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Chapter 11

Discussion and Summary of this thesis

Recent reports on variation in process and outcomes of care between hospitals, in combination with several healthcare scandals, have led to a societal call for more information on hospital quality of care. These calls have been further amplified by the rapidly increasing costs in healthcare. Care providers are more and more being held accountable for the quality of care delivered and for the spending of health care means. In order to maintain societies trust in quality of care in the Dutch hospitals, and to control healthcare costs, valid information on hospital performance is needed. To answer these needs, a new system for systematic registration and feedback of information on treatment processes and outcomes of care was introduced: Clinical auditing.

In 2009 the Dutch surgeons introduced clinical auditing in the Netherlands, with the start of the Dutch Surgical Colorectal Audit (DSCA, www.clinicalaudit.nl). The goals of the se surgeons were

- to give hospitals an instrument for *improvement* of their practices and *outcomes*, and to gain insight in and reduce hospital variations in practice, guideline adherence and outcome,
- to gain more insight in *national* practice and *performance*, to set benchmarks, and identify aspects that need improvement and to find and implement best practices
- to evaluate and monitor the *implementation of new techniques*
- to answer the need for *transparency* to all stakeholders

However, a uniform methodology to realize these goals was not available. One of the most urgent research questions was the definition and content of ‘valid and meaningful feedback information’. Therefore, the aim of this thesis was to investigate how data from clinical audits can be used to produce valid and meaningful feedback information, which may support improvement of quality of care, using the DSCA as an example. **Part one** aims to evaluate the *use of clinical auditing as an instrument for the improvement of quality of care in surgery*. **Part two** investigates *how data from clinical audits can be used to monitor and improve national practice and performance*, especially for high-risk patient groups. **Part three** investigates the use of clinical auditing for the *evaluation and monitoring of the implementation of new techniques on a national level*. **Part four** investigates how data can be used to *evaluate quality of care and give transparency to all stakeholders*. We investigate how various aspects of quality of care are related and how these data can be used in composite-measures, which can be used by all stakeholders to evaluate quality of care as a whole.

The aim was to develop and improve methodologies that may be used by many other clinical audits.

Part 1. The use of clinical auditing as an instrument for improvement of quality of care

Many studies report on the positive effects of clinical auditing on quality of care. In clinical audits various aspects of the care process and its outcomes are registered and used to provide feedback of benchmarked performance information to individual hospitals. For example the national surgical quality improvement program (NSQIP) was initiated 20 years ago in the Veterans Affairs hospitals in the United States, after reports that the quality of care in these hospitals was far below the national average. After the introduction of this clinical audit a 45% reduction in postoperative morbidity and a 27% reduction in mortality after surgery was observed in 7 years¹. Similar results were reported after introduction of this auditing system in the private sector. Other examples of the positive effect of clinical auditing are a 25% reduction in postoperative mortality after Coronary Artery Bypass Graft surgery, only one year after feedback of outcome data to the surgeons², or the reduction of local recurrence after rectal cancer resections in Norway after the introduction of clinical auditing from 28% to 7%.³ We showed in a systematic review that clinical auditing has a positive effect on the outcomes of surgical care. [Chapter 2] A similar result was found for quality of care in non-surgical care in a recent Cochrane review.⁴

However, it remains difficult to prove that the quality improvements shown can be attributed to clinical auditing alone, as there may be more mechanisms that contribute to the quality improvement.

- The first mechanism is *regression to the mean*: a hospital with a high mortality rate in one year is very likely to have a lower mortality rate the next year as a result of statistical random variation. Therefore, when a hospital participating in a clinical audit, takes action to improve substandard results of the previous year, it is highly likely that an improvement is found. The effect of random variation is larger when hospital volumes are smaller, or the event-rate of the outcome measure is lower.⁵ However, the continuous overall improvement as described after implementation of national clinical audits cannot be discounted by this effect.^{1,6}
- The second mechanism is that of *autonomous quality improvement*. The simplest example for autonomous quality improvement is the implementation of a new treatment during the clinical audit, which may contribute to the improvement outcomes. Also, autonomous quality improvement is often seen during participation in a study as a result of the increased focus on outcomes: the Hawthorne effect. However, this effect may also be seen as the basis of clinical auditing: the constantly renewing focus on outcomes of care creates a continuous 'Hawthorne effect'. Although the Hawthorne effect is commonly used in industrial psychology as a strategy to enhance human performance,^{7,8} the idea of using this Hawthorne effect in medicine, to improve quality of care is relatively new. Clinical auditing adds a control system to this 'Hawthorne effect', by providing timely

