Improving colonoscopy services. Ten years of quality assurance in the Norwegian Gastronet quality improvement initiative

A study of the Norwegian Quality Register Gastronet

PhD thesis

by

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2 List of papers

Paper 1

Moritz V, Bretthauer M, Holme Ø, Fagerland MW, Løberg M, Glomsaker T, de Lange T,
Seip B, Sandvei P, Hoff G:
Time trends in quality indicators of colonoscopy.
United European Journal February 2016; 4: 110-120

Paper 2

Moritz V, Bretthauer M, Ruud HK, Glomsaker T, de Lange T, Sandvei P, Huppertz-Hauss G,
Kjellevold Ø, Hoff G:
Withdrawal time as a quality indicator for colonoscopy – a nationwide analysis.
Endoscopy 2012; 44: 476-481

Paper 3

Moritz V, Holme Ø, Leblanc M, Hoff G
An explorative study from the Norwegian Quality Register Gastronet comparing self-
estimated versus registered quality in colonoscopy performance.
Endoscopy International Open February 2016 Mar; 4(3): E326-E332

Paper 4

Hoff G, Moritz V, Bretthauer M, Aabakken L, Berset IP, Glomsaker T, Høie O, de Lange T:
Incontinence after colonoscopy – an unrecognized and preventable problem. A cross-
sectional study from the Gastronet quality assurance program.
Endoscopy 2012; 44: 349-353
3 Abbreviations

ADR: adenoma detection rate
CI: confidence interval
CIR: cecal intubation rate
CRC: colorectal cancer
ESGE: European Society of Gastrointestinal Endoscopy
GRS: Global Rating Scale
JAG: Joint Advisory Group
OR: odds ratio
OWT: overall withdrawal time
PCT: Practical clinical trials
PDR: polyp detection rate
QA: quality assurance
RCT: Randomized controlled trials
SD: standard deviation
VWT: visual withdrawal time
WT: withdrawal time
4 Definitions

Quality assurance:

Activities implemented to assure that a service complies with defined quality standards either by feedback on appropriate quality or by implementation of improvement measures where quality is not appropriate. (1)

Cecal intubation rate (CIR):

An individual endoscopist’s rate (in percent) of colonoscopies with complete examination of the entire rectum and colon including cecum, the uppermost part of the colon, with identification of the ileocecal valve. In the literature some authors exclude colonoscopies with impassable strictures in the colon from the calculation of cecal intubation rate (also called adjusted CIR). In our project we operate with unadjusted CIR not excluding procedures with impassable strictures. (2)

Polyp detection rate:

An individual endoscopist’s rate (in percent) of colonoscopies where one or more polyps of any kind and independent of its histology were found. (2) Polyp detection rate is either restricted to screening procedures or, as in Gastronet, the rate includes all colonoscopies including patients with symptoms.
Adenoma detection rate:
An individual endoscopist’s rate (in percent) of screening colonoscopies with one or more detected polyps containing adenomatous tissue on microscopic examination.(3)

Insertion time:
Mean time for an individual endoscopist needed to insert the colonoscope from the anus to the uppermost end of the colon, the cecum.(4)

Overall withdrawal time:
Mean time for an individual endoscopist needed to retract the colonoscope from the uppermost end of the colon, the cecum, to the anus. Overall withdrawal time includes both pure inspection, time for biopsy sampling and time for therapeutic interventions.(5)

Visual withdrawal time:
Mean time for an individual endoscopist needed to retract the colonoscope from the cecum to the anus in colonoscopies with only inspection of the colon. Colonoscopies with biopsy sampling or therapeutic interventions are excluded from this calculation.(5)

Gastronet patient questionnaire:
Gastronet form delivered to the patient by the endoscopist or nurse assistant immediately after the procedure with questions concerning pain, bloating, satisfaction with treatment and information and inconveniences related to bowel cleansing. The
form contains a space where the patient can write a commentary. The patient is asked to fill in the questionnaire on the day after the examination. See appendix figure 4 and 6.

Gastronet endoscopist report form:
A form filled in by the endoscopist immediately after the procedure containing medical and technical details of the procedure (type of gas for insufflation, use of sedation and/or analgesia, quality of bowel cleansing, previous surgery, type of procedure (diagnostic or therapeutic), completeness of procedure, duration of total procedure and withdrawal phase, use of imaging support systems, indications, findings, diagnosis and complications. See appendix figure 5 and 7.

Pain related to colonoscopy
In the Gastronet patient questionnaire the patient is requested to evaluate the grade of pain suffered during or within 24 hours after the colonoscopy by using a four point verbal rating scale with the categories no pain, slight pain, moderate pain or severe pain.(6)
Know yourself. Don`t accept your dog`s admiration as conclusive evidence that you are wonderful.

- Ann Landers, American advice columnist, 1918-2002
5 Introduction

5.1 Evaluation of health care

Medicine and medical services have developed at an enormously rapid pace during the last two centuries. Alongside the progress in medical diagnostic methods and treatment, health care authorities and the public have become increasingly aware of the need to question quality delivered by health care providers. It has been a long way from individual enthusiastic health workers of the nineteenth century struggling for local improvement of medical services to international health institutions authorized to define processes and strategies for enhancement of quality. In 1847, Ignaz Semmelweis, a Hungarian born physician, started exploring why the rate of post-delivery mortality due to childbed fever was much higher among women delivered by physicians and medical students compared to midwife trainees or midwives. He concluded that the reason for the higher rate of infection was the handling of corpses during autopsies before attending the pregnant woman. He blamed “cadaveric material” from autopsy corpses as source of infection and significantly reduced the infection rate by implementing handwashing using a chloride of lime solution for all physicians and medical students attending a child birth.(7)
Because Semmelweiss` innovation met a lot of resistance and rejection by peers and the medical environment, it took a long time until this quality improvement measure was generally accepted.

Nowadays, in contrast, the highest ranking institution for health care affairs, the World Health Organization, sets standards for decision-makers and managers at country level and recommends a process for making strategic choices in health care systems in order to improve quality of care.(1)

5.2 Definition of quality in health care

The World Health Organization has given a working definition of quality of health care.

Quality in health care requires that the health care system is:

- effective, delivering health care that is adherent to an evidence base and results in improved health outcomes for individuals and communities, based on need;
- efficient, delivering health care in a manner which maximizes resource use and avoids waste;
- accessible, delivering health care that is timely, geographically reasonable, and provided in a setting where skills and resources are appropriate to medical need;
- acceptable/patient-centered, delivering health care which takes into account the preferences and aspirations of individual service users and the cultures of their communities;
- equitable, delivering health care which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location, or socioeconomic status;
- safe, delivering health care which minimizes risks and harm to service users. (1)

Rather than regarding quality as a fixed structure, the WHO suggests to understand quality as a cyclical process containing the three categories analysis, strategy and implementation as depicted in figure 1.(1)

Figure 1
A process for building a strategy for quality (from WHO Quality of care(1))

According to WHO this cyclical process reflects a frequently adopted approach to quality improvement – understand the problem, plan, take action, study the results, and plan new actions in response.

This systematic quality improvement strategy was developed by W.E. Deming and W. A. Shewhart in the last century.(8, 9) Originally designed for industrial production, it became increasingly popular in other contexts, particularly within health care.
According to this cycle, systematic quality improvement is achieved by a 4-step approach.

The first step is to plan how to identify domains (Plan) with need for potential improvement strategies. In the second step (Do) one develops a strategy how quality can be measured. In the third step (Study or check) one performs analyses and measures effectiveness of the strategy. In the fourth step (Act) one adopts or abandons strategies based on the results. The repetitive implementation of such cycles can constitute continuous quality improvement. (10)

The Norwegian Directorate for Health and Social Affairs developed a national strategy for quality improvement in health and social services in 2005. (11) This strategy plan is directed at decision-makers and leaders within the Norwegian health care. It defines strategic aims and action plans that support improvement of quality as depicted in figure 3.
Already several decades ago the need for assessment of quality of care in health systems were recognized and strategies to achieve improvement were called upon. In 1988 Donabedian proposed to distinguish between three classes of quality dimensions:

1) **Structure** encompassing facilities, equipment and personnel as well as organizational aspects
2) **Process** defining how health care is provided and

3) **Outcome** denoting the effects of care on the health status of patients and populations. (12)

This three-part approach was proposed because good structure increases the likelihood of good process, and good process increases the likelihood of a good outcome. It has previously been demonstrated that assessment and feedback of quality to the providers of health care can result in observed consistent improvement of health care. (13-15)

Assessment of quality itself has to be based on high quality methods. Flawed and inconsistent rating methodologies are possible and not rare. They can actually reward low-performing providers and penalize true high performers. (16) Due to limited resources it is unrealistic to claim that quality assessment should cover every detail of the multifaceted steps in the process of health care delivery. (17) Porter also proposes public reporting of health care evaluations because this might accelerate innovation by motivating providers who seek improvement relative to their peers. This would clearly be beneficial for all stakeholders in health care including the patient. In order to achieve optimal results with true benefit for all involved, it is necessary to define high standards for quality measurement and improvement. (18, 19) Panzer et al emphasize that the transition to measures from electronic health records and allocation of sufficient resources are important issues for future quality improvement initiatives. Some authors recommend to incorporate the patient’s perception of quality of health care in the process of quality assessment. (20) In the current world of restricted resources it is clearly very important that the cost of data collection for quality measurement initiatives have to be weighed against its benefit for the community. (21) In 2005 a project defining
Standards for Quality Improvement Reporting Excellence (SQUIRE) was initiated providing guidelines for quality improvement. (22)

Health authorities are increasingly aware of the need to establish structures that assure quality improvement and assurance of health services in general. In Norway this change in attitude resulted in an immense increase in the number of national health registers. During less than five years the number of national medical quality registries has increased from less than twenty to currently 54 registries (www.kvalitetsregistre.no). In the field of gastroenterology, the national registry Gastronet was initiated with an aim of improving the quality of colonoscopy – later expanding to include ERCP. The focus of this PhD thesis is on quality of colonoscopy in Norway. For a deeper understanding, the following passage will provide a short summary of the history of colonoscopy.

