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Value of outcomes research in colorectal cancer care

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Citation

Gietelink, L. (2017, November 30). *Value of outcomes research in colorectal cancer care*. Retrieved from <https://hdl.handle.net/1887/55849>

Version: Not Applicable (or Unknown)

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Note: To cite this publication please use the final published version (if applicable).

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Title: Value of outcomes research in colorectal cancer care

Issue Date: 2017-11-30

Chapter 9

GENERAL DISCUSSION AND FUTURE PERSPECTIVES

PART I: RISK-ADJUSTMENT IN CLINICAL AUDITING

Patient populations treated for a specific condition usually differ across hospitals.¹ Casemix is a confounder for between-hospital comparisons based on outcomes and therefore, casemix adjustment needs to be applied when comparing outcomes across hospitals with the aim to judge quality of hospital care. The casemix correction models are logistic regression models that include the most important predictors of the outcome parameter that are available in the audit.² Despite incorporating casemix adjustment, many risk adjustment models could be considered suboptimal.³ In casemix adjustment we come across several problems. When comparing hospitals there is always random variation; fluctuations in outcomes of hospitals based on chance.⁴ Random variation becomes smaller when the study population and frequency of events (the studied outcome) increases. This is specifically important regarding the fact that some serious but infrequent adverse events – like mortality rates - gain much attention in colorectal cancer care. The frequency of postoperative mortality, especially after rectal cancer resections is low and hospital variation could be due to random variation instead of a difference in performance.

Another problem associated with casemix adjustment is the low frequency of specific patient populations in the majority of hospitals, while these are overrepresented in a few centres. The population of referral centres consist of a carefully selected group of patients based on the rarity of the disease or the high complexity of the treatment. These referral centres have a significantly different patient population, but are compared with general hospitals in one casemix correction model (this thesis). In chapter 2 we demonstrated that variable effects of predictors that are included in the currently used casemix model differed between referral and non-referral centres when we created separate casemix models for these two populations. As we hypothesized casemix correction models based on the total population showed the most resemblance with the non-referral population. The currently used casemix model (general model) that is fitted in the total population performs equally well in the non-referral population as a casemix model specifically fitted in non-referral hospitals only. In contrast, the general model performs worse in the referral population when compared to a model specifically fitted in referral hospitals only. It remains unclear

if the differences in casemix correction caused undercorrection for referral centres (this thesis). However no referral hospital was an outlier on the outcomes that were studied within the time frame of this study.

It seems plausible that a bigger gain lies in the registration of typical characteristics of the referral population as the DSCA casemix models only include the most frequently occurring factors of influence.² For hospitals with a specific patient population, like referral centres, it seems plausible that the registration of certain factors that are typical for this group of complex patients; i.e. detailed information about previous surgery, index surgery, multimodality treatments, and medication use therefore could be of influence on the correction of postoperative outcomes. Furthermore factors dictating the technical difficulty of the procedure are difficult to register with clear definitions – such as the detailed information about previous surgery – leading to suboptimal correction of postoperative outcomes. The possible solutions to these problems have their own disadvantages. Adding more variables to the dataset would make the registration burden bigger and the DSCA wants to keep the dataset compact for users. Creating two separate casemix correction models would raise the question which hospital should be added to which population group. Beside from all university hospitals and two other hospitals that are generally seen as referral centres it is complex to decide whether hospitals treat a sufficiently different population in order to be compared to referral centres.

Interpretation of hospital comparisons

A certain amount of unmeasured confounding in casemix correction of outcomes will remain, meaning that even casemix adjusted outcome rates should always be interpreted with caution. This is especially important as there is a growing demand for public transparency of hospital outcomes. Hospitals and surgeons are naturally held responsible for their outcomes and transparency to a public that is not informed on how to interpret this data could lead to unwanted reactions, such as the avoidance of high-risk surgery.⁵ Healthcare providers are less willing to register openly if this leads to adverse reactions and this disturbs the audit cycle. Therefore it is important that transparency is carefully introduced with the necessary information to interpret the data. Herein lies an important task for the national audits.