feedback on the magnitude of the improvement needed, and the results of improvement interventions. Where the Hawthorne effect, in its traditional form (e.g. without feedback) is thought to be 'fading over time',⁹ clinical auditing provides periodic change of outcome measures, and constant motivation and improvement impulses, which may help to constantly renew the Hawthorne effect.^{9,10}

- The third mechanism is the *perverse incentive*. Although clinical auditing is designed to monitor the treatment process as a whole, there are always 'holes in the maze'. For example, in-hospital mortality may be improved by rapidly discharging patients to a hospice. After a few years of auditing, some hospitals may discover these 'holes in the maze', and learn to use them to improve their outcomes in the registration, without improving their quality of care.¹¹ Thorough data validation with other data sources may prevent this *perverse incentive*.

The missing link

Although in most industries it is common practice to frequently 'audit' process and outcomes, in order to improve efficiency and results, this idea is relatively new in medicine. Most industries work according to a PDCA circle (Plan-Do-Check-Act), which enables a constant quality improvement. The audit results in an improvement plan, which is carried out, the effect of the improvement intervention is evaluated and additional improvement interventions are initiated where needed. In medicine however, too often, innovation is limited to a 'PD' cycle: an innovation is designed and implemented, but no 'check' is performed to see if these new innovations are effective. Also, audits to identify flaws in the care process were uncommon. Clinical auditing is the missing link in medicine, which enables caregivers to monitor and improve, and be transparent on the quality of their care, on a hospital level, but also on a national level. However for an (inter)national clinical audit to be successful, good data quality and timely availability is essential.

A successful audit

The first key to a successful (inter)national clinical audit is an up-to-date complete and valid database, which is described on five levels.

- *Participation*: all hospitals in the target area participate. For example, the Project on Cancer of the Rectum (PROCARE) Belgium has a voluntary participation policy resulting in only 40% of all patients treated in Belgium being registered in the audit. All other hospitals do not benefit from the audit. Also, results from this audit may not give a fair reflexion of national performance, as participating hospitals most likely to be the more dedicated hospitals with better results.
- *Case-ascertainment*: all cases in each hospital are registered. In the United Kingdom, participation in the National clinical Bowel Cancer Audit (NBOCAP) is also voluntary. Although participation has increased from 44.3% in 2006 to 90.1% in 2011, case ascertainment is still poor, and 23.3% of all hospitals still fail to submit more than 50%

of their colorectal workload.¹² Recent studies have shown that hospitals submitting all data on all patients had a significantly lower 30-day mortality compared to hospitals submitting less than 10% of all cases.¹² A possible explanation is that the hospitals submitting all data were the more dedicated hospitals with good outcomes, resulting in a selection bias.^{13,14} Using such data as a national reference may result in an unrealistic representation of national performances, depicting average performing hospitals as negative outliers, and discouraging average and underperforming hospitals to submit their data.

- *Completeness*: all relevant clinical information of each case is registered. For example, when case-mix information is incomplete, hospitals risk-adjusted outcomes may be insufficiently adjusted for their case-mix, and quality of care may thus appear worse (or better) than it actually is.
- *Timeliness*: registration is preferably synchronized with clinical reports, or at least done shortly after information becomes available. Previous studies have shown that frequent and timely feedback is an important driver for quality improvement.¹⁵ In the Netherlands, the NKR registered outcomes of cancer care long before the DSCA was initiated, however, data only became available a year after the date of surgery. Therefore, reports based on these data were considered 'out-dated' and were seldom used to improve quality of care.
- *Validity*: registration is truthful, and can be validated against other data sources.

