





*“Systems awareness and systems design are important for health professionals, but are not enough. They are enabling mechanisms only. It is the ethical dimension of individuals that is essential to a system’s success. Ultimately, the secret of quality is love.”*

*Avedis Donabedian*

*To Marit, Sigurd, Åse and Idunn*



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## Acknowledgements

I am personally indebted to many individuals for their support and guidance while completing this research. I want to express my gratitude to my mentor Rolv-Ole Lindsetmo for keeping me on track, giving me constructive feedback and for pushing me to the finish. I first got to know Rolv-Ole in 1998, we attended the surgical on-call team: he as the experienced surgeon, me as the novice. Little did we know then, that he ten years later became my scientific mentor. His friendliness has resulted in numerous of discussions leading to several on going projects, and tons of new research ideas! He showed me the true meaning of trust by introducing me for his international colleagues.

In particular I am indebted to Conor Delaney, who warmly welcomed me at Department of Colorectal Surgery, University Hospitals, Cleveland, USA. The international trial would not have been possible without his support and constructive feedback. A special gratitude for outstanding research collaboration must be directed to Harry Reynolds (jet pilot and colorectal surgeon), Brad Champagne (colorectal surgeon), Fabien Leblanc (research fellow), Jonah Stulberg (surgical resident) and Johnie Rose (statistician and Markov model builder). Johnies hard efforts to teach me decision-analytic modelling will never be forgotten.

My colleagues at the Department of Digestive Surgery has been outermost supportive: Arthur Revhaug, Christian Rushfeldt, Stig Nordervald, Kristoffer Lassen, Trond Dehli and Kim Mortensen.

The North Norwegian randomised colon cancer follow-up trial would not have been possible without patient support from Ranveig Aspevik, Stefan

Dehof, Torunn Nestvold, Caroline Sagatun, Henriette Fagertun, Unni Ringberg and Frank Hauboff.

A special expression of gratitude is due both to Helse Nord for their funding support, and to Jan Norum for his persistent advice on cost-effectiveness analyses.

I have to thank all colleagues at the Norwegian Centre for Integrated Care and Telemedicine: Bjørn Engum, who have been supportive all the way to the thesis finish line. Heidi Jacobsen for always keeping a calm head despite organisational turbulence. Trine Hansen for maintenance of our research database. Sture Pettersen for encouraging discussions on patient flow. Gro Berntsen for introducing me to the chronic care model. To all my research colleagues: The mix of technology and health service research has an unreleased potential. Keep up the good work friends!

I dedicate this thesis to my wife, best friend and soul mate: Marit. This would not have been possible without your everlasting support and love. I am indebted to your clear-minded advice. Our path through life has brought us three kids: Sigurd, Åse and Idunn. You guys amaze me every day, and truly teach me what life is all about.



# List of papers

## Paper 1

Augestad KM, Lindsetmo RO, Stulberg JJ, Reynolds H, Senagore AJ, Champagne B, Heriot AG, Leblanc F, Delaney CP. International preoperative rectal cancer management: staging, neoadjuvant treatment, and impact of multidisciplinary teams. *World Journal of Surgery* 2010; 34; 2689-2700.

## Paper 2

Augestad KM, Lindsetmo RO, Stulberg JJ, Reynolds H, Senagore AJ, Champagne B, Heriot AG, Leblanc F, Delaney CP. International trends in surgical treatment of rectal cancer. *American Journal of Surgery* 2011; 201: 353–8.

## Paper 3

Augestad KM, Lindsetmo RO, Stulberg J, Reynolds H, Champagne B, Senagore AJ, Delaney CP. System-based factors influencing intraoperative decision-making in rectal cancer by surgeons. An international assessment. *Colorectal Disease* 2012 Oct; 14(10): e679-88.

## Paper 4

Augestad KM, Vonen B, Aspevik R, Nestvold T, Ringberg U, Johnsen R, Norum J, Lindsetmo RO. Should the surgeon or the general practitioner (GP) follow up patients after surgery for colon cancer? A randomised controlled trial protocol focusing on quality of life, cost-effectiveness and serious clinical events. *BMC Health Service Research* 2008; 8; 137.

## Paper 5

Augestad KM, Norum J, Dehof S, Aspevik R, Ringberg U, Nestvold T, Vonen B, Skrøvseth SO, Lindsetmo RO. Cost effectiveness and quality of life in surgeon versus general practitioner organised colon cancer surveillance. A randomised controlled trial. *BMJ Open* 2013.



## 1.0 Definitions

*Decision-making:* The process of making a selective intellectual judgment when presented with several complex alternatives consisting of several variables, and usually defining a course of action or an idea (Medical Subject Heading).

*Organisational decision-making:* The process by which decisions are made in an institution or other organizations (Medical Subject Heading).

*Care pathway:* A methodology for the mutual decision-making and organization of care for a well-defined group of patients during a well-defined period. Defining characteristics of care pathways includes: An explicit statement of the key elements of evidence based care; The facilitation of communication and coordination in the multidisciplinary team; The evaluation outcomes; The identification of the appropriate resources.<sup>1</sup>

*Evidence based medicine:* the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.<sup>2</sup>

*Teamwork:* Care of patients by a multidisciplinary team usually organised under the leadership of a physician. Each member of the team has specific responsibilities and the whole team contributes to the care of the patient (Medical Subject Heading).

*Clinical audit:* A detailed review and evaluation of selected clinical records by qualified professional personnel to improve the quality of patient care and outcomes (Medical Subject Heading).

*Health care quality assurance:* Activities and programs intended to assure or improve the quality of care in either a defined medical setting or a program. The concept includes the assessment or evaluation of the quality of care; identification of problems or shortcomings in the delivery of care; designing activities to overcome these deficiencies; and follow-up monitoring to ensure effectiveness of corrective steps (Medical Subject Heading).

*Organisational culture:* Beliefs and values shared by all members of the organization. These shared values are reflected in the day to day operations of the organization (Medical Subject Heading).

*High reliability organisations:* Groups characterized by a commitment to safety at all levels of the organization, an environment where individuals are expected to report errors without fear of blame or punishment, an encouragement of collaboration across organizational levels and units to solve safety problems, and an organizational commitment of resources to address these issues. <sup>3</sup>

## 2.0 Abbreviations

CRC: colorectal cancer

IRCSG: International rectal cancer study group

NCCN: National comprehensive cancer network

ESMO: European society of medical oncology

NGICG: Norwegian Gastrointestinal Cancer Group

COLOFOL trail: Assessment of frequency of surveillance after curative resection in patients with stage II and III colorectal cancer.

GILDA trial: Follow-up of colorectal cancer patients after resection with curative intent

FACS trial: Follow-up study of patients who have undergone surgery for stage I-III colorectal cancer

QoL: Quality of life

EORTC QLQ C-30: The European Organization for Research and Treatment of Cancer QoL Questionnaire

EQ-5D: The EuroQoL-5D

EMR: Electronic medical record

SCE: Serious clinical event

RCT: Randomised controlled trial

CI: Complex intervention

TEM: Transanal edoscopic microsurgery

TME: Total mesorectal exisicion

CRM: Circumferential margin

MRI: Magnetic resonance imaging

ERUS: Endoscopic rectal ultrasound

MDT: Multidisciplinary team

GPs: General practitioners

ANOVA: Analyses of variance

LOCF: Last observation carried forward

### **3.0 Introduction**

Non-technical skills in surgery consist of communication, teamwork, leadership and decision-making.<sup>4,5</sup> Decision-making ability is considered as the most important personal trait for a surgical trainee, and the surgeon as a central decision-maker has an effect on a number of important surgical outcomes.<sup>6-9</sup> Important characteristics of the decision-making process include ascertaining objectives, collecting information, identifying different courses of action, evaluating each course of action, choosing the best option, and reviewing and changing choice if necessary.<sup>10</sup> However, there is wide variability surrounding surgical decisions.<sup>11</sup> A large proportion of decisions is performed in a non-operative environment (preoperative and postoperative) and is often different in nature when compared to operative decision making.<sup>11</sup> Characteristic features of intra-operative decisions include irreversibility, high stakes and time pressure.

Numerous independent factors have been shown to influence decision-making. These include personal factors like experience, teamwork and behaviour.<sup>12-16</sup> Similarly, work environment and organizational characteristics are likely to influence decisions. However, little is known regarding the influence of work environment and traditional department practices on surgical decisions. Department traditions and structure may either positively or negatively influence decision-making and surgical outcome. Furthermore, departmental politics and bias may influence the surgical dogma taught during residency, or during work experience at other institutions.