5.3 History of colonoscopy

The method of colonoscopy was developed at the end of the 1960s. Dr William I. Wolff and Dr. Hiromi Shinya from the Beth Israel Medical Center in New York performed the first complete diagnostic colonoscopy in June 1969. (14) They used a flexible fiberoptic endoscope which was a further development of already existing technology, i.e. flexible sigmoidoscopy and gastroscopy. After initial skepticism in the medical community and public media, it took about one decade for this new method to become generally accepted and appreciated. The two pioneers, Wolff and Shinya, performed complete inspection of the rectum and entire colon with their fiberoptic colonoscope without complications. (23) In September 1969, only three months after the first fiberoptic
complete diagnostic colonoscopy, the first therapeutical intervention of a snare polypectomy with complete removal of a colonic polyp was successfully performed. (14)

In 1971 Wolff and Shinya published a series of 241 successful colonoscopies in the New England Journal of Medicine. (23) They showed that diagnostic colonoscopy with biopsy and therapeutic snare polypectomy was feasible without serious complications.

In Norway, the University Hospital Rikshospitalet startet colonoscopy in 1973. The first polypectomy was performed in 1974. (24) At Telemark Hospital in Skien, colonoscopy was introduced in April 1973. Within six months 35 diagnostic colonoscopies including biopsies were performed on 27 patients. Each examination was compared with a barium enema examination which was the initial diagnostic method. In 10 out of 27 patients, additional findings not seen with barium enema were revealed by colonoscopy. The authors, Dr Arne Rosseland and Dr Kaare Solheim, concluded that colonoscopy was a very good supplement to X-ray examinations. (25)

5.4 General aspects of quality in colonoscopy

Colonoscopy is a procedure in which a tube-like flexible instrument with a length ranging between approximately 130 and 170 cm and a diameter ranging between approximately 10 and 14 mm is gently pushed through the anus and rectum and the entire colon in addition to the terminal ileum when required. High definition, real time video pictures from a camera in the tip of the instrument are displayed on screens visible for the endoscopist, assisting staff and the patient. There is an enormously wide range of settings in which this procedure is used. It ranges from a healthy person attending an outpatient clinic for an electively scheduled screening colonoscopy for cancer or cancer precursor lesions to a seriously ill patient with rectal bleeding undergoing emergency
colonoscopy to identify the source of bleeding and treat it. In the situation of a critically ill patient, there is usually little or no focus on quality assessment of an endoscopic procedure because all resources are engaged in patient management. In addition, such patients are not amenable or may not be willing to participate in quality assurance trials requiring informed consent. Therefore, apart from a very small study analyzing the development of colonoscopy quality among hospitalized patients in the course of two decades, there is virtually no literature dealing with colonoscopy quality in patients admitted to hospital. (26) On the other hand, it may also be a concern to expose a healthy, asymptomatic person to a cancer screening colonoscopy - an invasive procedure with potentially serious complications such as bleeding or perforation. These conflicts entail two consequences. First, virtually all studies on colonoscopy quality exclude inpatient colonoscopies and focus on outpatient procedures. Second, the competence requirements for endoscopists performing screening colonoscopy are often set higher than the requirements for endoscopists performing outpatient colonoscopies on symptomatic patients. (3) An unpublished study of Hoff et al. analyses the differing standards for cecal intubation with regard to the varying clinical settings (screening versus symptomatic patient). Preliminary results do not support the need to define lower standards for cecal intubation in symptomatic patients.

The colonoscopy procedure in itself has a wide range of technical possibilities associated with greatly varying need for technical skills by the endoscopist. A procedure can consist of pure visual inspection. It can contain biopsies taken with small forceps on a catheter introduced through the instrument’s working channel. Bleeding foci can be treated with argon plasma coagulation, small polyps can be removed with biopsy forceps, and bigger polyps can be removed with diathermic snare polypectomy. The spectrum culminates in
very advanced procedures dedicated to expert endoscopist such as the removal of very large polyps with endoscopic submucosal dissection by dissection of the submucosa from the muscularis propria with a needle knife and insertion of self-expanding metal stents in malignant colon strictures. (27)

As a natural consequence of the complexity of this procedure, there has been significant variability in the quality of it. Recent studies have documented an inverse relationship between an endoscopist adenoma detection rate and interval colorectal cancers and death. (28, 29) Several countries have therefore established quality assurance guidelines for colonoscopy which are discussed in detail in the following paragraph.

5.5 International colonoscopy quality guidelines

In 2000, the United States of America initiated the U.S. Multi-Society Task Force on Colorectal Cancer. This collaborative project assembled representatives of leading Gastroenterology associations (American College of Gastroenterology, The American College of Physicians, the American Society of Internal Medicine, the American Gastroenterological Association and the American Society for Gastroenterological Endoscopy). The project addressed issues in colorectal cancer detection and prevention. In 2002, they published their recommendations on “Quality in the Technical Performance of Colonoscopy and the Continuous Quality Improvement Process for Colonoscopy.” (30) The American College of Gastroenterology and the American Society for Gastroenterological Endoscopy published their guidelines on “Quality Indicators for Colonoscopy” in 2006. (31) These were recently (2015) updated. (3)
In 2010, the European Union financed and commissioned an international collaborative project involving 90 experts serving as authors, contributors, editors or reviewers from 32 countries including 21 EU Member States (Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, Portugal, Spain, Sweden, the Netherlands and the United Kingdom), one EU-applicant (Croatia, member of EU from 2013) and other countries outside the European Union (Argentina, Australia, Canada, China, India, Israel, Japan, Republic of Korea, Norway and the United States of America). This project developed the “European guidelines for quality assurance in colorectal cancer screening and diagnosis”. (32, 33)

The European Society of Gastrointestinal Endoscopy (ESGE) gave a statement on quality in screening colonoscopy which was published in 2012. (34) In December 2016 the Quality Improvement Initiative of the ESGE preliminary published a draft of guidelines on performance measures for lower gastrointestinal endoscopy which will be published as soon as the revision process is finished. (35)

In the United Kingdom, the Joint Advisory Group on Gastrointestinal Endoscopy published the “BSG Quality and Safety Indicators for Endoscopy” in 2007 providing recommendations for quality standards for several gastrointestinal endoscopic procedures including colonoscopy. (36) Guidelines for quality standards in colonoscopy were developed by the NHS Bowel Cancer Screening Programme in 2011. (37)

Canada established the Cancer Care Ontario program which commissioned a special project of the Colonoscopy Standards Expert Panel in 2007 with the intention of defining standards for colonoscopy quality. (38) In 2012 and 2014 Canadian guidelines for colonoscopy quality assurance were updated.(39, 40)
In Australia “Clinical Practice Guidelines for Surveillance Colonoscopy” were developed by a project partially funded by the Australian Government Department of Health and Ageing under the National Bowel Cancer Screening Program in December 2011. (41)

In the Netherlands the National Institute for Public, Health and the Environment implemented a protocol for the authorization and auditing of colonoscopy centres and endoscopists. (42)

For Gastronet, the European (represented by the EU guidelines and the European Society of Gastrointestinal Endoscopy guidelines) and US American guidelines were crucial for the development of quality indicators. (3, 32, 34) The differences between these guidelines are generally small. In America, there is greater focus on different quality requirements for different settings with higher claims for screening compared to clinical procedures than in Europe.

The Europeans recommend the audit of ADR but leave the definition of specific ADR levels to screening boards. In contrast, the American guidelines make specific recommendations for different procedure settings and patient gender. Also, the quality guidelines from the other countries mentioned in this chapter are mainly comparable to the European and US American standards but important differences will be discussed in chapter 9.2. Canadian guidelines recommended a CIR ≥ 85% in symptomatic patients in 2008. (43) This rather low threshold was increased to a CIR ≥ 90 % in new Canadian guidelines in 2012. (40)

Table 1 provides an overview of a selection of different quality indicators for various Western countries or regions.
Table 1
Summery of different quality indicators for colonoscopy according to guidelines from different Western regions.