PART II: QUALITY ASSURANCE AND IMPROVEMENT IN DUTCH COLORECTAL CANCER CARE

Quality assurance is an important aspect of the healthcare industry. All components of the patient's healthcare process are of importance and influence the overall quality of treatment. Ernest J. Codman already noted at the beginning of the 20th century that careful registration of healthcare processes and patient outcomes would provide important feedback information. He wanted an end-results system to track the outcomes of his patient's treatments as an opportunity to identify clinical misadventures that would serve as the foundation for improving the care of future patients.⁶ Doctor Codman was ahead of his time and was expelled from the staff of the Massachusetts General Hospital.⁷ Fortunately his ideas on quality of care are regarded as highly relevant nowadays.^{8, 9}

Hospital volume

New thoughts on quality assurance at the beginning of this century were largely focussed on the relationship between hospital or surgeon's volume and quality.¹⁰⁻¹⁶ This relationship was also analysed in the Netherlands with multiple papers describing the positive relationship between hospital volume and patient outcomes.¹⁷⁻¹⁹

The Netherlands is a small country with 90 hospitals. As a result low-volume high-risk procedures could be centralized in a smaller number of hospitals, with acceptable travelling distances for patients.¹⁷ Besides the fact that a larger volume per surgeon will lead to more experience, it is generally believed that volume is a 'proxy' for other important structural and process factors in the chain of multidisciplinary treatment.²⁰

This further enhanced centralisation of technically challenging procedures such as rectal-, pancreas-, oesophageal- and bladder cancer resections. The Association of Surgeons of the Netherlands (ASN) set an obligatory minimal volume standard of 20 resections per hospital per year.²¹ Hospitals with lower annual volumes of rectal cancer resections are no longer allowed to carry out this procedure. With data from the DSCA this decision could further be substantiated (this thesis). Chapter 3 shows the significant influence of hospital

volume on CRM involvement in the Netherlands. In the light of these results an obligatory volume for rectal cancer care seems justifiable. It is however important to conclude that hospital volume is merely a proxy for healthcare processes and that hospital volume does not guarantee quality.²² Individual small volume hospitals can provide the same standard of care compared to high volume hospitals as shown in this thesis. Over the last years focus has shifted towards value of care instead of volume of care.^{23, 24}

Clinical auditing

Amongst other initiatives the DSCA was founded in 2009 and provides risk-adjusted benchmarked feedback evaluating quality of surgical colorectal cancer care on hospital level and compares hospitals with their peers. It gives surgeons and their teams information about their performance and stimulates the development or improvement of hospital processes.² Amongst other great improvements in the field of colorectal cancer surgery the introduction of clinical auditing has been successful.^{2, 25} Important aspects of surgical colorectal cancer care improved significantly since the start of the audit. As clinical auditing provides healthcare professionals with essential information on their performance in comparison to their peers, multiple improvements can be made. There are several requirements for surgical audits to provide valuable information.²⁶ The definitions used in the surgical audit should be unambiguous and feedback information should be reliable, accompanied by a risk-adjusted benchmark. Furthermore the information has to be up to date and easily accessible to involved healthcare providers. Most importantly the feedback information should be relevant, meaningful and actable which necessitates the formation of the surgical audits content by those personally engaged in the surgical activity concerned.⁶ In addition, the effect of clinical auditing in hospitals is probably influenced by the attitude of the healthcare providers towards the national audit. Are surgical teams learning from their data and are they keen to start improvement projects or are they merely collecting this information as an obligatory burden? In the Netherlands, 86% of colorectal surgeons discuss their results periodically with their colleagues and 76% started improvement projects in response to the DSCA. The majority of colorectal surgeons are content with the DSCA.²⁷

