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Measuring quality of care for colorectal cancer care : comprehensive feedback driving quality improvement

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Chapter 7

Evaluating the validity of quality indicators for colorectal cancer care

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Abstract

Background

Quality indicators (QI) have been developed to measure quality of colorectal cancer care in the Netherlands. The aim of this study is to evaluate if these QI correlate with each other (construct validity) and if these QI consistently assess the quality of colorectal cancer care in a hospital (internal consistency).

Methods

The performance of 85 hospitals participating in the Dutch Surgical Colorectal Audit between the 1st of January 2010 and 31st of December 2010, were evaluated on nine QI: three process indicators for colon cancer, three process indicators for rectal cancer and three outcome indicators. Correlations between all QI were evaluated for colon and rectal cancer care separately and consistency between all QI was assessed.

Results

Hospital performance on the nine QI ranged widely. Most evaluated process indicators for colorectal cancer care did not correlate with each other, but were associated with better hospital specific patient outcomes. There was little consistency between any of the combinations of process and outcome indicators in assessing hospital performance.

Conclusion

QI on colorectal cancer care do provide complementary information, but individual QI are not suitable as a surrogate measure for the quality of colorectal cancer care. More comprehensive measures are needed for true assessment of hospital performance.

Introduction

In order to increase transparency and improve quality of healthcare, numerous organisations have developed quality indicators (QI) to measure the quality of colorectal cancer care. 2,4-6 QI are defined as “measurable aspects of care that reflect the quality of care” and serve as benchmarks by which healthcare providers, payers and policy makers can measure processes and outcomes of care.

Most often, QI reflect process measures. Process measures have the advantage that data are usually readily available from (administrative) databases and the influence of patient or tumour characteristics (‘case-mix’) is limited. Also, process measures usually are actionable. Outcome measures, on the contrary, reflect the results of care for the patient and therefore have a more intuitive relation with quality of care, but they are highly influenced by case-mix factors and more difficult to obtain.⁷

In the Netherlands, the Healthcare Transparency Program (HTP), a governmental project introduced to coordinate the development of quality indicators, has defined eight indicators for colorectal cancer care. 8-12 In addition to the HTP, the Dutch Healthcare Inspectorate (DHI) uses “the unplanned reoperation rate after colorectal surgery” as a QI for colorectal cancer care. 13,14 All these QI have been developed in expert consensus meetings and are derived from (inter-)national evidence-based guidelines. The QI were developed with apprehension of the criteria for a good quality indicator and are regularly revised and evaluated (see textbox).

These QI were originally developed as a screening tool for the quality of care, with the assumption that process indicators, reflecting the organization of care, correlate with each other and with patient outcomes at a hospital level: if a hospital performs well on one indicator, it will perform well in other areas. However, a consistent relation between favourable results on process indicators and patient outcome has not always been shown. 15,16 Moreover, adherence to process measures may even have led to unintended harm. 17 With the increasing use and public reporting of hospital-specific QI results, a more robust scientific base is needed. Validity of QI can be evaluated by testing several aspects, including criterion, construct and content validity and internal consistency (see textbox). Although reports are emerging on the criterion validity of individual indicators, the other aspects remain underexposed.

To monitor and benchmark the quality of colorectal cancer care in the Netherlands, in 2009 the Dutch Surgical Colorectal Audit (DSCA) was initiated (www.clinicalaudit.nl). In this national registry, detailed data on both diagnostic and therapeutic processes and short-term outcomes are collected. Also, data on patient characteristics are registered, allowing adjustment for differences in case-mix between hospitals.

The detailed registration of the DSCA provides the opportunity to investigate the validity of QI for colorectal cancer care in the Netherlands on two aspects:

What makes a good Quality indicator (QI):[1,2]

Important: the QI must be relevant, involve a high-risk condition or represent an opportunity for improvement

Scientific acceptable: the measure must be reliable and valid.

- **Reliability** means that the indicator gives the same result on repeated measures; this requires the use of uniform definitions and complete data.
- **Validity**[3] means that the indicator measures what it is intended to measure: quality. This requires first that the methodological quality is good, i.e. that differences in case-mix and random variation are taken into account (criterion validity). Secondly, the number of indicators has to be a representative sample to give 'appropriate coverage' of the quality of care in a hospital (content validity) and the indicators have to correlate with each other (internal consistency). Third, an indicator has to be correlated with quality, thus with other performance measures and patient outcomes (construct validity).

