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Evaluating and improving quality of colorectal cancer care

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Chapter 2

'Clinical auditing', a novel tool for quality assessment in surgical oncology

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ABSTRACT

Objective: To determine whether systematic audit and feedback of information about the process and outcomes improve the quality of surgical care.

Design: Systematic review.

Method: Embase, Pubmed, and Web of Science databases were searched for publications on 'quality assessment' and 'surgery'. The references of the publications found were examined as well. Publications were included in the review if the effect of auditing on the quality of surgical care had been investigated.

Results: In the databases 2415 publications were found. After selection, 28 publications describing the effect of auditing, whether or not combined with a quality improvement project, on guideline adherence or indications of outcomes of care were included. In 21 studies, a statistically significant positive effect of auditing was reported. In 5 studies a positive effect was found, but this was either not significant or statistical significance was not determined. In 2 studies no effect was observed. 5 studies compared the combination of auditing with a quality improvement project with auditing alone; 4 of these reported an additional effect of the quality improvement project.

Conclusion: Audit and feedback of quality information seem to have a positive effect on the quality of surgical care. The use of quality information from audits for the purpose of a quality improvement project can enhance the positive effect of the audit.

INTRODUCTION

'Clinical Auditing' is a relatively new quality instrument in the Dutch healthcare system. Where regular evaluation of processes and end products is common in most branches, this is not the case for healthcare. In 1915, dr. Ernest Amory Codman, surgeon at Harvard University, advocated implementation of auditing, 'the systematic and critical analysis of quality of care delivered, including the process of diagnosis, treatment and outcomes of care, by those who deliver it', in medical practice. However, his visionary ideas were not appreciated by his colleagues. Only a century later, the use of auditing for quality improvement, transparency and accountability was internationally appreciated. Clinical auditing is most commonly used in surgical oncology, as in this specialty, the relation between intervention and outcomes, or quality and costs is most obvious: a complication can result in repeated investigations, percutaneous interventions, reoperations, a long hospitalization and even treatment in an intensive care unit, all associated with substantial costs. Therefore, continuous improvement of quality of care is in the best interest of patients, but also of society.

In 2009 the 'Dutch Surgical Colorectal Audit' (DSCA, www.dica.nl) was initiated, following previous international examples such as the 'National Surgical Quality Improvement Program' (NSQIP; www.acsnsqip.org) in the United States and the 'National Bowel Cancer Project' (NBOCAP) in the United Kingdom (www.ic.nhs.uk/services/national-clinical-audit-support-programme-ncasp/cancer/bowel). The DSCA is a initiative of the Dutch Society for Surgical Oncology (NVCO), the Dutch Society for Gastro-intestinal Surgery (NVGIC) and the Dutch Colorectal Cancer Group (DCCG). By 2010, more than 20.000 patients are registered in this nationwide process and outcome registration for primary colorectal carcinoma. 98% of all Dutch hospitals participate, and from 2010 on,

participation in the DSCA is a national performance indicator. Purpose of this registration system is to realize demonstrable quality improvement by means of systematic registration and feedback of reliable, case-mix adjusted information on the processes and outcomes of care delivered.

Recently, various medical professional associations have been facilitated by the Dutch Institute for Clinical Auditing (DICA; www.dica.nl) to develop a clinical audit for breast, oesophagus, gastric and lung cancer, all according to the principles pioneered by the DSCA. These, and new developing audits now cover most of the surgical oncology field. However, clinical auditing also requires investments, not in the least from professionals, for whom the registration load is considerable. We therefore investigated the available evidence on whether measurement and feedback of information on process and outcome of surgical care result in improvement of process and outcomes of care by means of a systematic review of the available literature.

METHODS

Search strategy

We searched for relevant articles in Pubmed, Web of Science and Embase, published before May 15th 2011. In this search, combinations of the 'medical subject headings' (MeSH-terms) 'surgery' (subdivided in 'surgical care' and 'operative procedure') and 'outcome- and process assessment' (subdivided in 'medical audit', 'outcome assessment', 'clinical audit', 'quality assurance' and 'benchmarking') were used. Outcome measures were process and/or outcomes of care, or guideline adherence. There were no restrictions on publication language. In addition, relevant websites and reference lists of included articles were screened for relevant articles.

