	0.999 (0.995-1.004)	0.998 (0.994-1.002)
	Patient monitoring	582,601 (76.7)	14	2.66 [73 %] (2.257-3.141)	**1.006 (**1.004-1.008)	**1.012** (1.004-1.019)	**0.988** (0.979-0.996)
Hospital characteristics			**Hospitals (n=25)**				
University affiliation:	No	283,853 (37.4)	14	2.18 [69 %] (1.832-2.593)	**1.004** (1.002-1.007)	**1.010** (1.001-1.018)	**0.987** (0.976-0.998)
	Yes	475,860 (62.6)	11	2.23 [69 %] (1.860-2.684)	**1.005** (1.003-1.007)	**1.006** (1.001-1.012)	**0.992** (0.986-0.998)
Location:	Southern Denmark	259,998 (34.2)	4	3.11 [76 %] (2.425-3.991)	**1.006** (1.004-1.008)	**1.008** (1.002-1.014)	**0.989** (0.981-0.997)
	Central Denmark	78,816 (10.4)	5	2.19 [69 %] (1.830-2.618)	**1.003** (1.001-1.005)	**1.010** (1.005-1.016)	**0.983** (0.974-0.992)
	North	72,739 (9.6)	4	1.84 [65 %] (1.466-2.305)	1.003 (0.999-1.007)	1.004 (0.983-1.025)	0.998 (0.975-1.021)
	Zealand	189,121 (24.9)	4	2.19 [69 %] (1.413-3.400)	**1.008** (1.002-1.013)	1.008 (0.991-1.025)	0.990 (0.979-1.001)
	Capital	159,039 (20.9)	8	2.07 [67 %] (1.730-2.468)	**1.004** (1.002-1.005)	**1.007** (1.000-1.015)	0.990 (0.980-1.000)
Number of hospital beds:	<300	45,801 (6)	7	1.77 [64 %] (1.466-2.138)	**1.003** (1.001-1.005)	1.006 (0.994-1.019)	0.991 (0.976-1.007)
	301-600	213,657 (28.1)	7	2.50 [71 %] (2.019-3.085)	**1.005** (1.002-1.007)	**1.013** (1.004-1.022)	**0.984** (0.974-0.994)
	601-900	339,225 (44.7)	8	2.32 [70 %] (1.863-2.894)	**1.006** (1.003-1.009)	1.006 (1.000-1.012)	**0.989** (0.982-0.997)

		Processes of care (n=759,713)	Types of processes of care (n=43)	Prior to accreditation		During accreditation	Post accreditation
				Level	Trend	Change in trend	Change in trend
				OR [probability] (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
	>900	161,030 (21.2)	3	2.25 [69 %] (1.585-3.179)	**1.005** (1.003-1.008)	1.002 (0.999-1.005)	1.000 (0.991-1.009)
Experience with accreditation:	No	543,853 (71.6)	16	2.30 [70 %] (1.925-2.745)	**1.005** (1.003-1.007)	**1.007** (1.001-1.014)	**0.990** (0.983-0.998)
	Yes	215,860 (28.4)	9	2.07 [67 %] (1.767-2.417)	**1.004** (1.003-1.006)	**1.009** (1.002-1.015)	**0.988** (0.979-0.998)
Accreditation compliance:	Partially	547,696 (72.1)	17	2.16 [68 %] (1.843-2.539)	**1.004** (1.003-1.007)	1.007 (1.000-1.013)	**0.992** (0.984-1.000)
	Fully	212,017 (27.9)	8	2.35 [70 %] (1.873-2.856)	**1.004** (1.002-1.006)	**1.010** (1.004-1.015)	**0.985** (0.978-0.993)

OR=Odds Ratio; Bold = p<0.05

5.4 Qualitative phase—Study 3

5.4.1 Method

5.4.1.1 Design

A qualitative study was conducted, consisting of eight semi-structured interviews with hospital staff at a Danish public hospital.

5.4.1.2 Accreditation

The second version of DDKM was launched in April 2012, and in late 2015, the Ministry of Health decided to cancel the third version of DDKM. The Ministry of Health and Regional Public Authorities believed that the potential for further improvements through DDKM was exhausted for public hospitals, and therefore found no reason to continue with the mandatory accreditation programme. Due to the termination of the third version of DDKM, the hospital investigated was not subject to the requirements of DDKM when the empirical data were collected. The case hospital achieved accreditation with no remarks in the two first versions of DDKM (81).

5.4.1.3 Data collection and analysis

The selection of informants was based on the criterion of recruiting a diverse group of staff. The informants included medical doctors, nurses, quality coordinators and one employee of the central quality department at the hospital. With this sampling, we aimed to capture as much variation of experience as possible. The secretary at the hospital quality department agreed to establish contact with the relevant departments. The informants covered the disease areas of acute stroke, heart failure and adult diabetes; these areas were selected based on the findings of Study 2. The heart failure and diabetes quality coordinators did not participate in the research due to personal reasons, resulting in eight interviews. The interview approach was semi-structured, allowing the interviewer to make use of cues and prompts to help encourage informants to consider the questions further, thus allowing more detailed data to be gathered (82). Additionally, the semi-structured approach allowed the interviewer to explore ideas and experiences from the informants that may have been unanticipated (83).

The initial interview guide was based on knowledge gathered from several informal site visits made while working on Study 1 and Study 2, as well as observations made during an external survey and the results from Study 2. The initial interview guide was discussed with peers and amended before being pilot-tested at another hospital. Eventually, the semi-structured interview guide contained the following three themes: organisation of the quality of work, compliance with DDKM and the effect of DDKM. The interview questions focused on obtaining information on hospital staff's experiences working with DDKM and their perception of how accreditation had affected their everyday work.

