Measuring, comparing and improving clinical outcomes in gastrointestinal cancer surgery

Henneman, D.

CHAPTER 5

Hospital variation in failure to rescue after colorectal cancer surgery: results of the Dutch Surgical Colorectal Audit

D. Henneman
H.S. Snijders
M. Fiocco
N.J. van Leersum
N.E. Kolfschoten
T. Wiggers
M.W.J.M. Wouters
R.A.E.M. Tollenaar

Annals of Surgical Oncology 2013; 20(7):2117-2123

ABSTRACT

Background: Postoperative mortality is frequently used in hospital comparisons as marker for quality of care. Differences in mortality between hospitals may be explained by varying complication rates. A possible modifying factor may be the ability to let patients with a serious complication survive, referred to as *failure to rescue (FTR).*

Purpose of this study is to evaluate how hospital performance on postoperative mortality is related to severe complications or to FTR and to explore the value of FTR in quality improvement programs.

Methods: All patients operated for colorectal cancer from 2009-2011, registered in the Dutch Surgical Colorectal Audit, were included. Logistic regression models were used to obtain adjusted mortality- complication- and FTR rates. Hospitals were grouped into 5 quintiles according to adjusted mortality. Outcomes were compared between quintiles.

Results: 24 667 Patients were included. Severe complications ranged from 19% in the lowest to 25% in the highest mortality quintile (OR=1,5; 95% CI 1,37-1,67). Risk-adjusted FTR rates showed a marked difference between the quintiles, ranging from 9 to 26% (OR=3.0; 95% CI 2,29-3,98). There was significant variability in FTR rates. Seven hospitals had significantly lower FTR rates than average.

Conclusions: High-mortality hospitals had slightly higher rates of severe complications than low-mortality hospitals. However, FTR was three times higher in high-mortality hospitals than in low-mortality hospitals. In quality improvement projects, feedback to hospitals of FTR rates- along with complication rates- may illustrate shortcomings (*prevention* or *management* of complications) per hospital, which may be an important step in reducing mortality.

INTRODUCTION

Increasingly, society focuses on effectiveness and efficiency in healthcare, and differences in hospital performances have become subject to research. Recent studies have shown great differences in hospital (surgical) mortality rates[1,2] even after adjustment for differences in case-mix[3]. One of the explanations of these differences is sought in the handling of postoperative complications, eg. ‘*failure to rescue*’ (FTR).

The term, introduced by Silber et al.[4] is defined as “the mortality rate among patients with complications”. These authors found that hospital rankings based on adjusted complication rates did not correlate with rankings based on adjusted mortality rates. Ghaferi et al. defined FTR as “mortality among patients with serious complications” and found that hospitals with high mortality rates had higher FTR rates rather than higher complication rates[5-7]. Almoudaris et al. introduced the term “failure-to-rescue-surgical”, defined as death among patients that underwent reoperation. These authors found that hospitals with high mortality rates had higher death rates among patients that underwent reoperation after colorectal surgery, while reoperation rates were the same in high- and low-mortality hospitals[8].

Colorectal surgery is considered high-risk surgery as it brings along a relatively high risk of complications. Patients that experience a complication have a substantial increase in risk of dying[9]. Hence, mortality and complication rates are considered important outcome measures in colorectal surgery.

Many publications on FTR used administrative data, in which the risk of identifying preoperative conditions as a postoperative complication is substantial[10,11]. The valuable insight into “failure to rescue” that the publication based on the National Surgical Quality Improvement Program (NSQIP) clinical dataset provided, lacked details on procedure-specific complications such as anastomotic leak[5]. After the example of the NSQIP and other international audits, in 2009 the Dutch Surgical Colorectal Audit (DSCA) was introduced[12], in which approximately 95% of patients undergoing surgery for colorectal cancer in the Netherlands are included. By clarifying the hospital variation of FTR on a national level, its potential value in quality improvement programs is explored.