## 3.1 Theoretical aspects of decision-making

### 3.1.2 Decision-making and uncertainty

The ability to perform good decisions despite uncertainty is ranked as the most important personal trait for a surgeon.<sup>6</sup> Decisions made under uncertainty have its own rules and standards, and can be studied systematically, learned, and perfected by the application of rationale principles. The areas of uncertainty may arise from several sources:

- *Errors in clinical data:* Data gathered from patient histories, physical examination is subject to error.
- *Ambiguity of clinical data and variation of interpretation:* Information obtained by physical examination or a diagnostic procedure may be intrinsically ambiguous and may thus be observed different from different observers.
- *Uncertainty of clinical findings:* The relation between clinical signs, symptoms and disease are not the same in every patient.
- *Uncertainty of evidence based medicine:* In surgery, there exist several controversies about correct diagnostics, the effects of treatments, and postoperative care.
- *Uncertainty of communication:* Interactive communication is associated with improved patient outcomes. Similarly poor communication leads to poor coordination of care, incorrect treatment decisions and consequently adverse events.
- *Uncertainty of clinical handover:* Handover of clinical information by referrals, on-call handover or multidisciplinary handover. Improper



handover of clinical information may cause uncertainty in the decision-making process.<sup>17</sup>

<b>Factor types</b>	<b>Influencing Contributory factors</b>
Institutional context	Economic and regulatory context
Organizational and management factors	Financial resources and constraints Organizational structure Policy standards and goals Safety culture and priorities
Work environment factors	Staffing level and skills mix Workload and shift patterns Design, availability, maintenance of equipment Technology (EMR and videoconferencing)
Team factors	Administrative support Verbal communication Written communication Supervision Leadership
Individual staff factors	Knowledge and skills Competence Physical and mental health
Task factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results
Patient factors	Condition (complexity and seriousness) Language and communication Personality and social factors

**Table 1.** Factors Influencing Patient Outcome.<sup>18</sup>

### 3.1.2 Decision-making and influence on outcome

” In the present state of knowledge, we do not know which factors are most critical to outcome, beyond patient risk factors, basic levels of individual skill and the organization of care”. Charles Vincent

The outcome of surgery is dependent on the quality of care received throughout the patient’s stay in hospital and the performance of a considerable number of health professionals, all of whom are influenced by

the environment in which they work. Vincent et al argues that a much wider assessment of factors that may be relevant to surgical outcome and argues that broader views of decision making are important.<sup>18</sup> I.e. to expand operative assessment beyond patient factors and the technical skills of the surgeon; to extend assessment of surgical skills beyond bench models to the operating theatre; to provide a basis for assessing interventions and to provide a deeper understanding of surgical outcomes (table 1).

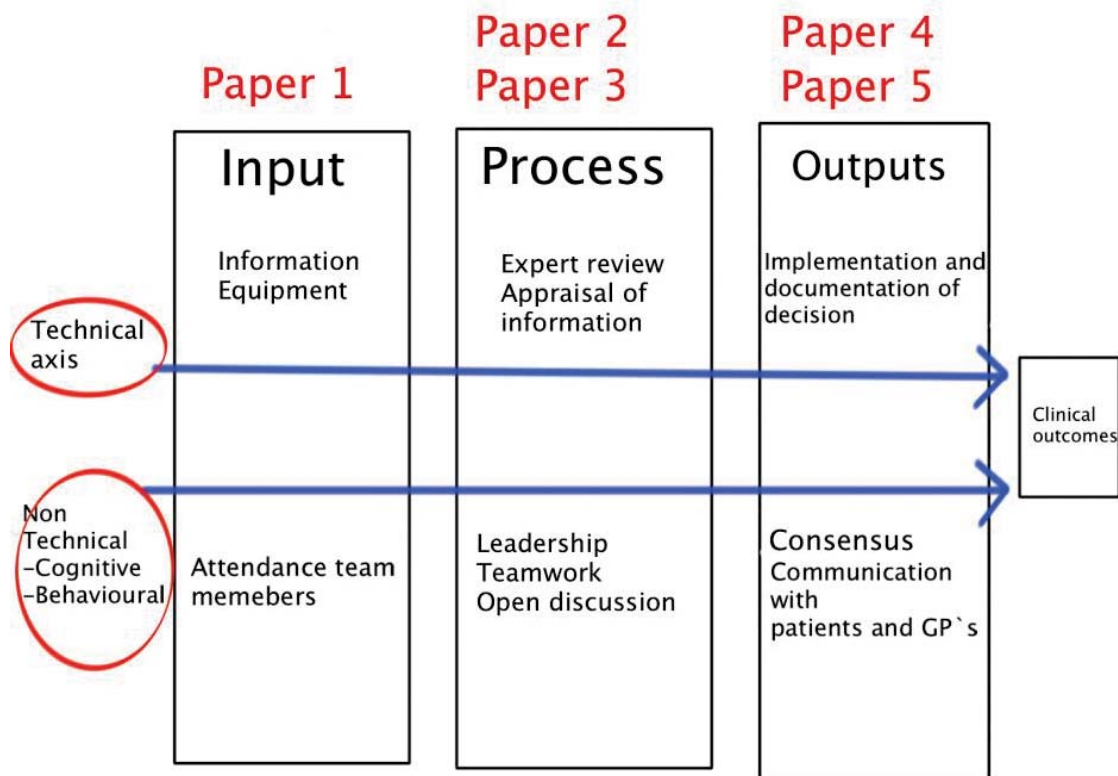
### 3.1.3 Decision-making frameworks

*“There is one problem that is the very root of all of our other difficulties, and it is this: We attempt to pass judgment on what we do not understand. Ask an individual to talk about quality health care, and you are likely to get a catalogue of platitudes. Ask two people, and you will probably get an argument. Ask three, and you will probably have chaos. The reason is that each, like the proverbial blind man, has some different portion of the elephant in his hand”. Avedis Donabedian.*

*The structure-process-outcome framework:* Adopting the Donabedian paradigm, we consider decision-making in three domains: structure, process, and outcomes.<sup>19,20</sup> The systems-based framework for defining health care quality through structure, process, and outcome allows one to distinguish the actual care given (process) from the environment within which the care was provided (structure) and the consequences of the interaction between the actual care given and the environment (outcome). *Process* are meant to refer to the care that patients actually receive and are attractive as quality indicators.<sup>21</sup> *Structure* refers to the organizational factors that define the system under which health care is provided. Structural measures of the health care system have been used successfully as measures of quality, and examples of structural measures include measures of staff expertise, the availability of hospital resources and measures of procedural volume,

whether at the individual physician or hospital level (surgical volume vs. hospital volume).<sup>22</sup> *Outcome* refers to the consequences of care and therefore is often thought of not as a component of but as a product of care. The relative importance between the care given (process) and the environment within which the care was given (structure) can be said to determine the outcome, and one's definition and measurement of quality can be engineered to fit their goal of measurement.

*The input-process-output framework:* This model has been used extensively in teamwork literature and aviation industry, and provides a useful framework for studying surgical teams.<sup>23</sup> The model permits the relationship between team factors and team performance, in this case factors that affect surgical decision making, to be defined and manipulated. Technical factors that affect decision-making include the information about patients, robust electronic medical record and video-conferencing equipment, a minimum dataset with expert review of radiological and pathological information, implementation and recording of the surgical decisions. Non-technical factors with an impact on decision making include attendance of team members at meetings, leadership, teamwork, open discussion, consensus on decisions and communication with patients and general practitioners. This thesis will be discussed on the basis of the input-process-output framework (figure 1).



**Figure 1.** Roadmap for dissertation (Paper I-V) in relation to a system's approach of surgical decision-making. (From West M, Borrill C, Unsworth K. Team effectiveness in organisations. In: Cooper C, Robertson I, editors. International review of industrial organisational psychology. 13th ed. Chichester: Wiley & Sons; 1998).<sup>23</sup>

### 3.2 Decision-making controversies in colorectal cancer

#### 3.2.1 Pre and operative CRC practice

Several reports suggest that adoption of evidence-based clinical practice in colorectal surgery is slow.<sup>24</sup> Adherence to evidence based clinical practice in colorectal surgery has been shown to be inconsistent in several reports

analysing surgical practice at a national level. Despite the documented advantages of enhanced recovery programs and the lack of evidence for nasogastric decompression, transabdominal drains or bowel cleansing, colorectal surgeons continue to depend on “traditional tenets” rather than evidence.<sup>25-27</sup> Recommendations and guidelines for colorectal cancer have been published, yet there is no universal consensus pertaining to surgical technique and peri-operative decision-making. Guidelines may lag behind current standards in therapy and it is not known if they are used consistently or universally even within their respective country.<sup>28-32</sup> Standardized incorporation of optimized operative techniques and pre and postoperative decision-making could have major impact on morbidity and outcome after surgery for colorectal cancer.<sup>33,34</sup> Differences in practice may influence colorectal cancer survival and morbidity. Although there is increasing level one evidence for the management of rectal cancer, decision-making vary, and the surgical management of colorectal cancer has never been analysed internationally.

### **3.2.2 Postoperative colon cancer follow-up**

Despite the generally poor outcomes among patients with recurrent colon cancer, most patients treated with curative intent are included in some form of surveillance program involving periodic evaluation. Reviews comparing various follow-up programs have suggested that more intensive strategies tend to increase five-year survival with 5-10%.<sup>35-37</sup> However, wide consensus has not been reached regarding just what an intensive follow-up strategy should entail.<sup>30,31,38,39</sup> Two systematic reviews, comparing follow-

up trials have been published.<sup>35,36</sup> Due to the variation in the follow-up programs included in these reviews, it is not possible to infer the best combination of consultations, blood tests, colonoscopy, radiological investigations and level of care to maximise the outcomes.<sup>36</sup> These controversies are mirrored in the wide variation of national follow-up guidelines.<sup>30,31,37,38</sup> New surveillance trials in progress are not likely to fully settle the issue either.<sup>40-43</sup> Large randomised trials are under way (COLOFOL, GILDA, FACS) but results are most likely years away.<sup>40-42</sup> What none of the available clinical recommendations for follow-up have addressed adequately is the *setting* where this follow-up should occur: conducted by surgeons who originally treated the cancer at hospitals, or in the offices of local GP's.<sup>36</sup> A randomised controlled trial was carried out to assess the impact of a GP organised colon cancer follow-up program.

