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## **Measuring, comparing and improving clinical outcomes in gastrointestinal cancer surgery**

Henneman, D.

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**Author:** Henneman, D.

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# CHAPTER 6

## **Failure to rescue after colorectal cancer surgery and the association with three structural hospital factors**

D. Henneman

N.J. van Leersum

M. ten Berge

H.S. Snijders

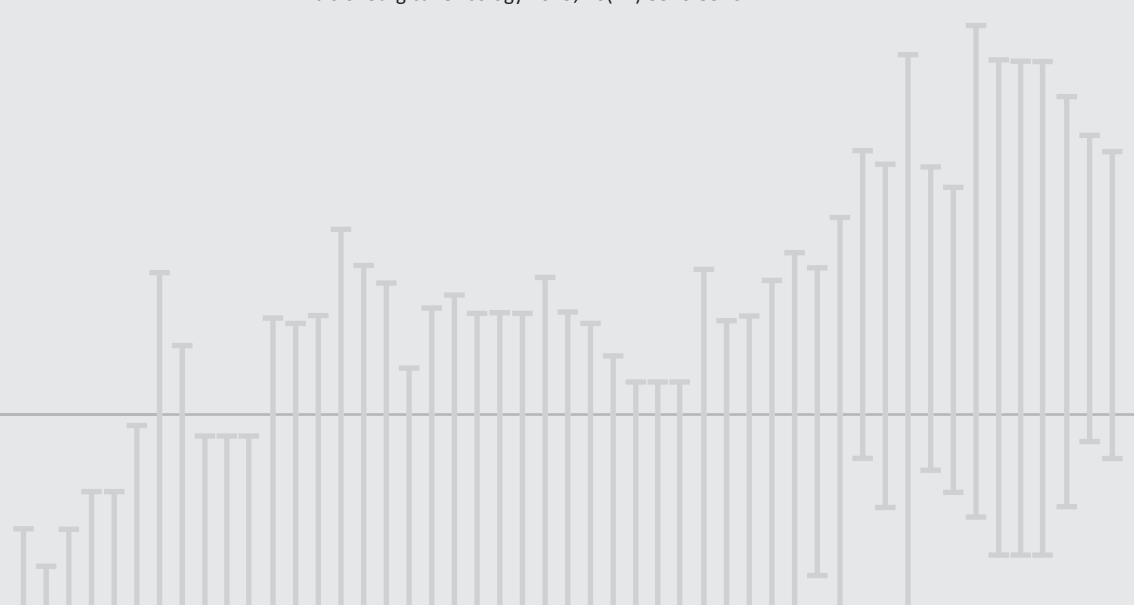
M. Fiocco

T. Wiggers

R.A.E.M. Tollenaar

M.W.J.M. Wouters

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## ABSTRACT

**Background:** Evidence suggests that a large hospital variation in failure to rescue (FTR) in colorectal surgery is causing hospital differences in mortality rates. Which structural hospital factors are associated with better FTR rates remains largely unclear. The purpose of this study is to evaluate the association between FTR and hospital volume, teaching status and level of Intensive Care facilities, in colorectal cancer surgery.

**Methods:** All patients undergoing colorectal cancer surgery from 2009 through 2011 in 92 Dutch hospitals were analysed. Univariate and multivariate logistic regression models including casemix, hospital volume, teaching status and different levels of ICU facilities were used to analyse risk-adjusted FTR rates.

**Results:** 25591 patients from 92 hospitals were included. The average failure-to-rescue rate was 17% [0-39]. In univariate analysis, high hospital volume (>200 patients/year versus ≤200/year), teaching status (academic versus teaching versus non-teaching hospitals) and high level of ICU facilities (highest level 3 versus lowest level 1) were associated with lower FTR rates. Only the higher levels of ICU facilities (2 or 3 compared to level 1) were independently associated with lower FTR rates (OR 0.72 (95% CI 0.65 – 0.88) in multivariate analysis.