The aims of this study are to evaluate:

1. to what extent mortality rates after colorectal surgery vary between Dutch hospitals, when adjusted for casemix
2. whether, and to what extent, hospitals with higher mortality rates have higher severe complication rates
3. whether, and to what extent, hospitals with higher mortality rates have higher FTR rates
4. the variability in FTR after colorectal surgery between Dutch hospitals and the presence of positive and negative outliers

METHODS

Data was derived from the DSCA, a national quality improvement project in which over 200 variables concerning patient and tumor characteristics, treatment, and outcomes are collected prospectively. All 92 hospitals performing colorectal cancer surgery participate. The dataset shows a high level of completeness on most items, including anastomotic leakage on validation against the National Cancer Registry (NKR) dataset[13,14]. Information concerning individual patients and hospitals are made anonymous, making it possible to compare hospitals without identifying them.

Patients

For this study, no ethical approval or informed consent was required under Dutch law.

All patients (n=26 410) undergoing surgical resection for primary colorectal cancer between the 1st of January 2009 and 31st of December 2011, and registered in the DSCA before March 15th 2012, were evaluated.

Minimal data requirements to consider a patient eligible for analyses were information on tumor location, date of surgery, complications and mortality (25 591 eligible patients). To minimize the risk of selection bias, patients from hospitals that failed to register more than 10 patients in a year were excluded (36 patients from nine hospitals in 2009, none in 2010 and 2011). To analyze a clinically homogenous patient cohort, patients with multiple synchronous tumors (n=888) were excluded.

From the subset of patients operated in 2011 (n=8885), a detailed description of both surgical and non-surgical complications was available.

Mortality

The definition of mortality is shown in panel 1. Potential patient- and disease-specific risk factors (casemix) for mortality were selected from the dataset. The methods used to calculate the expected mortality have been described in an earlier publication by the Dutch Surgical Colorectal Audit group[3]. In univariate analysis, categorical variables were compared by χ^2 tests, while 2-sample *t* tests were used for continuous variables. A 2-sided $P \leq 0.05$ was considered statistically significant, but casemix factors were selected for multivariate analysis when reaching a significance of $p<0.10$. Backward stepwise logistic regression models were employed to estimate the final model and calculate expected rates of mortality. The casemix factors age, sex, American Society of Anesthesiologists (ASA) classification, Charlson co-morbidity index, body mass index (BMI), emergency surgery, tumor location, preoperative complications from the tumor, oncologic stage and neoadjuvant therapy proved to be contributing to the correction model. Data were aggregated on hospital level and observed-to-expected rates were multiplied with the average mortality in the study population in order to obtain casemix-adjusted mortality rates. Hospitals were grouped into five equally sized, risk-adjusted quintiles of mortality according to previous publications[5,8].

Severe complications

With the same methods, adjusted severe complication (see panel 1 for definitions) rates were calculated for each hospital. The casemix factors sex, ASA classification, Charlson co-morbidity index, BMI, emergency surgery, tumor location, pre-operative complications, oncologic stage and additional resections for extended disease were significant contributors to the model. Adjusted severe complication rates were compared between the mortality quintiles.

Failure-to-rescue

For FTR, the casemix factors age, sex, ASA score, Charlson co-morbidity index, emergency surgery, oncological stage and neoadjuvant therapy contributed to the model. Adjusted FTR rates were compared between the mortality quintiles.

Hospital variation and outliers in FTR

A mixed logistic regression model with hospitals as random effects was employed to account for the presence of variability between hospitals.

The fixed effects predictors in the model are the same as employed in the first model for FTR described before. The variance in the random effects model quantifies the degree of variation in the outcome between hospitals after adjustment for case mix. The likelihood ratio test was used to assess whether the variance of the random effect was significant.