### **3.3 Objectives**

The main objectives of this thesis is to identify decision-making controversies among colorectal surgeons, to assess organisational (structural) impact on decision making, and to assess whether organisational (structural) changes might improve outcome among patients surgically treated for colorectal cancer, i.e.

#### **3.3.1 Paper I-III (international survey of rectal cancer practice)**

1. Identify international practice of preoperative staging and neoadjuvant treatment of rectal cancer.

2. Assess the impact of multidisciplinary teams on preoperative rectal cancer decision-making.
3. Identify international practice of intraoperative rectal cancer decisions.
4. Analyse organizational characteristics association with rectal cancer decision-making.

### **3.3.2 Paper IV-V (Randomised trial of colon cancer follow-up)**

To compare, in a randomised controlled trial, surgeon organised follow-up versus general practitioner (GP) colon cancer follow-up i.e.

1. Assess the impact of a GP organised colon-cancer follow-up program on patient specific quality of life.
2. To perform cost-effectiveness analyses of a GP organised follow-up program.
3. To compare rate of serious clinical events and time to recurrent cancer diagnoses.

## **4.0 Methods**

### **4.1 Paper I – III. International questionnaire survey**

A questionnaire survey was carried out at international centres treating rectal cancer.

*International Rectal Cancer Study Group*; A group of six surgeons from USA, Australia and Europe constituted the working members of an International Rectal Cancer Study Group (IRCSG). All surgeons had more than 10 years of experience with rectal cancer. IRCSG is an independent

group without financial support from any companies or organizations, and have representatives from Asia, Europe and North America. The aim of the study group is to evaluate current international treatment practices of rectal cancer.

*Invited colorectal centers and surgeons to IRCSG:* Centers and representative surgeons were selected based on prior publications, presentations or participation at national or international meetings and via a Pub Med search for scientific reports on rectal cancer. All respondents were invited to become members of IRCSG. To ensure an experienced international panel, we used two strategies:

1. *Pub Med search:* We performed an unsystematic search with the following search terms *rectal cancer* combined with *staging, treatment, chemotherapy, radiation, surgery*. Based upon this search corresponding authors were identified and included in the survey sample.
2. *Oral presentation at an international scientific meeting:* The working committee of IRCSG participated in several international rectal cancer conferences in the time period from 2006 to 2008. Oral presenters in these conferences were identified and included in the survey sample.

*The questionnaire:* The questionnaire was developed and validated during several meetings of IRCSG. The aim was to cover all aspects of preoperative rectal cancer treatment. Modifications of the survey items were performed by literature review and e-mail discussions. The questionnaire consisted of 59 questions. An average of 20 minutes was needed to finish the questionnaire.



*Study logistics:* The survey was sent to the identified colorectal surgeons both as document form attached to an e-mail and as a Web based survey link forwarded to each participant. The Web based option was offered through SurveyMonkey.com. Two follow-up e-mails were sent to non-responders, and the survey was open for a total of 16 weeks.

*Review of national guidelines:* Six rectal cancer treatment guidelines were reviewed (NCCN USA 2009, World Congress 2007, French 2007 Guidelines, Norwegian 2008 Guidelines, ESMO 2008, Danish Guidelines 2009) to compare national recommendations. The aim was to gain insight in similarities and differences of guideline recommendations.

*Organizational characteristics included in analyses:* From the IRCGS database, the following surgeon and organizational characteristics were identified: Busy departments (> 50 cases/annually), European centers, university hospital, clinical audits, multidisciplinary teams, high personal caseload (> 30 cases annually), experienced surgeon (> 10 years of surgical experience). All variables were bivariate (assuming 1=yes, 0=no) (table 1).

*Surgical performance parameters included in analyses:* After discussion in the IRCGS working group, 17 surgical decisions/management choices were included in the regression analyses as dependent variables. We only included potential decision elements which have been considered to be associated with improved outcomes. All surgical performance parameters analysed were bivariate (assuming 1 = yes, 0 = no).

## **4.2 Paper IV – V. Randomised controlled trial**

A randomised controlled trial with institutional ethical approval and patient written consent was carried out in Northern-Norway. Patients were eligible if they were aged less than 75 years and have had recent surgery for colon cancer with Dukes stage A, B or C.

### **4.2.1 Description of intervention**

This complex intervention consisted of the following parts: <sup>44,45</sup>

*GP organised colon cancer follow-up:* The patients were referred to their general practitioner for postoperative follow-up according to national guidelines (table 2). Information was given about surgery, any complications, Dukes' staging, time and location of chemotherapy (for Dukes C patients), and risk of recurrence.

*Patient decision-support pamphlet:* Received at the baseline consultation, containing information about; a) Their own disease; b) The aim and objective of the trial; b) The current national follow-up guidelines; c) In case of a serious clinical event, relevant phone numbers and contact information was given.

*GP decision-support pamphlet:* Sent at time of baseline appointment to all GPs that got a patient allocated to their practice.

Examination/test	Follow-up cycle (months postoperative)														
	1	3	6	9	12	15	18	21	24	30	36	42	48	54	60
Chest x-ray			X		X		X		X		X		X		X
Contrast enhanced liver ultrasound (CEUS)			X		X		X		X		X		X		X
Colonoscopy					X								X		
CEA measurement	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Clinical examination	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Red: Length of trial participation (24 months, 9 follow-up cycles). CEA: carcinoembryonic antigen.

**Table 2.** Norwegian Gastrointestinal Cancer Group (NGICG) 2007 follow-up program.

#### 4.2.2 Randomisation

If the patients provided informed consent at baseline, they were randomised to follow-up either by their GP (intervention) or at the surgical outpatient clinic (controls) using a web-based randomisation service. The randomisation ratio was 1:1, patients were stratified according to the Dukes' staging (A,B,C) and whether they had a stoma. The local trial investigator was not involved in the subsequent follow-up appointments in any way. Recruited patients were not informed about other patients recruited in the same trial. Similarly, no information regarding trial progress and allocation was revealed to participating GPs or surgeons. However, as GP organised follow-up represented a new practice, blinding was not possible in the intervention arm.

### 4.2.3 Primary outcome. Quality of life

Quality of life : QoL measurements were collected at baseline and 3, 6, 9, 12, 15, 18, 21 and 24 months.

*The European Organization for Research and Treatment of Cancer QoL Questionnaire (EORTC QLQ C-30):* EORTC QLQ C-30 incorporates nine multi-item scales: five functional scales (physical, role, cognitive, emotional and social); three symptom scales (fatigue, pain, nausea/vomiting); and a global health status/QoL scale. Six single-item scales are also included (dyspnoea, insomnia, appetite loss, constipation, diarrhoea and financial difficulties).<sup>46</sup>

*The EuroQol–5D (EQ-5D; EuroQol Group, Rotterdam, The Netherlands):* Is a standardized generic instrument employed to measure of health outcome. EQ-5D measures five dimensions of health-related QoL (HRQOL): mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is rated at three levels: no problems (1), some problems (2) and major problems (3).<sup>47</sup> Based on preferences elicited from a general population, EQ-5D health states (e.g. 1-1-2-1-3) may be converted into utility scores (= index scores, IS). In this trial we used preferences elicited from a UK population, as no similar Norwegian preferences exist.<sup>48</sup> EQ Visual Analogue Scale (EQ VAS) records the respondent's self-rated health status on a vertically graduated (0–100) visual analogue scale.

#### **4.2.4 Secondary outcome 1. Cost-effectiveness**

Resources used (baseline to 24 months) were registered prospectively based on reports by the patients and on hospital EMR review. The cost elements included costs related to hospital visits, GP visits, laboratory tests, radiology examinations, colonoscopy, examinations due to suspected relapse (radiology, colonoscopy, CT of thorax or abdomen, PET scan), treatment of recurrence, travelling/transportation, production losses, co-payments and other patient/family expenses.

#### **4.2.5 Secondary outcome 2. Time to cancer diagnoses**

Time to cancer diagnoses is defined as the time from occurrence of a serious clinical event (SCE, dated in the GP referral or hospital EMR record) until the date of diagnoses of a cancer recurrence. A serious clinical event (SCEs) is defined by an episode where cancer recurrence is suspected. A SCE can be triggered by patient symptoms (at follow-up or in between follow-up), clinical findings at follow-up or findings by the screening test. A SCE was defined as: Cancer suspect lesion found at colonoscopy, increase in CEA measurements shown by repeated measurements, blood in stool detected by the Hemofec (FOB) test, unexplained abdominal pain, unexplained weight loss of 5 kg during the last three months, cancer-suspect lesions detected by rectal examination, lymphadenopathy, metastatic suspect lesions shown by chest x-ray, ultrasound of liver or CT scan, cancer suspect findings at clinical examination, occurrence of cancer suspect symptoms.