Article selection

Studies describing the effect of auditing on process and/or outcome indicators were selected. Auditing was defined as 'systematic measurement and feedback of structure, process and/or outcome information, in order to improve quality of care'; where needed, changes may be implemented at individual, team, hospital or national level and monitored by a new audit cycle.

Inclusion criteria were: a) at least one process or outcome indicator, or guideline adherence was measured, before and after the audit; b) the indicator or guideline was developed to evaluate quality of care, c) the indicator or guideline was focused on surgical care.

Relevant articles were selected by 2 independent researchers (NK en NvL), evaluating title and abstract of all retrieved publications. Discrepancies were discussed and when necessary, a third reviewer (MW) was consulted. Selected articles were included when all criteria were met. Included articles were subdivided in articles describing (a) the effect of auditing only, (b) the effect of auditing in combination with a quality improvement project and (c) comparing the effect of auditing with and without a quality improvement project. The level of evidence was assigned according to the CBO-guideline for 'Evidence-based Guideline development' (www.cbo.nl/thema/Richtlijnen/EBRO-handleiding/A-Levels-of-evidence/).

RESULTS

The search resulted in 2415 publications. After screening of titles and abstracts, 62 relevant articles were identified. After screening the reference lists of the selected articles, 9 more articles were selected. After reading

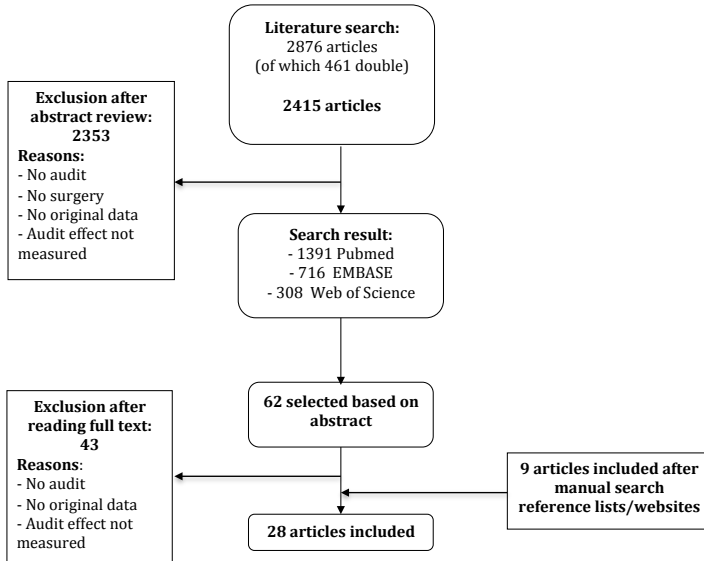


Figure 1. Process of selecting articles for systematic review.

the full text, 28 articles were included (figure 1). Reasons for exclusion after reading the full text were: the audit did not fit our definition; the article did not describe original data, or the effect of the audit was not quantified.

Tables 1, 2 and 3 give an overview of the selected articles. Most articles were prospective cohort studies. Comparative studies (comparing two interventions) were summarized in table 3. We found 2 randomized controlled trials (RCT) (table 3). Most studies were conducted in the United States in the last 5 years.

Table 1. Overview of prospective cohort studies investigating the effect of auditing in surgical interventions.