The adjusted FTR rates per hospital are presented in a funnel plot, showing the overall average FTR rate with its 95% confidence limits, based on a Poisson distribution, varying in relation to the population size. The plot allows to identify hospitals with FTR rates that are significantly higher or lower than average.

Statistical analyses were performed in PASW Statistics, Rel. 20.0.2012 (SPSS inc., Chicago, Il) and R 2-14 (http://cran.r-project.org/).

RESULTS

Patient characteristics

A total of 24 667 patients, registered by 92 hospitals met the inclusion criteria and were included in the study. Hospitals were grouped according to adjusted mortality rates and the total group of hospitals was divided into quintiles. Patient characteristics are displayed in table 1. There was no evidence of systematic differences in case mix across hospital quintiles, as reflected by quite similar overall expected rates of death per quintile, based on casemix. Average mortality was 4.3% and the percentage of patients with a severe complication was 23%.

Table 1: Patient characteristics by risk-adjusted-mortality quintile

Mortality Quintile		**1st**	**2nd**	**3rd**	**4th**	**5th**
Number of patients		4841	4879	5134	4988	4825
Number of hospitals		20	18	16	19	18
Sex	Males (%)	2632 (54.4%)	2677 (54.9%)	2810 (54.7%)	2769 (55.5%)	2625 (54.4%)
Age	mean	69.2	69.9	69.8	69.8	69.8
Body Mass index	kg/m^2, mean	25.9	26.2	25.9	25.9	26.2
Charlson co-morbidity index	2 or higher	1083 (22.4%)	963 (19.7%)	1260 (24.5%)	1155 (23.2%)	1129 (23.4%)
Pathological TNM stage	X	137 (2.8%)	174 (3.6%)	195 (3.8%)	140 (2.8%)	243 (5.0%)
	I	1013 (20.9%)	1042 (21.4%)	989 (19.3%)	1048 (21.0%)	957 (19.8%)
	II	1638 (33.8%)	1538 (31.5%)	1804 (35.1%)	1668 (33.4%)	1562 (32.4%)
	III	1478 (30.5%)	1544 (31.6%)	1602 (31.2%)	1515 (30.4%)	1508 (31.3%)
	IV	575 (11.9%)	581 (11.9%)	544 (10.6%)	617 (12.4%)	555 (11.5%)

Table 1: Patient characteristics by risk-adjusted-mortality quintile (continued)

Mortality Quintile		**1st**	**2nd**	**3rd**	**4th**	**5th**
Number of patients		4841	4879	5134	4988	4825
Number of hospitals		20	18	16	19	18
Procedure	ileocaecal resection	53 (1.1%)	44 (0.9%)	44 (0.9%)	65 (1.3%)	52 (1.1%)
	right hemicolectomy	1509 (31.2%)	1512 (31.0%)	1577 (30.7%)	1608 (32.2%)	1541 (31.9%)
	transverse colectomy	100 (2.1%)	117 (2.4%)	113 (2.2%)	92 (1.8%)	128 (2.7%)
	left hemicolectomy	358 (7.4%)	330 (6.8%)	383 (7.5%)	372 (7.5%)	316 (6.5%)
	sigmoid colectomy/low anterior resection	2283 (47.2%)	2102 (43.1%)	2117 (41.2%)	2202 (44.1%)	2079 (43.1%)
	subtotal colectomy	39 (0.8%)	22 (0.5%)	194 (3.8%)	28 (0.6%)	65 (2.3%)
	abdominoperineal resection	387 (8.0%)	374 (7.7%)	520 (10.2%)	450 (9.0%)	450 (9.4%)
	panproctocolectomy	28 (0.6%)	19 (0.4%)	48 (0.9%)	48 (1.0%)	47 (1.0%)
	other	84 (1.7%)	359 (7.4%)	138 (2.7%)	123 (2.5%)	147 (3.0%)
Urgency of the procedure	urgent/emergency	680 (14.0%)	742 (15.2%)	819 (16.0%)	837 (16.8%)	663 (13.7%)
Approach	laparoscopic	1891 (39.1%)	1822 (37.3%)	2270 (24.2%)	1418 (28.5%)	1798 (37.3%)
Mortality	Expected (based on casemix)	4.0%	4.3%	4.3%	4.3%	4.1%

Mortality

After adjustment for casemix, a marked variation in mortality rates between hospitals was observed ranging from 1 to 9 %. Figure 1 shows the hospitals grouped in risk-adjusted mortality quintiles (left series).