The Dutch Surgical Colorectal Audit (DSCA), initiated in 2009, was designed after these many international examples. Within two years, all Dutch hospitals participated in the audit. Case-ascertainment was 92% in 2010 and 95% in 2011, and completeness was 100% on almost all items. [Chapter 3] We identified the 'driving' key elements that lead to this successful implementation of this audit, and describe recent results after introduction of this audit. These 'driving' key elements were

- a leading role of the professional association in the development of the dataset and outcome measures
- integration of the audit in the national quality assurance policy of the professional association
- a web-based registration system and registration by medical specialists
- weekly updated online valid and meaningful feedback to participants
- annual external data verification with other data sources
- quality standards set by the professional association and introduction of improvement projects to meet these standards, the first standard being participation and full case-ascertainment in the audit. [Chapter 3]

These key elements have recently been confirmed in a systematic review.¹⁶ The DSCA was designed as a blueprint for auditing in the Netherlands, and many clinical audits have followed since.

Results from the DSCA

Hospitals participating in the DSCA receive weekly updated feedback data on their performance, compared to those of all other hospitals in the Netherlands. These feedback data include data on patient and tumour characteristics, and treatment and outcome. Feedback data on treatment concerning all crucial steps required in the treatment of colorectal cancer, as described by the national evidence based guidelines. From 2009 to 2011, a significant increase in overall guideline adherence was found on several processes, such as the percentage of patients discussed in a preoperative multidisciplinary team, the use of preoperative Magnetic Resonance Imaging (MRI) for rectal cancer surgery, and the standard of pathological reporting of the Circumferential Resection Margin (CRM). Moreover, we also found that variation in hospital performance decreased. **[Chapter 3]** After 2011 guideline adherence has even further improved.¹⁷

Feedback data on outcomes of colorectal cancer care also included postoperative morbidity, length of hospital stay and mortality. Postoperative morbidity, length of hospital stay and postoperative mortality and complications decreased significantly from 2009 to 2011 both for colon and rectal cancer surgery. Also, duration of hospital stay diminished by 2 days (both after colon and rectal resections). **[Chapter 3]** After 2011 outcomes improved further on a national level.¹⁷

As stated before, other mechanisms than clinical auditing only may have contributed to these improvements. However, the continuous improvement on various outcomes, the reduction of hospital variations, and the thorough validation with the Netherlands Cancer Registry support the idea that clinical auditing can be used as an instrument for the improvement of surgical quality of care.

Part 2. The use of data from clinical audits to evaluate and improve national practice

Audit data can be analysed at a national level, to investigate current national practice and results, to identify high-risk patients and evaluate current referral patterns for these high-risk patients. Extensive research has described risk factors for unfavourable outcome after colorectal surgery, and hospital differences in case-mix. However, neither the distribution of 'high-risk patients' between different hospitals in the Netherlands nor the impact of known risk-factors on outcomes in the Dutch population had been studied before. As high-risk patients are often not included in clinical trials, information on outcomes of treatment for these patients, and scientific evidence on their best treatment are limited. Data from national clinical audit may help to gain more insight in treatment and outcomes for these patient groups.

We have shown that the ‘expected mortality’: the patient’s predicted mortality risk during or after colorectal cancer surgery in the Netherlands, based on the patients’ case-mix factors, can help to gain insight on how high-risk patients are distributed between Dutch hospitals. We found considerable differences in ‘expected mortality’ between individual hospitals and different types of hospitals. We also found that patients with colon cancer with a high risk for postoperative mortality in the Netherlands were more likely to be treated in low-volume hospitals or non-teaching or teaching hospitals, rather than in university hospitals. The higher expected mortality in these hospitals was mostly explained by these hospitals treating patients with a higher ASA-classification, with more comorbid diseases, and more often in a non-elective setting. We found no differences in Standardized Mortality Rates between different types of hospitals. [Chapter 4] In the Netherlands, referral of colorectal cancer patients to university hospitals, or high volume specialized centres is based on the stage of disease, and the existence of complex co-morbidities. However, this referral system does not result in a higher expected mortality in these hospitals. Although patients with complex co-morbidities are often referred to larger or academic centres, the low-volume, non-teaching or teaching hospitals treat more elderly patients with multiple comorbidities. Especially when these patients are treated in a non-elective setting, mortality risk is extremely high and can go up to 41% [Chapter 5].