**Conclusions:** Hospital type and annual hospital volume were not independently associated with FTR rates in colorectal cancer surgery. Instead, the lowest level of ICU facilities was independently associated with higher rates. This suggests that a more advanced ICU may be an important factor that contributes to better FTR rates, although individual hospitals perform well with lower ICU levels.

## INTRODUCTION

Hospital differences regarding quality of care have received much attention in recent years. Complications and mortality are outcomes frequently used to compare hospital performance in colorectal cancer surgery. *Failure to rescue* (FTR) is another outcome measure that indicates the ability of a surgical team to keep patients alive when severe complications occur. The term, introduced by Silber et al.<sup>1</sup> is defined as “the mortality rate among patients with complications”. These authors found that hospital rankings based on complication rates did not correlate with rankings based on mortality rates. Recent literature suggests that high hospital mortality after colorectal surgery is best explained by higher FTR rates rather than by higher complication rates<sup>2,3</sup>. Hence it may be considered an outcome that is actionable, reflecting the ability of a surgical team to timely recognize and treat major complications once they emerge.

The fact that higher FTR rates, and not higher complication rates are the main determinant of higher mortality rates was recently confirmed by the Dutch Surgical Colorectal Audit (DSCA) group<sup>4</sup>. Dutch hospitals showed variability between 0 and 40% in FTR rates. It remains largely unclear which factors account for this variation. Some potential factors have been suggested. Surgical teams may vary in the ability to adequately and timely recognize and treat postoperative complications by differences in expertise, experience with the procedure, and by more advanced resources.

The number of procedures performed annually, might be a proxy for the experience of a surgical team with a specific procedure and its perioperative care. Increasing hospital volume is associated with better outcomes in many surgical procedures including colorectal surgery<sup>5</sup>. An American study using Medicare data showed that lower postoperative mortality rates after gastrectomy, esophagectomy and

pancreatectomy in higher volume hospitals were strongly related to lower FTR rates<sup>6</sup>. Yet, the association between hospital volume and FTR in colorectal surgery remains largely unexplored.

Another hospital-related factor that has been associated with differences in outcome, is its teaching status. University hospitals have been associated with favorable outcomes compared to non-teaching hospitals for many procedures and conditions like prostatectomy<sup>7</sup>, cystectomy<sup>8</sup> and cardiovascular events<sup>9,10</sup>. Teaching status has been mentioned as a factor inversely related to FTR<sup>11</sup>. It has been suggested that this association may be related to more advanced resources in university hospitals. A logical next step is to explore the relation between intensive care (ICU) capacity and outcomes. The relationship between level of care in ICU facilities and FTR after colorectal cancer surgery has not been investigated yet but higher ICU staffing has been associated with lower mortality in critically ill medical, surgical and pediatric patients<sup>12</sup>. In the Netherlands, ICU units are classified into three levels according to capacity, staffing and resources<sup>13</sup> (table 1), making it possible to study the influence of enhanced ICU facilities on outcomes.

This study looks at the association between three major structural hospital factors and failure-to-rescue rates in colorectal cancer surgery:

1. Annual hospital volume in colorectal cancer procedures
2. Teaching status (Academic-, teaching- and non-teaching hospitals)
3. Level of Intensive Care (ICU) facilities

**Table 1:** main differences between the three levels of ICU care<sup>13</sup>.

|  | ICU level 1                                      | level 2   | level 3   |
|--|--|---|---|
| Medical responsibility for patient     | Responsibility not transferred to intensivist    | Responsibility transferred to intensivist                   | Responsibility transferred to intensivist                   |
| Continuity of care                     | Intensivist available during working hours       | Intensivist available exclusively for ICU 7x24 hours / week | Intensivist available exclusively for ICU 7x24 hours / week |
| Intensivist staffing                   | 0,1 - 0,15 fte / bed                             | 0,35 - 0,42 fte / bed                                       | 0,45 - 0,55 fte / bed                                       |
| Other medical staff                    | 5 -6 fte ICU-trained doctors working in hospital | 0,55 fte / bed  | 0,6 - 0,9 fte / bed   |
| ICU nurse staffing                     | 2,7 fte / bed                                    | 3,5 fte / bed   | 4,2 fte / bed   |
| Minimum no. of ventilation days / year | .  | 1250  | 1500  |
| Minimum no. of beds                    | 6  | 12  | 12  |