Author, year	Type of surgery	Setting	Feedback		Effect*	Level of evidence†
			Type	Frequency		
Antonacci, 2008 ¹	All types of surgery	3 hospitals	Meeting Report	Weekly Annual	Improvement: • Decrease of no of incidents in theatres (wound infections, conversion, waste of implants and cancelled procedures)	B
Duxbury, 2003 ²	Colorectal cancer surgery	1 hospital	Not specified	Once	Improvement: • Guideline adherence from 33 to 72%§	B
Freeman, 2002 ³	Hip fractures	10 hospitals	Not specified	Once	Improvement: • Process improved‡ • Morbidity decreased‡ • Mortality unchanged	B
Galandruk, 2004 ⁴	Colorectal surgery	23 surgeons	Meeting Report, newsletter	Every month Annual Not specified	Improvement: • Guideline adherence improved‡	B
Hall, 2009 ⁵	All types of surgery	NSQIP	Report	2/year	Improvement: • In 66% of hospitals O/E mortality decreased ‡ • In 82% of hospitals O/E morbidity decreased ‡	B
Hammermeister, 1994 ⁶	Coronary bypass surgery	45 hospitals	Report	2/year	Improvement: • Decrease of O/E mortality (p = 0,06)	B
Henke, 2010 ⁷	All types of surgery	MSQC, NSQIP	'Real time'- interface Meeting	Continuous 4/year	Improvement: • Morbidity decreased from 15,8 to 13,8%‡ • Mortality unchanged	B

Table 1. Overview of prospective cohort studies investigating the effect of auditing in surgical interventions. (continued)

Author, year	Type of surgery	Setting	Feedback		Effect*	Level of evidence†
			Type	Frequency		
Khuri, 2002 [§]	All types of surgery	NSQIP	Report	2/year	Improvement: <ul style="list-style-type: none"> • Morbidity decreased 45%[§] • Mortality decreased 27% 	B
Khuri, 2008 [§]	All types of surgery	NSQIP	Report	2/year	Improvement: <ul style="list-style-type: none"> • Mortality decreased with 8,7%[‡] • Wound infections decreased with 9,1%[‡] • Renal complications decreased with 23,7%[‡] 	B

NSQIP = National Surgical Quality Improvement Program (VS); MSQC = Michigan Surgical Quality Collaboration, a part of NSQIP; O/E = Observed/Expected (standardized for case-mix)

*Compared to baseline measurement before audit.

†Level B; prospective cohort study insufficiently controlled for confounders.

‡P < 0,05.

§Statistical significance not investigated

Table 2. Overview of prospective cohort studies investigating the effect of auditing in combination with a quality improvement project in surgical interventions.

Author, Year	Type of surgery	Setting	Feedback		Improvement project	Effect*	Level of evidence
			Type	Frequency			
Aitken, 1997 ¹⁰	All types of surgery	LSA	Meeting Report	Weekly Annual	Specialized ward Introduction of new methods	Improvement: • Decrease of mortality and complications†	B
Aletti, 2009 ¹¹	Treatment of ovary cancer	1 Hospital	Not specified	Not specified	seminars cadaver training	Improvement: • Increase radical resections: 63 to 79%‡	B
Dellinger, 2005 ¹²	All types of surgery	44 Hospitals	Report	4/year	Development of guidelines for prevention of surgical site infections	Improvement: • Decrease in wound infections: 2.3 to 1.7%‡	B
Doran, 1998 ¹³	All types of surgery	2 Hospitals	Report	Every 2 weeks	Development of guidelines Adjustments to process of care	Improvement • Detubation within 6 hours: 5% to 70% • Decreased costs \$18,200 to \$14,700 per patient • Decreased median hospital-stay: 8.6 to 6.0 dayst	B
Forbes, 2008 ¹⁴	All types of surgery	1 Hospital	Report	Every month	Development of guidelines for prevention of surgical site infections	Improvement: • Guideline adherence improved‡ • Surgical site infections: unchanged	B

Table 2. Overview of prospective cohort studies investigating the effect of auditing in combination with a quality improvement project in surgical interventions. (continued)

