

## European Audit on Colorectal Cancer Treatment Outcome – The Next Step in Quality Assurance Initiated by the European Society of Surgical Oncology

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### Abstract

In recent years there have been significant improvements in rectal cancer outcome. New surgical techniques and effective neoadjuvant treatment regimens have contributed to these improvements. It is important to spread these advances to every rectal cancer patient and to make sure that it is not only patients treated within the framework of clinical trials who may benefit from these advances. Throughout Europe there have been interesting quality programmes that have been proved to facilitate the spread of up-to-date knowledge and skills among medical professionals, resulting in improved treatment outcomes. Despite these laudable efforts, there is still wide variation in treatment outcomes between countries, regions and institutions, which calls for a European audit on cancer treatment outcomes.

### Keywords

Colorectal cancer, rectal cancer, outcomes assessment, audit

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Currently, quality of healthcare is a hot topic, and this is especially true for cancer care. Patients try to seek the best care available. As a result, several ranking lists can be found on the Internet and in the popular press worldwide. Unfortunately, many of those lists do not meet the requirements needed for a fair comparison of healthcare providers and can therefore give misleading results. Nevertheless, the search for quality is plausible because there seem to be substantial differences in quality of care between countries, hospitals and doctors.<sup>1</sup> In addition to patients, politicians, insurance companies and medical professionals also strive for a higher quality of care, all with their own reasons and strategies. In many countries, governments have tightened their existing regulations and created new ones when trying to improve quality of care in a 'top-down' manner. Obviously, medical professionals also put great effort into improving their quality of work, but this happens in a 'bottom-up' manner. All initiatives to improve quality of care can be nominated as 'quality assurance'. Although lacking a strict definition, quality assurance can be summarised as "the complete set of systematic actions that is required to achieve a treatment result that meets a certain standard".<sup>2</sup>

Quality assurance in surgical oncology is relatively new compared with other medical fields such as chemotherapy and radiotherapy. For a long time, surgery was thought to have too much unexpected variation to be feasible for standardisation and quality control. However, the conception of surgery is steadily shifting from being a non-definable craft to a transparent and well-defined skill. Currently, many quality assurance programmes have been rolled

out successfully in surgical oncology with encouraging results, in particular for the treatment of rectal cancer. In the early 1990s, the outcome after rectal cancer surgery was poor, with survival and recurrence rates of approximately 45%.<sup>3</sup> In addition, there was a remarkable variation in outcome between hospitals and between individual surgeons.<sup>4,5</sup> In that time the total mesorectal excision (TME) technique was introduced by Heald et al.<sup>6</sup> Instead of a blunt dissection, the rectum is sharply dissected within its mesorectal fascia under direct vision. Many European countries initiated quality assurance projects as an answer to these challenges. In this article, we will describe different aspects of quality assurance, and will conclude with a framework for the future of surgical oncology in Europe.

### Clinical Trials

Several European studies have shown improvements in outcome after implementation of the TME technique in rectal cancer surgery.<sup>4,7</sup> Studies showing the benefits of the TME technique have contributed to the quality of rectal cancer care in two ways: on the one hand by publishing, spreading and recommending the new technique, and on the other hand because standardised and quality-controlled surgical trials seem to have a positive effect that reaches further than the patients and doctors who participated in the study. Improvements in quality of care as a direct consequence of registering surgical data have been observed in multicentre clinical trials with mandatory criteria for surgical technique and quality of care. A good example is the Dutch TME trial,<sup>8</sup> which studied the value of pre-operative short-term radiotherapy in

**Table 1: European National Audit Projects Concerning Rectal Cancer**

Country	Audit	Since
Norway	Norwegian Rectal Cancer Project	1993
Sweden	Swedish Rectal Cancer Registry	1995
Denmark	Danish Colorectal Cancer Database	1994
UK	National Bowel Cancer Audit Programme	1999
Belgium	Project on Cancer of the Rectum	2005
The Netherlands	Dutch Surgical Colorectal Audit	2009

combination with standardised TME surgery in patients with rectal cancer. Standardisation and quality of treatment was continuously emphasised by means of master classes, supervision and visitation. This resulted in lasting positive effects.<sup>9</sup> Rectal cancer patients in the region of the Comprehensive Cancer Centres South and West were clustered in three groups: before, during and after the trial period of the TME study (1996–1999). Of the 3,179 patients analysed, only 421 (12%) participated in the TME trial. Survival improved for all patients in the period during the trial, and in the last period survival improved even more.