The basis of clinical auditing is an intrinsic motivation of medical professionals to improve the care they provide. Nevertheless it is known that intrinsic motivation is subject to daily change, it lies in the human nature. The so-called Hawthorne effect is a type of reactivity in which individuals modify an aspect of their behaviour in response to their awareness of being observed.²⁸ This is a bothersome effect in the interpretation of results of medical research but a welcome effect in clinical auditing. Due to this effect the DSCA stimulates the quality of care that is measured. If problems in healthcare processes get identified, the national audit can give extra attention to these aspects (this thesis). Awareness usually leads to quality improvement projects and in depth investigation of underlying problems.²⁷ When this action has led to the aimed results – i.e better national mean outcome and decreased hospital variability - the raised awareness can be loosened and registration of the item could be stopped to keep the registration burden manageable (figure 1). Sometimes this loosened awareness causes old hiatus to come back. When data sources are linked in the future it might get easier to periodically bring these aspects back to the attention, as this would not imply greater registration burden.

CRM registration and involvement

At the start of the DSCA the percentage of patients with a resection for rectal cancer that had a reported CRM was only 50 percent (chapter 4). The CRM is a significant prognostic factor for local recurrence, distant metastasis and survival after rectal cancer surgery.^{29,30} Before – at the time of the Dutch TME trial (1996-1999) - the availability of the CRM due to a standard pathology report, which included the CRM, had been an important aspect of the study.³¹ During this period reporting of CRM was therefore high (97%) in participating centres.³² We can conclude that focus on registering the CRM greatly diminished after the Dutch TME trial had finished. Another conclusion we can extract from this information is that trial data not always represent real life data. Only 3 years after the start of the DSCA CRM reporting improved to 94.2 percent nationally (chapter 4). We think that this improvement in CRM reporting is almost exclusively attributable to the increased awareness of the healthcare providers raised by national audit (this thesis). Due to renewed focus in each hospital this valuable information on the quality of surgery and on the long-term prognosis of the patient became available again to the healthcare providers.

During the first five years of the DSCA registration incidence of CRM involvement decreased from 14 to 6 percent; an absolute reduction of more than fifty percent (chapter 4). Clinical auditing lays tremendous focus on the outcome of the CRM, which was, to our opinion, a driving force for the significant improvement of this outcome parameter leading to better long-term outcomes for rectal cancer patients. Furthermore the DSCA stimulated guideline adherence leading to a higher percentage of patients that were preoperatively discussed in a multidisciplinary team (MDT) meeting.² The stimulated guideline adherence led to a higher percentage of patients in whom local staging by MRI was performed. Both improvements could have attributed to the quality of rectal cancer surgery (this thesis). The present analysis shows that quality indicators play an important role in identifying quality concerns and variation, and enable targeted quality improvement projects. Few other interventions in the care of rectal cancer patients have led to such magnitude of improvements in a relatively short period of time and it shows the value of national auditing as a tool for quality improvement. Furthermore, centralisation of the technically challenging rectal cancer surgery has had significant influence on CRM involvement (chapter 3). The minimal annual volume of 20 rectal cancer resections has had a positive influence on CRM involvement.

International comparisons

The information from the DSCA makes it easier to compare current national practice in the Netherlands with international peers. As described in chapter 5 of this thesis, van Leersum et al. found that the use of radiotherapy for patients with stage I / low-risk stage II rectal cancer (cT1-3N0) in the Netherlands was high compared to other European countries.³³ The national audit therefore increased national insight on this subject and raised awareness in Dutch hospitals of being the European exception regarding RT-use. This laid the foundation for guideline revision and the fast implementation by healthcare providers afterwards (chapter 5). Our study shows the impact of the revised national colorectal cancer guideline immediately after it became available to the community. The use of radiotherapy in patients with cT1N0 disease was abandoned and radiotherapy treatment in patients with cT2-3N0 disease significantly decreased within one year (this thesis). In addition to guideline revision as the ultimate tool to rapidly change clinical practice, it appears to be very important to create a well-informed

medical field. Secondly the audit is a useful tool to verify whether the changed indication for radiotherapy altered postoperative outcomes. This thesis shows that CRM involvement did not increase after RT-use radically changed (figure 2). Clinical auditing in this case proves to be a useful tool for quality control after guideline revision.