All interviews were conducted by the principal researcher (PR) and were audio recorded for further analysis. Interviews were held in individual rooms with a minimum of disruption at the hospital premises. The interviews lasted between 30 and 60 minutes. The PR has a Master of Health Science and possesses a thorough knowledge of DDKM and the Danish healthcare system. During the data collection, the PR received methodical guidance from a co-author who is a trained sociologist.

Audio files were imported to NVivo 11 (qualitative research software) for coding and analysis. Quotations presented in this thesis were translated from Danish into English by the PR and a colleague. The letters 'D' (for doctor) and 'N' (for nurse) and the numbers 1 to 3 are used to distinguish the three speciality areas (for reasons of anonymity, the specialities were anonymised) when presenting these quotations.

5.4.1.4 Data analysis

The data were analysed using framework analysis (84), which comprises five stages: familiarisation, identifying a thematic framework, indexing, charting and mapping, and interpretation. The PR conducted all five stages but compared the codes with a co-author who had listened and coded one interview to ensure uniformity in coding. A summary of the process of carrying out the framework analysis is presented in the below subsections.

Familiarisation

The aim of this stage was to 'get to know' the data extensively. The PR conducted all of the interviews, so the overall 'feel' of the data already existed, but all audio recordings were listened to once again. In the process of re-listening to the interviews, preliminary notes on content were developed using NVivo and categorised according to the themes from the interview guide. Overall notes were made by hand to maintain and store spontaneous ideas that arose during this stage.

Identifying a framework

The aim of this stage was to organise the data in a meaningful and manageable way. An important lesson in this stage was to allow the process of developing framework categories to be informed both by former concerns (reflected in the interview guide) and emergent issues that arose during the familiarisation step. In retrospect, the blind use of a priori categories was a bad approach. Therefore, the PR examined the notes on content and the spontaneous ideas once again with a focus on managing and organising the dataset. The recurring ideas were collated and grouped into themes. After some back-and-forth work, the key issues were divided into two themes: (i) implementation and compliance and (ii) Implications.

Indexing

The aim of this stage was to organise the interviews into the framework categories. After the first couple of interviews, it was clear that all of the data did not fit into the framework categories, which gave rise to an 'Other' category. This category was used when the content was considered 'perhaps interesting topics for additions to the framework categories or topics for future research'. The development of the framework was, in this case, an ongoing process where the theme of implications was eventually divided into subthemes of priorities, culture, structures, processes and cancellation of Version 3. See Figure 5.5 for an example of indexing in NVivo.

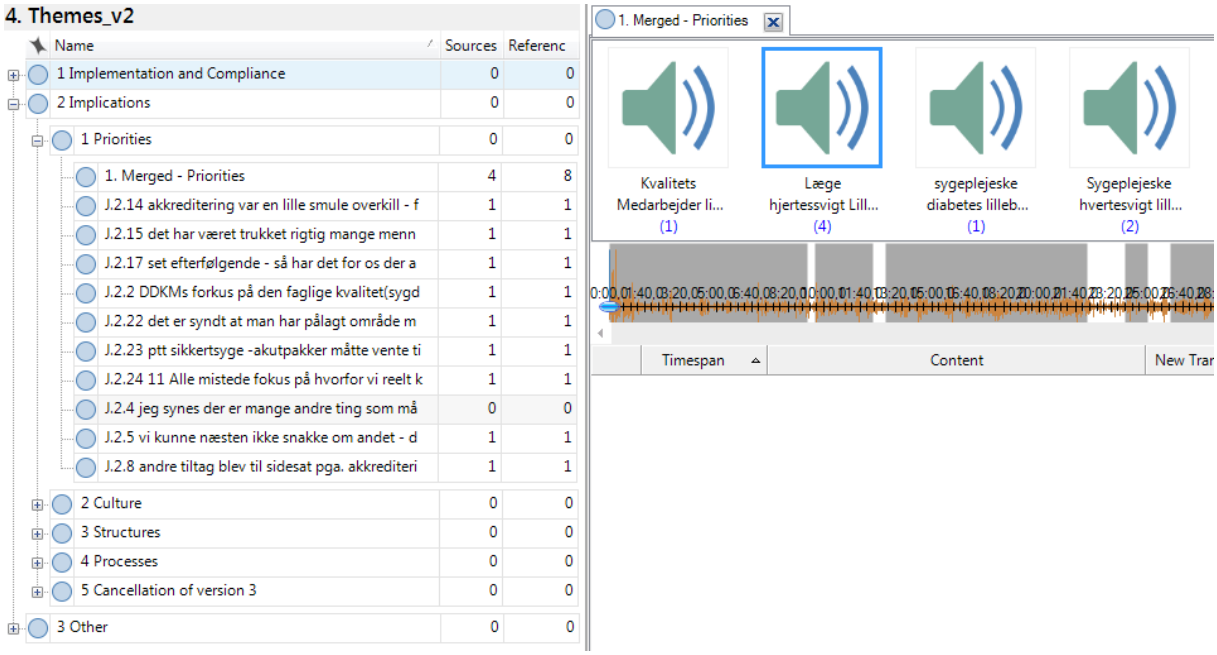

Figure 5.5: Extract from NVivo showing the indexing of data

Charting

The aim of this stage was to organise the data into a more manageable format by summarising the indexed data by category and then organising them in chart form. The indexing of data provided a clear audit trail from the original raw data to the summary of themes. The challenge in this phase was to avoid a loss of details in the data without repeating whole sections of the interview, but still reducing the dataset.