Feasible: data for reporting QI should be feasible to obtain

Usable: the intended audience must understand results of the measure

construct validity: do process indicators correlate with each other and with short-term outcomes?

Internal consistency: do indicators consistently assess the quality of colorectal cancer care in a hospital?

Methods

Data

The dataset was retrieved from the DSCA, a nationwide, web-based database in which patient-, tumor-, diagnostic- and treatment characteristics as well as pathology and outcome data are registered for patients that undergo a resection of a primary colorectal carcinoma in the Netherlands. Details of this dataset regarding data collection and methodology have been published previously.¹⁸ The dataset was based on Dutch evidence-based guidelines (www.oncoline.nl). After crosschecking with the Netherlands Cancer registry (NCR), estimated completeness in the year 2010 was 93%.^{19,20} All Dutch hospitals participated in the registry. (www.clinicalaudit.nl)

Hospitals and patients

All hospitals participating in the DSCA between the 1st of January 2010 and 31st of December 2010, were evaluated. Patients of hospitals that registered less than 30 patients with a date of surgery in 2010 were excluded. Furthermore, as case-mix correction is imperative for evaluating outcome of care, hospitals that failed to fill in the required case-mix factors for more than 15% of the registered patients were excluded.

Analyses of hospital performance were done on all patients with a date of surgery between the 1st of January 2010 and 31st of December 2010, and inclusion before March 15th 2011. Patients that underwent an urgent or acute resection, or were treated for a recurrence of a colorectal carcinoma or multiple synchronous colorectal tumours were excluded.

At March 15th 2011, 91 hospitals registered a total of 8835 evaluable patients with a date of surgery between January 1 and December 31 2010 in the DSCA. After exclusion of hospitals that registered less than 30 evaluable patients (3 hospitals, 16 patients), patients with multiple synchronous tumours (253 patients) and urgent and acute patients (1228 patients) and hospitals that had not filled in detailed case-mix factors for more than 15% of their patients (4 hospitals, 367 patients) a total of 85 hospitals treating 6971 patients, were included for analyses.

Quality indicators

A team of medical experts developed QI used in the DSCA, using the Delphi method.²¹ All QI are based on (inter-)national evidence based guidelines and reflect guideline adherence.^{9,13} The definitions of five QI are equal to the QI used by two governmental agencies, the DHI and HTP. All QI are described in detail in the appendix.

Process indicators

Hospital performance on process indicators was calculated for colon and rectum cancer care separately, as the process of care for patients with a colon carcinoma encompasses different aspects than for patients with a rectum carcinoma.

The following process indicators were selected in this study, each reflecting different stages of colorectal cancer care.

Process indicators for the treatment of colon cancer:

- The percentage of patients, who had a *'complete colonoscopy'* before the resection. Complete colonoscopy is defined as a complete visualisation of the colon until Bauhini's valve by colonoscopy or ct-colonography
- The percentage of patients who had *adequate staging* by visualisation of lungs and liver before resection, by either CT-thorax or X-thorax and CT-abdomen or ultrasound respectively.
- The percentage of patients for whom *more than 10 lymph nodes* retrieved are examined pathologically after the resection.

Process indicators for the treatment of rectal cancer:

- The percentage of patients, who are *discussed in a multidisciplinary meeting* before the resection. In a multidisciplinary meeting participation of at least a surgical oncologist, medical oncologist, pathologist, radiologist and radiotherapist are required.
- The percentage of patients who had *adequate tumour staging* before the resection by a MRI or CT of the pelvis.
- The percentage of patients with a *reported circumferential margin (CRM)* of the resection specimen in the pathology report.

Outcome indicators

The following outcome indicators were selected for both colon and rectal cancer care:

- The percentage of patients who had an *unplanned reoperation*.
- The *risk-adjusted 30-day mortality*, defined as mortality within 30 days after resection.
- The *risk-adjusted morbidity* rate, defined as patients with postoperative complications requiring a re-intervention, patients who deceased or patients with a postoperative length of stay longer than 14 days.