A possible explanation is that patients in need of an urgent resection may not have the time to choose or be referred for treatment in a high-volume, specialized hospital, and therefore are treated in the local, low volume hospital. Although we failed to find a significant difference in case-mix adjusted outcome between different types of hospitals, [Chapter 4] previous research has shown that a higher annual volume of colorectal cancer resections results in better postoperative outcome. However, a minimum or maximum number needed to treat has never been identified.¹⁸ Also, previous studies have demonstrated that the presence of a specialised surgeon during a non-elective operation improves outcome.^{19,20} Although referral of high-risk patients may be a logistical challenge, it is likely that referral of such patients to specialised centres, where proper facilities for peri-operative care including a specialised surgeon during on-call hours are available, improves outcome. The Association of Surgeons in the Netherlands is currently working on a statement on minimal requirements of hospitals treating patients with colorectal cancer, including the availability of a specialized surgical oncologist or gastro-intestinal surgeon during on-call hours.

By analysing data from clinical audits on a national scale, high-risk patient groups can be identified, and their distribution among Dutch hospitals can be studied. More insight is gained in the current state of treatment and outcome for high-risk patients in the Netherlands, and the magnitude of their operative risk. These data can be used to inform patients and guide clinical decision-making. Also, the relationship between treatment processes and outcomes for these high-risk patients, who are generally excluded from clinical trials, can be analysed. This can lead to the identification of best practices to improve outcomes for these patients.

Part 3. The use of clinical auditing for the evaluation and monitoring of the implementation of new techniques

Clinical audits also form the perfect platform for quality assurance, and the evaluation and monitoring of the implementation of new advances in (surgical) treatment. Although new techniques are extensively investigated in randomized controlled trials before implementation in clinical practice, results after implementation are not often studied. However, the study population included in clinical trials is known to be a specific, often younger and healthier subgroup, whose outcomes may not reflect the outcomes of the full population. Therefore studying the results of a new technique after implementation in the full population may be seen as the essential 'check' step of the PDCA cycle. Also, differences in use and experience may be evaluated using data from a national clinical audit.

A leading example of quality assurance is the Dutch Total Mesorectal Excision (TME) trial, in which the new TME technique was compared to the standard operative technique at the time. To reduce variation in skill and interpretation of the technique between surgeons, participating surgeons were properly trained using workshops videotapes and supervision during the first five procedures. Also, surgeons received immediate feedback on their performance by the pathologist. The new TME technique resulted in a 50% reduction of local recurrence.²¹ However, after the trial was completed, focus on the TME resection diminished. As a result for only 48% of all patients with a rectum carcinoma, a CRM was reported in the DSCA in 2009. 3 years after the introduction of the DSCA, the reporting rate of the CRM had increased to 80%, [Chapter 3] illustrating the importance of a continuous feedback system.

Another example of quality assurance using clinical audits is the introduction of laparoscopic surgery in the Netherlands. In 2007 the Dutch society for endoscopic surgery developed a quality assurance program for the introduction of new laparoscopic techniques. This system was based on a plan-do-check-act cycle involving the development of guidelines for the use and maintenance of instruments, a structured training and certification program and a registration and evaluation system. We showed how this quality assurance system has resulted in a safe and successful introduction of laparoscopic resections for colorectal cancer in the Netherlands. The laparoscopic resection rate in the Netherlands is high compared to international standards with an acceptable conversion rate. [Chapter 6] We also showed that short-term outcome after laparoscopic resections in the Netherlands was better than after open resections, even after correction for case-mix, while outcome after conversion was not different from outcome after open resection. This is in contrast with previous studies, which did not find better outcomes after laparoscopic surgery.²² A possible explanation is that previous randomized controlled trials (RCT's) included a selected, low-risk population, while the benefit of laparoscopic surgery may be larger for more high-risk patients,²³ who are included in national clinical audits such as the DSCA. Although we found differences in laparoscopic resection and conversion rates between hospitals, we found no evidence that these differences affect hospital outcomes of care. [Chapter 6]

Part 4. Using clinical auditing to evaluate quality of care and give transparency to all stakeholders

Overwhelming media attention for variation in hospital quality of care, has lead to a strong societal call for transparency in quality of care. Data on hospital performances on treatment and outcomes of care may be used as 'quality indicators', to evaluate quality of care, and give transparency on quality of care to different stakeholders. These data are thought to improve outcomes of care via two pathways:²⁴

Selection: data may be used by patients to choose a hospital for treatment, or by insurance companies to selectively contract hospitals, ratio being that this 'free market' policy will drive hospitals to improve quality of care and reduce costs. Also, healthcare inspectorate may use these data to identify underperforming hospitals.