## METHODS

Data was derived from the DSCA, a nationwide, continuous quality improvement project in which a wide range of variables concerning patient and disease-specific details, diagnostics, treatment, and outcomes are collected prospectively. The dataset is disease-specific for colorectal cancer and shows a nearly 100% completeness on most items, and high accuracy level on comparison against the Netherlands Cancer Registry (NCR) dataset. The latter is constructed with data retrieved from chart review by independent, trained researchers<sup>14,15</sup>.

### 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 15<sup>th</sup> 2012, were evaluated. Minimal data requirements to consider a patient eligible for analyses were information on tumor location, date of surgery, complications and mortality. For calculation of average annual hospital volume, no cases were excluded.

### Definitions

#### *Hospital volume*

Hospital volume was divided into five groups: <51 cases/year, 51-100 cases/year, 101-150 cases/year, 151-200 cases/year and more than 200 cases/year. Subsequently, we used five different cutoff points for volume (0-50 versus more than 50 cases/year; 0-100 versus more than 100 cases/year, and so on). The groups were formed around 100 cases per year, as the average hospital volume was 99 cases per year,



with most hospitals performing between 50 and 200 procedures annually.

### ***Hospital type***

Hospitals were categorized as either academic hospitals, teaching hospitals or non-teaching hospitals. In the Dutch healthcare system there are eight university hospitals, which function as referral centers for high-complex, low-volume care like surgery for locally advanced tumors and synchronous metastasectomies<sup>16</sup>. Each university hospital is affiliated with a number of teaching hospitals, providing the surgical residency programs together. The remaining hospitals were defined as non-teaching hospitals.

### ***ICU facilities***

According to the guidelines “organization of ICU departments for adults in the Netherlands”<sup>17</sup>, three levels of ICU facilities are defined. Table 1 displays the main differences per level, as described by the guideline.

The level of ICU facilities is a quality indicator that hospitals must provide to the Dutch healthcare inspectorate on a yearly basis. For this study, the level of ICU facilities for each hospital was derived from the website with the databank of these quality indicators<sup>13</sup>. If a hospital had changed levels within the study period of 2009-2011, the category noted in most of these years was used.

### ***Failure to rescue***

The definition of FTR is displayed in panel 1 and was formulated in accordance with the definition in a previous study<sup>4</sup>. Unadjusted FTR rates were compared between different hospital volumes, hospital types and between hospitals with different levels of ICU facilities with the  $\chi^2$  test. Subsequently, multivariate logistic regression analysis was

used for risk adjustment and to determine whether the structural hospital factors were independently associated with differences in FTR rates. Risk adjustment was done for age, sex, ASA score, location of the tumor, Charlson co-morbidity index, urgency of the operation, TNM stage, additional resections, multiple synchronous colorectal tumours and neoadjuvant therapy.

A 2-sided  $P \leq 0.05$  was considered statistically significant. Statistical analyses were performed in PASW Statistics, version 20 (SPSS inc., Chicago, IL, USA) and R 2-14 (The R Project for Statistical Computing and The Comprehensive R Archive Network; <http://cran.r-project.org/>).