#### **4.2.6 Sample size**

In June 2007 sample size calculations were based on a significance level of 5% and power set at 80%, this indicated that we needed 136 patients to detect a 10 units difference (i.e. a small to moderate improvement of QoL) on EORTC QLQ C-30 Global Health score with a standard deviation of 20. Definition of “a small to moderate improvement on QoL” (i.e. 10 units on the global health score), and standard deviation estimates of QoL (colon cancer patients with localised disease), were retrieved from previous published publications.<sup>49,50</sup>

### **4.3 Statistical methods**

Descriptive statistics used in this thesis were performed by percentages, 2x2 contingency tables, Chi Square, Fisher Exact test and t-test. Results were expressed as mean differences for continuous outcomes with corresponding standard deviations (SD), 95% confidence intervals, and associated p-values. P-values were reported with two decimal places with p-values less than 0.001 reported as  $p < 0.001$ . For all tests we used  $p = 0.05$  level of significance. All data were analysed by IBM SPSS Statistics v.19.0 (San Francisco, California).

#### **4.3.1 Multivariate analyses (paper I and III)**

To analyse organizational characteristics (predictors) association with independent surgical decision-making (outcome) we performed multivariate logistic regression. Initially, to identify significant model contributors, a

univariate analyses were performed. All predictors were independently analysed for influence on the outcome. To address the problem of multiple comparisons, a Bonferroni correction was performed, i.e. adjusting the significance level by adjusting with the number of outcomes. Secondly, multilevel analyses were performed, i.e. all department characteristics were included in a multivariate regression model. The criterion for inclusion in a back-wise stepwise regression was  $p = 0.05$ . The analyses were set to arrive at a model after 20 iterations. To estimate the overall fit of the final model, Hosmer and Lemeshow test were performed. All results are presented using odds ratios, p values and 95% confidence intervals.

#### **4.3.2 Analyses of variance (ANOVA) (paper V)**

The base case analyses (n=110, 600 complete follow-up questionnaires/cycles) were performed on intention to treat principle. The main analyses examined whether differences in QoL outcome between baseline, 3, 6, 9, 12, 15, 18, 21 and 24 months existed in all QoL outcome measures (EORTC QLQ C-30 and EQ-5D). A general linear model was employed, where time (1-24 months) and intervention group (GPs versus Surgeon) were predictors in analyses of variance (between groups ANOVA). When there were missing items within a form, we treated the score for that scale as missing. When there were missing forms, missing data were imputed by the last observation carried forward (LOCF).

#### **4.4 Cost-effectiveness analyses (paper V)**

BMJ guidelines for economic analyses alongside randomised controlled trials were employed.<sup>51</sup> As the trial revealed no difference in quality of life a cost-minimisation analysis was carried out. The economic evaluation had a societal perspective. A 3% discount rate was used to discount future costs and benefits. For this publication cost elements have been converted from Norwegian kroner (NOK) into British Pounds at the rate of GBP 1£ = NOK 9,39 NOK as of the Norwegian National Bank the 27th of June 2012. Details of the unit costs assigned to health care resource use are shown in table 2. A one-way sensitivity analysis was used to assess the robustness of the results and impact of variance. Societal cost of 24-month follow-up was assessed for low, base and high input values, and the result expressed as a many inputs, one output tornado chart. To increase generalisability, unit costs from the UK were included in the sensitivity analyses. Costs for GP consultation and diagnostic testing, have been reported to be 30-40% higher than unit costs applied in this trial and relevant cost elements were increased accordingly in sensitivity analyses.<sup>52</sup>

## **5.0 Results**

### **5.1 Participating international centers**

Of the 173 invited participants, 123 (71%) responded. The surgeons come from 28 countries, mainly located in Europe, North America and Australasia. Seventy-eight % are affiliated with a university hospital, 93% have more



than 5 years experience with rectal cancer surgery, and 70% work in departments that manage more than 50 rectal cancers per year. Seventy-three % perform more than 20 rectal surgeries annually, and 20 % perform more than 50 surgeries annually.

## **5.2 Paper I. Multidisciplinary teams, staging and neoadjuvant treatment**

55% utilize CT scan, 35% use MRI, 29% use ERUS, 12% digital rectal examination and 1% PET scan in all rectal cancer. 74% consider threatened circumferential margin (CRM) as indication for neoadjuvant treatment. 92% prefer 5-FU based long course neoadjuvant chemoradiation (CRT). A significant difference practice exists between US and non-US surgeons: poor histological differentiation as indication CRT (25% vs. 7.0%,  $p = 0.008$ ), CRT for stage II and III rectal cancer (92% vs. 43%,  $p = 0.0001$ ), MRI all RC patients (20% vs. 42%,  $p = 0.03$ ), ERUS all RC patients (43% vs. 21%,  $p = 0.01$ ).

*Impact of multidisciplinary teams:* Departments with regular multidisciplinary team meetings are more likely to prefer MRI for local staging (RR 3.62) and there is a trend towards significance ( $p = 0.06$ ). Similarly, patients with threatened circumferential margin are more likely to receive neoadjuvant treatment in departments with team meetings (RR = 5.67,  $p = 0.03$ ). Other significant impacts of team meetings were found upon pathology report quality (RR = 4.85,  $p = 0.01$ ), new chemotherapy regimen if liver metastases (RR = 6.41,  $p = 0.02$ ), one stage surgery when liver metastases (RR = 0.25,  $p = 0.02$ ).

### **5.3 Paper II. Intraoperative decisions**

*Tumour localization and anatomical description:* A majority of the surgeons (76.1 %) stated that distance from “the anal verge to the lower edge of the tumor” is the most appropriate way to describe the localization of a rectal tumor. There was a significant difference between USA and non-USA surgeons applying this definition (61% vs. 83%,  $p = 0.008$ ). Significantly more of the non-USA surgeons prefer to use radiological imaging to precisely describe the localization of the tumor (22% vs. 5%,  $p= 0.01$ ). There were large discrepancies in anatomical definition of the rectum. Most surgeons (50%) preferred the definition “15 cm measured from the anal verge”. There were significant differences between US and non-US surgeons applying this definition (34% vs. 58%,  $p=0.03$ ).

*Operative decisions:* Seventy-one % of the surgeons personally performed laparoscopic resection for rectal cancer, significantly more in the USA (82% vs. 66%,  $p=0.05$ ). Fifty % of the surgeons aim for a 5 cm distal resection margin and a colorectal anastomosis when possible. More of the non-US than US surgeons preferred a rectal stump wash out (73 % vs. 35%,  $p=0.0001$ ). Sixty-nine % of the surgeons prefer a high tie of inferior mesenteric artery (IMA), and 50% always take down the splenic flexure. 35 % always leave drains after surgery, significantly more for non-US surgeons (42 % vs. 23%,  $p=0.03$ , table 1). One stage operation with synchronous liver metastasis is preferred by 79% of the US surgeons vs. 52% of non-US surgeons ( $p=0.003$ ).

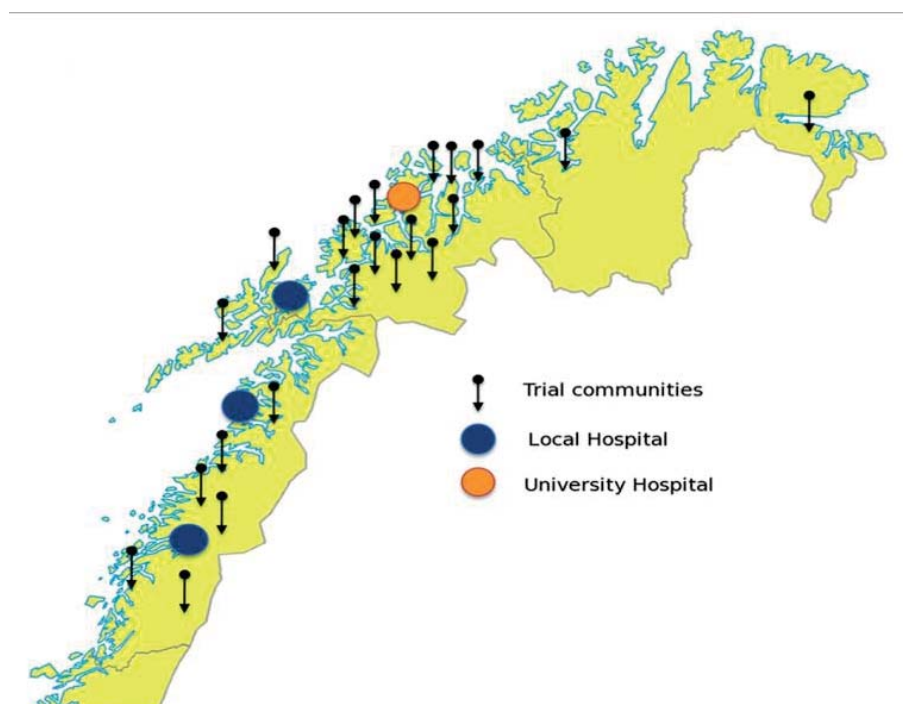
*Indication for diverting stoma:* Seventy-five % of surgeons prefer diverting stoma in cases with coloanal anastomosis, 49 % when anastomosis is lower than the distal third. Significantly more of the US surgeons perform a diverting stoma routinely after preoperative radiation (69% vs. 43 %,  $p=0.01$ ), and in cases with coloanal anastomosis (87% vs. 69%,  $p=0.05$ ).