Each quintile represents a group of hospitals with a different (adjusted) mortality rate, the first mortality quintile having the lowest casemix-adjusted mortality (2 %), with adjusted mortality increasing stepwise per quintile to 6.6% in the 5th (highest) quintile. The OR for mortality of the highest quintile was 3,5 (95% confidence interval 2,79 – 4,54; p<0,001) compared to the lowest quintile. The other

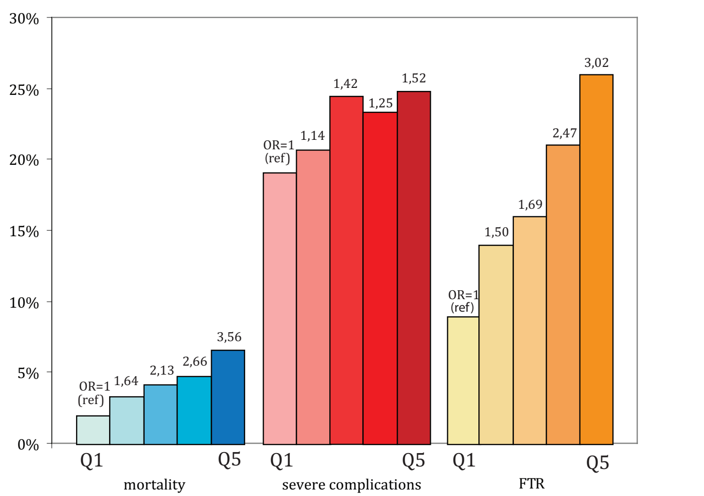

Figure 1: risk-adjusted mortality, severe complication, and FTR rates per quintile. Odds ratios are given, compared to quintile 1 (reference). RR=relative risk; Q= mortality quintile; FTR= failure to rescue

quintiles had significantly higher adjusted mortality rates than the first quintile as well.

Severe complications

An increase in adjusted percentage of patients with a severe complication was observed when comparing the lowest to the highest mortality quintile (figure 1, middle series). The percentages ranged from 19% in the lowest to 25 % in the highest mortality quintile- with the OR for severe complications of the highest being 1,5 (95% confidence interval 1,37 – 1,67; p<0,001) compared to the lowest quintile. The

Table 2: details of the severe complications in the subset of patients operated in 2011.

Total no. of patients (2011)		**8885 (100%)**
Any severe complication		1882 (21,2%)
Surgical complications		
	anastomotic leak	440 (5,0%)
	intra-abdominal abcess	139 (1,6%)
	postoperative haemorrhage	51 (0,5%)
	ileus	106 (1,2%)
	fascial dehiscence	99 (1,1%)
	iatrogenic bowel injury	34 (0,4%)
	iatrogenic injury to ureter/bladder	11 (0,1%)
	other	187 (2,1%)
General complications		
	Pulmonary	415 (4,6%)
	Cardiac	222 (2,4%)
	Thrombo-embolic	45 (0,5%)
	Septic/infectious (non-pulmonary, non-surgical)	216 (2,4%)
	Neurologic	74 (0,8%)
	Other	367 (4,1%)

other quintiles had significantly higher adjusted severe complication rates than the lowest quintile as well.

Details of the severe complications in the subset of patients operated in 2011 are displayed in table 2.