Mapping and interpretation

The aim of this stage was to interpret the dataset in light of the original objective of the study. The PR reviewed the summaries and research notes and compared the themes with each other and with the original audio recordings to consider the data context. The final outcome of the mapping and interpretation of the data is presented below.

5.4.2 Results

5.4.2.1 Implementation and compliance through the accreditation cycle

DDKM implementation process was perceived as chaotic and with uncertainty by most of the informants. A variation in the perceived meaningfulness of DDKM existed among the informants:

> That was, in fact, DDKM's big problem, it was hard to see a meaning with it because it was simply so confusing. (D1)

> Honestly, nobody would say that the purpose of DDKM was a bad idea. Our way of working with […], our way of working with our work is actually very healthy, but how we should do that was downright difficult. (N1)

These quotations illustrate the challenge that leaders (or other key personnel responsible for implementation) faced when they had to explain and justify the interventions related to DDKM. Overall, the implementation of DDKM was perceived as successful, and standards were complied with throughout the accreditation cycle. Version 1 of DDKM introduced some changes that were maintained, although the hospital began to focus on Version 2 upon its release. Version 2 was perceived as an extension of Version 1, and the implementation was more straightforward, but still seen as a daunting task.

5.4.2.2 Priorities

In the implementation period, there was a significant focus on DDKM, especially during the couple of months prior to the external survey. The increased focus on DDKM compelled doctors and nurses to ask for more office time at the expense of time with patients. Moreover, other improvement initiatives, which were perceived as more relevant to patient care, were put on standby during the preparation period, as captured in the following quotation by a nurse:

> Anything else had to be put aside, I would say, if one asks management, there was simply no focus on anything else. We couldn't talk about anything else, couldn't commit us to anything else, many things that were impossible because of accreditation. (N2)

In contrast, the implementation process ensured that some of the processes that were usually neglected now were priorities.

5.4.2.3 Structures

During the preparatory work in the lead-up to Version 1 of DDKM, a new and more extensive structure on how they work with quality improvement was created—a structure that was adjusted and tightened during the process. The new structure became a foundation that was crucial to the manner in which the hospital subsequently worked with quality improvement. This perception is expressed in the following quotation:

> DDKM has made a mark that does not disappear, that's for sure […]. It has been fantastically rewarding to take part in peeping into the engine room […] it has been tremendous and rewarding. (D3)

The nurses emphasised the importance of the online platform that was implemented due to the requirements of the guidelines. DDKM Standard for Documentation and Data Management (7) requires policies, guidelines and instructions to be updated at least every three years. In this case, the online platform sends out a reminder to the responsible person at least every two years.

5.4.2.4 Processes

The informants did not believe that DDKM had contributed to improved processes of care monitored through national registries. The disease-specific standards did not add any new requirements and were considered irrelevant. However, where guidelines did not exist, the requirement of guidelines compelled staff to consider how work should be done. Staff used this opportunity to search the scientific literature for best practice, or they aligned their work processes with other hospitals in the region.

The work to meet DDKM requirements was not without cost. Several informants stressed that the amount of time spent on writing guidelines led to reduced care for patients during the preparation period before the external survey, and especially during the preparation for DDKM Version 1, as expressed in the following quotation:

> The first time we sought accreditation, I must say, well, there wasn't any focus on our core business. All these guidelines and instructions to make us clean the shelves once a month that had to be documented, really, there it got out of control, and that actually moved the attention away from our core business, we could really tell. It affected patient care; people wouldn't talk about anything else: What is it we will not get done on time? Who should get this done? When should we find time for this task? Instead of having professional development in focus. (N3)

5.4.2.5 Termination of DDKM Version 3

Most informants expressed relief that the hospital would not be undergoing a third version of DDKM. The analyses showed that the informants had confidence in the culture of quality at the hospital. They expected that the positive changes in the organisation due to accreditation would be maintained and that the focus on improvement would continue. The fact that there would be no external survey in the future was not perceived as a problem.

> It is not a problem that DDKM is abolished. It has been running so long, the good things are jammed in, and it has become part the everyday work. And where it frustrated us, we skip it. (N2)

Chapter 6: Discussion

6.1 Triangulation of Findings

This thesis examines the effect of hospital accreditation on process performance measures. We tested the overall hypothesis, which can be summarised, that hospital accreditation serves as a framework for continuous quality improvement.

We found that process performance measures were improved throughout the 2004–2008 study period. An improvement was observed irrespective of voluntary accreditation. In broad terms, this was also the case when hospitals were accredited by the mandatory DDKM. The overall process performance measures improved throughout the first accreditation cycle of DDKM, but the trend of improvement began to plateau after the external survey.

DDKM disease-specific standards demanded action when quality was identified as unsatisfactory. This requirement might be the reason that processes with an unsatisfactory level of quality were positively affected by DDKM to a greater extent. However, the hospital staff did not confirm this association. Staff did not perceive DDKM to have contributed to improved processes of care addressed directly in the disease-specific standards. Staff argued that these processes were already well implemented before the introduction of DDKM.

Qualitative analyses also showed that DDKM occupied a considerable part of the staff's attention; in some cases, this attention was taken from patient care. If this had been a general trend in Danish hospitals, it might explain why the improvement trend for heart failure and breast cancer decreased in the preparation period, only to increase again post-accreditation. However, nothing in the qualitative analyses indicated why heart failure and breast cancer should be affected by DDKM in a different way than the other conditions.

