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Abstract

**Manuscript title** Improvement in quality of hospital care during accreditation: A nationwide stepped-wedge study

**Objective** To assess changes over time in quality of hospital care in relation to the first accreditation cycle in Denmark.

**Design, setting and participants** We performed a multi-level, longitudinal, stepped-wedge, nationwide study of process performance measures to evaluate the impact of a mandatory accreditation programme in all Danish public hospitals. Patient-level data (n=1,624,518 processes of care) on stroke, heart failure, ulcer, diabetes, breast cancer and lung cancer care were obtained from national clinical quality registries.

**Intervention** The Danish Healthcare Quality Programme was introduced in 2009, aiming to create a framework for continuous quality improvement.

**Main outcome** Changes in week-by-week trends of hospital care during the study period of 269 weeks prior to, during and post accreditation.

**Results** The quality of hospital care improved over time throughout the study period. The overall positive change in trend (OR 1.002 per week; 95% CI 0.997-1.006) observed when comparing the period *during accreditation* with the period *prior to accreditation* was not significant. However, when restricting the analyses to processes of care where the performance did not meet target values for satisfactory quality prior to accreditation, we found a significant positive change in trend (OR 1.006 per week; 95% CI 1.001-1.011). When comparing the post accreditation period with the period during accreditation, we found a significantly reduced trend (OR 0.994 per week; 95% CI 0.988-0.999), indicating the improvement in the quality of care continued but at a lower rate than during accreditation.

**Conclusion**

These findings support the hypothesis that hospital accreditation leads to improvements in patient care.
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KEYWORDS

Accreditation; standards of care; patient safety; quality of care; stepped-wedge design, segmented regression, external evaluation.
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Manuscript text

Introduction

Today’s health care system is complex (1). Standardisation in the form of policies, standards, guidelines, procedures and pathway packages is a popular strategy among health care leaders to improve the quality of care. One way to promote standardisation is to apply an accreditation model, attempting to ensure consistent quality of care and continual improvement of care in line with rising standards (2). In the last decade, accreditation has spread to over 70 countries (3). Although research in healthcare accreditation has received attention, a strong relationship between applying predefined accreditation standards and continued improvement in the quality of care has yet to be demonstrated (3-5).

In 2009, a mandatory national accreditation programme for hospitals was introduced in Denmark, with the aim of providing a framework for quality improvement for all public hospitals (6). High compliance with the standards from this programme has been shown to be associated with lower 30 days mortality risk and shorter length of stay (7, 8), but despite the goal of doing so, it is still unknown whether the accreditation programme per se promotes improvements in quality of care. Since the accreditation programme was mandatory, it is not possible to assess the impact of accreditation through a randomised controlled trial that traditionally is seen as the gold standard methodology for evaluations of causal interventions (9). However, Denmark was new to mandatory hospital accreditation, which gives the opportunity to assess the impact of nationwide implementation of an accreditation programme. The aim of this study was to assess changes over time in hospital process performance measures in relation to the first accreditation cycle, at a census of all non-psychiatric public hospitals in Denmark.

We hypothesised (Hypothesis 1) that the impact of the accreditation programme would be reflected in an increased trend in process performance measures during accreditation compared to prior to accreditation. We expected that the external pressure that results from the accreditation process would subsequently play a less dominant role once the on-site survey was completed. Therefore, we hypothesised (Hypothesis 2) that the improved trend would decrease post accreditation. Finally, since identifying areas with room for
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improvements is a vital part of the accreditation process, we hypothesised (Hypothesis 3) that the improvement effect would be more evident for process performance measures where the hospitals prior to the accreditation delivered the quality of care at an unsatisfactory level.

Methods

Study design, context and study population

We designed a longitudinal, nationwide study of process performance measures related to the introduction of a mandatory accreditation programme from November 1, 2008, to December 31, 2013. The 5.6 million inhabitants in Denmark have free access to public hospitals, which have approximately 1.1 million admissions and 11.5 million outpatient contacts annually (10). Public hospitals in Denmark treating patients with at least one of the six following conditions were included: acute stroke, heart failure, ulcer (perforated and bleeding), diabetes, breast cancer and lung cancer. Several hospitals merged during the study period, and each merger (n=6) was considered as one hospital. Thus, a census of 25 hospitals was included.