Despite all of these improvements, there remain differences between European rectal cancer studies that cannot be easily explained. For instance, the five-year survival rate in the German CAO/ARO/AIO-94 study<sup>10</sup> exceeds the five-year survival rate of the Dutch TME trial<sup>11</sup> by more than 10% (75 versus 64%). Differences in study design could play a major role in these variations in outcome, besides differences in infrastructure and patterns of care between the hospitals participating in these studies. Another downside of relying on clinical trials as a tool to judge and improve quality of care is that most patients are treated without being enrolled in clinical trials. Elderly patients or those with multiple co-morbidities are often excluded from clinical trials, leaving little evidence for the treatment of these categories of patients.

## Multidisciplinary Treatment

The importance of multidisciplinary treatment cannot be emphasised enough. Even the best surgeon is helpless without an adequate radiologist, pathologist, medical oncologist and radiotherapist. Much effort has been put into the multidisciplinary approach of cancer treatment for rectal cancer patients. Radiologists had to facilitate magnetic resonance imaging diagnostics, whereas pathologists had to adapt according to the protocol of Quirke et al.<sup>12</sup> to adequately identify lateral spread of tumour. Radiotherapists had to shift to pre-operative radiation treatment schemes for a majority of patients. It is essential to include all multidisciplinary fields of cancer treatment in quality assurance programmes by standardising, training and visitation with feedback.

## Concentrating Treatment to High-volume Centres

A growing number of studies report variation in outcomes between institutions providing healthcare. For cancer surgery in particular, a relationship exists between hospital or surgical volume and patient outcomes in terms of operative mortality, complications and overall survival.<sup>13</sup> In most western healthcare systems, efforts are made to reduce this hospital variation. Most initiatives focus on selective referral, encouraging patients to seek care in high-volume hospitals. A strategy whereby a larger proportion of patients is treated in

specialised centres could evidently improve overall results for complex surgical procedures such as oesophagectomies and pancreatectomies.<sup>14</sup> Although there are also multiple studies showing a positive volume–outcome relationship for colon and rectal cancer,<sup>15–17</sup> variation is smaller compared with oesophagectomies or pancreatectomies. Besides, one must keep in mind that there are also low-volume providers who perform very well and high-volume providers with unacceptable outcomes. In addition, the expertise for diagnosis and treatment of common types of cancer should preferably be widespread and easily accessible for all patients.

## National Audits

As an alternative to volume-based referral, hospitals and surgeons might improve their results by learning from their own outcome statistics and those of colleagues treating a similar patient group. Surgical audit is a quality instrument that collects detailed clinical data from different healthcare providers, which can be adjusted for baseline risk and subsequently fed back to individual hospitals or surgeons. Identifying, communicating and adopting ‘best practices’ might improve the quality of care nationwide.<sup>18</sup> An important condition for the success of outcome registries is the quality of the collected data. Data have to be prospective, complete, case-mix-adjusted and, preferably, collected by independent investigators.<sup>19</sup> In addition, the quality of the data has to be assured by a second independent registry.

In Europe, several national rectal cancer audit registries have been established since the 1990s (see *Table 1*). The most important advantage of these audit registries compared with clinical trials is the fact that they include the entire patient population without excluding certain patient groups. After case mix adjustments, a fair judgement can be made on the quality of cancer treatment, and healthcare providers can be faced with their own results compared with those of colleagues treating the same patient category. For instance, the Norwegian Rectal Cancer Project, founded in 1993, includes more than 99% of patients operated on for rectal cancer.<sup>20</sup> After four years the results of this audit were remarkable. The proportion of TME surgery rose from 78 to 92%, and the local recurrence rate dropped from 28 to 7%.<sup>20</sup> These results, published in 2002, are indeed spectacular. In addition, the audit proved to be very cost-effective, with the cost of every saved life being less than €700.<sup>21</sup> Swedish initiatives were also successful. The Swedish Rectal Cancer Registry was started in 1995, with over 97% of patients with

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rectal cancer included.<sup>22</sup> The post-operative mortality rate was less than 2.5%, with a local recurrence rate of less than 10%. Survival dramatically improved. Patients with rectal cancer had an even better five-year survival rate than those with colon cancer.<sup>23</sup> This is remarkable because in the same period important improvements in chemotherapy for patients with colonic cancer had been achieved.