<table>
<thead>
<tr>
<th>Region</th>
<th>Organization, year (reference)</th>
<th>CIR screening</th>
<th>CIR symptomatic</th>
<th>ADR</th>
<th>PDR</th>
<th>Withdrawal time</th>
<th>Discomfort / pain</th>
<th>Adequate bowel preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>ACG/ASGE, 2015 (Rex)</td>
<td>≥ 95 %</td>
<td>≥ 90 %</td>
<td>≥ 25 % (♂ ≥ 30% / ♀ ≥ 20%)</td>
<td>≥ 6 min</td>
<td>≥ 85 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Europe</td>
<td>ESGE, 2016 (Kaminski)</td>
<td>≥ 90 %, minimum</td>
<td>≥ 25 %, minimum</td>
<td>≥ 40 %, minimum</td>
<td>≥ 6 min, minimum</td>
<td>Standards for patient experience desirable but yet unknown</td>
<td>≥ 90 %, minimum</td>
<td></td>
</tr>
<tr>
<td>Britain</td>
<td>Quality Assurance Guidelines, 2011 (Chilton)</td>
<td>≥ 90 %</td>
<td>≥ 35 %, screening</td>
<td>≥ 6 min</td>
<td>Audit recommended, no standards defined</td>
<td>≥ 90 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>CAG, 2012 (Romagnuolo, Armstrong)</td>
<td>≥ 95 %</td>
<td>≥ 90 %</td>
<td>≥ 25 % (♀)</td>
<td>≥ 8 min</td>
<td>Patient feed- back desired, standards not yet set</td>
<td>≥ 90 %</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>Clin. Pract. Guidelines for Surveillance Colonoscopy, 2011 (Cancer Council Australia)</td>
<td>≥ 95 %</td>
<td>≥ 90 %</td>
<td>≥ 20 % (in patients ≥ 50 y)</td>
<td>≥ 6 min</td>
<td>Abnormal discomfort / pain warranting hospital admission in less than 1 in 100 patients</td>
<td>≥ 90 %</td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>Protocol for the Authorization and Auditing of Colonoscopy Centres and Endoscopists, 2012 (National Institute for Public Health and the Environment)</td>
<td>≥ 95 %</td>
<td>≥ 90 %</td>
<td>≥ 30 %</td>
<td>≥ 6 min</td>
<td>Recording of patient discomfort / pain desirable but standards not yet set</td>
<td>≥ 90 %</td>
<td></td>
</tr>
<tr>
<td>Norway</td>
<td>Gastronet, 2015</td>
<td>≥ 90 %</td>
<td>≥ 25 % (polyps ≥5mm)</td>
<td>Feedback to endoscopist given, no standard defined</td>
<td>≤ 12.3 % (average severe pain score for 2015)</td>
<td>Feedback to centres with low mean BBPS compared to others</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
References: USA (3); Europe (35); Britain (37); Canada (39, 43); Australia (44); Netherlands (45); Norway (www.krefregisteret.no/gastronet, result tables for quality indicators only accessible for endoscopists with user name and password provided by Gastronet)
CIR: cecal intubation rate, ADR: adenoma detection rate, PDR: polyp detection rate
BBPS: Boston Bowel Preparation Scale assessing the degree of preparation in each of the three colon segments (right colon, transversum and left colon/rectum) with 0 for worst and 3 for perfect preparation (minimum score 0 and maximum score 9). (46)

5.6 Complexity of quality in colonoscopy

Colonoscopy is a complex procedure. Its quality depends on many different factors which are directly or indirectly related to the procedure. The focus of this thesis is on quality directly related to the endoscopy team and its impact on the patient service. Other important elements with quality impact, such as building facilities, administrative structures, equipment maintenance, equipment cleansing and hygiene routines, service from affiliated departments as for example department of pathology and radiology, adequate access to the procedure with acceptable waiting times and appropriate health care capacities for colonoscopy go beyond the scope of this thesis and are not mentioned.

Quality indicators can be divided into indicators valid for all sorts of different endoscopic procedures in general and indicators specifically related to colonoscopies. Outcome indicators, for example incidence of colorectal cancer or frequency of complications, are generally preferred because they represent final results. They are, however, often cumbersome to measure because large amounts of data have to be collected and processed or long-term follow-up is needed for proper conclusions. Therefore, process indicators such as adenoma detection rate and cecal intubation rate are frequently used rather than an outcome indicator like cancer incidence reduction which, in a screening setting, may require at least 10 years to be collected. Process indicators are more
convenient to measure but they depend on the evidence that supports their associations with clinically relevant outcomes. According to the phase of the procedure, indicators are categorized as preprocedure, intraprocedure or postprocedure indicators. (3)

The following lists (table 2) provide an overview of quality indicators in endoscopy and specifically in colonoscopy. The list on indicators valid for all endoscopic procedures in table 2a is based on guidelines by the American College of Gastroenterology and the American Society for Gastrointestinal Endoscopy which were published by Rizk et al. (47) The list on colonoscopy specific quality indicators in table 2b is based on a guideline by the same gastroenterological societies published by Rex et al. (3)

Table 2a

**Proposed quality indicators common to all endoscopic procedures** (O=outcome/ P=process indicator)

**Preprocedure:**
- Proper indications for the procedure (P), consent (P), patient history and physical examination prior to the procedure (P), sedation (P), prophylactic antibiotics in risk patients (P), management of antithrombotic treatment (P), proper team pauses (P), documentation of proper endoscopist and nurse competency (P)

**Intraprocedure:**
- Frequency and documentation of photo documentation (P), patient monitoring in sedated patients (P), administration of medication (P), use of reversal agents and procedure interruptions due to sedation related issues (P)
**Postprocedure:**

- Implementation of discharge criteria (P), adequate patient instruction (P), plan for pathology follow-up (P), completeness of procedure report (P),
  documentation and
  frequency of early and late adverse events (O), patient satisfaction (P)* and communication with referring center (P).

*From Gastronet`s point of view it would be preferable to define patient satisfaction as an outcome indicator rather than process indicator because a patient`s satisfaction is an important issue in health care. Other papers support this view. (48-50)

Table 2b

**Proposed quality indicators for colonoscopy** (O=outcome/ P=process indicator,
performance target (recommended percentage of procedures that meets the quality requirements))

**Preprocedure:**

- Documentation of appropriate colonoscopy indication (P, >80%),
- Proper obtained consent (P, >98%),
- Definition of proper surveillance intervals (P, ≥90%)  

**Intraprocedure:**

- Description of preparation quality (P, >98%),
- Adequate adaption of surveillance or screening intervals to quality of preparation (P, ≥85%),
- Photo documentation of cecum (P, not available),
- Cecal intubation rate (P, ≥90% for all types of colonoscopies and ≥95% for screening procedures),
- Adenoma detection rate (O, for male patients ≥30%, for female patients ≥20%, combined for both sexes ≥25%),
- Frequency of withdrawal time measurement (P, >98%),
- Average withdrawal time in negative-result screening colonoscopies (P, ≥6min),
- Frequency of biopsy specimen in negative colonoscopies for patients with chronic diarrhea (P, >98%),
- Appropriate tissue sampling in patients with inflammatory bowel disease (P, >98%),
- Frequency of endoscopic (in contrast to surgical) removal of polyps ≤2cm (O, >98%)

**Postprocedure:**

- Incidence of perforation (O, all examinations <1/500, CRC screening <1/1000),
- Incidence of post-polypectomy bleeding (O, <1%),
- Frequency of successful endoscopic management of post-polypectomy bleeding (O, >90%),
- Appropriate recommendation for timing of repeat colonoscopy according to histologic results (P, ≥90%).
Another quality indicator which was implemented in the European guidelines (32) is the annual procedure volume per endoscopist. In a study by Singh et al., endoscopists with a procedure volume of 300 colonoscopies per year had a significantly lower complication rate than endoscopists with a lower volume. (51) The European guidelines comment that a large number of procedures is not sufficient proof of competency because bad habits can persist even in very experienced endoscopists. Experts within the European guidelines panel also mention retrieval rates for pathological material in screening colonoscopies as a possible and easily measurable indicator. Specific benchmarks have not been proposed so far. (52) Small polyp size, removal of polyps with a cold snare, flat serrated polyps and location of polyps in the proximal colon have been identified as factors indicating a high risk for unsuccessful polyp retrieval. (53) It has been demonstrated that retrieval rates can improve if endoscopists receive proper training on polyp retrieval and feedback on their retrieval rates. (54) Another potential quality indicator has appeared in recent years. Williams et al. found a correlation between polypectomy rate defined as rate of colonoscopies in which one or more polypectomies were performed and adenoma detection rate. Benchmark polypectomy rates of 40% and 30% correlated with ADRs greater than 25% and 15% for men and women, respectively. (55) Other studies supported a strong correlation between polyp detection (or resection) rate and adenoma detection rate. (56-59) To my knowledge there have been no studies that did not document a correlation between these two factors. A recent study showed that PDR, too, is inversely associated with interval colorectal cancer. (48) In order to get to the roots of suboptimal performance, Robertson et al. proposed a framework for basic colonoscopy curriculum for all colonoscopy trainees. (60) The
principle of a structured curriculum or assessment of colonoscopy competency have been supported by others (61-64)