#### **5.4 Paper III. Impact of organisational factors**

Seventy-eight % (96) of colorectal departments were affiliated with a university hospital, 69% (86) of the departments were defined as busy. Sixty-five % (73) perform regular clinical audits, 86% (97) perform regular multidisciplinary team meetings. Sixty-nine % (86) of surgeons were defined as experienced, 44% (55) are high caseload surgeons. Multivariate analyses: Sphincter saving surgery: Decisions of sphincter saving surgery are more likely to be performed at university hospitals (OR = 3,63) and by high caseload surgeons (OR = 2,77). University hospital ( $p = 0,006$ ) and high caseload ( $p = 0,006$ ) are significant model predictors in goodness of fit analyses. Rectal stump washout: Departments with clinical audits are less likely to perform rectal stump washout (OR = 0,29,  $p = 0,007$ ). European centres ( $p = 0,04$ ), university hospital ( $p = 0,006$ ), busy department ( $p = 0,01$ ) and clinical audits ( $0,007$ ) are significant predictors in goodness of fit analyses. Diverting stoma (DS): European centers have increased risk of diverting stoma when coloanal anastomoses (OR = 4,14,  $p = 0,004$ ). Diverting stoma when intraoperative difficulties are more likely to be performed at departments with clinical audits (OR = 3,06,  $p = 0,02$ ). One stage surgery: Multidisciplinary teams are significant model contributor for

the decision of one stage surgery ( $p = 0,02$ ). Furthermore decision of one stage surgery is less likely ( $OR = 0,24$ ) at departments with multidisciplinary teams (table 4).

## 5.5 Paper IV-V. RCT of colon cancer follow-up



**Figure 4.** Participating hospitals and communities.

Three hospital trusts and the University Hospital of North Norway trust are located within the Northern-Norwegian Health Region, serving a population of 470 000. Median travel time with car from primary care communities to hospital were 2 hours.

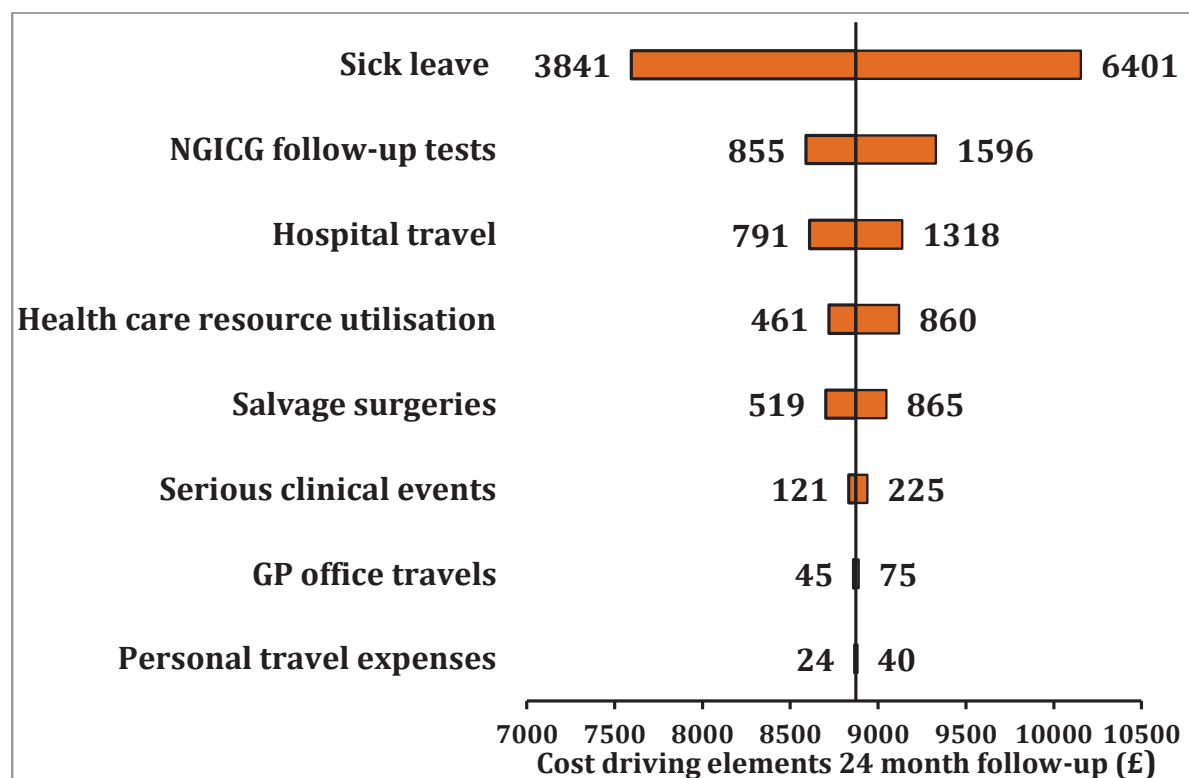
*Trial flow:* 110 patients surgically treated for colon cancer met the inclusion criteria and agreed to participate. During the follow-up period 628 follow-up cycles (i.e. 1884 follow-up months; GP 942 months vs. surgeon 942 months) were performed (GP 314 cycles vs. surgeon 314 cycles). 28 questionnaires (5%) were excluded from analyses (GP 15 vs. surgeon 13) due to incomplete

data or missing information, i.e. 600 follow-up questionnaires (95%) (GP 299 vs. surgeon 301) were included in analyses. 84 patients (75%) (GP 41 vs. surgeon 44) were followed for 12 months, 58 patients (52%) (GP 29 vs. surgeon 29) were followed for 24 months. Eleven patients withdrew during trial due to no wish of follow-up (GP 5 vs. surgeon 6), 20 patients were transferred to a new follow-up program (GP 9 vs. surgeon 11) (Figure 4 and 5).

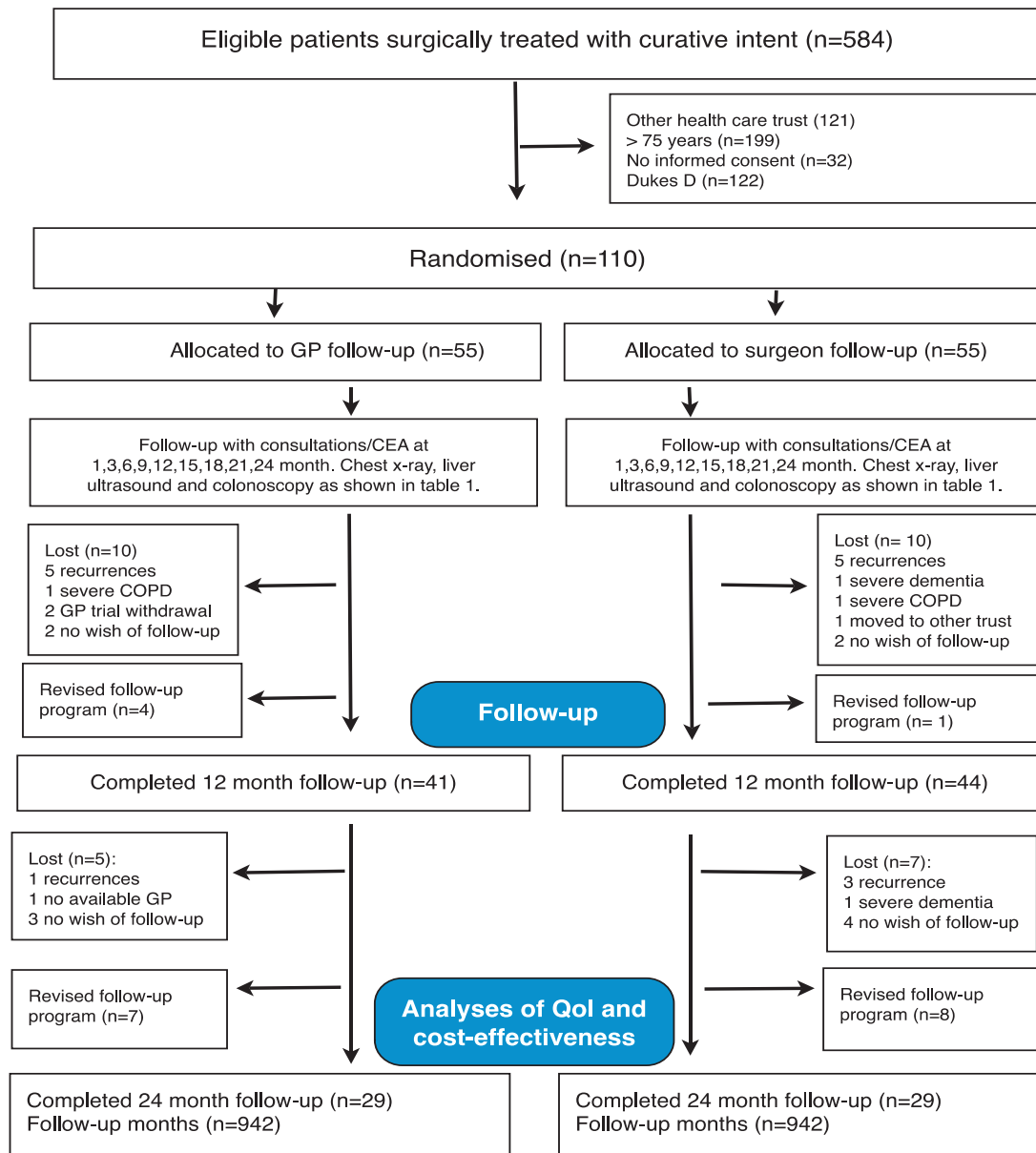
*Cost-effectiveness:* There were no significant difference on primary QoL measure (Global health status), and a cost minimisation analyses were performed. A total of 778 travels (consultations, radiological investigations, colonoscopy) to hospital were registered, 528 in the surgeon group and 250 in the GP group, respectively. A total of 1186 health-care contacts (regular appointments, emergency appointments, phone consultations) were registered, 678 in the GP group versus 508 in the surgeon group. Mean cost of follow-up per patient per follow-up cycle was £292 in GP group and £351 in surgeon group ( $p=0.02$ ). Overall mean societal cost per patient for 24 months follow-up were £ 9889 in the surgeon group and £ 8233 in the GP group ( $p<0.001$ )(Figure 7).