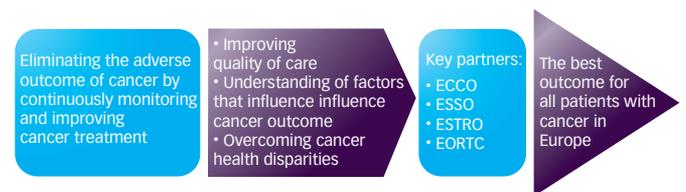
**Table 2: Results of European National Audit Projects Concerning Rectal Cancer**

Country	Period	Coverage (%)	Five-year Survival (%)		TME (%)		Five-year Local Recurrence (%)		30-day Mortality (%)	Number of Patients
			Before	After	Before	After	Before	After		
Norway	1994–1997	>99	55	67*	78	92	28*****	7	2.74	3,319
Sweden	1995–2003	>97	53.6**	62	–	–	28*****	9.5	2.4	13,434
Denmark	1994–1999	93	F42/M37	F63/M55	–	–	–	–	5	5,021
UK	2001–2006	17	–	–	–	–	–	–	5	64,700
Belgium	2006–2008	50***	46.6	–	–	–	–	–	3	2,300
The Netherlands	2009	>95	64****	–	–	–	–	–	–	3,200

F = female; M = male; \*Four-year survival; \*\*Swedish rectal cancer mortality in period 1990–1994; \*\*\*Calculated out of yearly incidence of rectal cancer and yearly included patients in audit; \*\*\*\*Dutch Total Mesorectal Excision (TME) trial; \*\*\*\*\*Swedish rectal cancer local recurrence rate in period 1990–1994; \*\*\*\*\*Median follow-up 30 months.

Rectal cancer patients did not benefit from these changes, as adjuvant treatment after rectal cancer surgery is still considered experimental in many European countries. Besides, rectal cancer is much more technically demanding because, in contrast to colonic cancer, the pelvic area, including the rectum, contains little space in which to perform a radical resection. Nevertheless, the fact that survival of rectal cancer patients was superior to that of colon cancer patients shows the considerable impact of surgical training and feedback. The Danish Colorectal Cancer Database also produced satisfying results.<sup>24</sup> Since 1994, 93% of all colorectal cancer patients have been included. After five years of auditing, five-year survival increased from 42 to 63% for women and from 37 to 55% for men.

More recently, other European countries have followed the Scandinavians by creating their own national (colo)rectal audit programmes. In 2001 the Association of Coloproctology of Great Britain and Ireland started the National Bowel Cancer Audit Programme. With 17% of all trusts in England and Wales submitting complete data in 2007, there is not yet enough coverage to allow solid feedback.<sup>25</sup> However, it is enough to create risk-adjusted models required to give fair comparative feedback in the future. In 2005 Belgian surgeons initiated the Project on Cancer of the Rectum.<sup>26</sup> After standardisation and implementation of guidelines, prospective registration started in 2006 on a voluntary basis. To date, around 2,300 patients have been included. Besides registering crude outcome data after rectal cancer treatment, extensive efforts and means are used to train surgeons, pathologists and radiologists in the latest standards of rectal cancer treatment. In 2009 the Dutch Society of Surgical Oncology, Dutch Society of Gastrointestinal Surgery and Dutch Colorectal Cancer Group started the Dutch Surgical Colorectal Audit (DSCA).<sup>27</sup> Although the audit was initiated and organised by the profession, independent from governmental organisations, the Dutch Ministry of Health, Welfare and Sport adopted the programme, gave financial support and made participation in the DSCA a ‘quality indicator’ for healthcare institutions. These quality indicators are established by the Netherlands Health Care Inspectorate to monitor (differences in) quality of care provided by Dutch hospitals. The performance of individual hospitals on this extensive set of quality indicators is made public through the Internet.<sup>28</sup> Considering the magnitude of the improvements in outcome shown by all rectal cancer audit projects, the costs are futile in comparison with the costs of several adjuvant therapies. Most importantly, the benefits for individual patients of most adjuvant therapies are several orders of magnitude smaller than those of the major improvements achieved by the audits described above.

**Figure 1: Vision and Strategy for European Audit on Cancer Treatment Outcome Project**

ECCO = European CanCER Organisation; ESSO = European Society of Surgical Oncology; ESTRO = European Society for Therapeutic Radiology and Oncology; EORTC = European Organisation for Research and Treatment of Cancer.