Recently new quality indicators for colonoscopy have been proposed. To avoid a rather rough binary definition of adenoma detection rate for an endoscopist based on the proportion between colonoscopies with one or more adenomas and colonoscopies without adenomas, Denis et al. suggested a rate based on number of adenomas or polyps per colonoscopy. (65, 66) This might provide more detailed reflection of continuous endoscopic thoroughness because colonoscopists who consciously or unconsciously reduce their thoroughness in inspection after having found one polyp or adenoma might have a lower rate of polyps or adenoma per colonoscopy than those colonoscopists who maintain high concentration during the entire procedure. Adenoma detection rate might be equal for these endoscopists although quality is different. This might discourage endoscopists with possible cunning and dishonest intentions (“Now that I have found one adenoma I do not need to be so thorough with the inspection of the remaining bowel because a positive impact of this procedure on my individual adenoma detection rate is secured”). Other authors confirmed a strong correlation between adenoma detection rate and number of adenomas per colonoscopy rate. (67) In comparison, the adenomas per colonoscopy rate has a stronger correlation to the detection of advanced adenomas than adenoma detection rate. (68) To my knowledge there has been no study refuting the strong correlation between adenoma detection rate and adenomas per colonoscopy rate. Even if the adenomas per colonoscopy rate may turn out as a powerful quality indicator, it is clearly hampered by the inconvenience that both histology results and number of adenomas have to be connected to the
colonoscopy report. This cumbersome characteristic may make it difficult to implement it in routine endoscopy service.

The performance measures for lower gastrointestinal endoscopy by the quality improvement committee of the European Society of Gastrointestinal Endoscopy were very recently published as a draft. They include seven domains of colonoscopy service (Pre-procedure, completeness of procedure, identification of pathology, management of pathology, complications, patient experience and post-procedure). (35) The committee defined one evidence-based key performance measure for each domain. Three of those domains were supplemented with two to four minor performance measures. The following text describes the new aspects emerging in the guidelines. An important new aspect is the fact that patient experience is regarded as a key performance measure due to its potential to impact participation in screening programs, adherence to surveillance recommendations or even patients’ diagnostic work-up for large bowel symptoms. (69)

Innovative minor performance measures were proposed such as adequate time allocation for the procedure (minimum standard of at least 30 minutes for clinical and primary screening colonoscopy and 45 minutes in work-up procedures for positive fecal occult blood tests), (70) tattooing resection sites to ease relocation after polypectomy or guidance of surgical management, (71) use of advanced imaging techniques such as chromoendoscopy for demarcation and easier removal of flat or depressed neoplastic lesions (by use of either dye, for example methylene blue, or narrow band imaging technique), (72) and the use of the Paris classification for the description of polyp morphology (pedunculated, sessile, flat, depressed or ulcerated).

Other refined performance measures like advanced ADR defining the rate of colonoscopies in which high risk adenomas were found and proximal PDR or ADR
defining the rate of polyps or adenomas found in the proximal colon beyond the splenic flexure have been proposed. (73, 74) The role and meaning of these indicators with regard to colonoscopy quality has not yet been specified. A recent study from Austria showed a deterioration of the advanced ADR although PDR, ADR and the detection rate of proximal lesions improved during the course of the study. (75) It remains to be seen which of these indicators are going to be adopted in endoscopic societies in the near future.

5.7 The Norwegian National Register Gastronet

The aim of Gastronet is improvement of the quality of endoscopy. Participation was voluntary until 2012 both for centres and individual endoscopists. Since late 2012, Gastronet has achieved status as a national quality register to which the national and regional health authorities have tried to make reporting compulsory. So far, non-participation in Gastronet does not entail any form for punitive actions against the centre. Currently, Gastronet includes both colonoscopies and endoscopic retrograde cholangiopancreatographies (ERCP). For colonoscopy, only outpatient procedures are included. Gastronet covers approximately one third of all outpatient colonoscopies in Norway where roughly 80,000 procedures have been performed annually in recent years (about 80% of these are outpatient procedures). Gastronet was founded in 2003. Twenty-one Norwegian, seven Swedish and one Polish endoscopy centre participated in the colonoscopy register in 2014. So far, approximately 150,000 colonoscopies and almost 10,000 ERCPs have been registered in Gastronet.

The Gastronet register uses two questionnaires for each colonoscopy performed. One form contains procedural variables to be filled in by the endoscopist and/or nurse and the other contains questions on discomfort and satisfaction to be filled in by the patient.
at home on the day after the examination. Both forms take only one to two minutes to be filled in. The forms are mailed to the Gastronet secretariat. The endoscopist form includes information about referral date, indication, previous abdominal surgery, sedation, type of insufflation gas (carbon dioxide or air), cecal intubation, duration of examination and time to cecum, use of fluoroscopy/magnetic endoscopic imaging, endoscopic findings, clinical diagnosis, detected number of polyps with estimated diameter of 5 mm or larger and quality of bowel cleansing.

The patient form includes a validated four-point verbal rating scale for pain (no pain, slight pain, moderate pain and severe pain)(76) and questions about satisfaction with treatment and information, degree of involuntary leakage after the examination, details related to the bowel cleansing process.

Validation of a test requires a thorough literature search to identify available tests which are best to evaluate the construct of interest. Development of a test is a long process necessitating contributions from many experts in several stages of review. Numerous research efforts are required to substantiate a test’s validity. Choosing a suitable sample for validation studies is needed to provide reliable generalizability to the target population. Good concepts of validity are of vital importance because they enable us to evaluate success of treatment and to justify continued intervention. Many creators of test instruments are unaware of their accountability for the validity of their instrument. They are responsible if the test measurements are not meaningful. This is a problem that often hinders communication. It makes it difficult to compare findings and draw reliable generalizations. (77)

Figure 4 and 5 in the appendix section show the original Norwegian patient and endoscopist forms. Figure 6 and 7 show the same forms translated into English. The
patients mail the completed form directly to the Gastronet secretariat in a prepaid envelope. Results on performance indicators are provided yearly to all participating endoscopists who have registered at least 30 colonoscopies during the last year and to each participating centre. Each endoscopist knows only his or her identity code in the reports. As from 2014, results per centre are available to all endoscopists and the general public while results per endoscopist remain concealed also during discussions within the Gastronet community. Each endoscopist is, however, encouraged to reveal his or her results during quality assurance discussions at the local gastrolab. Measures that may be taken locally to improve quality are not routinely reported to Gastronet.

5.8 Quality indicators for colonoscopy in Gastronet

In Gastronet there are two levels of quality feedback. The first level is designed for feedback to the individual endoscopist via emails to the endoscopists with personal results in an anonymized fashion once a year. Each endoscopist is allocated a code number. Each endoscopist knows only his/her own code, but not the code numbers of other participants. This guarantees anonymity, but allows comparing own results with those of others.

The second level of quality feedback is designed for the centres. Once a year Gastronet arranges a meeting inviting Gastronet representatives from all participating Norwegian hospitals. At these meetings, centre-related results are presented and discussed. In this context results for the centres (individual endoscopist results remain anonymized) are not anonymized in order to facilitate effective improvement work and discuss measures to be taken.
At the level of the individual endoscopist, Gastronet has implemented seven different quality indicators taking into account different phases of the procedure (pre-, intra- and postprocedural) and the nature of the indicator (general endoscopic or colonoscopy specific). Table 3 summarizes quality indicators in Gastronet.

Table 3: Summery and characterization of quality indicators used on individual endoscopist level in Gastronet Colonoscopy

<table>
<thead>
<tr>
<th></th>
<th>General endoscopy quality indicators</th>
<th>Colonoscopy specific quality indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preprocedural</td>
<td>1) Rate of procedures with sedation and/or analgesics given before start</td>
<td>None</td>
</tr>
<tr>
<td>Intraprocedural</td>
<td>1) Rate of procedures with sedation and/or analgesics given on demand during the procedure</td>
<td>1) Cecal intubation rate (CIR in %)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2) Type of colonoscopy (%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>diag.,/therapeutic )</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3) PDR-5mm (% of colonoscopies with polyps ≥5mm)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4) Pain during colonoscopy (% no, slight, moderate, severe)</td>
</tr>
<tr>
<td>Postprocedural</td>
<td>1) Patient satisfaction with treatment and information (No, slightly, moderately, very in %)</td>
<td>1) Diagnosis (% frequencies of different main diagnoses)</td>
</tr>
</tbody>
</table>

At the endoscopy centre level the respective representatives of the various participating centres are informed about details on the colonoscopy service provided. By means of
clearly laid out bar graphs and tables, the results can easily be evaluated and compared with others. The information comprises numbers of reported colonoscopies, mean age distribution, indications for the examination, use of sedation and analgesia, type of analgesics used, type of gas used for insufflation of the colon (CO2/air), involuntary stool leakage after the procedure, quality of bowel cleansing, type of colonoscopy (diagnostic/therapeutic), cecal intubation, reasons for intubation failure, most significant findings at colonoscopy, detection of polyps ≥ 5mm, immediate complications (observed at the endoscopy centre), patient reply coverage, pain during colonoscopy, satisfaction with service provided, satisfaction with information received, categorization of the patients’ free text comments (positive/negative), pain/discomfort after colonoscopy, degree of intelligibility of cleansing instructions and quality of taste of the cleansing fluid.