Regarding processes with an unsatisfactory level of quality, diabetes was the only disease that was positively affected. When stratified according to type of care, diagnostic performance process measures were affected positively in the preparation period. Nothing in the qualitative analyses indicated why DDKM should have affected some processes differently than others. Additionally, qualitative analyses showed that improvement initiatives were neglected in favour of DDKM preparatory work, but on the positive side, the preparatory process shed light on processes that usually were neglected. The influence of DDKM on management priorities was also indicated by the pattern in the development of process measures, where a shift in one direction was likely to be followed by a shift back in the opposite direction. Further, DDKM was perceived to have created an organisational structure that was considered a foundation for improvement and was expected to last despite the termination of Version 3. The new structure was considered crucial for future quality improvement at the hospital.

6.2 Comparison with Existing Literature

6.2.1 Study 1 and Study 2

Study 1 and Study 2 used hospital process performance measures to evaluate the effect of hospital accreditation. Nine studies in the scientific literature on hospital accreditation (37–41, 43–46) used process performance measures to evaluate hospital accreditation, whereof only five studies examined the effects over time (37–41). Findings in Study 1 were in accordance with results from two studies (38, 41). However, both studies only included processes measures from one disease. In contrast to the findings in Study 1, Pollack et al. also showed results in favour of accredited hospitals, but the effect decreased over time, which was likely due to selection bias in the earlier years of the study period. The possible selection bias disappeared when accreditation become mandatory for all treatment facilities (39). In a large US study, Schmaltz et al. showed that accredited hospitals outperformed non-accredited hospitals in both the level and magnitude of improvement over time (40). The difference in results might be explained by the lack of systematic monitoring of performance measures in the US, as was the case in Denmark. In the US, no such system existed until JCAHO introduced it. Since 2002, JCAHO-accredited hospitals have been required to collect and submit selected performance measures continuously. Thus, accreditation set additional requirements compared with non-accredited hospitals—a difference that did not exist in Study 1 because monitoring performance measures were mandatory independent of accreditation. The staff in Study 3 reinforce this explanation, stating that accreditation did not contribute anything new regarding performance on process measures.

Study 2 showed a positive trend during accreditation followed by a decreased change in trend when the external survey was conducted. A change in trend caused by accreditation is supported by Devkaran and O'Farrell, who conducted a time-series analysis based on data from a single hospital (37). That hospitals ramp up their performance in the preparatory period before the external survey show how accreditation requirements affect how hospital managers prioritise their focus. This is reinforced in Study 2, which showed that process measures beneath the target level were more likely to increase in the during accreditation period than the process measure above. This can be linked to the requirement in DDKM that action should be taken when a process is beneath the target value. Devkaran and O'Farrell did not include data points before the accreditation process; thus, it is not known whether accreditation contributed to the improvement trend leading up to the external survey. Further, the authors only included data from one hospital, thereby making it difficult to generalise to other settings and cultures. Homogeneous culture and reduced bureaucracy are linked to smaller organisations, which can make the implementation of quality improvement initiatives easier (85). One study found that benefits of accreditation were associated with hospital size, where the perceived effect by nurses was greater in small- and medium-sized hospitals (51). However, such a link is not demonstrated in this thesis, where hospital characteristics were not found to be predictors of the effectiveness of accreditation on hospital performance. To the best of our knowledge, no other studies have examined whether the effects of accreditation vary between types of care.

6.2.2 Study 3

A central finding in Study 3 was hospital staff's perception that accreditation had given rise to an improvement in processes that were usually neglected. This observation is in line with a survey carried out by Duckett (86), who defined accreditation as a potent weapon used for the completion of tasks that would otherwise be overlooked. El-Jardali et al. demonstrated that Lebanese nurses perceived accreditation to be a tool for improvement in the quality of care (19). El-Jardali et al. indicated that the involvement of hospital staff in the accreditation process is crucial, and such involvement helps hospitals to improve their quality results. Study 3 showed that staff played a central role in implementing DDKM; thus, according to El-Jardali's reasoning, the prerequisite for improvement was present. This is, however, in limited accordance with Study 3, as improvements in one area appeared to have been at the expense of focus in another. Study 3 showed that DDKM had affected management priorities and that the external survey provided the cut-off date for a shift in managers' focus. This supports the cut-off date used in Study 2 and by Devkaran and O'Farrell (37).

Pomey et al. (2004) found that the hospital under investigation learned the importance of a writing culture (87). This finding is similar to this study, where staff allocated time to reflect on their daily routines, search the literature or spar with other hospitals. These processes fostered the formalisation of guidelines stored in an online platform, which is accessible in the daily work and recognised as essential for delivering quality care in a diverse environment. In a later study, Pomey et al. (2010) found that, after ten years with accreditation, Canadian hospitals no longer considered accreditation challenging (88). Study 3 found that the perception of yield and meaningfulness of DDKM increased over time. DDKM was perceived to have contributed to positive change in the organisational structure and was expected to be critical for future quality improvement work. Shaw et al. also found that accreditation promotes structures, but that the promotion of structures has a limited effect on the delivery of evidence-based practice (49).

6.3 Methodological Considerations

6.3.1 Quantitative studies

Study 1 and Study 2 used a quantitative design to examine hospital accreditation and the development of processes of care, while Study 3 used a qualitative design. Both approaches required methodological considerations of how the choice of design might have affected the results presented in the thesis.

6.3.2 Selection problems

Study 1 and Study 2 were conducted as nationwide studies that included all relevant hospitals. Analyses were based on prospectively collected data from population-based registries independent of the study hypothesis. Together with free access to healthcare for the whole population, this reduces the risk of systematic exclusion of patients.