PART III: DATA FROM CLINICAL AUDITS AS A SUPPLEMENT TO RCT'S

Hospital outcome variation can be the result of differences in the structural and procedural differences between hospitals.³⁴ The higher the degree of variation between hospitals on a particular subject the more we can usually learn from this information. The national audit is a rich source that can be used for such research. The audit provides us with “real-time” information as the data is frequently updated and it provides us with “real-world” data as all patients are included, meaning all patients who underwent resection of colorectal cancer in case of the DSCA. This part of the thesis provides examples of how clinical audit data is used to answer several clinically relevant questions in the field of surgical treatment of colorectal cancer.

Laparoscopic colorectal surgery

Laparoscopic surgery has been a major change in abdominal surgery.³⁵ The technique was introduced by gynaecologists and in the 90's adapted by other specialists.^{36, 37} In colorectal cancer surgery, laparoscopic surgery resulted in faster postoperative recovery compared to conventional open surgery, without compromising oncological outcomes.^{38, 39} Long-term benefits of laparoscopic surgery for colorectal cancer are better cosmetics, less incisional hernias due to preserved abdominal wall integrity, and less adhesion related small bowel obstruction.⁴⁰⁻⁴² Due to these results laparoscopic surgery makes up for the majority of colorectal cancer surgery in present times.⁴³

Randomized controlled trials can provide solid prove on non-inferiority of new techniques. But this type of research comes with some drawbacks; i.e. they take a long time to conduct, handle strict inclusion criteria and usually do not include large numbers of patients.⁴⁴ These

issues can cause clinically relevant questions to remain unanswered.³⁵ In chapter 6 we describe an example; is laparoscopic surgery in colorectal cancer care influencing postoperative mortality? This remains unanswered because mortality was a rare event in most RCT's including a relatively low-risk population. As the technique is already widely introduced and next to the earlier mentioned unwanted characteristics of the RCT regarding this subject, the effectuation of an RCT on the matter would no longer be regarded ethically sound. This chapter shows that population studies are able to include higher numbers of patients with different operative risk levels from daily clinical practice showing interesting results. It demonstrates the significantly reduced risk of postoperative mortality after laparoscopic surgery compared to open surgery in patients with non-locally advanced, non metastatic colon cancer in an elective setting. Moreover it endorses the hypothesis of the positive influence of laparoscopic surgery on postoperative outcomes in elderly patients with or without comorbidity.⁴⁵⁻⁴⁷ To deal with the inherent methodological problems of non-randomized comparisons, a risk-stratified comparison between relatively homogenous subgroups using raw data was used, thereby minimizing selection and allocation bias.

Ideally all developments in medicine should be extensively tested before they are introduced to patient care. However development is an important element of quality assurance and healthcare professionals in all areas need to keep up with latest developments. There is a thin line between fast introduction of new techniques and providing evidence-based medicine. In reality techniques are already implemented while large randomized or prospective studies are still running.⁴⁸ A national audit can be used to monitor the implementation of new techniques providing regular feedback of patient outcomes to the surgical teams. If a relatively high number of adverse events would be observed, the professional society and their members can take actions.

Kolfschoten et al. analysed the introduction of laparoscopy for colorectal cancer in the Netherlands and concluded that the introduction had been completed safely.⁴⁹ In the Netherlands the percentage of laparoscopic colorectal cancer resections is high, especially compared to the surrounding countries. We may therefore expect that the learning curve in the Netherlands has been passed through with better postoperative

outcomes at present.⁵⁰ Furthermore, laparoscopy encouraged the subspecialisation of colorectal surgeons, further enhancing surgical quality. Moreover laparoscopic surgery became available for the technically more challenging patients, and now those are also profiting from its short- and long-term advantages (this thesis). Frequently quoted outcomes after laparoscopic surgery however are from older RCT's such as the COLOR II trial.⁵¹ Chapter 7 complements older studies by showing the current outcomes of a comparable population, matched to the Dutch population of the COLOR II trial. This study demonstrates that patient outcomes after laparoscopic surgery for rectal cancer largely improved and that older RCT's do not provide representative outcomes anymore. It shows once again the value of national audits because they are able to provide us with real-time data and an accurate representation of national performance.