Improvement: transparency of quality of care data to other stakeholders may further stimulate hospitals to use data from clinical audits improve their practice and outcomes.

[Chapter 2 and Chapter 3]

Quality of care is often evaluated using 'quality indicators'. Although quality indicators are widely used, the ideal quality indicator, which is appreciated by all stakeholders, has not yet been described.

Quality indicators

Quality indicators are defined as measurable aspects of care that reflect quality of care as a whole. A good quality indicator has several requirements, concerning *importance*, *scientific acceptability* and *usability*.²⁵

- *Importance:* Is the indicator relevant to a large population at considerable risk, and is there an opportunity for improvement? For example, it could be argued that the opportunity for quality improvement is greater in a low risk population, as in a high risk population the influence of the patient and disease related risk-factors is much stronger than the possible influence of quality of care provided. Also, the event-rate of the indicator must be adequate to allow hospital comparisons.^{5,26} However, the definition of an 'adequate' event-rate remains unclear.
- *Scientific acceptability:* data must be reliable and valid.
 - Reliability means that data are reproducible and that all patients concerned are included. Uniform data collection and clear definitions are of major importance for reliable quality indicators. Also, to reliably compare hospital performances, results must be adjusted for hospital differences in case-mix and random variation.
 - Validity means that the quality indicator measures what intends to measure. This means that there is a clear and consistent relation between a good result on the quality indicator, and high quality of care. Currently, hospital quality of care is most often assessed on their performances on process indicators, based on the assumption that a hospital that treats patients according to the latest guidelines will also have good

outcomes. However, for most process indicators currently used in colorectal cancer surgery, an association with outcomes of care has not been proven or studied.²⁷ Moreover, as hospital scores on different indicators are known to be inconsistent,^{28,29} and the use of a single indicator to evaluate the quality of care as a whole bears the risk of a perverse incentive, indicators may also be combined into composite measures.

- *Usability*: the results must be understandable and usable for the intended audience. The usability of an indicator may vary for different stakeholders. For example, the Healthcare Inspectorate may be most interested in safety and effectiveness, while insurance companies may be more interested in efficiency. For patients, information on safety, effectiveness, timeliness, and patient centeredness may be more important. Therefore, when choosing a quality indicator for transparency, *usability* for the intended audience must be kept in mind.

Clinical audits and quality indicators

In the Netherlands, societal call for transparency in quality of care has led to an overwhelming list of quality indicators, which are used to rank and rate hospitals in media and play a large role in the purchase policies of insurance companies. However, for most of these quality indicators, importance, reliability, validity and usability have not been studied, or have proven to be questionable.^{30,31} This is not surprising, as before the implementation of clinical auditing in the Dutch healthcare system, no registration system for quality of care information was available to study quality indicators. Clinical Audits contain detailed, uniformly registered information on processes and outcomes of care, which enable the research for 'good' quality indicators for the Dutch healthcare system.

Process and outcome

Most commonly used quality indicators for colorectal carcinoma are process indicators, as they are less influenced by case-mix and random variation than outcome indicators. However, valid process indicators must concern a process relevant to all selected patients, and have a proven association with relevant outcomes. We studied the association between process and outcome indicators in the DSCA and found that, for some of the process indicators, a good hospital score was associated with favourable scores on outcome indicators; however, this was not true for all process indicators. [Chapter 7] This varying association may be explained by a lack of consistency between different process indicators: hospitals with a good score on one indicator did not necessarily have a good score on another process indicator. Therefore, combining process indicators into one composite measure may be preferable. We have shown how a good score on composite measures for guideline adherence is associated with good postoperative outcome. [Chapter 8] As most processes described in guidelines are thought to have an effect on long term (disease free) survival, but do not influence patients chances for good postoperative outcome, it is not surprising that on a patient level, there was no association between guideline adherence and a patients' chance for good postoperative outcome. [Chapter 8] However, when data were