The difference-in-differences analysis used in Study 1 assumes that the outcomes in each group would change in the same way in the absence of accreditation (33). This makes the composition of groups in Study 1 a concern, and we cannot be confident that accreditation would have affected hospitals in a similar way, as assumed in the design. However, groups were found to be comparable in size and proportion of teaching hospitals in Study 1, and nothing in Study 2 indicated that hospital characteristics are important.

6.3.3 Information problems

It was mandatory for all hospitals to monitor and report process performance measures during the routine clinical setting. Structured audit processes were carried out by the clinical quality databases regularly on a national, regional and local basis to assess the quality of the dataset critically (89). Nevertheless, misclassifications of data in Study 1 and Study 2 would inevitably have occurred to some extent due to manual processes conducted by a variety of staff from different departments and hospitals. Since data were collected prospectively and independent of the present thesis, misclassification would most likely have been non-differential. The same applies for missing values, which are considered missing at random. Further, we cannot rule out the risk of gaming in relation to accreditation, despite there being no known financial incentives for reporting false data. In this case, it would probably be differential misclassification, which can cause bias in both directions.

In Study 2, the division of periods is a potential limitation. Inaccurate divisions would most likely have led to non-differential misclassification and would lessen our ability to detect changes in trends between periods, therefore producing estimates that are more conservative.

6.3.4 Confounding

In Study 1 and Study 2, the possibility of confounding was limited due to the restrictive eligibility criteria for the individually examined processes of care, which increases the homogeneity of patients included across all hospitals. Further, analysis in Study 1 was based on hospitals' change in outcome, which limited the possibility of confounding. The same applies to Study 2, but at the national level. Only time-variant variables are at risk of being confounders. Potential confounders could be improvement initiatives or administrative regulations that can affect the hospital process performance. In Study 1, five of the six accredited hospitals belonged to the same regional management (former county), which could have influenced the results if any initiatives had been targeted process performance measures for these hospitals. The design used in Study 2 is immune to many of the threats to the internal validity often seen in other observational designs. In this case, it is limited to the risk that other interventions could have influenced the process performance measures. Due to the stepped-wedge inclusion of hospitals, a potential bias should have occurred simultaneously relative to the external survey for all hospitals, which is considered unlikely.

6.3.5 Precision

Study 1 and Study 2 were based on large sample sizes and complete samples of data from national clinical quality registries, thereby reducing the risk of random errors. All quantitative analyses were presented with 95% CI, making it possible to evaluate the precision of the estimates.

Study 1 adjusted for cluster effects at the hospital level to allow adjustments for heterogeneity between hospitals. Study 2 also allowed adjustments for heterogeneity between hospitals. This was addressed using random intercepts and random slopes of each period. A general recommendation when conducting segmented regression to ensure precision in trends is a minimum of 12 data points before and 12 data points after the intervention (90). In Study 2, the during accreditation period had the lowest number of data points (26 time points), securing very precise periodic trends. In addition, we tested Study 2 for seasonal variation, but it was not found to be relevant.

6.4 Qualitative Study

6.4.1 Interviews

The semi-structured interviews created narratives related to the themes in the interview guide. The role of the interviewer was to create a comfortable situation and listen carefully to the informants' narratives. All informants seemed motivated and talked freely about their experiences and perceptions, which supports the assumption that the semi-structured interview approach was appropriate.

As DDKM was terminated four to five months before the interviews were conducted and some of the themes involved experiences from Version 1 of DDKM, the findings are at risk of recall bias. A systematic error like this is not considered essential to the findings because all but one informant talked easily about experiences and had much to share. One informant, who just returned after 12 months' maternity leave, struggled a little in the beginning and had difficulty providing examples for her statements, but it eventually became a valuable interview. Recall bias cannot be completely ruled out, as people might remember certain situations better than others might; however, nothing in the findings indicated that the informants' statements were contradictory, which argues against recall bias affecting the conclusions.

6.4.2 Sampling

Study 3 was restricted to a small sample size from a single hospital, which made it challenging to generalise to other hospitals. However, the sample in this study provided a rich vein of material with a diverse range of responses from different positions within the hospital, along with useful insights into the value of accreditation. At first, the sample size was set to include two disease areas, but diabetes was eventually added. The last few interviews introduced nothing new, except more examples of the same, therefore supporting the assumption that we

reached data saturation in the primary findings in the study. A limitation is that the sampling did not include staff from other hospitals, but time and resources did not enable the sample to be increased further.

6.4.3 Analysis

The framework method applied in this study is considered a useful approach for shedding light on accreditation as a framework for continuous quality improvement. Methodologically, it provided a clear audit trail from the original raw data to the final themes, including the illustrative quotations. It is recommended that an experienced qualitative researcher should lead and facilitate all aspects of the analysis (91). Therefore, it is a limitation that the PR is a novice in using framework analysis and in qualitative research in general. However, the step-by-step process of the framework method proved to be an amenable and appropriate way of carrying out the data management process. The data management process was supported and guided by the co-authors.

6.4.4 Reflexivity

As in all qualitative research, the PR influenced the quality of the empirical evidence gathered and the interpretation of the data. The PR is a physiotherapist and a Master of Health Science and is mainly quantitative trained. The PR possesses a thorough knowledge of DDKM, the Danish healthcare system and results from Study 1 and Study 2. In particular, the knowledge of Study 2 and the fact that PR is a novice in qualitative research may have compromised elements of the research—how questions were asked, knowing when to move on to another question and how the data were interpreted and summarised. Despite efforts to limit this effect, which included using a pilot-tested interview guide, comparing coding with a trained sociologist and providing a clear audit trail, there remains an inherent risk from these elements in this study.