5.9 Reception of feedback

There are three addressees receiving quality feedback from Gastronet. The endoscopist and the endoscopy centre participating in Gastronet and the public.

Once a year the endoscopist receives an email from Gastronet with summary tables covering all colonoscopy quality indicators as outlined in chapter 5.8. The endoscopist knows only his or her own endoscopist code number which enables each endoscopist to identify his or her individual results. Figure 8 gives an example of the lay-out for feedback on pain.
Figure 8: Example of feedback table for pain during colonoscopy emailed to endoscopists (only a small clip for demonstration).

<table>
<thead>
<tr>
<th>Gastronet 2014, Table V</th>
</tr>
</thead>
<tbody>
<tr>
<td>GH 09.03.2015</td>
</tr>
<tr>
<td>Percent distribution of patients' pain grading.</td>
</tr>
<tr>
<td>Distribution among endoscopists registered with &gt;=30 colonoscopies January - December 2014</td>
</tr>
</tbody>
</table>

**Average for all endoscopists:**

| Suggestion for all with scores above average on pain: Aim at least for the present average |
| No results in this table for endoscopists with <30 patient reply forms received at Gastronet secretariat. |
| Patient report form coverage per endoscopist varies from less than 60% to more than 90%. |
| This implies that at least some of the apparent no-return of patient report forms are related to some endoscopists being less careful to secure that patients have their reply form when leaving the endoscopy unit. |

<table>
<thead>
<tr>
<th>Endoscopist code no.</th>
<th>No. of colonoscopy categor.</th>
<th>Matching (%)</th>
<th>Patient reported pain</th>
<th>% Not stated</th>
<th>% Severe pain</th>
<th>% Moderate pain</th>
<th>% Slight pain</th>
<th>% No pain</th>
<th>% Pain stated</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30-50</td>
<td>93.6%</td>
<td>0%</td>
<td>38.6%</td>
<td>27.3%</td>
<td>27.3%</td>
<td>6.8%</td>
<td>11.5%</td>
<td>9.5%</td>
</tr>
<tr>
<td>2</td>
<td>&gt;500</td>
<td>75.3%</td>
<td>4%</td>
<td>32.7%</td>
<td>38.0%</td>
<td>17.9%</td>
<td>10.1%</td>
<td>6.0%</td>
<td>10.1%</td>
</tr>
<tr>
<td>3</td>
<td>51-100</td>
<td>69.8%</td>
<td>2.7%</td>
<td>35.1%</td>
<td>40.5%</td>
<td>13.5%</td>
<td>8.1%</td>
<td>5.0%</td>
<td>13.5%</td>
</tr>
<tr>
<td>4</td>
<td>201-300</td>
<td>72.6%</td>
<td>1.2%</td>
<td>30.5%</td>
<td>45.7%</td>
<td>16.5%</td>
<td>5.1%</td>
<td>6.5%</td>
<td>16.5%</td>
</tr>
<tr>
<td>13</td>
<td>101-200</td>
<td>72.8%</td>
<td>1.2%</td>
<td>34.5%</td>
<td>35.1%</td>
<td>20.5%</td>
<td>7.2%</td>
<td>7.0%</td>
<td>20.5%</td>
</tr>
<tr>
<td>14</td>
<td>101-200</td>
<td>79.5%</td>
<td>7%</td>
<td>33.3%</td>
<td>52.0%</td>
<td>4.7%</td>
<td>9.3%</td>
<td>5.0%</td>
<td>9.3%</td>
</tr>
<tr>
<td>18</td>
<td>201-300</td>
<td>77.5%</td>
<td>0%</td>
<td>41.2%</td>
<td>33.0%</td>
<td>12.1%</td>
<td>12.7%</td>
<td>7.0%</td>
<td>7.0%</td>
</tr>
<tr>
<td>19</td>
<td>101-200</td>
<td>73.2%</td>
<td>0%</td>
<td>48.5%</td>
<td>35.6%</td>
<td>8.0%</td>
<td>6.0%</td>
<td>6.0%</td>
<td>6.0%</td>
</tr>
</tbody>
</table>

At centre level, feedback of centre results occurs in different ways. The main forum is an annual meeting gathering Gastronet representatives from the centres as mentioned above. The results of the centres are discussed openly and the participants try to identify weaknesses and positive results, find explanations and make proposition for improvement measures. Figure 9 shows an example of how results are presented at the meeting.
Figure 9

Example of feedback provided at the Gastronet meeting: Pain during colonoscopy reported by the patient. Each column represents one endoscopy centre.

The result slides of this meeting are also e-mailed to the centre leads in order to facilitate quality improvement work. Participating endoscopists also have access to these slides via the Gastronet website (www.kreftregisteret.no/gastronet). Participating endoscopists and nurses may access more detailed results in a password protected part of the website.

A third addressee has emerged in recent years. Public media, in particular national newspapers, have promoted a desire to enable access to Gastronet data. Therefore, the Gastronet board initiated a modification of statutes in agreement with the centre representatives. Since 2014, the public has had access to centre identifiable results on
the Gastronet website. The access is free and allows patients to compare the quality of different endoscopy centres.

5.10 The goal of improving quality in colonoscopy

The goal of any quality register is analysis of the present and improvement of poor quality. (78, 79) So far, Gastronet has no defined structures for quality improvement measures. Individual and centre related quality feedback is provided for endoscopists and centre leads, but it is the responsibility of individual endoscopists and centre leads to act on their Gastronet results and initiate improvement measures. Gastronet does not systematically collect information about local efforts for improvement based on their Gastronet results. It is expected that participants with suboptimal performance on individual or centre level initiate improvement measures as for example internal discussion of results between the centre lead and the individual endoscopist or the group of endoscopists, participation in training courses, visiting high quality centres or other actions. Gastronet does not have any authority to impose improvement measures neither on individuals nor on centres, but may provide assistance in local quality assurance work.

Free access to identifiable centre results on internet is meant to be a service provided for users, i.e. patients referred to an endoscopic examination. This information helps them to evaluate whether they are referred to a centre participating in Gastronet and if so, what level of quality is awaiting them.
6 Aims

The general objective of this thesis was to evaluate and improve colonoscopy quality for procedures registered in Gastonet by means of different quality indicators.

The specific objectives were:

Study 1
To examine the 10-year time-trends for quality of colonoscopy in Gastonet specifically for the quality indicators cecal intubation rate, detection of colorectal polyps ≥ 5mm and the patient’s experience of severe pain during colonoscopy.

Study 2
To examine if characterization of endoscopists by their mean withdrawal time in colonoscopies without time-spending biopsy and therapy would be a good predictor for their ability to detect polyps ≥ 5mm.

Study 3
To examine to what degree an endoscopist is able to self-assess his or her own colonoscopy performance with regard to several quality indicators before being presented with the actual performance observed through registrations in Gastonet.

Study 4
To examine if the insufflation of the large bowel using carbon dioxide rather than air during colonoscopy reduces the risk of post-procedure faecal incontinence for the patient.
7 Materials and methods

7.1 Institutional status of Gastronet

Gastronet emerged from the quality assurance module developed in the flexible sigmoidoscopy screening trial NORCCAP (Norwegian Colorectal Cancer Prevention). It was launched as an independent quality assurance program for routine clinics in 2003. Since 2007 it has been funded by the South-East of Norway Regional Health Board. Approval for financial allowances had to be renewed every year. In 2012, Gastronet was acknowledged as a National Quality Register in Norway by the Directorate of Health entailing a more stable and reliable financial frame. The board of Gastronet includes thirteen members, including one patient representative since 2015. A general assembly including board members and Gastronet representatives from participating endoscopy centres is summoned once a year. Board members are elected for 2-year periods.

7.2 Permissions

Through more than 10 years of Gastronet, approvals from the Data Inspectorate and the Directorate of Health have been modified several times according to regulations and needs. To secure correct matching of forms filled in by endoscopists and patients, the forms are presently returned with identification of the patients. Paper forms are destroyed after matching of data, electronic filing and database quality assurance. Patient identification is kept only when patient reply forms (=informed consent) is obtained within 3 months. Otherwise, data are anonymized. In accordance with Norwegian law, the Regional Ethics Committees waived the requirement for approval of the study because it was performed within the Gastronet
quality assurance program, which has been approved by the Norwegian Data Inspectorate. Therefore, there was no need to obtain ethical approval for any of our four studies.