Failure-to-rescue

The OR of FTR in the highest mortality quintile was 3.0 (95% confidence interval 2,29 – 3,97, $p<0.001$) compared to the lowest mortality quintile, with an incremental increase per quintile (figure 1, right series). The difference in FTR rate was also significant for the other quintiles when compared to the lowest quintile.

Hospital variation and outliers

The variance in the random effects model quantified the degree of variation in FTR between hospitals; this was 0.09 with a standard error of 0.038. A likelihood ratio test showed that the variance of the random effects was statistically significant.

Figure 2 shows that the adjusted FTR rates of the 92 hospitals varied between 0 and 39%. For 85 hospitals (92%), results were within the 95%-confidence limits of the average. Seven hospitals showed statistically significant lower percentages than average. Each hospital is colored according to mortality quintile: the hospitals in the lower mortality quintiles fill the lower regions of the funnel plot, and the hospitals in the higher mortality quintiles are displayed on the higher part of the funnel plot.

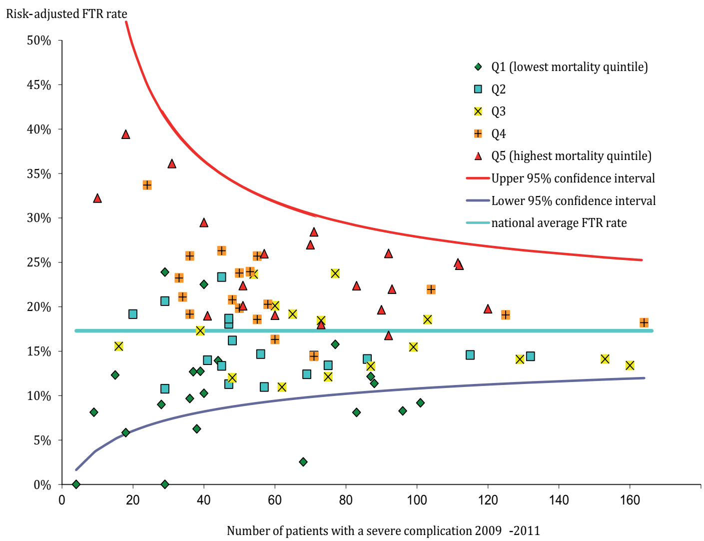

Figure 2: funnel plot showing differences in risk-adjusted failure to rescue (FTR) rates between hospitals

DISCUSSION

Colorectal surgery is not without adverse events. This study acknowledges the fact that postoperative casemix-adjusted mortality rates after colorectal surgery vary by hospital. Our study shows that higher mortality rates seem to be only partially explained by higher rates of severe complications: the 1,5-fold increase in severe complication rate seems insufficient to explain the 3-fold increase in mortality between the first and fifth quintile. Failure to rescue seems to play a role as modifying factor, with a vast increase in failure to rescuebetween the lowest and highest mortality quintile. Moreover, we demonstrated that there was variability in FTR between individual hospitals, after adjusting for casemix.

High- and low-mortality hospitals were distinguished by their ability to treat and save patients with severe complications. These findings are consistent with recent literature[5-8].

Our study adds that in a specific, homogeneous group of surgical procedures, colorectal cancer surgery, failure to rescue plays an important role in explaining the variability in hospital mortality. The dataset we used was disease-specific and did, unlike some other studies, include anastomotic leak. Therefore we were able to accurately characterize the impact of failure to rescue on mortality in patients that underwent colorectal surgery. Secondly, this paper is the first from the European continent that describes hospital variation in FTR, whereas most publications concerning FTR originate from the United States[4-7] or United Kingdom[8]. Despite differences in health care systems, FTR seems to be the main determinant of differences in hospital mortality after colorectal surgery in populations from different countries. Moreover, we found that FTR rates vary significantly between hospitals, with some hospitals having a significantly lower FTR rate than average ("best practices").