Author, Year	Type of surgery	Setting	Type		Improvement project	Effect*	Level of evidence
			Feedback	Frequency			
Garnerin, 2007 ¹⁵	All types of surgery	1 Hospital	Presentations	4/year	Development of guidelines for prevention of 'wrong site/patient surgery'	Improvement: • Increased guideline adherence from 32 to 63%	B
Haynes, 2009 ¹⁶	All types of surgery	3 Hospitals	Not specified	Once	surpass checklist	• Decreased mortality: 1.5 to 0.8%† • Decreased morbidity: 11 to 7%‡	B
Holman, 2004 ¹⁷	coronary bypass surgery	21 Hospitals	Not specified	Once	Defining performance-indicators 'site-visits' Education	Improvement • Improved performance at most indicators† • Outcomes unchanged	B
O'Connor, 1996 ¹⁸	coronary bypass surgery	5 Hospitals	Report	3/year	Annual meeting Quality training Site visits	Improvement: • Decreased mortality: 4.8 to 3.6%†	B
Potenza, 2009 ¹⁹	All types of surgery	1 Hospital	Meeting	Every month	Development of guidelines for safe surgery	Improvement: • Increased guideline adherence: from 80 to 91%	B
Richardson, 1998 ²⁰	All types of surgery	1 Hospital	Not specified	Not specified	Development of guidelines for ordering packed cells to reduce the crossmatch/transfusion ratio	Improvement: 'crossmatch/transfusion-ratio' from 2.8 to 1.8†	B

Table 2. Overview of prospective cohort studies investigating the effect of auditing in combination with a quality improvement project in surgical interventions. (continued)

Author, Year	Type of surgery	Setting	Feedback		Improvement project	Effect*	Level of evidence
			Type	Frequency			
Tavris, 1999 ²¹	All types of surgery	15 Hospitals	Not specified	Once	Development of performance indicators for postoperative pain management	Improvement: • Improved performance on indicators 14 of 15 hospitals	B

LSA = Lothian Surgical Audit (Scotland).

*compared to baseline measurement before audit.

Level B: prospective cohort study insufficiently controlled for confounders.

† Statistical significance not investigated.

‡P < 0.05.

Table 3. Overview of studies comparing effect of auditing with auditing combined with an improvement project in surgical care.

Author, year	Design* (Comparison)	Type of surgery	Setting	Feedback		Improvement project	Effect
				Type	Frequency		
Berenguer, 2010 ²⁶	Prospective cohort study (Audit + improvement project vs. audit)	Colorectal surgery	1 hospital in NSQIP	Report	2/year	Guideline for prevention of SSI	<ul style="list-style-type: none"> • Audit + improvement project: • Guideline adherence improved from 38 to 92%† • Decrease of SSI from 13,3 to 8,3%† • Audit only (NSQIP): • Increase of SSI from 9,7 to 10,5%
Campbell, 2010 ²⁷	Prospective cohort study (Audit + improvement project vs. audit)	All types of surgery	MSQC	Meeting Report	4/year 2/year	MSQC: meetings and best practices in addition to audit and feedback NSQIP: audit and feedback	<ul style="list-style-type: none"> MSQC: decreased morbidity rate from 10,7 to 9,7%† NSQIP: no difference in morbidity rate (12,4%), no difference in mortality Odds: ratio for complications (MSQC vs NSQIP): 0,90†
Ferguson, 2003 ²²	RCT (Audit + improvement project vs. control ‡)	Coronary bypass surgery	NCD	Not specified	Not specified	Educational products, Presentations, Opinion leader, call to action letters	<ul style="list-style-type: none"> Larger improvement in preoperative β-blockade in intervention group than in control group† Other process indicator not improved

Table 3. Overview of studies comparing effect of auditing with auditing combined with an improvement project in surgical care. (continued)

Author, year	Design* (Comparison)	Type of surgery	Setting	Feedback		Improvement project	Effect
				Type	Frequency		
Guadagnoli, 2000 ²³	RCT (Audit + improvement project vs. audit)	Breast cancer surgery	Not specified	Not specified	Once	Opinion leaders presentations and educational products	In both groups the possibility of a breast conserving treatment was more often discussed† In both groups the frequency of breast conserving surgery increased† no difference in effect between groups
Neumayer, 2000 ²⁴	Prospective cohort study (Audit + improvement project vs. audit)	All types of surgery	NSQIP	Report	2/year	Guideline for prevention of SSI	Decrease in SSI from 5.5 to 2.9%† Hospital returned from negative outlier in NSQIP to average performing hospital
Reilly, 2002 ²⁶	Prospective cohort study (Audit, then improvement project)	All types of surgery	1 hospital	Report	Every month	Guideline for prevention of SSI	SSI: Before audit 14% After audit 10%† After improvement project 8%†
Sheikh, 2002 ²⁵	Prospective cohort study (Audit + improvement project vs. control ‡)	Prostate cancer surgery	Not specified	Not specified	Not specified	Presentations and information Treatment guideline	No difference in radical prostatectomy rates between groups