The risk-adjusted mortality rate was calculated as the quotient of the observed mortality rate, and the expected mortality rate, multiplied by the average mortality rate in the population. An expected mortality was calculated for each patient using a multivariate model. The model included all case-mix factors registered in the DSCA: age, gender, comorbidity (Charlson Comorbidity Index), previous abdominal surgery, Body Mass Index, American Society of Anaesthesiologists classification (ASA), local tumour invasiveness (T-stage), disseminated disease (M-stage), neoadjuvant (chemo-)radiation therapy, preoperative tumour complications, type of resection, additional resection for tumour invasion and/or metastasis. The average expected mortality in a group of patients formed the expected mortality rate of that group.⁷

In a similar way, hospital risk-adjusted morbidity rates were calculated.

Statistical analyses

QI intend to measure the quality of care in a hospital, therefore all analyses were performed *at a hospital level*. First, means and ranges of hospital performance were calculated for each of the 9 selected QIs. After this, different metrics were used to evaluate construct validity and internal consistency.

Construct validity

The construct validity describes how process indicators correlate with each other and with short-term outcomes.³ To evaluate criterion validity, the correlations between all combinations of process and outcome QI were calculated using a Pearson correlation test and results were presented in matrix scatterplots. Next, a Poisson regression, for colon and rectal cancer apart, was performed to test the correlation between process indicators and outcome indicators.

Internal consistency

The content validity describes if indicators give appropriate coverage of the overall quality of care and do consistently assess the quality of colorectal cancer care in a hospital (internal consistency).³ To evaluate this, internal consistency between all process and outcome indicators for colon and rectal cancer care, was measured using the Cronbach's alpha. Cronbach's Alpha computes the inter-item correlations or covariances of all pairs

of variables and Cronbach's Alpha statistic for the scale formed of them. The measure α , indicates how different items test the same concept and is often used to validate psychometric tests, questionnaires and other scoring systems.²² An α statistic ≥ 0.80 is considered as good consistency, an α statistic 0.60- 0.80 as acceptable consistency. In the first step the inter-item correlation between all indicators is calculated. In the following steps, the indicator with the lowest value is removed from the model and the inter-item correlation is recalculated.

All statistics were performed using STATA version 10.0.

Results

From January 1 to December 31 2010, 85 hospitals included a total of 6971 patients in the DSCA, 4732 patients with colon carcinoma and 2239 patients with rectal carcinoma. Hospital performance on the nine QI ranged widely (table 1).

Table 1: Hospital performance on process and outcome indicators for colorectal cancer care of 85 hospitals in the Netherlands treating patients that underwent a resection of a primary colorectal carcinoma between 1 January 2010 and 31 December 2010.

Hospital level	Indicator	Mean (%)	Median (%)	IQR (%)
Colon	Imaging lung and liver	91	95	89-98
	Complete colonoscopy	71	69	60-76
	10 or more lymph nodes	79	79	73-86
	Unplanned re-operation	11	11	jul-15
	Risk-adjusted morbidity	20.8	19.7	14.4-26.9
	Risk-adjusted 30-day mortality	3.6	2.9	1.4-5.2
Rectal*	MRI pelvis	88	94	84-100
	MDC	90	98	92-100
	CRM	62	64	50-81
	Unplanned re-operation	10	8	5-15
	Risk-adjusted morbidity	27.2	26.7	18.2-35.8
	Risk-adjusted 30-day mortality	2.1	0	0-3.5

MRI: MRI or CT of the pelvis for staging the tumor, before resection

MDC: discussion in multidisciplinary meeting, before resection

CRM: reported circumferential margin (CRM) of the resection specimen in the pathology report

Construct validity

Figure 1 shows the correlation at a hospital level between all combinations of process and outcome indicators in matrix scatterplot for colon cancer (a) and rectal cancer (b). A significant correlation for colon cancer care was seen between 'complete imaging of liver and lungs' and 'more than 10 retrieved lymph nodes'. For rectal cancer care, there was a significant correlation between a high 'discussed in preoperative multidisciplinary meeting' and a lower hospital 'risk-adjusted mortality' rate.