analysed on a hospitals' level, there was a strong association between guideline adherence and good postoperative outcome. These associations were even stronger when only high volume hospitals were included, indicating that the association was only ameliorated by less reliable results from small volume hospitals. [Chapter 8] Although in some cases there may be good reasons for multidisciplinary team to defer from the guidelines, this will concern the minority of patients. To realize a full guideline adherence for all other patients is an organizational challenge. Therefore, rather than measuring a causal effect, it is more likely that the association between guideline-adherence and outcome represents the 'hospital effect'; the influence of the efforts of dedicated caregivers and a well-organized logistical process, which results in favourable outcome.

Composite measures

Although some outcome measures may be of special importance to a specific patient group, a list of individual outcome indicators representing the quality of care in a hospital may be difficult to interpret by patients: how does one choose between a higher risk for complications, and a lower risk for postoperative mortality? However, previous research has shown that patients would be interested in using a composite measure for outcome indicators: the 'textbook outcome' measure. 'Textbook outcome' represents the percentage of patients for whom all desired (postoperative) health outcomes were accomplished, to choose a hospital of treatment.^{32,33} This measure is simple and *usable* to all stakeholders. For patients, it represents their chances for the most favourable outcome in a specific hospital. For caregivers it gives feedback information on how often treatment is successful. For insurance companies and hospitals, it summarizes patient safety, effectiveness and efficiency, and may therefore be useful in selective contracting. For the healthcare inspectorate this score may guide surveillance-programs. By combining important outcomes of care in one comprehensive measure, the 'textbook outcome' prevents defensive, indicator driven practice. Good clinical decision-making will therefore result in an optimal score on 'textbook outcome'. Moreover, this measure seems discriminative, as only 49% of all patients had a textbook outcome, but hospital 'textbook outcome' rates ranged between 27 and 71%. Even after case-adjustments, there were hospitals with half as many textbook outcomes than expected, but also hospitals with 1.4 times as many textbook outcomes than expected based on their case-mix. We identified eight outlier hospitals, in which quality of care was worse than average, on several aspects. [Chapter 9]

Case-mix adjustments

As hospital processes and outcomes of care are largely influenced by the characteristics of the patients and diseases treated, appropriate case-mix adjustment is thought to be imperative for comparison of hospital performances. However, as registration of case-mix factors is time consuming, questions are raised if case-mix adjustments are necessary for *all* outcome measures. Dimick showed that for coronary artery bypass surgery, unadjusted and adjusted outcomes are highly related, and equally well predicted hospital performances in

the next years. From this research it was concluded that for coronary artery bypass surgery, case-mix did not differ between hospitals. A possible explanation is that the patient group undergoing coronary artery bypass surgery is relatively homogenous.³⁴ Similarly, Snijders et al showed that the large hospital variation in anastomotic leakage rates after colorectal cancer resections in the Netherlands could not be explained by differences in case-mix. This suggests that there are other factors that explain the hospital variation in anastomotic leakage rates.³⁵ We showed, by calculating the expected mortality for all patients treated for colon cancer in Dutch Hospitals, based on only their patient and disease characteristics, hospital average expected mortality ranged from 1.5 to 14%, clearly illustrating the need for case-mix adjustments when comparing hospitals based on mortality after colorectal cancer resections. **[Chapter 4]** These results are supported by the recent findings of Snijders et al, showing that hospital variation in postoperative mortality was significantly reduced after adjustments for case-mix.³⁵

Although hospital variations in outcome indicators may be partly explained by differences in case-mix, this may not be equally important for all outcomes. However, case-mix adjustments still remain imperative for the face-validity of hospital comparisons based on outcome indicators.^{34,35} Without these adjustments, care providers may lose their trust in the validity of hospital comparisons, reducing the incentive for quality improvement, and possibly even resulting in a perverse incentive to, for example, refer the sickest patients in order to improve outcomes. Therefore, when comparing hospitals based on outcome indicators, results should always be adjusted for case-mix.