High-risk patients

Healthcare industry is naturally ever changing. Due to the aging population, patients with colorectal carcinoma are older and have a higher perioperative risk.⁴⁶ Furthermore there is growing interest for patient-tailored treatment.⁵² Different patients and tumor characteristics benefit from tailored treatment. Not surprisingly, this has an effect on the treatment of colorectal cancer patients. With these changes there is a need for real-time and real-life data, providing us with end results after specific treatment schedules, changed processes and providing us with data on specific patient groups. A significant proportion of colorectal cancer patients are underreported. They are excluded from RCT's due to advanced disease, multiple-comorbidity or their age. For instance, if you apply the exclusion criteria of the COLOR II trial (chapter 7) to the DSCA population in 2014, only 70% of patients with a laparoscopic resection for rectal cancer would have been included in the COLOR II trial.

Chapter 8 describes the clinical-pathological characteristics, treatment strategies and short-term outcomes after resection of 6,918 patients with locally advanced colon carcinoma (LACC), comprising 17.5% of the registered patients who underwent resection for colon cancer during a 6-year study period in the Netherlands. Hospital variation regarding this oncological high-risk frail patient population is informative. Best practices might be able to educate us on improving outcomes for this

fragile patient population that deserves more attention.⁵³ As high-risk patients are underreported in large RCT's shared decision-making is difficult in this population. LACC patients for instance had worse postoperative outcomes compared to non-LACC patients regarding length of hospital stay, complication rate, re-intervention rate and mortality rate (chapter 8). There has been much more interest in rectal cancer surgery during the past decades, and it is only in recent years that focus on LACC is increasing. Audit data can be used in this way to provide information for identifying areas for potential improvement and knowledge gaps that necessitate new research. From a patient perspective, these data can help in shared decision making and managing of expectations.

FUTURE PERSPECTIVES

Due to the accomplished successes of clinical auditing the need for clinical feedback information of healthcare providers will grow. This thesis shows the usefulness of real-world and real-time data provided by clinical audits. It not only serves as risk-adjusted feedback to healthcare providers, it serves other important causes as well by providing clinical information of a merely non-selected group of patients. Growth in these areas of usage is needed and expected.⁴⁴

Clinical audits already provide information on specific groups of patients that are underreported in literature. Outcomes research in this patient population is providing important information for shared decision-making in the clinical setting. The inclusion of patient reported outcome measurements (PROMS) can potentially deepen this information by linking on patient level to structure – process and outcome data. This information should be at hand in daily clinical practice and patients could then be informed on the clinical outcomes and patient reported functional outcomes of patients like them who received different types of treatment. Although interpretation of such data might still be difficult due to, for example, relevant inter-individual variability in perceiving treatment effects.

This thesis provides a clear example of how international treatment variation can lead to practice change in the Netherlands. Through

international comparison we became aware of the overuse of radiotherapy in rectal cancer treatment, which led to the revision of the national guideline on the treatment of rectal cancer (chapter 5). International benchmarking will bring forth extensive practice variation – regarding structural, process and outcome measurements - making it a rich source of valuable clinical feedback information and outcomes research. Orientation towards international clinical auditing is growing with the set up of multiple European initiatives like EURopEan CanCER Audit (EURECCA) or European Reference Networks (ERNs).^{54, 55} International audits should be erected with unambiguous definitions, which is challenging due to existence of multiple national initiatives. The ICHOM colorectal cancer set is a good example of an internationally available compact set of outcome measurements composed by professionals and patients, which can be implemented in every hospital around the globe.⁵⁶ This does not only apply to audit data; all data in healthcare should be reusable for other parties in order to get the most out of it. The FAIR data principles act facilitated by a broad community of international stakeholders is a good example of the lobby for the reusability of data holdings for sharing knowledge around the globe.⁵⁷ FAIR data pleas for good data stewardship with findable, accessible, interoperable and reusable data.