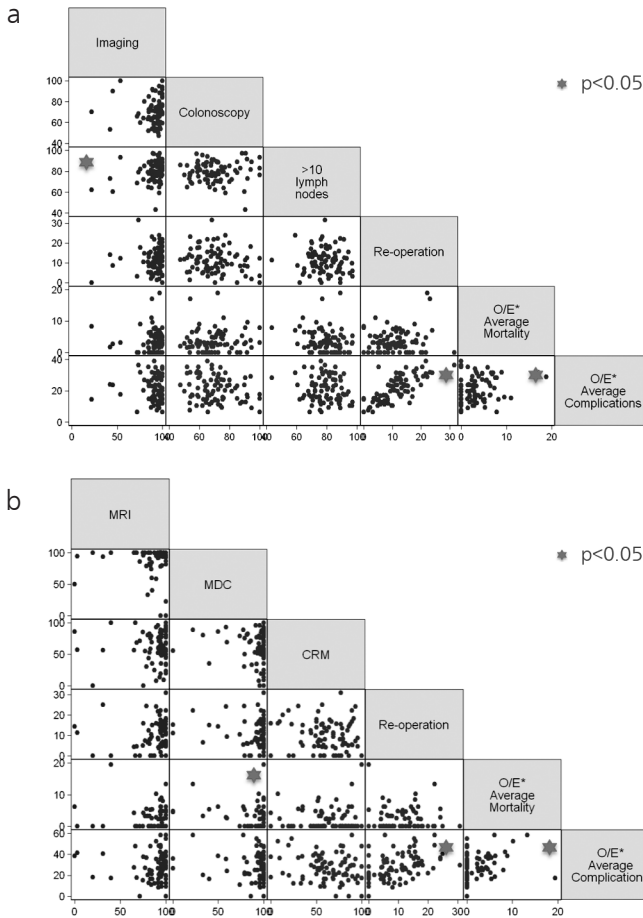


Figure 1: Matrix scatterplot for correlation at a hospital level between all combinations of process and outcome indicators for colon cancer (a) and rectal cancer (b)

Table 2: Average inter-item correlation and Cronbach’s alpha for selected process indicators, measuring the performance of 85 hospitals treating patients that underwent a resection of a primary colorectal carcinoma between 1 January 2010 and 31 December 2010 in the Netherlands.

Process indicators		Cronbach’s Alpha	Correlation
Colon	Imaging – colonoscopy – 10+nodes	0.21	11.3
Rectum	MRI – MDC – CRM	0.10	15.8
Colorectal	Imaging – colonoscopy – 10+nodes – MRI – MDC – CRM	0.20	12.5

Table 2 shows the correlation between process indicators and outcome indicators at a hospital level using poisson regression. In colon cancer care, a high rate of completed colonoscopies was correlated with a lower hospital specific ‘unplanned re-operation rate’ (RR 0.4 (0.3-0.8)), and lower risk-adjusted morbidity (RR 0.5 (0.4-0.8)). The QI ‘10 or

more retrieved lymph nodes' was correlated with lower hospital specific morbidity (RR 0.5 (0.3-0.8) and lower '30-day mortality' (RR 0.1(0.05-0.4).

In rectal cancer care, a high rate of patients discussed in a multidisciplinary meeting was correlated with a lower hospital specific unplanned re-operation rate (RR 0.5 (0.4-0.8), lower risk-adjusted morbidity (RR 0.8 (0.6-0.9) and lower 30-day mortality (RR 0.2 (0.1-0.3). A high rate of reported circumferential margins was associated with lower re-operation rates (RR 0.6 (0.4-0.8) and risk-adjusted morbidity (RR 0.8 (0.7-0.9). A high rate of patients who had a preoperative MRI of the tumour was associated with lower 30-day mortality (RR 0.4 (0.2-0.7).

Internal consistency

The results of the consistency tests for all QI using average inter-item correlation and Cronbach's alpha are shown in table 3 for colon and rectal cancer care separately. In both domains, there was little consistency between any of the tested combinations of process

Table 3: Evaluation of the correlation between process indicators and hospital specific patient outcomes, of 85 hospitals treating patients that underwent a resection of a primary colorectal carcinoma between 1 January 2010 and 31 December 2010 in the Netherlands. Correlation is tested by Poisson regression analysis. The results are shown for each selected outcome measure and are stratified for colon and rectal cancer care.