Relevance, the volume needed to assess quality

Another major difficulty in comparing hospital performances is the ‘problem of small sample size’: when procedural volume is low or adverse events are rare, it is difficult to assess hospital performance, as the confidence intervals for the adverse event rate will be very wide. As a result of this statistical phenomenon, outcomes of low volume hospitals may be five times higher than expected, but there will still be no proof that they are out of the normal range. **[Chapter 10]** We therefore propose a combined measure for volume and outcome to identify hospitals that deliver reliable proof of good quality of care within an acceptable observation period. For these hospitals the combination of their outcomes and the number of patients treated are such that they provide sufficient proof that their outcomes next year, (with consistent performance) will not be worse than a predefined level of substandard care. We found that this combined measure for volume and outcome performed better than measures for volume-only or outcome-only in predicting hospital performance the following year. However, this combined measure for volume and outcome performed better for morbidity than for mortality. **[Chapter 10]** Previous studies have shown that the influence of random variation on hospital performances is larger when outcome measures have a low event-rate, while the proportion of variation between hospital performances explained by systematic variation such as hospital practices is larger when the outcome measure occurs more frequently.²⁶ This may explain why the combined measure for volume and outcome

performed better for morbidity than for mortality, which has a much lower event-rate. Therefore, when comparing hospitals based on outcome measures, the event-rate of the outcome measure must be taken into account.

'Good' quality indicators

When comparing hospital performances, process measures may be used to evaluate implementation of specific processes in hospitals. However, results on a single indicator will not always give a fair reflexion of the quality of the whole process of care. When combined together into a composite measure for guideline adherence, a good hospital performance, reflecting a well-organized care-process and a dedicated team, is highly consistent with good outcome. Therefore a composite measure for guideline adherence is more *valid* and *usable* as an indicator for quality of care. When comparing outcomes of care, one should keep in mind that outcomes of care are often interrelated, and that a good outcome not only involves safety but also effectiveness and efficiency. Furthermore, outcome indicators should be adjusted for case-mix to assure face-validity, and the event-rate of the outcome indicator should be adequate to assure that outcomes are reliable.

Other studies have suggested composite measures combining both process and outcome,^{28,36,37} and even adding structure indicators to this measures, such as hospital volume, teaching status, or nurse to patient ratio's.^{38,39} These studies found that hospital rankings based on these composite measures differ very much from hospital rankings based on simple outcome measures such as mortality or morbidity alone, showing again that quality of care encompasses more than mortality or morbidity alone. Dimick found that his composite measure combining volume, morbidity and mortality and other structural aspects of care, performed well in predicting future hospital performances.³⁸ However, indicators included in these scores were selected and weighted completely based on their ability to predict hospital performances, and not based on (clinical) rationale. Although these scores have a good statistical performance, they may be difficult to interpret for different stakeholders, therewith impairing their *usability*. A hospital failing the measure, will not be able to explain on what basis it failed the measure, or improve performances accordingly. For example, although hospital procedural volume is included in the measure, a hospital failing the measure will not be able to extrapolate the number of procedures needed to improve outcomes the following year.

Therefore we propose a more simple measure combining volume and outcome, which selects hospitals with adequate performances and a sufficient volume to assure that outcomes are likely to be adequate the following year. This combined measure may also be used to evaluate hospital scores on 'textbook outcome', to select those hospitals with a high percentage of patients for who all desired (postoperative) health outcomes were accomplished, in a sufficient volume to assure future performances will be adequate.