## DEFINITIONS

**Mortality:** A patient that died within 30 days after the operation or during the index hospital admission.

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

**Failure to rescue:** The percentage of patients with a severe complication that died in-hospital or within 30 days after the resection; (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

**Table 2:** hospital-, patient-, tumor- and treatment characteristics

| Hospital characteristics    |   | Total patient group | Non-teaching hospitals | Teaching hospitals | University hospitals |
|-----------------------------|---|---------------------|------------------------|--------------------|----------------------|
| Annual hospital volume      | Mean (range)                                  | 74 (20-118)         | 144 (41-287)           | 78 (41-115)        |                      |
| ICU level 3 (highest)       | Number of hospitals                           | 0                   | 16                     | 8                  |                      |
| ICU level 2                 | Number of hospitals                           | 2                   | 23                     | 0                  |                      |
| ICU level 1 (lowest)        | Number of hospitals                           | 36                  | 7                      | 0                  |                      |
| Patient characteristics     |   |                     |                        |                    |                      |
| Sex                         | Male  | 14072 (55%)         | 55%                    | 55%                | 58%                  |
| Age                         | Mean (standard deviation)                     | 70 (11)             | 70 (11)                | 70 (11)            | 67 (12)              |
| BMI                         | kg/m <sup>2</sup> , mean (standard deviation) | 26 (4,8)            | 26 (4,6)               | 26 (4,8)           | 26 (4,6)             |
| Charlson co-morbidity index | 0   | 14189 (55%)         | 55%                    | 56%                | 53%                  |
|                             | 1   | 5555 (22%)          | 23%                    | 21%                | 22%                  |
|                             | 2   | 3419 (13%)          | 13%                    | 13%                | 15%                  |
|                             | 3 or higher                                   | 2428 (10%)          | 9%                     | 10%                | 11%                  |
| ASA classification          | I-II  | 19100 (75%)         | 72%                    | 76%                | 76%                  |
|                             | III   | 5389 (21%)          | 22%                    | 20%                | 21%                  |
|                             | IV-V  | 496 (2,0%)          | 3%                     | 2%                 | 2%                   |

**Table 2:** hospital-, patient-, tumor- and treatment characteristics (continued)

|                        | Total patient group                      | Non-teaching hospitals | Teaching hospitals | University hospitals |
|------------------------|--|------------------------|--------------------|----------------------|
| Pathological TNM stage | Unknown                                  | 3%                     | 4%                 | 1%                   |
|                        | X  | 3%                     | 4%                 | 4%                   |
|                        | I  | 22%                    | 20%                | 18%                  |
|                        | II                                       | 32%                    | 34%                | 30%                  |
|                        | III                                      | 32%                    | 31%                | 30%                  |
|                        | IV                                       | 11%                    | 11%                | 18%                  |
| Location of tumor      | Right hemicolon                          | 34%                    | 32%                | 29%                  |
|                        | Left hemicolon                           | 12%                    | 12%                | 10%                  |
|                        | Sigmoid colon                            | 29%                    | 28%                | 23%                  |
|                        | Rectum                                   | 26%                    | 28%                | 38%                  |
| Procedure              | Ileocaecal resection                     | 1%                     | 1%                 | 1%                   |
|                        | Right hemicolectomy                      | 33%                    | 31%                | 29%                  |
|                        | Transverse colectomy                     | 2%                     | 2%                 | 1%                   |
|                        | Left hemicolectomy                       | 8%                     | 7%                 | 6%                   |
|                        | Sigmoid colectomy/low anterior resection | 45%                    | 43%                | 42%                  |
|                        | Subtotal colectomy                       | 1%                     | 2%                 | 1%                   |
|                        | Abdominoperineal resection               | 7%                     | 9%                 | 15%                  |
|                        | Panproctocolectomy                       | 1%                     | 1%                 | 2%                   |
|                        | Other                                    | 2%                     | 3%                 | 4%                   |
| Urgency                | Urgent/emergency resection               | 17%                    | 15%                | 13%                  |

## RESULTS

### Patients

A total of 25591 patients, registered by 92 hospitals were included in this study. Patient, tumor and treatment characteristics are displayed in table 2. Average mortality was 4.3% and the percentage of patients with a severe complication was 23%, with an average FTR rate of 17%. University hospitals treated a higher proportion of patients with rectal cancer. Patients treated in university hospitals were younger, but had slightly more comorbidity and more often stage IV disease. Consequently, additional resections and metastasectomies were performed more often in university hospitals, and patients in these hospitals were treated with preoperative chemoradiotherapy more frequently. Non-elective surgery was slightly less common in university hospitals, compared to other hospital types.