The fast spread and implementation of (future) innovations necessitates reliable data registration systems. Clinical audits, connected to other data systems, should be part of such registration systems, connecting registered new techniques to clinical outcomes and PROMs. As not all changes can be extensively tested – i.e. in RCT's – these registration systems could play a part in the safe implementation of new techniques and enabling timely intervention in the case of adverse events.⁵⁸ Connection to other data systems will give insight in the influence of clinical changes on healthcare costs and provide information on costs effectiveness of clinical innovations.⁵⁹ In this way clinical auditing could play a major role in providing value based healthcare.

There is an on-going transition from intervention-centered clinical audits to multidisciplinary, patient-centered clinical audits. The DSCA started as a monodisciplinary clinical audit in 2009, concentrated around the surgical resection for patients with colorectal cancer and is slowly changing to a multidisciplinary audit. Now gastro-enterologists, radiologists, radiotherapists and medical oncologists joined the audit

changed its name recently to the multidisciplinary Dutch ColoRectal Audit (DCRA). A full transition to a patient-centered audit is yet to be completed, as only patients with a resection for colorectal cancer are currently registered. In order to create the ultimate patient-centered clinical audit patients receiving only adjuvant treatment or no treatment at all should be included. Only then the audit will provide us with complete information on clinical care and outcomes without the current blind spot of patients that fall behind the inclusion criteria of the clinical audits. This will create the true basis for shared decision-making as patients can get all the information that is available on patients like them who underwent different types of treatment or no treatment. Moreover such a system would create a rich resource for further outcomes research bringing valuable new insights to the whole medical community.

An extensive patient-centered registration system will not be able without far-going connection between multiple data-systems. Again this underlines the importance of data that is recorded once at its source that is suitable for data connection and for re-use in different settings. In this way information is gathered with minimal registration burden for healthcare providers. The DCRA started recently with the inclusion of synoptic reporting of surgical resections in the clinical audit. Furthermore the structural input of pathology reports in the audit is already effectuated by a connection to PALGA (the national archive of pathology data).

END CONCLUSION

This thesis shows the value of outcomes research with clinical audit data. Real-world and real-time data of clinical audits complement RCT's due to large numbers of patients and the inclusion of high-risk patients. Furthermore they provide a basis for international comparison and valuable information on patients that are excluded from RCT's and underreported in literature. The evolution of clinical audits to patient-centered registrations and the connection with multiple other data registrations will lay the basis for a registration system that can be used for shared-decision making, providing value-based healthcare and further extensive outcomes research.