*Quality of life:* There was no significant effect on the QoL main outcome measures. However, on the EORTC QLQ C-30 subscales, there were significant effects in favour of GP follow-up, i.e. role functioning ( $p=0.02$ ), emotional functioning ( $p= 0.01$ ) and pain ( $p=0,01$ ) (Figure 6).

*Sensitivity analyses:* The single factor with greatest impact on overall societal costs was sick leave followed by cost of follow-up tests and cost of hospital travels. Variances in cost related to GP office travels and follow-up appointments had minor impact on overall cost.



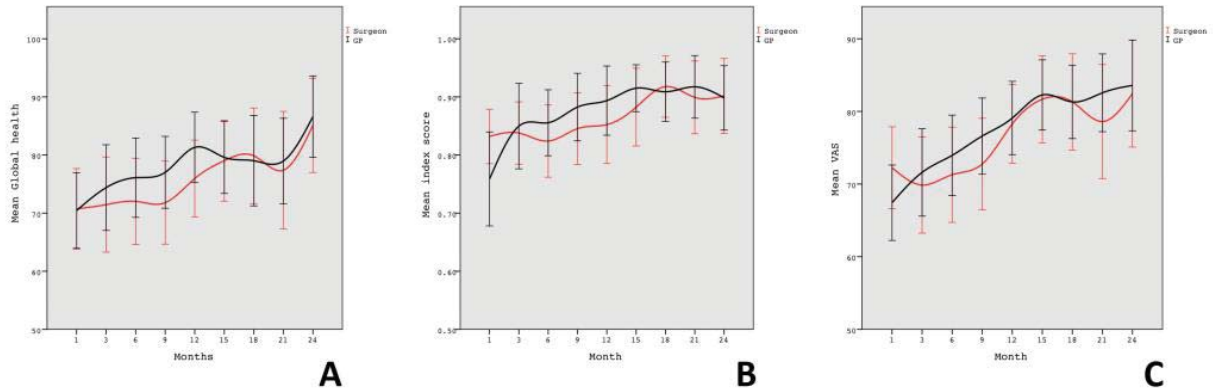
**Figure 4.** Sensitivity analyses of cost driving elements in colon cancer surveillance. Societal cost per patient (£) for 24-month colon cancer follow-up. Most critical variable in terms of impact is listed at the top of the graph, and the rest ranked according to their impact thereafter.



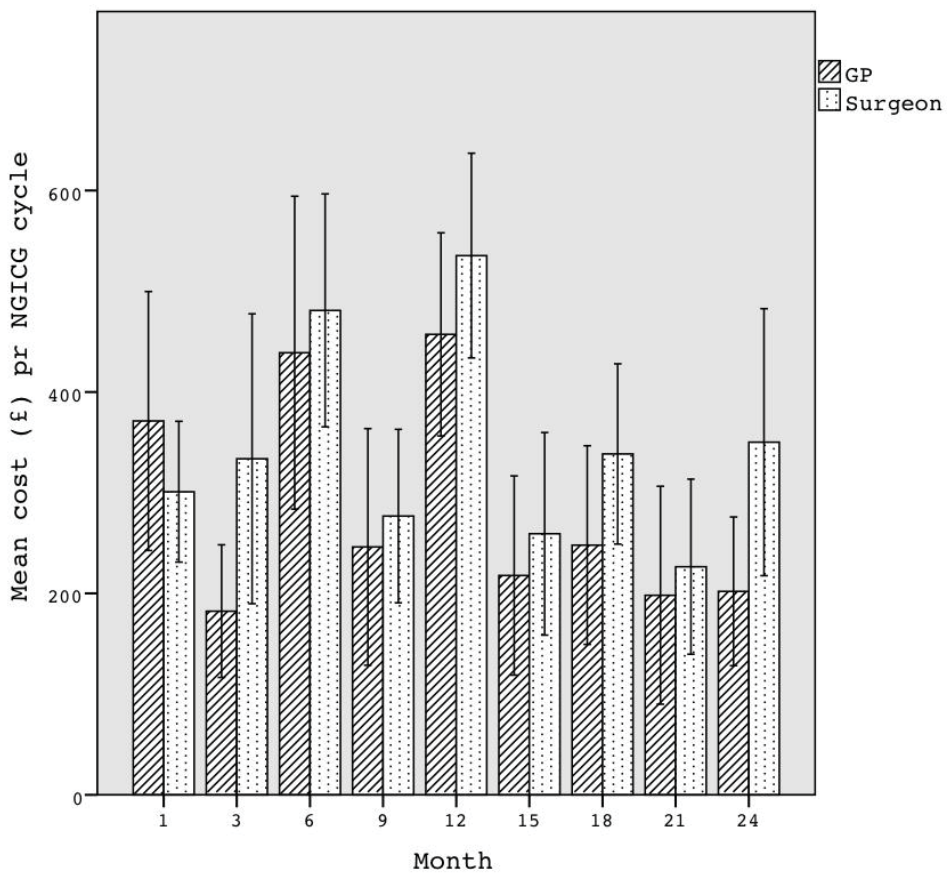
**Figure 5.** Flow of participants.

Patients were enrolled in the 2007 NGICG (Norwegian Gastrointestinal Cancer Group, table 1) follow-up program in both trial arms. The program are divided in 3 months cycles i.e.; clinical examination at 1 (baseline), 3,6,9,12,15,18,21 and 24 months, carcinoembryonic antigen (CEA) measurement at 3 months intervals, chest x-ray and contrast enhanced liver ultrasound every 6 months, and colonoscopy 1 time during 24 months (table 2).





**Figure 6 A, B, C.** Health related quality of life 1-24 postoperative month. EORTC QLQ C30 Global Health, EQ-5D index score and EQ-5D visual analog scale.



**Figure 7.** Cost of follow-up.



Mean cost of follow-up per patient per 3 month follow-up cycle with error bars (95% confidence intervals). In a general linear model, mean difference between groups was 60.0 £ (95 CI interval: 7.0 – 113.0,  $p = 0.02$ ).

*Time to cancer diagnoses:* 48 serious clinical events (SCE) occurred, mean time until diagnosis of a serious clinical event was 45 days in the surgeon group and 35 days in the GP group ( $p=0.46$ ). Of patients with SCE, 14 patients had cancer recurrence and 7 patients (50%) were offered metastases surgery. Median time to diagnoses of recurrence was 21 days in the GP group (range 2-270 days) and 30 days in the surgeon group (range 3-45 days) (table 7). Five patients died (all deaths caused by disseminated colon cancer) during the follow-up period (GP 1 vs. surgeon 4).

## **6.0 Discussion**

### **6.1 Methodological limitations**

#### **6.1.3 Limitations of questionnaire survey**

*Validation:* There was no pre-validated questionnaire available as a gold standard and validation and piloting of this questionnaire was not done. This could affect overall results, as well as comparison of results between hospitals. However, this was not feasible in this survey, due to the amount of work connected to the validation process. Furthermore, this limitation will have minor impact on our main conclusion, i.e. wide variation in surgical practice.

*Language:* Participants from multiple non English countries replied to the questionnaire. It can not be excluded that some of the respondents may have misinterpreted the questions, however as English is the dominant medical language we believe the degree of misinterpretation is minimal.

*Selection bias:* It might be argued that the cohort of hospitals and surgeons is not representative of a true international cross sectional survey of department organization and international practice. We do not believe this is the case as the centres included in the survey were selected by identifying experienced surgeons (appendix 1, paper I) representing well-known hospitals. The respondents came from large university hospitals throughout the world (78%) as well as from other large hospitals with relatively high volume of rectal cancer patients, and the participants are all published authors and teachers at national meetings. Similarly the surgical experience among the respondents are high, 93% of the responding surgeons have experience with rectal cancer treatment more than five years, 35% have an experience more than twenty years. Thus, in our opinion the respondents are good representatives for their national rectal cancer practice.

*Qualitative versus quantitative research:* A questionnaire may not be the ideal research tool to examine impact of organisational factors on decision-making; recent surveys assessing surgical decision-making have used qualitative methods interviewing surgeons in a systematic manner. In a recent survey by Pauley, surgeons were interviewed and a timeline of important decisions was created, enabling a deeper understanding of the decision process.<sup>4</sup> Furthermore, in every group there are experienced surgeons with superb clinical skills who are influential in the decision making process of

the other surgeons.<sup>53,54</sup> We believe these kinds of dynamics will not be reflected in this survey. Observational surveys have some methodological limitations. We acknowledge a potential discrepancy between statistical modelling and clinical reality. A predictor (in our case organizational characteristics) that is independently associated with an outcome does not necessarily imply causation.