7.3 Study design

In our first cohort study, prospectively registered outpatient colonoscopies from different Norwegian endoscopy centres participating in Gastronet in the period from 2003 to 2012 were included. In the second cohort study outpatient colonoscopies from different Norwegian Gastronet centres performed in the period from January to September 2009 were included. The endoscopists were contacted either by mail, telephone or sms and asked to estimate their colonoscopy experience as the number of examinations prior to this study (30 – 100, 101 – 500, 501 – 1000, 1001 – 5000, 5001 – 10000 colonoscopies). In our third explorative study, Norwegian and Swedish endoscopists were presented a questionnaire which asked them to self-estimate their colonoscopy performance before receiving their first feedback on personal performance results from Gastronet. This questionnaire was sent to all endoscopists joining Gastronet during the period from 2008 to 2013, regardless of their speciality (gastroenterologist or surgeon). The questionnaire is shown in figure 10 in the appendix section. The fourth prospective cohort study comprised outpatient colonoscopies from different Norwegian Gastronet centres. The inclusion period was from January to December 2009.
7.4 Study participants

All colonoscopies registered in Gastronet were eligible for our studies. This included outpatient colonoscopies performed at Norwegian centres on patients eighteen years of age or older in addition to inpatients colonoscopies at the National Hospital in Oslo (OUS Rikshospitalet) where most colonoscopies are performed on inpatients. In study 1 colonoscopies by endoscopists reporting only a low volume of procedure (less than 300 colonoscopies during the entire study period), cecal intubation not intended and procedures not providing a cecal status (cecum reached/not reached) were excluded. The study was confined to Norwegian centres. Reasons for exclusion of procedures in study 2 were delayed reporting of procedures, incorrect (outdated) reporting forms used, procedures by endoscopist reporting only a low volume to Gastronet (less than 30 procedures), incomplete procedures, unusual inspection technique (antegrade - inspection on the way in instead of inspection during withdrawal) and missing data on cecal status, sex and patient age. Also, this study encompassed Norwegian centres only. In study 3 all new endoscopists requesting enrolment in Gastronet during the study period and having their colonoscopies registered in Gastronet until first result feedback, were eligible. The majority of endoscopists were from Norway but in addition some Swedish participants were included.Colonoscopies registered in Gastronet during the study period were eligible for inclusion. Exclusion criteria were patient form not returned, information on type of gas, sex, age and sedation missing. In study 4 all colonoscopies reported to Gastronet during the study period were eligible. Procedures were excluded if the patient questionnaire was not returned, the insufflation method was not stated or the reply forms lacked information about incontinence, sex, age or sedation.
7.5 Development of Gastronet questionnaires

Figures 4, 5, 6 and 7 in the appendix section depict the original Norwegian patient and endoscopist forms and their translations into English. The forms originate from the Norwegian Colorectal Cancer Prevention (NORCCAP) trial. (80-82). This randomized controlled trial explored the effect of flexible screening sigmoidoscopy on the incidence and mortality of colorectal cancer. In case of polyp findings at initial sigmoidoscopy the patient was referred to a subsequent colonoscopy. The patient and endoscopist questionnaires developed in the NORCCAP trial were the templates for the questionnaires used in Gastronet.

For the analysis of pain the patient experienced during the procedure, a four-point verbal rating scale (no, slight, moderate or severe pain) was used. It was validated in comparison with the visual analog scale. Sensitivity was found to be higher for visual analogue scale than for four-point verbal rating scale. (76) A recent review article comprising various clinical settings analyzed different assessment tools for evaluation of pain intensity. In twelve out of 54 trials, a four-point verbal rating scale was compared with either visual analogue scale or numerical rating scale. In eight of these trials, there was found no preference of one tool over the other. Two trials favoured visual analogue scale due to higher sensitivity and two trials favoured verbal rating scale due to lower failure rates and large variability of verbal rating scales. In general, verbal rating scales were associated with higher compliance. In addition, they were preferred by less educated and elderly participants. (83) Gastronet decided to sacrifice higher sensitivity of the measurement tool to secure better compliance especially among elderly patients who constitute a large proportion of patients subjected to colonoscopy.
The two forms in Gastronet are meant to be filled in at different times. The endoscopist is expected to fill in the form immediately after the procedure in order to secure correct memory of the endoscopy details and, thus, minimize the work load for the endoscopist in a busy clinical work setting. In contrast, the patient is asked not to fill in the form until the subsequent day to give the patient space and time to process the experience connected to the procedure and to minimize a patient desire to please the doctor and the nurse assistant while filling in the form with the endoscopy team present at the outpatient clinic. The patient returns the form in a pre-paid return envelope directly to the Gastronet secretariat and forms with information of importance for local follow-up are immediately forwarded to the responsible endoscopist.

The variables of both forms are continuously subject to adaption and update according to topics declared by the annual meeting of representatives to be of interest for quality assurance. Both patient and endoscopist forms are strictly confined to one page in order to support high compliance. Modifications of the forms are discussed at the Gastronet meetings or via email with the representatives of the participating centres. If the patient adds a remark in the free text area of the patient form, a copy of it is also mailed to the endoscopist.
8 Summary of results

8.1 Study 1: Time trends in quality indicators of colonoscopy

During the ten year course of this study 73,522 colonoscopies performed by 73 endoscopists from 25 participating endoscopy centres were included. The trends of three quality indicators (cecal intubation rate, severe pain and detection of polyps ≥ 5mm) were analyzed separately. All colonoscopies included were available for analysis of cecal intubation rate. In the analysis of severe pain, 17,795 procedures were excluded because the patient had not returned the questionnaire or the endoscopist did not intend to intubate the cecum (960 out of 17,795 procedures). In the analysis of polyp detection, 50,459 colonoscopies were excluded because the variable “polyp size” was not implemented in the endoscopist form until 2006 or the endoscopist did not intend to intubate the cecum. Cecum intubation and polyp detection remained unchanged in the course of the study. The rate of colonoscopies with severe pain improved and was reduced from 14.8% at start to 9.2% in the tenth year of the study.

The number of procedures per endoscopist varied between 302 and 6763 (0.4% to 9.2% of total) and between 76 and 9553 (0.1% to 13% of total) per endoscopy centre.

Detailed tables are provided in table 4 and 5 in the appendix section.

8.2 Study 2: Withdrawal time as a quality indicator for colonoscopy – a nationwide analysis

In this study, 4429 colonoscopies performed by 67 endoscopists from 19 Norwegian centres were included. The colonoscopies of endoscopists with a mean withdrawal time
of less than six minutes during procedures with no therapeutical interventions, i.e. diagnostic procedures, were compared with the colonoscopies of endoscopists with a mean withdrawal time of six minutes or more in diagnostic procedures. On the basis of this division into two groups of endoscopists, we analyzed all their procedures (both diagnostic and therapeutic) with regard to the detection of polyps of 5 mm in diameter or larger. A mean withdrawal time of less than 6 minutes was registered for ten endoscopists. They performed a total of 829 diagnostic and therapeutic procedures. A mean withdrawal time of six minutes or more was recorded in 57 endoscopists with a total of 3600 diagnostic and therapeutic procedures. There was no significant difference in polyp detection between the groups. The endoscopists with slower withdrawal did not find significantly more polyps than those endoscopists who retracted the colonoscope at a faster pace. More time used for inspection on withdrawal did not yield a significant increase in polyp detection. Therefore, we concluded that withdrawal time using 6 minutes as a threshold should not be used as a quality indicator for colonoscopy.

The number of procedures per endoscopist varied between 17 and 398 (0.4% to 9.0% of total) and between 38 and 495 (0.9% to 11.2% of total) per endoscopy centre. The mean number of colonoscopies per endoscopist was 66 (2.9% of total) and per endoscopy centre 233 (5.2% of total). Detailed tables are provided in table 6 and 7 in the appendix section.
8.3. Study 3: An explorative study from the Norwegian Quality Register Gastronet comparing self-estimated versus registered quality in colonoscopy performance

In this explorative study encompassing 2654 colonoscopies performed by 39 new Norwegian and Swedish endoscopists enrolling in Gastronet, endoscopists were asked to self-estimate their colonoscopy performance based on their procedure volume before receiving their performance data from Gastronet. The participation rate was low as only 39 out of 99 invited endoscopists responded to the invitation. Self-estimates on cecal intubation rate, polyp detection rate for polyps ≥ 5mm, withdrawal time, total examination time and rates for severely painful and pain-free colonoscopies were returned before the endoscopists received their first performance feedback from Gastronet’s registered and calculated values for the respective quality indicators. Self-estimated and registered values were compared. On average, the endoscopists underestimated their individual performance with regard to cecal intubation, total procedure time and the rate of pain free colonoscopies. There was, however, a wide range from personal overestimation, good estimation to underestimation. Therefore we concluded that self-estimated quality may not be a sufficient surrogate for systematic registration of quality.
8.4 Study 4: Incontinence after colonoscopy – an unrecognized and preventable problem. A cross-sectional study from the Gastronet quality assurance program