6.4.5 Transferability

The triangulation of Study 1 and Study 2 showed that Study 3 contributed valuable information and possible explanations that can assist in understanding the quantitative findings. No empirical generalisations can be made on the basis of the results, but it is believed that the experiences and perception of accreditation also applies to other settings. An argument for transferability is that accreditation through DDKM and reporting data to the national clinical quality registries was mandatory for all hospitals in Denmark. The fact that all hospitals were subject to both the DDKM and systematic monitoring of outcomes reinforced that the findings could be transferable to other settings. Conversely, it is well known that the effect of improvement initiatives is context-dependent (92, 93), and a total transferability cannot be expected.

Chapter 7: Conclusion

7.1 Voluntary Accreditation—Study 1

Both accredited and non-accredited hospitals significantly improved their processes of care performance throughout the study period. Improvements at the disease level did not depend on whether hospitals participated in an accreditation programme. However, the overall opportunity-based composite score improved more in non-accredited hospitals than accredited hospitals.

7.2 Mandatory Accreditation

7.2.1 Quantitative phase—Study 2

DDKM did not contribute to improvement, but development began to plateau when the external survey was conducted. DDKM affected performance development to a similar extent across all types of hospitals, but the effect varied across conditions and type of care. Additionally, process measures below best-practice target values were positively affected to a greater extent than processes above the target values. Heart failure and breast cancer were negatively affected by DDKM overall, but when analyses were restricted to include only processes below target values, diabetes and diagnostics were positively affected. Finally, when process measures were influenced in one direction by DDKM in the during accreditation period, it was likely to be influenced in the opposite direction in the post-accreditation period.

7.2.2 Qualitative phase—Study 3

DDKM served, in part, as a framework for continuous quality improvement in hospitals because it was perceived to have created a basis for improvement. In general, DDKM was not perceived to have contributed directly to improved process performance, which is in line with Study 2. Staff explained the lack of effect by a pre-existing management focus on this area. The opposite was the case for processes that had previously been neglected. During the preparatory work, these processes received increased attention, leading to perceived improvements. Staff reported that DDKM affected management's priorities, where office time and working on guiding documents was at the expense of time spent with patients and other improvement activities. This could explain why performance measures in some cases were negatively affected, as shown in Study 2.

Chapter 8: Perspective

This thesis contributes to the understanding of how accreditation affects hospitals. It showed how hospitals' performance developed throughout the first mandatory accreditation cycle and found that hospital characteristics were not a predictor of effectiveness, but that disease and type of care were. Future research should continue to explore whether accreditation is a generic method or whether it varies between different types of processes, as found in this thesis.

The staff interpreted that the general lack of accreditation effect on process measures reflected the fact that DDKM added nothing new. As with the other findings derived from Study 3, this was based on a limited sample from one hospital. To gain a more general view of the explanatory mechanisms in the accreditation process, further qualitative research is needed.

This thesis mainly addressed the effect of accreditation on process measures; however, it should also be determined whether accreditation influences patient outcomes such as mortality, length of stay, readmission and patient satisfaction. High compliance with DDKM has previously been linked to lower mortality and lower length of stay (73, 74), but the causal inference remains uncertain. Additionally, Study 2 detected patterns in the trend of improvement for performance measures during the cycle of the first version of DDKM. It could be relevant to examine whether a similar pattern was present in DDKM Version 2, and whether a similar pattern is present in other accreditation programmes used in other countries.

Despite the advantages, segmented analysis is not widely used in healthcare research. Segmented analysis requires data to be regularly collected over time, before and after the intervention. Segmented analysis is a design element that can strengthen causal inferences. The Danish national healthcare system provides detailed data on hospitals' performance from more than 60 registries (57), thereby giving Denmark a unique situation from which to conduct such analysis.

After an intense public debate about the bureaucratic burden of DDKM, hospital accreditation has been terminated in Denmark based on a political decision. As a substitute for the mandatory accreditation programme, a new national quality improvement programme has been launched. One of the aims of the new programme is to introduce a new approach to quality management that supports healthcare personnel's intrinsic motivation for providing high quality, which should lead to a culture where quality improvements are naturally embedded in daily work. This should be done by allocating more time to focus on quality improvement—time that is assumed to be released due to the termination of DDKM (94). Study 3 supported this assumption to some extent by showing that staff allocated a significant amount of time to working on guiding documents in the preparation period, but also that time spent decreased from the first version to the second. There are similarities between DDKM and the new quality improvement programme: they were both launched without an accompanying evaluation plan, and both were ambitious, nationwide and mandatory for all public hospitals without the

opportunity of randomisation. It would be advantageous to incorporate an evaluation plan from the start—an assessment that draws on both quantitative and qualitative approaches. We believe that the design used in this thesis to investigate DDKM is suited to evaluating natural experiments such as the implementation of such initiatives, and it is one of the strongest available designs for the task, given the described scenario.