Accreditation programme in Denmark

All public hospitals in Denmark were obliged to implement The Danish Healthcare Quality Programme (in Danish: Den Danske Kvalitetsmodel (DDKM)). The first version was launched in August 2009; the first hospital was accredited in May 2010 and the last in June 2012. DDKM’s aim was to create a framework for continuous quality improvement, to document and make the quality of healthcare transparent and to prevent errors that cause death and lower quality of life. The agency responsible for DDKM recommended that every hospital performs an internal survey six months before the external survey, in order to identify areas for improvements and to prepare for the announced on-site survey. A team comprising peer reviewers performed the on-site surveys, with the main task to evaluate to what extent the organisation meets the predefined standards. The surveyors used, among other methodologies, interviews with staff and patients and reviewing guidelines. The evaluation is documented in a report used by the accreditation body to evaluate the results of the survey and identify strengths and areas for improvement, which is used by the hospital to continuing the cycle of continuous quality improvement (11).
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The first version of the programme consisted of 104 standards grouped into three categories: organisational, general patient pathway and disease-specific standards. The standards incorporated the four steps in the plan-do-check-act cycle, a management method used for control and continuous improvement of processes (12). Each standard incorporated a number of indicators used to guide the hospitals to meet the standard. The disease-specific standards required documentation for specific actions when performance failed to reach the expected quality level (6). If a hospital reached a satisfactory level of quality, this level must be maintained as a minimum, and no further action was required. Disease conditions included in the disease-specific standards were based on incidence/prevalence, severity and complexity of patient care services with the aim to ensure high quality of care (6). All six diseases included in this study had its own disease-specific standards. An example of a standard is shown in Appendix 1. In addition to the disease-specific standards are standards that require policies related to clinical guidelines, documentation and monitoring and quality improvement at an organisational level expected to have the greatest impact on process performance measures (11).

Processes of care

Patient-level data on delivered processes of care were obtained from national clinical quality registries related to stroke, heart failure, ulcer, diabetes, breast cancer and lung cancer. To be approved as a national clinical quality registry at least 90 % of all patients treated at hospitals should be included (13). Reporting to these registries is mandatory for all hospitals according to Danish law.

Each clinical quality registry has a board with representation of relevant medical specialities and in many cases other health professionals (e.g. nurses, occupational therapists, physiotherapists, and dieticians). The board is responsible for identifying relevant processes of care to be monitored. A time limit was defined for each of the individual processes to capture the timeliness of the interventions. The selected processes of care and time limits reflect recommendations from national clinical guidelines for the individual conditions. The processes of care in our sample (n=1,624,518), were coded as 1 or 0, corresponding to whether an eligible patient had received a given process of care within the recommended timeframe or not. We computed process performance measures based on the individual processes of care. A target value at hospital level
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reflecting best practice was defined for each process performance measures by the health professionals (e.g., at least 90% of the patients with systolic heart failure should receive an angiotensin converting enzyme inhibitor or angiotensin II blocker). Forty-three different process performance measures were included in our study covering the six conditions (Content of the process performance measures and related target values can be seen in Appendix 2).

Statistical analysis

The five-year study was divided into three periods for each hospital: prior to, during and post accreditation. As shown in Figure 1, the on-site surveys occurred only at one hospital at a time, as a natural occurring stepped-wedge configuration, resulting in individual timelines for the 25 hospitals. Analysis to determine the impact of accreditation involved comparison of trends between the three periods according to the stepped wedge design (14). The period during accreditation was defined as a six months period; starting from the date at which DDKM recommended an internal survey to the date the on-site survey occurred. A segmented logistic regression model was applied which included (1) a variable for continuous time in weeks throughout the entire period; (2) a variable for time (weeks) after the beginning of the during accreditation period; and (3) a variable for time (weeks) after the beginning of the post accreditation period. These variables model (1) trends in the prior accreditation period, (2) change in trend between the prior to and the during accreditation period and (3) changes in trend between the during and the post accreditation periods. Analyses were performed as mixed effects logistic regressions in a stepped-wedge framework. We used mixed effects models in order to allow adjustment for heterogeneity between hospitals (15). In addition, we used random slopes at each period, to allow all hospitals to have individual trends through the study period. Intraclass correlation coefficients (ICC) were calculated to assess the heterogeneity between hospitals in both level and trends. We tested our model for seasonal variation (pattern in the level of process performance measures during calendar time) in the hospital performance. We excluded processes with missing data from our analyses, but the proportion of missing data for the individual processes of care was in general low (<10%) and expected to be missing completely at random.
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Since the DDKM specifically addressed processes of care where the performance at hospital level did not meet the pre-specified target value for best practice, we conducted a sub-analysis where only processes of care below the target values were included. A process performance measure beneath 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. In that way, we assessed whether accreditation, in particular, facilitated improvement initiatives for processes of care where the hospitals delivered unsatisfactory levels of quality. Data were analysed via Stata 13.1 (StataCorp LP, College Station, TX) and a two-sided significance level of 5 % was applied.