The way forward

The successful and fast implementation of the DSCA, and the impressive improvement of quality of care after its implementation have led to the initiation of many new audits. Using the DSCA as a blueprint, new audits can be developed and running within one-year. Also, auditing is not limited to the surgical or oncological field: the audit for melanoma has included systemic treatment after surgery, the Dutch vascular surgeons have initiated two audits evaluating treatment of abdominal aortic aneurysms and carotid surgery, for paediatric surgery a clinical audit is being developed, and there is a clinical audit for the treatment of cerebrovascular accidents and Parkinson's disease. We expect and hope that in a few years time, all major disease entities are evaluated in a clinical audit. A recent report of the Dutch Health Organization also underlines that clinical auditing may be the best way forward to transparency and improvement of quality of care.⁴⁰

However, increasing the number of clinical audits also means increasing the amount of administrative work. Although most Dutch hospitals are nowadays equipped with an electronic patient file (EPF) system, only very few hospitals have managed to integrate data collection within their daily practice, automatically submitting required data when writing up their patients notes. Although these techniques are widely available, and are likely to result in a more reliable and complete registration, implementation is often complex and laborious. However, the success of clinical auditing has pushed this issue to the top of the priority list of many stakeholders. Recently the Dutch federation of university hospitals has published a report advocating implementing a new, uniform way of documentation, which enables data collection straight from the electronic patient file system.⁴¹

Best practices and regional 'quality of care' conferences

Not only can feedback data be used by hospitals to improve their practice and outcomes, but data can also be used to discuss regional differences in 'quality of care' conferences. By sharing feedback data with other hospitals, lessons may be learned on how to change and improve performances. Those hospitals with better results may share the practices that lead to their results: best practices, which may be implemented in other hospitals in the region. Also these data may be used for organizational arrangements or referral of specific patient groups. For example the Dutch province Friesland has hired a consultant to develop an optimal referral system in the region based on data from clinical audits that improves outcomes and maybe even reduces costs.

Transparency of care

Until recently, data from the DSCA on individual hospital performances have not been publicly reported. Insufficient trust in validity of the data and fear of registration fraud, perverse incentives or naming and blaming or even repercussions, has prevented early disclosure of these data. However, recently the Boston Consulting Group published a report on quality

improvement using clinical auditing. Using the Swedish audits as an example they showed that disclosure of valid hospital-specific performance data does not result in a naming and shaming scandal, but in fast, nationwide improvement of quality of care, and reduction of healthcare costs.⁴² Therefore, in 2012, the ASN decided on a staged transparency program disclosing more data every year: the first year, only hospital case-volume is disclosed, the following year process indicators are published, and the third year, outcome indicators are disclosed. Such a staged transparency program anticipates time for data quality control, but also fulfils societal expectations and needs for insight in hospital quality of care. Twice a year medical specialists from the various audits and representatives of their professional organizations (e.g. the ASN), together with insurers and representatives of the patient organizations, define that years' quality indicators. Together they agree on the quality indicators that will be used that year to guide selective contracting and to inform patients.

The most important stakeholder in this case may be the patient. However, previous studies have shown that patients do not often use hospital quality of care information for their choice for a hospital of treatment, because they do not understand or trust it.^{43,44} Using the data from clinical audits, important, reliable, valid and usable information on hospital performances can be produced for patients to base their choice for a hospital of treatment on. Previous research has shown that patients would like to use a measure like the 'textbook outcome' to base their choices on.³² Further research should further explore how patients' needs for hospital quality of care information might best be fulfilled; e.g. the type of information patients are most interested in, and the best way of presenting this information so that is usable for patients. Furthermore, further research should evaluate if public availability of quality of care information, presented in the way patients find it most usable, also results in an increased understanding, trust and use of this information.

However, data from clinical audits only reflect one aspect of quality of care. Recently, the Dutch Federation of Cancer Patient Organizations (NFK) has defined four aspects of quality of care, which they consider relevant to patients. These are:

Structure information, describing what is available in a hospital, and whether a hospital meets the standards set by the professional associations concerned

Process and outcome information from clinical audits, describing if the hospital meets the standards for process and outcome indicators set by the professional associations concerned.
Patient Reported Outcome Measures (PROM's), describing results of treatment and postoperative quality of life reported by patients.

Consumer Quality index, describing the subjective experience of patients treated in that hospital.

The Dutch Institute for Clinical Auditing, together with the NFK and the Dutch Healthcare Insurance companies have recently started a transparency project integrating these four aspects of quality of care, using colorectal cancer as a showcase. Different aspects of quality of care are reported on a transparent and publicly available website. This website, of which

the design and contents are dictated by patients, may help regain societal trust in quality of healthcare in the Netherlands.

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