The study has some limitations. Firstly, since data are self-reported, registration bias cannot be excluded. However, the dataset is validated against the independently collected data of the Dutch National Cancer Registry, showing a very high rate of case-ascertainment, completeness and accuracy in terms of patient demographics, tumor stage, comorbidity, treatment and mortality[14]. The dataset consists of detailed, prospectively collected clinical data, registered by or under direct responsibility of colorectal surgeons. This avoids the problem that the use of administrative data brings along: difficulties in correctly distinguishing a comorbid illness from a postoperative complication[11].

The definition of a severe complication used in this study is arbitrary but it is believed to exclude the minor complications such as simple urinary tract infections or minor wound problems not hindering the postoperative course. However, it cannot be ruled out that some patients with a minor complication, who spent more than 14 days in the hospital due to other reasons, were incorrectly identified as having a severe complication. On the other hand, with the definition used in this study, a small number of mortality cases were not covered by our definition of a severe complication. Therefore we performed additional analyses using alternative definitions of severe complications (1. with all mortality cases included in the “severe complication” measure; 2. with exclusion from the data set of the 62 mortality cases with no postoperative complication), showing very similar results. However, the severity of illness associated with complications like anastomotic leak may vary widely. These differences may level out in larger groups of patients treated per hospital. However, we cannot exclude that differences in severity of complications between hospitals may have influenced the variation in FTR rates.

A possible form of bias may have emerged from complicated patients transferred to another hospital, dying after transfer. However, as a minimum of facilities (e.g. ICU) is mandatory for hospitals performing colorectal surgery in the Netherlands, patients with complications are rarely transferred. In this uncommon situation the mortality is ascribed to the hospital that performed the initial operation.

A drawback of using FTR is that it is a short-term outcome, whereas patients that experienced a complication following colorectal surgery are known to have a higher risk of mortality up to a year after the procedure[15-17]. The post-discharge period may be just as important as the immediate postoperative period, when aiming at improving mortality rates.

Nonetheless, the hospital variation in FTR rates may reflect differences in the postoperative care process. What these differences are, is beyond the scope of this study. Probably, FTR is affected by many factors including the usual postoperative care at each hospital, availability of resources like interventional radiology or a high level of Intensive Care facilities, staffing factors and equipment. Suggested factors related to FTR are nurse-to-patient ratios[18-19], high-technology status of a hospital (i.e., does the hospital perform organ transplant surgery open-heart surgery)[19], higher case-volume[6] and teaching status[6]. Probably as important as these structural factors are preoperative risk-assessment and appropriate case-selection, multidisciplinary treatment of patients with comorbid illnesses and timely recognition of complications. An active surveillance protocol has been shown to reduce the delay in diagnosis of anastomotic leak[20]. Whether the hospitals with lower FTR rates had a shorter delay between the onset of symptoms and the start of treatment of the complication is unknown and should be subject of further research- ideally not only focusing on anastomotic leakage but also on non-surgical complications. In the context of quality improvement, feedback of complications and FTR rates to hospitals illustrates shortcomings (*management* or *prevention* of complications), allowing targeted improvement efforts. Based on the results of this study, the DSCA started using FTR as feedback information to participating hospitals, enabling surgeons to evaluate detection and treatment of complications. Best practices can be identified and knowledge can be shared between surgical teams from different hospitals.

In conclusion, although the incidence of severe postoperative complications differed slightly across mortality quintiles, the adjusted rate of death in patients with a severe complication (failure to rescue) was markedly higher in hospitals with higher overall mortality. The chance that a patient dies once a severe complication has emerged was three times higher in a high-mortality hospital than in a low-mortality hospital. FTR rates show a wide, significant variation between hospitals, with seven hospitals having a significantly lower FTR rate than average. More research is needed to identify the underlying mechanisms and structural factors that account for differences in FTR rates between hospitals.

DEFINITIONS

Severe complication: a complication leading to a surgical, endoscopic or radiological reintervention or to a in-hospital stay of more than 14 days, or to death.