Results

We included 1,624,518 processes of care in the main analysis and 759,713 processes of care in the sub-analysis. Hospital characteristics are presented in Table 1. We tested for seasonal variation, which was found to be insignificant.

The quality of care as reflected by the assessed process performance measures improved throughout the study period (Figure 2). Table 2 presents the results of the main analyses including hospital level variances. At the start of the observation period patients experienced an overall 78% probability of receiving treatment according to clinical guidelines recommendations. A significantly positive weekly trend (OR 1.007; 95% CI 1.005-1.008) was detected in the period prior to accreditation. This positive trend was not significantly changed in the during accreditation period (OR 1.002; 95% CI 0.997-1.006) (Hypothesis 1 not confirmed). The positive trend subsequently slowed significantly during the post accreditation period (OR 0.994; 95% CI 0.988-0.999) but continued improvement in the process performance measures was observed, confirming Hypothesis 2.

When focusing on process performance measures where the hospitals had not achieved the target values six months prior to the during accreditation period, we found an overall 68% probability of receiving treatment according to clinical guidelines recommendations at the start of the period. Similar to the main analysis, the weekly trend in the prior to accreditation period was significantly positive (OR 1.005; 95% CI 1.003-1.006).
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The change in the weekly trend between the prior to and the during accreditation periods significantly increased adding support to Hypotheses 1 and 3 (OR 1.007; 95% CI 1.002-1.012). The positive trend subsequently levelled off during the post accreditation period, confirming Hypothesis 2 (OR 0.99; 95% CI 0.984-0.996).

The ICC in the main analysis indicated that 10% (95% CI 6-16%) of the total random variation in the process performance measures was due to heterogeneity between hospitals, whereas only 4% (95% CI 2-7%) of the random variation was due to heterogeneity between hospitals in the sub-analysis. Results stratified at the hospital level are presented in appendix 3.

Discussion

In this nationwide study of a census of public hospitals in Denmark, we found improvements in the quality of hospital care for care domains where the baseline hospital performance was below best practice target values following the introduction of an accreditation programme. Once the on-site survey concluded, improvements continued, but the rate levelled off. Essentially, the positive trend prior to accreditation increased during accreditation and continued post accreditation, but it began to plateau.

The impact detailed in the sub-analysis is likely to reflect the specific requirement of documentation for action taken when performance was below target values. The decrease in trend post accreditation may indicate that the hospitals’ focus on improvement is affected by the external pressure which follows the on-site survey. We cannot determine the exact mechanisms in a study of this kind, but this issue is worth examining using a qualitative design in future research.

In Denmark, the use of accreditation had taken place since 2002, where a few hospitals signed up for voluntary accreditation with international accreditation bodies. In contrast to these findings, past research from Denmark indicated that accredited hospitals appeared not to experience larger improvement in process performance measures compared with non-accredited hospitals (16). The difference between these and the present results may be that the DDKM requested hospitals to concentrate on processes of care beneath target values. This request may have meant that hospitals improved in the care domains where the quality of
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care was unsatisfactory. There is no consensus in the existing scientific literature regarding the effects of accreditation (3-5), and additional studies on its effects on process performance measures had been suggested (7, 17). As the first nationwide study, based on detailed individual-level data from multiple processes of care, this study contributes key data to filling this gap.

This study has a number of strengths. Data were collected systematically and prospectively from a census of all public hospitals. The validity of the data was in general high (e.g. the completeness of the registration of patients was >90% for all included clinical registries when compared with local hospital discharge registries) and a uniform registration practice across hospitals was supported by detailed data definitions and systematic yearly audits.

The use of segmented longitudinal analysis coupled with a naturally-occurring stepped-wedge effect is a strong design feature in evaluating the longitudinal effects of an intervention (18). This design feature reduced the risk that the observed trends were attributable to interventions other than accreditation. In addition, we used a mixed effect model (random intercept and random slopes for accreditation period) to allow adjustment for heterogeneity between hospitals. Together, this makes it possible to assess changes over time, related to hospitals and their individual accreditation cycles, whereby every hospital serves as its own control. This design controls for periodic trends in the data, thereby reducing bias that might otherwise manifest in studies with a pre and post design. As every hospital acts as its own control, the requirement to adjust for both patient and hospital characteristics are eliminated (18), unless changes in characteristics occurred simultaneously with the introduction of accreditation, for which there was no indication.