This study comprised 7,812 outpatient colonoscopies from 21 endoscopy centres registered in Gastronet. We explored to what degree procedure related faecal incontinence after colonoscopy represented a problem for the patients and if it is correlated to the sort of gas used to inflate the bowel for proper inspection. Air was applied in 5015 and carbon dioxide in 2797 colonoscopies. The two patient groups were comparable with regard to age, sex, indication for having the examination and sedation practice. In 4.3% of all included colonoscopies (336 out of 7812 procedures), the patients reported involuntary leakage from the back passage. In the carbon dioxide group 2.1% registered involuntary leakage and in the air group 5.5% reported leakage of stool or fluids after the examination. The difference was statistically significant. We concluded that about every 20th patient was exposed to post-procedural incontinence and by converting from air to carbon dioxide this problem can be reduced by 60%.
9 Discussion

9.1 Main findings

The subject of this thesis were the results of Gastronet, a Norwegian national quality register for endoscopic procedures, with focus on colonoscopies. The value of Gastronet is based on quality feedback to participating endoscopists and centres enabling evaluation of quality to provide initiation of quality improvement measures and monitoring of effect. In our main study, analyzing a long time span of a decade, we found that cecal intubation rates (equivalent to colonoscopy completion rates) remained fairly stable on a level of 90% or more. High cecal intubation is regarded as a strong quality indicator because endoscopists with high rates have significantly lower risks of missing significant lesions (including cancer) at colonoscopy. This inverse relation was shown in studies on administrative data with large procedure volumes. The proportion of procedures with detection of polyps ≥ 5mm also remained stable on a level between 21.5% and 25.5%. The rate of severely painful colonoscopies improved from a high level of 14.8% to 9.2%. In our second study, we found no correlation between mean withdrawal time for individual endoscopists in colonoscopies with no findings and detection rate for polyps ≥ 5mm. Therefore we do not recommend to use mean withdrawal time as a quality indicator in routine clinics. In a clinical setting including non-screening procedures, Sawhney et al. could not, similar to our results, find a correlation between long withdrawal times and polyp detection. The majority of studies analyzing this correlation were performed in a colonoscopy screening context and had contradicting results.
A recent systematic review outlines the range of differing results of studies analyzing the correlation of withdrawal time and detection of adenomas or polyps. (93) In our third study exploring if new endoscopists enrolling in Gastronet were able to estimate their performance on the background of their colonoscopy experience so far, we found that endoscopists often underestimate their performance. In addition there was a wide range from overestimation to good estimation and underestimation. (2) In our fourth study analyzing the effect of air or carbon dioxide insufflation on involuntary postprocedural fluid leakage we found that patients exposed to procedures using carbon dioxide instead of air had a 60% reduced risk of this happening on their way home after the procedure (2.1% in the CO2 group and 5.5% in the air group). (94)

On the basis of these studies, there are particularly four issues to discuss:

1. Defining high quality in colonoscopy in the international context
2. Compare research in randomized controlled trials with research on registrations from clinical routine work.
3. The effectiveness of feedback on performance quality.
4. Future perspectives for quality improvement work.

9.2 High quality colonoscopy in the international context

Colonoscopy has established its role as a “gold standard” examination for detection of pathology in the colon and rectum in different settings. This key role has not been jeopardized despite its potential for serious procedure-related complications and performer dependency with variations in polyp detection rates and overlooked cancers.
(29) Serious complications are reported in less than 0.28% and the mortality rate is less than 0.1%. (95-97) (98)

Based on Gastronet results, one can conclude that there is significant variation in colonoscopy quality between endoscopists. The annual results for percentage of endoscopists with suboptimal performance for cecal intubation varied between 16% and 31%. For severely painful procedures, this variation was between 25% and 63% and for polyp detection between 48% and 69%. (6)

The number of colonoscopies performed worldwide has increased considerably. In the USA, 14.2 million screening and follow-up colonoscopies were performed in 2002. (99)

In Norway, approximately 80,000 outpatient and inpatient colonoscopies were performed in 2013 according to the Norwegian Patient Register. This is more than a hundred percent increase since 2003 (approximately 27,000 colonoscopies) when a large proportion of bowel imaging was still done by double contrast barium enema.

Colonoscopy is regarded as the “gold standard” diagnostic procedure for pathology in the colorectum. Its quality depends on the individual endoscopist’s performance. Therefore, health authorities have called for clear definitions of high colonoscopy quality resulting in the establishment of guidelines as for example in the United States and Europe. (3, 32, 35) These guidelines are extensive and very detailed. Implementation of their defined quality indicators in clinical routine work might therefore be difficult and cumbersome due to limited time and staff resources.

The updated American guidelines have therefore defined priority quality indicators for colonoscopy (adenoma detection rate in screening procedures, implementation of appropriate surveillance intervals after polypectomy and cancer surgery and cecal...
intubation rate with photo documentation of landmarks). (3) Facing constraints on time and staff in routine clinics, Gastronet is very strict in limiting the forms used by patients and endoscopists to one page only and mainly ticking boxes so that it does not take more than 1 to 2 minutes to fill in a form. (79) Although the extra effort for the endoscopist is limited to a minimum of time, Gastronet covered only 28.5% (14,725 procedures) of all outpatient colonoscopies registered in the Norwegian Patient Register (51,734 procedures) in 2014. Table 8 shows the variation of degree of participation in Gastronet for every hospital and health region in Norway. Some of the centres show a very low rate of procedures which actually are registered in Gastronet. The lowest rate is 4.7%. Low rates clearly expose the results for selection bias. The highest rate for a hospital centre was 92%. Although far better there is still a possibility for selection bias because Gastronet does not have information on the remaining 8% which might constitute those procedures which were particularly difficult, time consuming and painful. It is also noteworthy that there are great variations in Gastronet participation between the different health regions. The South-East Health Region contributes most (41%) and the Northern Health Region least (10%). So far Gastronet cannot provide explanations for these immensely varying motivations in centres and health regions. Recently 30 centres not participating in Gastronet were sent a questionnaire with questions about the reason for not participating. Only three of them (10%) responded which leaves Gastronet in uncertainty about reasons for non-participation.
Table 8

Twenty-one (41%) from 51 Norwegian hospital centres performing colonoscopy reported to Gastronet in 2014. This figure shows how many of the colonoscopies registered in the Norwegian Patient Register (NPR) are registered in Gastronet. (www.kvalitetsregistre.no)

<table>
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<th>Endoscopy Centre</th>
<th>Registered in NPR</th>
<th>Registered in Gastronet</th>
<th>Coverage rate (%)</th>
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<td><strong>Total</strong></td>
<td>51,734</td>
<td>14,725</td>
<td>28,5</td>
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</table>

*Inpatient colonoscopies are not included in this table – except for the University Hospital Oslo where the majority of colonoscopies are performed on inpatients. Coverage for registration of inpatient colonoscopies may be falsely slightly increased.

** Only Elverum registered in Gastronet

§ Only Oslo University Hospital Rikshospitalet (OUS RH) registered in Gastronet

§§ DD-klinikken Sandnes: no data available from NPR, 698 colonoscopies registered in Gastronet.

The development of the European guidelines(32) reflects the widespread desire to raise quality assurance from a national to an international level. Twenty-two out of the 28 current EU-member states participated in the process of the guideline development. Only Bulgaria, Cyprus, Estonia, Greece, Ireland and Slovakia were not involved in this process. The population of these non-participating countries represent only a minority of
approximately 6% (30 out of 508 million of the EU-population according to the official website of the European Union (www.europe.eu). In addition, collaborators from non-EU European countries and countries from other continents (Norway and Argentina, Australia, Canada, China, India, Israel, Japan, Korea, and the United States of America) contributed to the development.

The panorama of guidelines for quality indicators in the various Western geographic regions is characterized by differing levels of agreement for various indicators. The following text highlights how Gastronet’s quality agenda in Norway compares to other countries or regions. There is unanimous agreement in all guidelines that CIR should be 90% or higher in a clinical setting with symptomatic patients. See table 1 on page 25. Only the USA, Canada, Australia and the Netherlands have chosen to define a higher CIR of at least 95% in screening colonoscopy. In accordance with guidelines from the ESGE and Britain Gastronet does not recommend a higher CIR in screening for two reasons.

First, the vast majority of procedures in Gastronet are clinical non-screening colonoscopies and, second, a paper “in press” from Gastronet did not show any difference in CIR in clinical routine or screening setting. (6) Therefore, there is no reason to recommend different performance levels for different settings.