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Appendix 1 - Templates for Accreditation Standards

Template
All accreditation standards are based on the same template as seen in figure 3 below. The template uses the same headlines and terms in the same order. Figure 3 describes the meaning of each space /point:

Title of standard	Describes the accreditation standard's theme and title and number out of the total number of accreditation standards within the theme in question
Standard	Describes the overall objective of the accreditation standard
Purpose of standard	Describes the purpose of the accreditation standard
Target group (responsible)	Describes who is **responsible** for observing the accreditation standards. The management takes the initiative to implement the accreditation standard and together with the staff the management is responsible for observing the accreditation standard. To ensure managerial independence each institution must define at which management level the responsibility is assigned, likewise tasks in relation to observing the accreditation standard are delegated. If the organisation is organised in a way which means that the target group is not the one who is actual responsible for the accreditation standard, it is the **content** of the accreditation standard which decides where to assign the responsibility.
Field of application	Describes at which organisational level in the institution the accreditation standard is going to be implemented and used. It thereby illustrates to whom the accreditation standard is divided to. As in connection with target group, DDKM is not normative in relation to how far out in the organisation the institution wishes to divide the accreditation standards.
Compliance of standard	**Indicators evaluating the compliance of the standard are listed in the steps below**
Step 1: **Guiding documents**	Step 1 requires the presence and contents of guiding documents. This could be a business mission, policies, plans or guidelines*, instructions* or checklists depending on the accreditation standard's focus area. As a principal rule the accreditation standards do not require which organisational level is responsible for the preparation of these documents. The responsibility is therefore placed by the management It will often be placed at an institutional level or unit level but it may also be placed centrally at a municipal level. Step 1 often includes guidance to help understand the indicator, e.g. in the shape of specifications, examples or further explanation **Validity period of guiding documents** In cases where the legislation decides time limits, these are valid. If *no* legislative time limits are stated the guiding documents included in DDKM must be revised when needed, so they are updated – however at least every 3 years. Some places in the accreditation standards it is stated that e.g. the business mission must be updated at least every 4 years. This is due to the business mission's revision in connection with the local elections
Step 2: **Implementation and use of guiding documents**	Step 2 requires knowledge and implementation of the guiding documents. Step 2 often uses the term "*are familiar with and use*" to emphasise that management and staff must be familiar with and use the guiding documents. Based on Bloom's taxonomy "use" means that you are "familiar with" the topic, but both parts are emphasised and both parts must be implemented for step 2 to be fulfilled. Unless anything else appears from the indicator there are no requirements about written documentation to rating achievement of indicators at step 2. Instead they will be assessed on the basis of observation and interview at external survey.
Step 3: **Quality surveillance**	The required quality surveillance at step 3 supports the compliance of the accreditation standard or parts of the standard. Step 3 includes i.a. the following data sources: ▪ National quality databases and NIP ▪ Patient administrative systems ▪ National patient satisfaction surveys ▪ Log books ▪ Adverse events in Danish Patient Safety Database ▪ Journal audit ▪ Observation In connection with several indicators there is a guidance which elaborates the indicator by using examples or explanations. Data sources, audit and journal audit are further described in the introduction and in appendices 1, 2 and 3.
Step 4: **Quality improvement**	Step 4 presupposes that data from step 3 are analysed and assessed and on the basis of this a managerial decision is made as to whether the quality level is satisfactory or whether, on the basis of the analysis, quality improving initiatives including quality surveillance is going to be intensified. The management at the relevant level should hereafter prioritise the initiatives which are going to be implemented and make a plan for the time perspective.
References	State selected references for the accreditation standard in question. The references are primarily Danish legislation, consolidated acts and reference programmes. The aim is not complete professional references.

Appendix 2 - A disease specific accreditation standard

Title of standard	Breast cancer 3.2.1 Breast cancer (1/1)
Description of the population comprised by the standard	Includes all women with breast cancer under the following ICD-10 diagnosis code: C50.X Malignant neoplasm of breast
Standard	Assessment and triage of newly diagnosed breast cancer patients is organised as an acute disease and assessment, treatment, care and rehabilitation is made in accordance with clinical, evidence-based practises and formulated on the basis of the Danish Breast Cancer Cooperation Group (DBCG) guidelines for diagnosis or treatment of breast cancer in Denmark or subsequent updates.
Purpose of standard	To ensure that all patients with breast cancer are assessed, treated, cared and rehabilitated in accordance with clinical, evidence-based practices
Target group (responsible)	Managers and staff in all units performing assessment, treatment, care and rehabilitation on patients with breast cancer
Application area	All surgical, radiological, pathological and oncological units involved in assessment, treatment, care and rehabilitation of patients with breast cancer
Compliance of standard	Indicator 1 There are guidelines for assessment, treatment, care and rehabilitation of patients with breast cancer based on newest research included in DBCG guidelines for diagnosis or treatment of breast cancer in Denmark or subsequent updates.
Step 2: Implementation and use of guiding documents	Indicator 2 Managers and staff are familiar with and use the guidelines.
Step 3: Quality surveillance	Indicator 3 The institution reports data in accordance with the clinical indicators defined by the Danish Breast Cancer Cooperation Group DBCG, and as a minimum, there are annual audit reports for this group of patients.
Step 4: Quality improvement	Indicator 4 Based on the quality surveillance, the management prioritises specific action to take on quality improvements, cf. Quality and risk management, standard 1.2.4. Indicator 5 During the three-year accreditation period, the institution documents quality improvements in the published DBCG indicators that failed to comply with the stipulated target value.

	If target values for the DBCG indicators are reached, the quality level must be maintained or improved during the accreditation period.