### Hospital volume

The average annual number of colorectal cancer resections per hospital was 99 and ranged between 20 and 206 procedures per year (table 2).

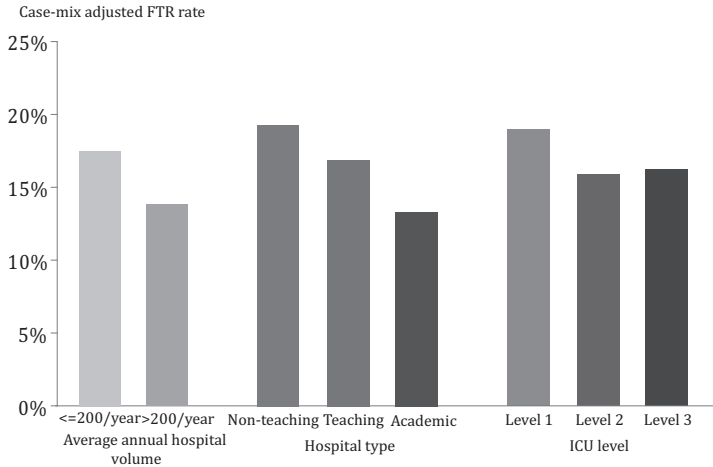
In univariate analysis, there was no difference in FTR rate between the five hospital volume groups, especially not between the lowest (<50 patients/year) and highest volume (more than 200 patients/year) group (data not shown). With the cutoff at 0-200 cases/year versus more than 200/year there was a significantly lower FTR rate in the higher volume group (table 3). Four hospitals had an average annual volume of more than 200 colorectal cancer resections. Adjusted for casemix, the difference in FTR between hospitals with more than 200 cases/year and the lower volume hospitals was 17% versus 14%;  $p=0.07$  (figure 1).

**Table 3:** unadjusted and adjusted failure-to-rescue (FTR) rates per hospital type and ICU level.

| Factor                        | Unadjusted FTR | Univariate                |             | Multivariate            |              |
|-------------------------------|----------------|---------------------------|-------------|-------------------------|--------------|
|                               |                |                           | OR (95% CI) |                         | OR (95% CI)* |
| Hospital volume               |                |                           |             |                         |              |
| low (<=200 cases/yr)          | 18%            | 1 (ref)                   |             | 1 (ref)                 |              |
| high (more than 200 cases/yr) | 13%            | <b>0.69 (0.51-0.95)</b>   |             | 0.75 (0.53 -1.06)       |              |
| Hospital type                 |                |                           |             |                         |              |
| Non-teaching hospital         | 21%            | <b>1.34 (1.15 - 1.55)</b> |             | 0.99 (0.76-1.3)         |              |
| Teaching hospital             | 17%            | 1 (ref)                   |             | 1 (ref)                 |              |
| University hospital           | 12%            | <b>0.72 (0.54 - 0.98)</b> |             | 0.84 (0.60-1.16)        |              |
| Level of ICU facilities       |                |                           |             |                         |              |
| ICU level 1                   | 21%            | <b>1.54 (1.31-1.83)</b>   |             | <b>1.39 (1.06-1.83)</b> |              |
| ICU level 2                   | 15%            | 1 (ref)                   |             | 1(ref)                  |              |
| ICU level 3                   | 16%            | 1.14 (0.96 -1.35)         |             | 1.16 (0.95-1.40)        |              |

**Bold** printed numbers are statistically significant (p<0.05). FTR= failure to rescue ICU= Intensive Care

\* casemix factors, hospital volume, hospital type and ICU level are included in the model



**Figure 1:** failure to rescue (FTR) rates, adjusted for casemix, per volume group, hospital type and ICU level.

### Hospital type and ICU level

All Dutch hospitals performing colorectal cancer surgery were included in the study: eight university hospitals; 46 teaching hospitals and 38 non-teaching hospitals.