Outcome	Process	Rate ratio	95%CI	p-value
Unplanned Re-operation *				
Colon	Imaging	1.4	0.8-2.4	0.2
	Colonoscopy	0.4	0.3-0.8	0.003
	10 or more nodes	0.6	0.3-1.3	0.2
Rectum	MRI	1.2	0.8-1.7	0.4
	MDC	0.5	0.4-0.7	<0.001
	CRM	0.6	0.4-0.8	<0.001
Risk-adjusted morbidity				
Colon	Imaging	0.9	0.6-1.3	0.6
	Colonoscopy	0.5	0.4-0.8	0.001
	10 or more nodes	0.5	0.3-0.8	0.006
Rectum	MRI	0.9	0.7-1.1	0.2
	MDC	0.8	0.6-0.9	0.003
	CRM	0.8	0.7-0.9	0.002
Risk-adjusted 30-day mortality				
Colon	Imaging	0.7	0.3-1.4	0.3
	Colonoscopy	1.4	0.6-3.3	0.5
	10 or more nodes	0.1	0.05-0.4	<0.001
Rectum	MRI	0.4	0.2-0.7	0.001
	MDC	0.2	0.1-0.3	<0.001
	CRM	1.0	0.5-1.8	0.9

Unplanned reoperation: not adjusted for casemix, % reresections/ hospital Morbidity and mortality: Adjusted for casemix: outcome Observed/Expected*average MRI: MRI or CT of the pelvis for staging the tumor, before resection. CRM: reported circumferential margin (CRM) of the resection specimen in the pathology report

and outcome indicators in assessing hospital performance. Only among the combined outcome indicators, acceptable consistency was observed, with Cronbachs α of 0.67 and 0.52 for colon and rectal cancer care respectively.

Discussion

In this study, most evaluated process indicators for colorectal cancer care do not correlate with each other, but they are associated with better hospital specific patient outcomes. A high rate of completed colonoscopies, and 10 or more retrieved lymph nodes, were correlated with improved patient outcomes in colon cancer care. In rectal cancer care, better hospital outcomes were seen in hospitals with a high rate of patients discussed in a multidisciplinary meeting, a high rate of patients having a MRI before surgery and a high rate of reported circumferential margins. These results show that these process indicators have solid construct validity in the assessment of hospital performance in colorectal cancer care.

On the contrary, the evaluation of internal consistency showed minimal consistency in any of the tested combinations of both process and outcome indicators. This indicates that the current QI provide complementary information, reflecting all different stages of colorectal cancer care. Yet, QI are not suitable to act as a surrogate for the overall quality of care individually.

The present study builds on previous studies evaluating construct validity of QI. The construct validity of individual QI has been evaluated before. Especially the association between lymph node evaluation for colon cancer and survival, has been extensively studied.^{8,16} At least, all evaluated QI have been tightly linked to patient outcomes in clinical trials or are included in clinical guidelines.^{23,24} Yet, reports evaluating the construct validity or internal consistency of multiple QI are relatively scarce and show various results, depending on the domains covered by the QI.

For example, a study by Werner et al. evaluated the construct validity of the 'hospital compare measures': ten QI concerning the treatment of acute myocardial infection, heart failure and pneumonia in the USA. This study showed a modest correlation between the selected QI and risk-adjusted mortality rates.²⁵ In another study by Bradley et al. process measures designed to evaluate the quality of care for acute myocardial infarction alone, were evaluated, all largely reflecting the same domain: medication prescription practices. These QI did not correlate with hospitals' short-term mortality rates, but the inter-item correlation was acceptable.²⁶