Appendix 3 - Processes performance measures

Condition	Process performance measure	Description	Time frame	Target value
Acute stroke	Admission after symptom onset	Admission after symptom onset	Three hours after symptom onset	90%
	Admission to a stroke unit	A unit that exclusively or primarily is dedicated to patients with stroke and which is characterised by having multidisciplinary teams, a staff with a specific interest in stroke involvement of relatives and continuous education of the staff	Second day of hospitalisation	95%
	Oral anticoagulant therapy	Initiation of treatment with oral anticoagulant therapy	14^{th} days of hospitalisation	95%
	Examination with CT/MR scan	Examination with CT/MR scan	First day of hospitalisation	80%
	Assessment by a physiotherapist	Formal bed-side assessment of the patient's need of rehabilitation	Second day of hospitalisation	90%
	Assessment by an occupational therapist	Formal bed-side assessment of the patient's need of rehabilitation	Second day of hospitalisation	90%
	Assessment of nutritional risk	Assessment following the recommendations of the European Society of Parenteral and Enteral Nutrition	Second day of hospitalisation	90%
	Angiography of neck vessels	Examination with ultrasound/CT-/MR-angiography of neck vessels	Fourth day of hospitalisation	90%
Heart failure	Echocardiography	Examination with echocardiography	During hospitalisation	90%
	NYHA classification	Formal assessment following the New York Heart Associations' classification	At discharge or first outpatient visit	90%

Condition	Process performance measure	Description	Time frame	Target value
	Medication (ACE/ATII inhibitors)	Initiation of treatment with Angiotensin Converting Enzyme-inhibitor /Angiotensin II Antagonist inhibitors-receptor antagonist	During hospitalisation	90%
	Medication (Beta-blockers therapy	Initiation of treatment with beta-blockers	During hospitalisation	80%
	Aldosterone therapy initiated	Initiation of treatment with aldosterone therapy	During hospitalisation	35%
	Referred to physical training	Referred to individual physical training	During hospitalisation	30%
	Patient education	Formal start of a structured patient education (inclusive nutrition, physical training, understanding medical treatment, risk factors and symptoms of the disease)	Twelve weeks after hospitalisation or first outpatient visit	80%
Diabetes	Measured HbA1c	Measure HbA1c level	During the last year	95%
	Measured Blood pressure	Measure blood pressure	During the last year	95%
	Measured cholesterol	Measure lipid level including Low-density lipoprotein cholesterol	During the last two year	95%
	Examination of renal function	Examination of albuminuria level	During the last two year	95%
	Eye examination (two years)	Formal examination for complications including ophthalmoscopy performed by an ophthalmologist or fundus-picture rated by Ophthalmologist/specialist nurse.	During the last two year	90%
	Eye examination (four years)		During the last four year	95%
	Foot examination	Formal examination for complications including inspection of skin lesions and wounds, palpation of pulse, systematic examination of sensibility/vibration sensitivity	During the last two year	95%

Condition	Process performance measure	Description	Time frame	Target value
Ulcer (Perforated)	Preoperative delay	Within the first 6 hours from hospitalization or decision on surgery	Six hours	75%
	Bodyweight	Daily weight measurement (three times daily)	Third day after surgery	90%
	Fluid balance	Daily weight measurement (three times daily)	Third day after surgery	90%
	Postoperative monitoring	Measurement and registration of vital signs (blood pressure, heart rate, temperature, pulse oximetry, level of consciousness) twice daily	Third day after surgery	90%
(Bleeding)	Treatment/Therapeutic endoscopic	Achievement of primary haemostasis	During hospitalisation	90%
	Endoscopic treatment of rebleeding	Achievement of endoscopic haemostasis	During hospitalisation	75%
	Surgical treatment of primary-/rebleeding	Surgical treatment of bleeding ulcus bot necessary	During hospitalisation or planed after discharge	90%
Breast Cancer	Diagnosis	Patients with IBC (C50), with a preoperative diagnosis prior to definitive surgery.	Prior to surgery	90%
	Axillary status by sentinel node	Patients with primary IBC (C50) without lymph node, where N (node) status has been clarified by SN method.	During hospitalisation	95%
	Examination >10 axillary lymph nodes	Axillary-pNp in patients with primary IBC (C50) where there are removed and examined at least 10 axillary lymph nodes as part of tended curative surgery.	During hospitalisation	95%
	High risk program	Patients included in a high-risk protocol	During clinical follow up	95%
	Low risk program	Patients included in the low-risk protocol	During clinical follow up	95%
Lung cancer	Surgery (treating hospital)	Patients operated - according to treating hospital	Within 42 days after the start of the diagnostic process	85%

Condition	Process performance measure	Description	Time frame	Target value
	Surgery (diagnosing hospital)	Patients operated - according to diagnosing hospital	Within 42 days after the start of the diagnostic process	85%
	Oncological treatment (treating hospital)	Patients started oncological treatment - according to treating hospital	Within 42 days after the start of the diagnostic process	85%
	Oncological treatment (diagnosing hospital)	Patients started oncological treatment - according to diagnosing hospital	Within 42 days after the start of the diagnostic process	85%
	Chemotherapy (treating hospital)	Chemotherapy commenced - according to treating hospital	Within 42 days after the start of the diagnostic process	85%
	Chemotherapy (diagnosing hospital)	Chemotherapy commenced - according to diagnosing hospital	Within 42 days after the start of the diagnostic process	85%
	Radiotherapy (treating hospital)	Radiotherapy commenced - according to treating hospital	Within 42 days after the start of the diagnostic process	85%
	Radiotherapy (diagnosing hospital)	Radiotherapy commenced - according to diagnosing hospital	Within 42 days after the start of the diagnostic process	85%
	Classification	Patients with accordance between cTNM and pTNM	Operation Date	80%
	Resection rate	Patients with non-small cell lung cancer, who had a resection	Operation Date	20%