In 43 hospitals only basic (level 1) ICU facilities were available, 25 hospitals had a level 2 ICU, and 24 hospitals had an ICU of the highest level 3. Hospital characteristics are displayed in table 2.

Differences in FTR rates between the different hospital types and levels of ICU facilities, derived from univariate- and multivariate analysis are displayed in table 3. Unadjusted FTR rates were significantly lower in university hospitals and significantly higher in non-teaching hospitals, compared to teaching hospitals.

Also, level 1 ICU hospitals had significantly higher FTR rates than hospitals with level 2 ICU capacity; there was no difference in FTR rates between level 2 and 3 ICU hospitals.

Adjusted for casemix, FTR rates were 19% (0-39%) in non-teaching hospitals, 17% (2-26%) in teaching hospitals and 13% (6-20%) in university hospitals. When stratified according to ICU level, casemix-adjusted FTR rates were 19% (0-39%) in level 1 ICU hospitals, 16% (8- 26%) in level 2 and 16% (6-23%) in level 3 ICU hospitals (figure 1).

As can be seen in table 4, the relation between teaching status and FTR lost its statistical significance when the factors hospital volume, hospital type and ICU level were entered as variables in the logistic regression model. Only ICU level proved to be independently related to FTR rates, with level 1 (lowest) ICU level being associated with sig-

**Table 4:** incidence of and failure-to-rescue (FTR) from various complications per level of ICU

| postoperative complication   | incidence (n/%) | FTR from complication (%) |             |             | p for difference  |
|------------------------------|-----------------|---------------------------|-------------|-------------|-------------------|
|                              |                 | ICU level 1               | ICU level 2 | ICU level 3 |                   |
| anastomotic leak             | 1315 (5%)       | 17%                       | 14%         | 16%         | ns                |
| abscess                      | 606 (2,4%)      | 9%                        | 6%          | 7%          | ns                |
| hemorrhage                   | 205 (1%)        | 23%                       | 17%         | 10%         | 0.05*             |
| ileus                        | 380 (2%)        | 15%                       | 5%          | 4%          | 0.006* / 0.003 ** |
| fascial dehiscence           | 409 (2%)        | 12%                       | 6%          | 9%          | ns                |
| iatrogenic bowel injury      | 109 (0%)        | 29%                       | 13%         | 22%         | ns                |
| other surgical complications | 759 (3%)        | 18%                       | 14%         | 12%         | ns                |
| non-surgical complications   | 2330 (9%)       | 27%                       | 22%         | 22%         | 0.021* / 0.016**  |

\* ICU level 1 vs level 3

\*\* ICU level 1 vs level 2



nificantly lower FTR compared to a level 2 ICU (reference category). When level 2 and 3 ICU hospitals were combined in one group, the OR for FTR was 0,72 (95% CI 0,65 – 0,88;  $p < 0,001$ ) when compared to level 1 ICU hospitals.

### **Complication types**

A characterization of FTR per complication type is displayed in table 4. Anastomotic leak, intra-abdominal abscess and non-surgical complications occurred most often. FTR rates were lower for all complications in ICU level 2 and level 3 hospitals when compared to hospitals with level 1 ICUs. This difference was significant for FTR from postoperative haemorrhage, ileus, and non-surgical complications.

## **DISCUSSION**

This study is the first to directly evaluate the association between FTR and hospital characteristics in colorectal cancer surgery. FTR was lower in patients operated in high volume hospitals, in university hospitals and in hospitals with higher levels of ICU facilities in univariate analysis. A higher level of ICU facilities was the only factor associated with lower FTR rates in multivariate analysis. Differences in level of ICU facilities might be a part of the explanation of the differences in FTR rates between hospitals.