Additional strengths include that the possibility of confounding was limited by the restrictive criteria for assessing the performance measures as these only included patients, which were considered eligible for the individual processes of care (i.e., the process performance measures were designed only to include care, which was considered relevant for the individual patients by the health professionals treating the patient).

Division of the study into time periods remains a limitation. We cannot be sure that hospitals followed the accreditation agency’s recommendation to perform an internal survey six months prior to the on-site survey.
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and then immediately began preparations. If this situation did occur, it would decrease the impact of accreditation and therefore is not considered to influence our overall conclusion. Finally, despite a lack of evidence and no financial incentives, we nevertheless cannot rule out the possibility of gaming (incorrect registration) of the process performance data. If gaming is present, it would, however, not affect the study results, since hospitals should start to report false data according to the division of the three periods, which is very unlikely since data are reported prospectively and with no relation to this study.

Conclusion

This is the first national-level study of a census of hospitals undergoing accreditation for the first time, following them across the accreditation cycle. It provides empirical support for the view that mandating an accreditation system and applying accompanying standards are associated with improved quality of hospital care. Studies from other settings are warranted to confirm the generalisability of our findings to other health systems.

Acknowledgments

We would like to thank the secretariat of The Danish Clinical Registries for their kind help with making data available for analysis.

Ethics approval

The study was approved by the Danish Data Protection Agency (J # 2013-41-1742) and informed patient consent was not required according to Danish law because of the use of data from national registries.

Funding

This work was supported by Region of Southern Denmark and University of Southern Denmark.

References

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Tables

<table>
<thead>
<tr>
<th>Table 1. Hospital Characteristics</th>
<th>Hospitals (n=25)</th>
<th>Processes of care (n=1,624,518)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaching hospital, counts (%)</td>
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<tr>
<td>Yes</td>
<td>14</td>
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<td>No</td>
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<td>626,059 (38.5)</td>
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<td>Census region, counts (%)</td>
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<td>The Capital Region of Denmark</td>
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<td>Region Zealand</td>
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<td>336,674 (20.7)</td>
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<td>The North Denmark Region</td>
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<td>Bed size, counts (%)</td>
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<td>&lt;300</td>
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<td>No</td>
<td>19</td>
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<td>Disease areas, counts (%)</td>
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<td>Stroke</td>
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<td>321,304 (19.8)</td>
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<td>Heart failure</td>
<td>24</td>
<td>107,804 (6.6)</td>
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<td>Ulcer</td>
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<td>Breast cancer</td>
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<td>31,251 (1.9)</td>
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<td>Lung cancer</td>
<td>20</td>
<td>57,043 (3.5)</td>
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### Table 2 Development of hospital process performance measures at Danish public hospitals prior to, during and post accreditation

<table>
<thead>
<tr>
<th>Three Segmented logistic regression</th>
<th>Main analysis (n=1,624,518)</th>
<th>Sub-analysis (n= 759,713)</th>
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<tr>
<td></td>
<td>Odds ratio</td>
<td>95 % CI</td>
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<td>Prior to accreditation</td>
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<td>Level (probability)</td>
<td>3.5 (78%)</td>
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<td>Trend</td>
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<td>1.005-1.008</td>
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<td>During accreditation</td>
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<tr>
<td>Change in trend</td>
<td>1.002</td>
<td>0.997-1.006</td>
</tr>
<tr>
<td>Post accreditation</td>
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<tr>
<td>Change in trend</td>
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<td>0.988-0.999</td>
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<tr>
<td>Hospital-level ICC</td>
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<td>0.06-0.16</td>
</tr>
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</table>

CI = Confidence interval; ICC = intraclass coefficient; n = Processes of care

a Containing processes where the target value not were met in the six months prior to the during accreditation period for the individual hospitals
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Figure 1 Timelines for accreditation of Danish public hospitals

Figure 2 Development in hospital process performance measures at Danish public hospitals according to the first accreditation cycle. Graph a shows development based on all processes of care. Graph b shows development from processes where the target values were not met in the 6 months prior to the during accreditation period for the individual hospitals.