NSQIP = National Surgical Quality Improvement Program (VS); MSQC = Michigan Surgical Quality Collaboration, part of the NSQIP; NCD = National Cardiac Database SSI = Surgical Site Infections

*Level of evidence: A2 (comparative clinical studies such as randomized controlled trials or large cohort studies sufficiently corrected for confounders).

†p < 0.05.

‡Control: no audit, no improvement project.

Interventions and outcome measures

Nine studies described the effect of auditing only (table 1).¹⁻⁹ Twelve studies described the effect of auditing in combination with a quality improvement project (table 2),¹⁰⁻²¹ such as the development of guidelines or checklists, in combination with educational meetings or newsletters. For example, one of these studies described the effect of a protocol for prevention of wound infections.¹² Seven studies (2 RCT's and 5 prospective cohort studies, of which one longitudinal) described the effect of audits in combination with a quality improvement project compared with auditing only (table 3).²²⁻²⁸ One of these studies compared results at three subsequent moments: before and after the start of the audit, and after the quality improvement project resulting from the audit.²⁸ The manner and frequency of feedback varied. Information was presented in newsletters, websites or during specialist meetings, once or on weekly or annual basis. Three articles did not describe method nor the frequency of feedback.^{20,22,25} Most commonly described outcome measures were process indicators and guideline adherence (6 articles),^{2,4,14,15,19,20} and the outcome indicators 'complications' and 'mortality' (13 articles),^{1,5-12,18,22,23,28} or a combination of these (8 articles)^{3,13,16,17,21,24,26,28}. Outcomes were often compared with a baseline measurement.

Effect of auditing

In 21 of 28 studies a statistically significant positive effect was described of auditing or of auditing in combination with a quality improvement project. In 5 studies, a positive effect was described, but no statistical tests were performed.^{5,8,10,13,15} In 1 study, the positive effect was not statistically significant ($p = 0.06$);⁶ another study found no difference.¹⁴ Six studies found a partial improvement, on some of the outcome measures investigated.^{3,7,11,14,16,25}

Effect of auditing in combination with quality improvement project

Three studies, as a part of the NSQIP, compared the results of local improvement projects with other participants of the NSQIP (benchmarking).^{24,26,27} Two of these studies described results of one hospital, which was a negative outlier in a previous report. In both studies, the improvement project resulted in the hospital returning to an average positioning in the NSQIP. This was interpreted as a faster improvement than the total group of participating hospitals. One RCT investigated the effect of auditing with or without a quality improvement project consisting of implementation of a treatment guideline.²³ The study described an overall increase of guideline adherence, but no additive effect was found of the improvement project. In 3 of 4 comparative prospective cohort studies, a statistically significant improvement was found in the group with an improvement project compared to the group with auditing only.

The second RCT investigated the effect of auditing in combination with a quality improvement project compared to no audit.²² Auditing, combined with this improvement project resulted in a significant quality improvement. Another, observational study compared the effect of auditing or improvement projects with no intervention and found no differences.²⁵

DISCUSSION

The results of our review suggest that the clinical auditing of process and outcomes of care, improves the quality of care. Clinical auditing can be combined with 'benchmarking', comparing own results with those of other hospitals, or with improvement projects. The improvement of

quality of care appears to be primarily accountable to the registration and feedback of information to professionals.

Previous reviews described similar results. A recent Cochrane review on the effect of auditing on the quality of care in a broader perspective than surgical care only, reported a positive effect of auditing on the outcome measures.²⁹ However, the magnitude of improvement varied strongly between studies. A larger effect of auditing was found when the baseline situation was poor, and the feedback was more frequent and combined with educational sessions. The Cochrane review was limited to RCT's of which only two described surgical patients.