Ghaferi et al. found higher hospital volume to be significantly associated with favourable FTR rates<sup>6</sup>, however this association concerned patients undergoing surgery that may be considered more challenging than colorectal cancer surgery (pancreatic and upper gastrointestinal surgery). In another study, teaching hospitals and overall hospital size of >200 beds were independently associ-

ated with lower FTR rates after pancreatic resections<sup>11</sup>. In this study, “high technology” (transplantation and cardiac surgery performed in the hospital) was also associated with lower FTR. Arguably, “high technology” may be a proxy for better ICU facilities. Almoudaris et al. describe a higher number of high-dependency unit beds in the quantile of hospitals with lowest postoperative mortality after colorectal surgery; however the number of ICU beds did not differ between quantiles<sup>3</sup>.

Colorectal cancer surgery is performed in the majority of Dutch hospitals, typically in a medium-volume setting (average 99 cases/year), though with many lower volume centers being present as well. Only a small number of hospitals perform more than 200 procedures/year, which may make it hard to reach significance.

Although we found that unadjusted FTR rates were lower in university hospitals and higher in non-teaching hospitals, these differences lost statistical significance when casemix factors and the three hospital characteristics were analyzed together in multivariate analysis. The availability of at least a level 2 ICU was the only structural hospital factor independently associated with better FTR rates.

Patients operated in hospitals with level 2 ICUs had a similar risk of FTR as patients from level 3 ICU hospitals. The differences in characteristics between ICUs of level 2 and 3 (table 1) appear relatively modest whereas differences between level 1 and 2 ICUs seem more distinct. The biggest differences between level 1 ICUs and level 2 or 3 ICUs are the exclusive 24 hours a day availability of an intensivist, the transfer of responsibility for the patient to the intensivist, and more intensive care staffing (table 1). Our findings suggest that these staffing factors of an ICU may be important factors that contribute to better FTR rates in colorectal surgery. Surgical complications such as anastomotic leak may lead to single or multiple organ dysfunction. Non-surgical complications may carry an additional risk of mortal-

ity in this relatively old and frail patient group. Therefore, adequate availability of ICU support seems essential in management of patients with severe complications after colorectal surgery.

The positive effects of higher ICU staffing and 24-hour coverage by an intensivist on ICU- and hospital mortality have been described before<sup>12,18,19</sup>. Our study builds on this, showing an association between these staffing factors and lower FTR rates in a specific surgical population.

Many Dutch hospitals with lower-level ICUs have regional agreements with hospitals with higher levels of ICU care on, for instance, teleconferencing. Although regional collaboration undoubtedly has a positive impact on outcomes, our study shows that despite these initiatives a lower level of ICU facilities was associated with higher FTR rates. However, some hospitals with low level ICUs performed well.

There are some limitations in this study. The data is self-reported, so selection bias cannot be completely excluded. However, the dataset is highly detailed and validated against data from the Netherlands Cancer registry (see methods). Secondly, the definition of severe complications (complications followed by a reintervention, a prolonged in-hospital stay of more than 14 days or to death) may be considered arbitrary. However, this definition distinguishes major complications from less severe complications that do not hinder the postoperative course<sup>20</sup>.

The variability of FTR rates within each group of hospitals' structural factors suggest that there must be other factors as well playing a role in explaining hospital differences in FTR rates. Firstly, these may be factors associated with timely recognition of complications<sup>21</sup>. For instance, higher nurse-to-patient ratios have been associated with lower FTR rates<sup>22</sup>. An in-depth study concerning factors reflecting differences concerning in-hospital processes should be conducted,

evaluating the daily ward rounds, responsibility for the ward patients, staffing outside office hours, vital sign collection and reporting, the level of experience in a surgical team, team communication, guideline adherence and quality of care from nurses. Secondly, hospital differences in FTR rates may be sought in differences in delay until the start of treatment of complications. For instance, early reintervention for anastomotic leak may prevent clinical deterioration and death. Alves et al. found lower mortality after reoperations performed before postoperative day five, although this difference was not significant<sup>23</sup>.

With identification of specific care processes that account for differences in hospital FTR rates, quality improvement initiatives can aim at reducing postoperative mortality by addressing the most important factors in the postoperative care process. Safeguarding adequate ICU capacity to support patients with complications after colorectal surgery seems one of these factors.

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