Similarly, a recent study evaluating QI of the US Surgical Care Improvement Project, showed that compliance to perioperative processes of care, covering infection and venous-thromboembolism prevention, was not correlated to risk-adjusted surgical outcomes.¹⁵ Yet, these processes relate to secondary and less prevalent outcomes, which can explain the lack of correlation with risk-adjusted mortality rates that are likely influenced by many factors

independent of the selected QI. Comparable results were seen in a study examining the correlation between the Leapfrog Safe Practice Scores results and risk-adjusted mortality.²⁷ In the present study, a positive correlation was seen between most of the evaluated process indicators and hospital specific outcomes. All evaluated process indicators represent different critical components in the multi-disciplinary work-up and treatment of patients who undergo an elective resection of colorectal cancer. This implicates that hospitals where these organisational features are well implemented, have superior patient outcomes. On the contrary, the present study showed weak consistency among the QI for colorectal cancer care. These process measures thus provide information that is complementary, each reflecting a unique dimension of quality. But none of these individual indicators can represent overall quality of care, since they lack content validity. The myriad components of high quality colorectal cancer care seem thus to be too complex to be captured in individual indicators.

Given this information, QI can be useful tool for screening for substandard care, though they are not suitable to assess the quality of colorectal cancer care as a whole. In the Netherlands, quality improvement programs have mainly focussed on measuring a small selection of process and outcome indicators. Meanwhile, the role of QI gets increasingly prominent in modern health care, with increasing use in pay for performance initiatives and public reporting. But, the provided information about the quality in a hospital can be misleading, as the assessment of the quality of care in a hospital relies on the choice of which QI is used.

Still, there is considerable variation in the quality of colorectal cancer care in the Netherlands.^{28,29} The wide range in hospital performance on the QI in the present study, confirms these findings and show the need for quality measurement to improve the quality of care and reduce variation in hospital performances.³⁰ Yet, what aspects should be measured to truly measure hospital performance and provide meaningful information for both physicians and external parties is not elucidated. Ideally quality measurement should consist of measuring whether the right patient receives the right treatment at the right time and whether that treatment is effective. Further research is needed to evaluate the role of composite measures that capture all these aspects.

A better alternative is monitoring hospital performance by a valid outcome registration ('clinical audit'): constant monitoring of patient characteristics, the process of diagnostics and treatment and patient outcomes. In the last decade there have been various successful examples of auditing. including the US, UK and the Nordic countries, where auditing has led to impressive improvements in survival.³¹⁻³³ A beneficial 'side-effect' of auditing is its value for research, providing reliable population based observational data, when a nearly complete percentage of patients is entered. Also, auditing is an ideal platform for implementing quality improvement projects.

The present study is the first, testing the construct validity and internal consistency

of generally used QIs for colorectal cancer care in a population based, clinical database, covering almost all hospitals in the Netherlands and at least 85% of the patient population. Nonetheless, the results of this study should be interpreted in the light of several limitations. The exclusion of seven hospitals, which were underreporting, could have interfered with our findings. If these *underreporting* hospitals, were also *underperforming* hospitals, a stronger correlation between the selected indicators and outcomes may have been observed.

In addition, although the completeness of the DSCA is high and estimated to be over 93% in 2010, patient selection could have influenced the results. The comparison with the NCR showed a similar distribution of baseline characteristics, procedures and postoperative outcomes. Although these results were not suggestive for patient selection, this cannot be excluded.

The sample size of 85 hospitals, (and the relative little variation on some QI) can limit the power of the observed correlations. Future projects in which European audits will be combined, will allow for more detailed evaluations of the validity of QI used in colorectal cancer care.³⁴

Last, in this study a positive correlation was found between most of the evaluated process indicators and hospital specific outcomes. This implicates that hospitals that have good organisational features also have superior patient outcomes. The use of process indicators is mainly based on this assumption. Yet, the observed correlation can be confounded since it is possible that hospitals that perform well on the selected process indicators, also do other things that actually account for these superior outcomes.

In conclusion, although nearly all evaluated QI for colorectal cancer care were associated with improved hospital specific patient outcomes, our results show little consistency among the QI. Therefore QI do provide complementary information, but they cannot function as a surrogate for the quality of colorectal cancer care.

Current quality improvement projects focus mainly on a selection of process measures that are evidently insufficient to measure the overall quality of care.

Monitoring of both processes and outcomes, adjusted for differences in case-mix, in a 'clinical audit' is a better alternative and efforts should be done to implement process and outcome monitoring in daily routine. Further research is needed for the development of valid QI and composite measures of quality.

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