Mortality: A patient that died within 30 days after the operation or within the same admission.

Failure to rescue: The percentage of patients with a severe complication that dies. (Number of patients that died secondary to a severe complication) / (total number of patients that experienced a severe complication)

Panel 1: definitions used in the current study

REFERENCES

1. Almoudaris AM, Burns EM, Bottle A et al. Single measures of performance do not reflect overall institutional quality in colorectal cancer surgery. Gut 2013;62(3):423-9.
2. Zheng H, Zhang W, Ayanian JZ et al. Profiling hospitals by survival of patients with colorectal cancer. Health Serv Res 2011; 46: 729-746
3. Kolfschoten NE, Marang van de Mheen PJ, Gooiker GA, et al. Variation in case-mix between hospitals treating colorectal cancer patients in the Netherlands. Eur J Surg Oncol 2011; 37: 956-963.
4. Silber JH, Rosenbaum PR, Schwarz JS, et al. Evaluation of the Complication Rate as a Measure of Quality of Care in Coronary Artery Bypass Graft Surgery. JAMA 1995; 274: 317-323.
5. Ghaferi AA, Birkmeyer JD, Dimick JB. Variation in Hospital Mortality Associated with Inpatient Surgery. N Engl J Med 2009; 361: 1368-1375.
6. Ghaferi AA, Birkmeyer JD, Dimick JB. Hospital Volume and Failure to Rescue with High-risk Surgery. Med Care 2011; 49: 1076–1081
7. Ghaferi AA, Birkmeyer JD, Dimick JD. Complications, Failure to Rescue, and Mortality With Major inpatient Surgery in Medicare Patients. Ann Surg 2009; 250: 1029-1034.
8. Almoudaris AM, Burns EM, Mamidanna R et al. Value of failure to rescue as a marker of the standard of care following reoperation for complications after colorectal resection. Br J Surg 2011; 98: 1775-1783
9. Longo WE, Vorgo KS, Johnson FE et al. Risk factors for morbidity and mortality after colectomy for colon cancer. Dis Colon Rectum 2000; 43: 83-91
10. Horwitz LI, Cuny JF, Cerese J et al. Failure to Rescue, Validation of an Algorithm Using Administrative Data. Med Care 2007; 45: 283-287
11. Moriarty JP, Finnie DM, Johnson MG et al. Do pre-existing complications affect the failure to rescue quality measures? Qual Saf Health Care 2010; 19: 65-68
12. Dutch Surgical Colorectal Audit. Annual Report 2009. www.clinicalaudit.nl
13. Dutch Surgical Colorectal Audit. Annual Report 2010. www.clinicalaudit.nl
14. Dutch Institute for Clinical Auditing. Annual Reports 2011. www.clinicalaudit.nl
15. Gooiker GA, Dekker JWT, Bastiaannet E et al. Risk factors for Excess Mortality in the First Year After Curative Surgery for Colorectal Cancer. Ann Surg Oncol 2012; Mar 7 [Epub ahead of print]
16. Visser BC, Keegan H, Martin et al. Death after colectomy: it's later than we think. Arch Surg 2009; 144: 1021–1027.

17. Dekker JW, van den Broek CB, Bastiaannet E et al. Importance of the first postoperative year in the prognosis of elderly colorectal cancer patients. Ann Surg Oncol. 2011; 18: 1533–1539
18. Lang TA, Hodge M, Olson V et al. Nurse-patient Ratios. JONA 2004; 34: 326-337.
19. Ghaferi AA, Osborne NH, Birkmeyer JD et al. Hospital characteristics associated with failure to rescue from complications after pancreatectomy. J Am Coll Surg 2010; 211: 325-330.
20. den Dulk M, Noter SL, Hendriks ER, Brouwers MAM, et al. Improved diagnosis and treatment of anastomotic leakage after colorectal surgery. Eur J Surg Oncol 2009; 35:,420-426.