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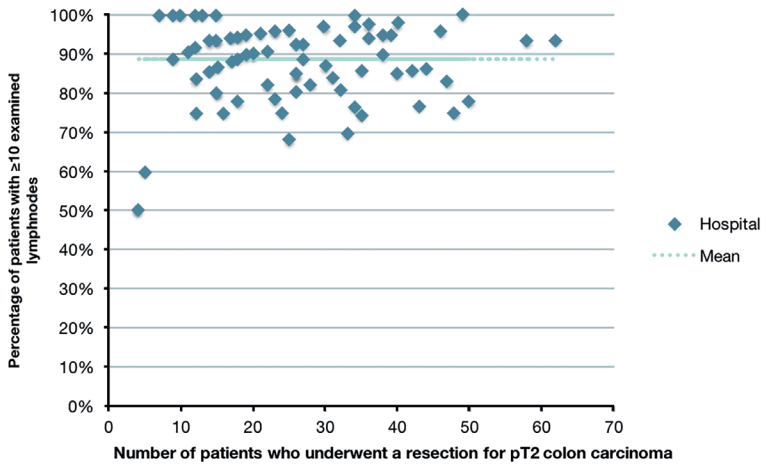
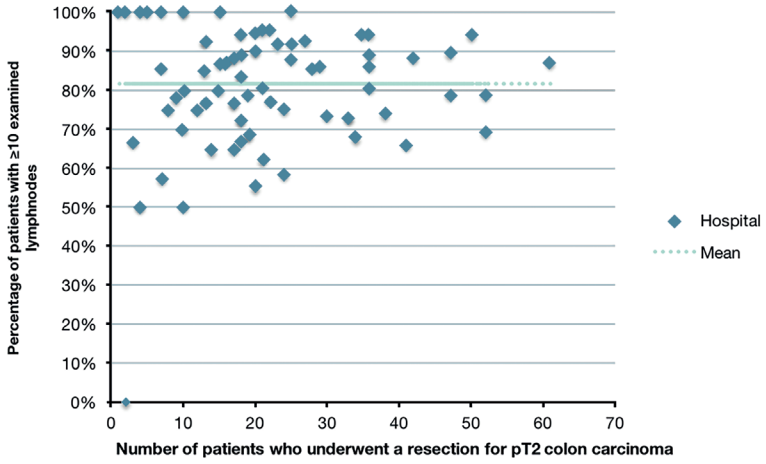
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FIGURES



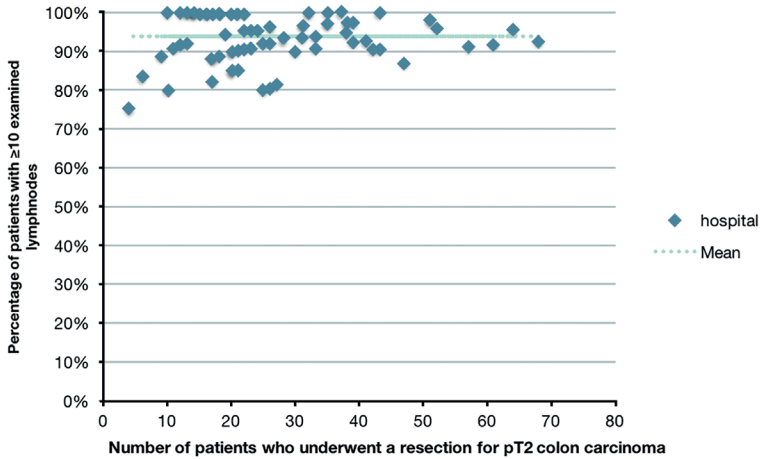


Figure 1a,b, and c. Patients with pT2 colon carcinoma with a minimum of 10 examined lymph nodes by a pathologist per hospital in 2009, 2011, and 2013.

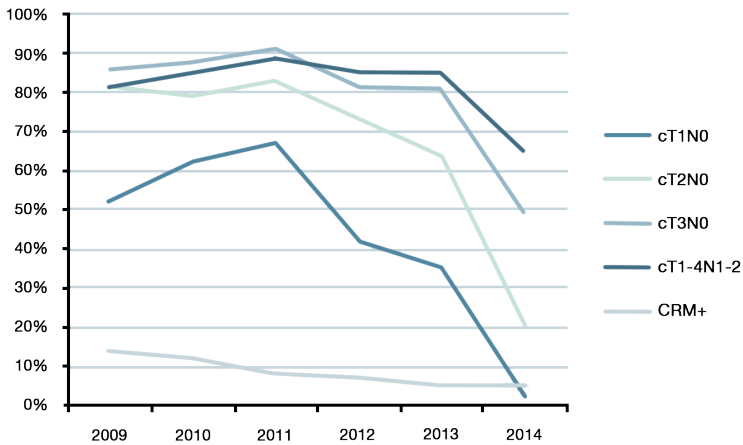


Figure 2. Use of preoperative radiotherapy for rectal cancer in the Netherlands for different clinical stages and the percentage of patients with an involved CRM (2009 – 2014).