A second review in 1991 also found a positive effect of auditing on quality of care, especially when a target for improvement was set before the start of the audit.³⁰ When the auditing process, including feedback, was build into the process of care, the effect was found to be greater. The present study supports the previous findings of a positive effect of auditing of quality of surgical care. By expanding our search beyond RCT's we were able to include more recent studies, reporting on various examples of clinical outcome registrations; apart from the RCT's we included 5 large prospective cohort studies with a level of evidence A2. However, most studies included had a longitudinal design, measuring the outcomes before and after implementation of the audit. A control group, in which no audit was conducted, was usually not available (level of evidence B). The observed improvements could therefore also be explained by autonomous evolvement of care instead of the clinical audit. Moreover, most studies only described short-term effects of clinical auditing. These effects could partly be explained by the Hawthorne-effect: the extra attention for the outcome measures brought on by the study, improves the medical practice for the duration of the study.

The value of clinical auditing

Although clinical auditing cannot resolve all challenges of surgical oncology, it may improve treatment and survival of cancer patients. Previous studies such as the Dutch 'Total mesorectal excision' (TME)-trial, in which quality of rectal surgery was standardized and reviewed, showed how quality assurance of the surgical procedure can improve local control and survival in the study population.³¹ However, patients included in studies often represent a specific, more favourable selection of the full population. National clinical audits can be used to evaluate the effect of clinical practice on the full population, and to optimize practice when needed. Until recently, very little was known about the extent to which guidelines were followed, and the reasons for not adhering to guidelines. Clinical audits can be used as a platform for guideline evaluation, and implementation of new advances in technique or improvement projects. Based on information from these audits, best practices can be identified and implemented, and the effect of these best practices can be evaluated. In this way, professionals get more insight in the quality of care they deliver, but are also guided in how they can improve.

Quality instrument

Clinical auditing is preferably used where a large effect can be established such as diseases involving large groups of patients or procedures that involve a considerable risk at adverse events. The data set should be based on an up-to-date evidence-based guideline, and an expert committee should be responsible for the definition of outcome measures and relevant case-mix factors (patient or disease related factors influencing the probability for the outcome measure). In this way, doctors are in the lead to define the essential processes which lead to the perfect hospitalization, and which will serve as their benchmarks. The success of clinical auditing therefore depends on the involvement and dedication of professionals. For a frequent and timely feedback, short af-

ter the completion of the care process, data are collected from electronic patient files or by means of a 'web based' registration system.⁷

With a complete national database, uniform definitions and the possibility to adjust for differences in case-mix and random variation, clinical auditing is a valid and reliable instrument for measuring and reporting on hospital quality of care. The results are of great value, not only for providers but also for policy makers, healthcare insurance companies, and patients. National clinical audits could also be used to support and control the imminent advances in oncological care such as centralization, regionalization and risk-based referral. Therefore, the implementation of a continuous clinical auditing cycle, consisting of guideline development and implementation, subsequent auditing, followed by education and visitation and finally auditing of the results, is strongly advised in any medical profession.

CONCLUSION

Clinical auditing is a relatively new quality instrument in surgical oncology, which offers healthcare providers an insight in quality of care delivered. Clinical auditing may not only facilitate reviewing and benchmarking of providers' practices, but also offer insight in targets for quality improvement. Final goal is to assure that all Dutch patients receive optimal quality of surgical care.

Take home message

- 'Clinical auditing' is defined as the systematic measurement and feedback of quality of care delivered, concerning patients, diagnostics, treatment and outcomes.

- The value of clinical auditing for practitioners should outweigh registration load
- Clinical auditing is increasingly used to monitor and improve quality of surgical oncological care.
- Clinical audits for the surgical treatment of bowel cancer, breast cancer, oesophagus and gastric cancer and lung cancer are now implemented in the Dutch healthcare system.
- Clinical auditing has a positive effect on the quality and outcomes of surgical care.
- Combining clinical auditing with a targeted quality improvement project, such as concentration of oncological care, or development of a treatment guideline, enlarges the effect.

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