### European Audit on Cancer Treatment Outcome – An International, Multidisciplinary, Outcome-based Quality Improvement Project of the European CanCER Organisation

Although all national audits and trial populations described above achieved excellent results, there remain differences between European countries that cannot be explained easily (see Table 2). On review of the results of the national audits, the 30-day mortality rate ranges from 2.4% (Sweden<sup>22</sup>) to 5% (Denmark<sup>24</sup> and the UK<sup>25</sup>). Although the differences in five-year survival are definitely getting smaller than before auditing, the proportions still range from 55% (Denmark<sup>24</sup>) to 67% (Norway<sup>20</sup>). In addition, there are substantial differences in (neo)adjuvant treatment regimens. In Sweden and The Netherlands every rectal cancer patient receives pre-operative radiotherapy, but in Norway a minority (4% between 1993 and 1997<sup>21</sup>) of patients receive radiotherapy. Nevertheless, local recurrence rates in Norway equal the rates in Sweden and The Netherlands.<sup>20</sup>

To generate the best care for rectal cancer in the whole of Europe and to meet political and public demands for transparency, a deep and broad insight into the results of rectal cancer treatment is needed in all nations. The inevitable conclusion is that a European audit registration is needed to ameliorate the treatment of rectal cancer even further and decrease variation in quality of care. Urged by these arguments, the European Society of Surgical Oncology initiated an international, multidisciplinary, outcome-based quality improvement programme, which has been fully embraced by the European CanCER Organisation (ECCO). ECCO has set the goal to “Uphold the right of all European cancer patients to the best possible treatment and care”. Registration of outcome-based quality measurements will provide transparency, benchmarking and internal feedback, which will rapidly lead to improvements in cancer care. In this article we have described the direct, measurable improvements that have been made by national audit initiatives to improve quality

of care in daily clinical practice. Although these national initiatives are successful, international initiatives are limited. In Europe a prospective international audit to monitor cancer care outcome has not yet taken place.

Our goal is to create a multidisciplinary European registration structure of patient, tumour and treatment characteristics linked to outcome registration (morbidity, mortality, locoregional control and survival). The registration will be used for benchmarking and internal feedback among participants and therefore further improvements in quality and efficiency of cancer care. Considering the multidisciplinary aspects of cancer treatment, collaboration between the European cancer organisations is pivotal for the success of this project. Key partners in realising the vision are ECCO, European Society of Surgical Oncology, European Society for Therapeutic Radiology and Oncologists, European Organisation of Research and Treatment of Cancer, European Union and national cancer networks (see *Figure 1*). Initially, the focus will be on colorectal cancer because of the experience in quality measurement and the already existing audit registrations. The project consists of two parts. In the first period of two years the registration will make use of currently existing audit systems for colorectal cancer as in Norway, Sweden, Denmark, the UK, The Netherlands and Belgium and start a benchmarking process. The national audit co-ordinators will provide access to their national databases and will form a multidisciplinary steering committee. The second period starts after development of the European registration system. The data will be used continuously for benchmarking and internal feedback among participants. Afterwards, this experience will be used to extend the audit to other solid malignancies such as breast, gastric and oesophageal cancer.

## Conclusion

Recent developments in quality assurance in surgical oncology have resulted in improvements that have a greater impact on survival than those of any of the adjuvant therapies currently under study. A European audit could advance future improvements and

spread these to every cancer patient in Europe. ECCO has recognised the importance of quality assurance and has created a framework to develop a European audit. As such, ECCO has established a strong, multidisciplinary organisation with a commitment to improving cancer care in Europe. ■

All information about this project can be found on the webpage [www.canceraudit.eu](http://www.canceraudit.eu). People involved in the treatment of colorectal cancer who are interested in joining or contributing to the European Colorectal Audit ECCO project can contact the authors.



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Marcel den Dulk is the co-ordinator and principal investigator of a multicentre project on anastomotic leakage. In 2001 he qualified as a medical practitioner, and then worked as a surgical resident at the Haga Hospital in The Hague. Dr den Dulk began his PhD research in the Department of Surgical Oncology at Leiden University Medical Centre in December 2005, and received a Fellowship of the European Society of Surgical Oncology (ESSO) for this project.



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