#### **6.1.4 Limitations of randomised controlled trials**

*Complex interventions:* Although an RCTs is defined as "the gold standard" in evidence based medicine, randomised controlled trials has limitations. In an increasingly complex health care system, there exist limitations in designing and interpret RCTs. An increased focus is needed on complex interventions (CI). A CI was defined by Cambell et al as an intervention that is "built up from a number of components, which may act both independently and interdependently".<sup>44,55</sup> The Medical Research Council in UK proposed in 2000 a framework for the development and evaluation of RCTs for complex interventions (theory, modelling, exploratory trial, definitive RCT, long term implementation), which was further improved in 2007.<sup>44</sup> The methodological challenges of complex interventions have been thoroughly discussed in the area of health service research.<sup>56,57</sup> Complex and large health organizations are characterized by flux, contextual variation and adaptive learning rather than stability, and a standardized intervention will not fit such organizations.<sup>58</sup>

*Choice of endpoint:* It might be argued that we were missing important information by choosing another endpoint than survival. However, this trial

was designed primarily to evaluate whether general practice follow-up results in effect on patient specific quality of life and cost effectiveness. We acknowledge that this choice of endpoint might impact the observed frequency of serious clinical events and time to cancer diagnoses, as a higher number of SCE and cancer recurrences would have occurred with a longer follow-up time. Even so, during our trial length of 1884 follow-up months we observed fewer recurrences than anticipated (15,4%), however this might be related to the decreasing rate of colon cancer recurrences at a national level (unpublished data Norwegian Cancer Registry). Similarly, costs will be impacted by a longer follow-up time. However, when health care cost of follow-up is analysed separately, cost spending are significantly lower in the GP group compared to the surgeon group.

*Generalizability:* Cost transferability across jurisdictions might be challenging, as elements of cost data may vary from place to place.<sup>59</sup> It might be argued that this is a single country trial with limited generalizability. However, we do not think this is the case. Comparable follow-up trials have been performed in countries like USA, Canada, UK, Australia, Netherland.<sup>60-</sup><sup>63</sup> These surveys are commonly cited and thus accepted as generalizable. In Norway, the GP has a traditional gatekeeper function and plays a central role managing resource use in secondary care. Similarly, many European countries have a health care organisation where the GP plays a central role as gatekeeper to access of secondary health care service. In our trial, guidelines for dealing with aspects of generalizability and transferability were applied, and variations in units costs were included in the sensitivity analyses.<sup>59</sup>

*Futility:* The trial was stopped early (after 1884 follow-up months) due to futility and implementation of a new national follow-up program. This might be a potential limitation. However, it would have been unethical to spend large resources over years to complete a trial with a 4% probability (conditional power shown at interim analyses) of proving our primary hypotheses.

## **6.2 Discussion of the main results**

Paper I-V will be discussed with the decision theoretical frameworks previously described as basis (please see introduction and figure 1).

### **6.2.1 Preoperative CRC decisions (input-process)**

This is the first survey of current practice among international colorectal centers regarding preoperative management of rectal cancer. The results demonstrate a wide variation in preoperative staging procedures, inconsistencies in indications for preoperative CRT as well as differences in treatment procedures for identical rectal cancers. This variation highlights the need for more and better scientific evidence to help guide rectal cancer treatment as well as the need for international focus upon a guidelines development.

*Guideline variability:* There exist several guidelines for rectal cancer treatment, both at a national and international level. These guidelines do however vary in their recommendations. Similarly, practice may vary between countries and continents because surgeons prefer treatment

according to their own guidelines. Implementation of national guidelines of clinical practice seems slow, as pointed out in other surveys (12, 13) and has also been demonstrated among colorectal surgeons (14-18).<sup>25-27,64-66</sup> The differences in preoperative staging and treatment options cannot be explained by the heterogeneity of the institutional affiliation among the participants. As the vast majority of the responding colorectal surgeons work in academic medical centers, the differences in current practices reflect the lack of clinical evidence or the slow implementation of such evidence. Evidence from the US about adherence to preoperative staging and treatment options suggests marked variation. For the eight centers that participate in the National Comprehensive Cancer Network (NCCN), adherence to guidelines and quality measures is variable.<sup>67</sup> Concordance with guidelines is discussed in a editorial by Browman.<sup>68</sup> Certainly, it is important to indicate how aligned a recommendation is to the evidence from which it is derived, but it is uncertain how practitioners interpret, respond to, or act upon a recommendation. We think our study reflect this argument, showing inconsistent practice also within continents and national borders.

*Radiologic imaging modalities:* Variations in preoperative staging imaging will select identical rectal cancer patients to different treatment regimens depending on the sensitivity and specificity of the selected imaging modality. MRI and rectal ultrasound have better diagnostic properties than CT for rectal cancer (20, 21), but still CT is used for local staging by 54.5% of the surgeons compared to 34.5 % that prefer MRI on all rectal cancer patients.<sup>69,70</sup> The distance to the CRM has been increasingly recognized as an important factor and a surrogate marker for local recurrence. In this context,

MRI has gained increasingly popularity because of its ability to decide the distance to the CRM, and should be used widely for the preoperative treatment planning. CT has little or no place in describing the distance to CRM because of low spatial resolution. In a recent published review, MRI is recommended to use upon all rectal cancer patients.<sup>16</sup> In our study, 11% never uses MRI and approximately 50% uses it in selected cases. In our opinion this number is surprisingly low, and might reflect slow implementation of evidence-based medicine among colorectal surgeons. All centers in this study use more than one staging procedure. CT has a role in evaluation of infiltration of other organs, i.e. usually for large T4 tumors. In addition CT is used to determine metastatic disease in the liver and/or lungs (M stage in the TNM classification). ERUS has a role for evaluation of the small tumors that might be feasible for local excision.<sup>16</sup>

### **6.2.2 Operative CRC decisions (input-process)**

The paper is very interesting...I'm surprised US vs. non US showed that large differences. Helen M. MacRae, MA, M.D., FRCSC. Department of Surgery, University of Toronto and Mount Sinai Hospital, Canada.

The survey shows a wide variety of anatomical definitions of a rectal tumor, operative techniques, indications for transanal endoscopic microsurgery (TEM) and use of drains and diverting stomas. Heald and coworkers have standardized the anatomical approach to rectal cancer by performing a TME with sharp dissection in the avascular plane surrounding the mesorectum.<sup>33</sup> Their data showed that precise anatomical dissection has an impact on rectal cancer specific survival. Studies have shown that the surgeon represents one of the major prognostic factors for treatment of rectal cancer, i.e. surgical technique has a major impact upon rectal cancer survival.<sup>8</sup>

*Anatomical descriptions:* There are large discrepancies between both anatomical descriptions of the rectum and more importantly the ideal distal point from which to measure location of a rectal tumor. The rectum has been defined as “the portion of the intestinal tract extending from the rectosigmoid junction to the anorectal ring”.<sup>71,72</sup> However, in the international literature there is no consensus regarding the length of rectum, and this is reflected in the answers given in the survey. Approximately 50% of the surgeons prefer the definition “15 cm from the anal verge” as a good surgical definition of rectum, but many other definitions are proposed. 80% of surgeons prefer to use a rigid proctoscope to measure the distance from the upper to lower edge of the tumor, and to describe the localization in rectum. This is also the preferred method described by Lowry et al.<sup>71</sup> However, about 30% of the surgeons prefer to use a flexible scope. This method of measurement probably has more potential for inaccuracy for defining the localization of a tumour, it is however good for biopsy purposes and inspection of the rectum.

*International practice:* The survey indicates differences in practice between US and non-US surgeons. A larger proportion of US surgeons prefers one stage operation with synchronous liver metastasis and performs TEM for T2N0 rectal cancers in medically unfit patients. Indications for TEM are still debated and the best treatment for simultaneously rectal cancer and liver metastases is unsolved.<sup>73</sup> Drainage after surgery is addressed in a meta-analysis by Urbach et al, where they conclude that colon and rectal anastomoses do not require routine drainage.<sup>74</sup> Despite hard evidence, 35% of surgeons in this study always leave drain after surgery, significantly more often by non-US surgeons. Diverting stomas after low anterior resection are



debated in the medical literature, and practice varies especially regarding stoma after preoperative radiation. Diverting stoma after radiation is preferred more frequently among the US surgeons (69% vs. 43%,  $p=0.01$ ). However, most surgeons prefer a diverting stoma for low anastomoses, in accordance with a recently published meta-analysis showing a diverting stoma decreases anastomotic leak and reoperation rates.<sup>75</sup>

### **6.2.3 Postoperative colon cancer surveillance (structure/outcome)**

*“I really look forward to this research project. I want to participate closer in the follow-up of cancer patients living in my community”; e-mail from GP.*

*“I refuse to participate in this research project, it is imposed on me against my will and I doubt it will make any difference for the patients”; e-mail from GP.*

A representative population of patients surgically treated for colon cancer participated in this trial, with an expected normal variance of demographic factors and colon cancer severity. In this study patients were followed for up to two years, i.e. the period with most cancer recurrences and serious clinical events, which again would impact QoL and costs of follow-up. We have shown that a decentralised colon cancer follow-up program will not impair QoL, on the contrary we observed a significant improvement in the following QoL subscales; role functioning, emotional functioning and pain. This is the first trial evaluating the economical implications of a GP organised follow-up program after curative resection for colon cancer. Despite a higher frequency of health care contacts in primary care, a decentralised GP organised follow-up program was associated with total cost savings due to decreased cost of primary care consultations and less hospital travels. Importantly, our result shows that GP follow-up was not associated with increased time to diagnosis

of a cancer recurrence (35 versus 45 days,  $p=0.46$ ), and the frequency of a SCE was similar in both groups.

*Comparison with on going trials:* Few published surveys have evaluated the effect of a GP organised follow-up program. Two surveys have reported on quality of life in a primary care based follow-up program, and a single cost-effectiveness analysis of intensified hospital based follow-up was published in 2004.<sup>62,76,77</sup> However, for other cancer conditions more cost-effective ways of organising follow-up is extensively described and evaluated. For breast cancer patients, nurse lead telephone and GP organised follow-up is cost-effective<sup>78,79</sup><sup>63</sup> with no increase in the frequency of SCE.<sup>61</sup> Nevertheless, the quality of primary care cancer management is still debated.  
80-82

*Implication for patients, decision makers and clinicians:* Colon cancer in numbers is the third largest cancer type worldwide and a considerable number of patients are enrolled in a post surgical surveillance program, resulting in significant societal cost. However, as there is no evidence-based consensus of how to design cost-effective follow-up programs, differences in tests, test frequency and level of care will have high impact on societal cost spending. For many patients, follow-up leads to a number of long distance travels to hospital, causing high societal cost. Thus, from an economical perspective, GP organised follow-up is cost-effective due to a better coordination of care. In a time with escalating health care cost, especially in cancer care, these aspects are of increasing importance. From a patient perspective, GP organised follow-up is associated with high quality of care. Our study demonstrates that a decentralised follow-up has no negative impact on quality of life, length to cancer diagnoses and follow-up guideline

adherence. Finally, patients surgically treated often have other chronic illnesses, and there is a trend towards higher involvement of primary care in treating these conditions as described in the chronic care model.<sup>83</sup> From a hospital perspective, a transfer of follow-up programs to primary care has economical and organisational implications. GP organised follow-up may be an effective way of reducing the burden on busy hospital clinics.

#### **6.2.4 Organisational (structural) impact on CRC decision-making**

*“..... organizational factors matters the most”: Eduardo Salas in the lecture: “Key competencies of highly reliable teams”. American College of Surgeons Annual Congress Chicago 2012.<sup>84</sup>*

The outcome of surgery is dependent on the quality of care received by the patient and is impacted by a considerable number of health professionals.<sup>85,86</sup> The organizational system in which these clinicians interact appears to influence patterns care. Vincent et al (Table 1) identified five higher-level influences that are of considerable importance for patient outcome; patient factors, task factors, individual factors, team functioning and working environment. In this thesis we have identified similar organizational characteristics and analysed influence on decision making for CRC. We have shown that organizational features like clinical audits, multidisciplinary teams, busy departments, caseload and university affiliation are associated with CRC decision-making choices. Furthermore: organisational boundaries, culture and communication impact decision-making choices. We have shown that novel ways of organising colon cancer follow-up is feasible by improving organisational communication (GPs versus surgeons) and decision-making. In a randomised trial, GP organised follow-up of patients

treated for colon cancer was cost effective, led to no decline in patients QoL, or increase in SCE frequency or time to cancer diagnoses. Based on our findings, we will discuss some central structural (organisational) features that impact CRC decision-making, i.e. teamwork, safety culture, and communication.

*Teamwork and decision-making:* Although evidence for technical or clinical benefit from teamwork training in surgery is weak group performance and decision-making has been studied in detail in other fields.<sup>87-90</sup> One theme that runs through decision-making research is that basic processes in groups can lead to either good or poor performance, depending on the context in which the processes are instituted.<sup>89</sup> It is theoretically possible that multi-specialty group decision-making may be superior to that of an individual clinical specialist addressing rectal cancer.<sup>91</sup> It has also been demonstrated that group members can develop stronger motivation and perform better in the presence of other group members than they would have done in pure isolation. These characteristics of groups may be directly associated with the superior decision-making with MDTs or clinical audit teams.<sup>92,93</sup> The process of “group think” may simply be superior in complex settings allowing groups to perform better than individuals (reach more optimal solutions, make fewer errors, etc.). High reliability teams plays a central role in complex organization, and are characterized by closed loop communication, information exchange, back-up behaviour, planning, error management, feedback and team self correction.<sup>94-96</sup> Teamwork and high quality team communication increases treatment quality for patients with colorectal cancer. MDTs have been shown to increase use of MRI and

improve indications for neoadjuvant treatment. The vast majority of colorectal MDT decisions are implemented, when alternative decisions are implemented it is almost always due to unexpected patient factors.<sup>93</sup> Eudaro Salas have performed extensive research on the characteristics of high reliability teams within surgery. According to his theories, eight factors define team performance (the eight Cs of team performance), i.e. *Communication*: exchange of information needed for high quality decision-making. *Cooperation*: motivation and desire to engage in coordinative and adaptive behaviour. *Coordination*: the process of orchestrating the sequence of independent actions. *Coaching*: Direct interaction with a team intended to help members make coordinated and task-appropriate use of their collective resources. *Cognition*: detecting and recognize pertinent cues, make decisions, problem solving, storing and remembering relevant information. *Cohesion*: Affective attraction to the team goals and desire to remain part of the team. *Collective efficacy*: belief in the ability of the team as a unit to accomplish shared goals. *Collective identity*: perception of oneness with a particular group of others.<sup>84,96,97</sup>

*Safety culture and decision-making*: Sixty five per cent of participating hospitals have regular clinical audits assessing complications in a structured manner. During past decade, there have been an increasing focus on surgical errors and some surgical societies have adopted the aviation industry procedures.<sup>98</sup> Implementation of a safe surgery checklist has been associated with concomitant reductions in the rates of death and complications. Known causes of error include fatigue, workload, cognitive overload, poor interpersonal communications, imperfect information processing, and flawed

decision-making.<sup>13,99</sup> The failure to think critically, to deliver disciplined treatment strategies, to recognize structural failures, and to achieve situational awareness contributes to the reported morbidities and mortalities.<sup>100</sup> There are also shown a relationship between aviation style non-technical skills training of and improved technical outcomes, suggesting that team training can improve the performance of theatre teams in a manner which is likely to bring clinical and operational benefits.<sup>87,88</sup> Finally, there are increasing evidence of the association between safety culture and rates of serious surgical complications.<sup>3</sup> In a recent study by Birkmeyer et al, they conclude that interventions designed to improve patient safety culture, particularly coordination and communication, are potentially important targets for quality improvement.<sup>3</sup>

*Communication and decision-making:* Effective communication is essential to coordinate surgical practice, however care of patients is often compromised by poor communication at hospitals and between primary and secondary care.<sup>101-103</sup> It is shown that poor coordination between primary and secondary care contributes to avoidable patient morbidity and mortality.<sup>104</sup> Thus, effective communication between primary care physicians and hospital specialists regarding patient referrals, consultations and treatment is necessary, and improves patient outcomes and physician satisfaction.<sup>105</sup> It is shown that poor communication has a central role as a driver of health care quality and cost.<sup>106-108</sup> Systematic structures, tools (decision support) and process for information creation, transfer, receipt and recognition by the sending and receiving physicians are needed to assist surgeon - GP communication.<sup>106</sup>

### **6.2.5 Final remarks**

The decision-making skills of an individual surgeon are influenced by the ‘ecological system’ this individual was trained and is working. We believe that open discussions of complications, and MDT meetings provide a good opportunity to benefit from other people’s experience, rather than to learn only from one’s own experience. Our assessment of various system characteristics affecting the care of the rectal cancer patient suggests that university hospitals, caseload, safety culture, and MDTs collectively impact surgical decision-making. Furthermore, we have shown that novel ways of organising postoperative colon cancer care (i.e. surveillance) is feasible. A GP organised follow-up of colon cancer patients is associated with cost savings, no decline in QoL and no increase in time to cancer diagnoses. We believe the decision-support tool (as part of the intervention) contributed to improved guideline compliance and better communication between surgeons and GPs. These findings emphasize the importance of surgical leadership creating a favourable environment for collective decision-making and outcome assessment for truly quality improvement in CRC management.

## **7.0 Conclusion**

1. The results demonstrate a wide variation in preoperative staging procedures, inconsistencies in indications for preoperative CRT, as well as differences in treatment procedures for identical rectal cancers.
2. There is a need for an international consensus guideline for rectal cancer

treatment with an increased focus on developing internationally recognized quality indicators.

3. Discrepancies in practice make it difficult to perform studies comparing CRC treatment.
4. There exist no international consensus on which colon cancer follow-up program that maximise survival and cost-effectiveness.
5. A GP organised colon cancer follow-up program led to no decline in patient related quality of life.
6. A GP organised colon cancer follow-up program was cost-effective.
7. There was no increase in time to cancer diagnoses in a GP organised follow-up program
8. Treatment variance of CRC patients appears to be significantly impacted by organisational characteristics and complex team based decision-making.
9. Organisational characteristics need to be considered as a source of outcome variation, which impact quality metrics.
10. These wide variations in CRC practice should alert national and international CRC experts as well as health care administrators. This will influence health care costs, side effects, quality of life, local recurrence and cancer specific survival.



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# Paper 1



# Paper 2



# Paper 3





# Paper 4



# Paper 5





ISBN xxx-xx-xxxx-xxx-x