Another two quality indicators characterized by high levels of agreement are withdrawal time and the rate of adequate bowel preparation. Apart from Canada recommending a minimum withdrawal time of 8 minutes, all other guidelines define 6 minutes as minimum duration for inspection. As our study 2 refuted a correlation between withdrawal time and polyp detection in the Gastronet data, no target for minimum withdrawal time was provided. (5) Endoscopists still receive feedback on personal withdrawal times as short times may play a role in suboptimal polyp detection for
selected endoscopists. All guidelines recommend a minimum rate for adequate bowel
preparation of 90% or higher. The ESGE guidelines recommend the use of the Boston
Bowel Preparation Scale. (46) A score of at least 6 in the Boston Bowel Preparation Scale
is regarded as adequate preparation. This is equivalent with only minor amount of
residual staining, small fragments of stool and/or opaque liquid in each of the three
segments of the colorectum (right colon with cecum and ascendens, transverse colon
including both flexures and the left colon from the descending colon to the anus). Only
the USA accept a lower threshold of at least 85%. Gastronet provides reports on bowel
preparation to centre leads in annual meetings. Centres with low performance compared
to others are informed. So far, no distinct standards have been established.
Collection of patient experience data, in particular discomfort or pain, is generally
accepted as quality indicator. Apart from the US guidelines all others express the desire
to adopt patient experience as quality indicator, but none has actually defined standards.
Australia recommends that less than 1 in 100 patients should experience pain warranting
hospital admission. Gastronet is the only institution that provides feedback to centres
and endoscopists annually on a regular basis. The defined minimum target for the
individual endoscopist is to aim at a rate of severely painful procedures which lies below
the average of all participating endoscopists. In 2015, for example, this rate was 12.3%.
Highly rated evidence has shown that ADR is inversely associated with interval colorectal
cancer and death. (28, 29) There is, however, a remarkable difference between
recommendations and national standards for ADR. Canada accepts an ADR of ≥ 15% in
women and Britain recommends an ADR ≥ 35% in screening procedures independent of
gender. (37, 39, 43) All other guidelines lie in between these two except for Gastronet
where ADR is not used. Gastronet has negotiated using detection rate for polyps ≥ 5mm
as a surrogate for ADR to circumvent the need for a second manual entry of data once the histopathology report is received and thus preventing several hospitals from opting out of Gastronet. No other guidelines have established a standard for polyp detection except for the European Society of Gastroenterology (ESGE). The ESGE recommendation of a polyp detection rate of \( \geq 40\% \) differs significantly from the Gastronet recommendation because Gastronet restricts polyp detection to polyps \( \geq 5\text{mm} \).

The feasibility of quality improvement work is an important aspect. All the above mentioned guidelines provide targets for quality, but their creators are to my knowledge not involved in the provision of regular and repetitive quality information to the same extent as providers of data to Gastronet. In Britain a large multi-centre colonoscopy audit was performed covering an impressively high percentage of 94% of all performed colonoscopies in the UK.\(^{(100)}\) In contrast to Gastronet, this audit was restricted to a registration period of two weeks. In accordance with Gastronet, polyp detection rate rather than adenoma detection rate was used as neoplasia detection parameter for the sake of feasibility. A recent study supports that PDR is inversely associated with interval colorectal cancer and can, therefore, be used as a quality measure.\(^{(48)}\)

The future will show if world-wide intercontinental recommendation for quality in colonoscopy may be feasible and/or meaningful.

9.3 Research in randomized controlled trials versus research on registrations from clinical routine work

Systematic reviews of randomized controlled trials are generally accepted as the highest level of evidence within medical research.\(^{(101, 102)}\) Randomized controlled trials (RCTs) are regarded as the most reliable form of research evidence, but their validity for clinical
practice has been questioned. (103) The major advantage of proper randomization is to minimize or avoid bias. (104) RCTs may, however, exclude a range of patients which normally attend routine clinics and select subgroups of patients referred to academic centres may be overrepresented. Both mechanisms might recruit a study population that is very different from the population of patients to which the RCT study results nevertheless are being applied. Further, participating patients in RCTs might receive more attention than patients outside the study would experience. Such characteristics threaten the external validity of research results. The conclusions valid for the participants within the trial might not be generalized to other populations outside the study. [60]

Due to these drawbacks related to RCTs, there has been a call for alternatives. Tunis et al. have therefore proposed a shift towards practical clinical trials (PCT) addressing practical questions about risks, benefits, and costs of an intervention as they would occur in routine clinical practice. (105) PCTs select clinically relevant interventions to be compared, they include a diverse population of study participants, they recruit from a variety of practice settings and they collect data on a broad range of health outcomes. (105) Results from such studies would be much more relevant for practicing clinicians, administrative decision-makers and policymakers. (106)

Differing results for the same intervention dependent on the type of study design within screening endoscopy have been demonstrated recently. (107) A case-control study from 1992 concluded that cancer screening with flexible sigmoidoscopy reduced the risk for colorectal cancer mortality with 60% to
Recent randomized trials have shown a significantly smaller reduction of only 28% for the risk of colorectal cancer mortality after screening sigmoidoscopy. (109)

It is possible that such design dependent variation of results also may apply for randomized controlled trials compared to practical clinical trials. Consequently, there has been a call for the implementation of practical clinical trials in recent years. (106, 110-112) A further refinement of study design has been proposed by Angus. (113) He advocates randomized, embedded, multifactorial, adaptive platform trial (REMAP-trial). If accruing information in the course of the trial identifies specific patient groups which are benefitting from a specific intervention, then the random allocation ratios can be changed in order to allocate a larger proportion of these patients to this specific intervention. The randomization process could be an integrated or embedded part of the patient’s electronic health record facilitating an extremely broad enrollment and inexpensive data collection. A large numbers of participants in such a study will allow exploration not only on two interventions conditional on a few exposures, but many different interventions conditional on multiple exposures. This trial would be adaptive meaning that aspects of the trial or entry criteria might be changed during enrollment if e.g. new research should emerge with identification of new genetic or molecular markers justifying a change of allocation of specific patient groups to specific interventions. This form of trial combines the advantages of extensive clinical data, also called big data, extracted from
electronic patient journals and random assignment. This type of study might serve both research and continuous quality-improvement work purposes. (111, 113)

Research within Gastronet is based on clinical routine procedures and consequently constitutes PCTs. Results from 2014 show that Gastronet covers 28.5% of all performed colonoscopies in Norway. Of 51,734 outpatient colonoscopies registered in the Norwegian Patient Register, 14,725 colonoscopies were registered in Gastronet. In study 1 exploring time trends in quality indicators of colonoscopy, 64% (73,522 procedures) of all 114,710 colonoscopies registered in Gastronet in the 10 year study period were eligible for our study. The nationwide total number of outpatient colonoscopies in this period was 335,463 procedures according to the Norwegian Patient Register. Due to exclusion criteria, the number of colonoscopies finally included for analysis of cecal intubation rate was 73,522 (22% of total nationwide number), for severe pain 55,727 (17% of total) and for polyp detection 23,063 procedures (7% of total).

From our point of view a coverage of 7% to 22% of the entire nationwide volume complies with a diverse study population characteristic for a PCT according to Tunis et al. (105) Other factors that are not in line with the characteristics of a PCT, are the exclusion of inpatient procedures and the non-participation of a number of centres and endoscopists especially in large tertiary centres. In Norway, 81,478 inpatient colonoscopies were performed during the study period according to the Norwegian Patient Register. It is unknown what impact the
inclusion of inpatient colonoscopies or a more extensive participation of tertiary centres might have on the quality results in Gastronet.

9.4 The effectiveness of feedback on performance quality

The overriding aim of medical registries is evaluation of quality and improvement through feedback if quality is not satisfactory. Van der Veer et al. performed a systematic review on how medical registries provide information feedback to health care providers. (78) The results showed that in four out of twenty-two registers the feedback on quality given to the providers had a positive effect entailing performance improvement on all primary outcome measures, eight found a mix of positive and no effects and ten found no effect on any of the outcome measures. Gastronet was also included in this study. Van der Veel et al. concluded that Gastronet represented a non-randomized and non-controlled study design with no effect of feedback including one or two multi-faceted approaches (Gastronet centre meetings (for those attending) in addition to direct feedback to individual endoscopists). These data were based on the results of the initial year of Gastronet which started in September 2003. The comparison of the three consecutive four-month periods with feedback to endoscopists and centres after the first period did not show statistical differences in defined endpoints. (79) In contrast to these initial results, the long-term results of Gastronet in study 1 revealed a significant decrease in severely painful colonoscopies whereas cecal intubation rate and polyp detection remained unchanged. (6) Since this study did not include a control group, it was
not possible to conclude that the improvement on pain reduction was a consequence of participation in Gastonet and not an effect over time with changing techniques and technologies, referral routines, indications and patient populations. Research on audit and feedback interventions in health care demonstrated that certain characteristics are prerequisites to accomplish effective feedback and quality improvement: (114-116)

1. Feedback should be perceived as supportive and not punitive.

2. It should be presented to the recipients in a multi-modal fashion, as for example in Gastonet e-mailed results and discussions in centre meetings.

3. Results should be delivered by a trusted person, as in Gastonet by the chairman.

4. Peer results, as in Gastonet in the form of anonymized results of other endoscopists, have to be available for comparing own results with peers.

5. Information about target performance has to be provided. Therefore, internationally accepted threshold values or/and median values for peer results are included in Gastonet feedback reports.

6. Improvement work is more efficient when feedback is given repeatedly as for example on a yearly basis in Gastonet.

7. The aim is to improve performance by evoking self-efficacy and goal commitment in individual endoscopists.

8. Another important issue pointed out by Ivers et al., is the provision of a clear action plan. (116) Gastonet does not recommend an action plan. It is expected that centre leads engage in developing an action plan for the individual endoscopist whenever performance is found to be below target level.
In contrast to Gastronet, Ball et al. chose to apply extensive quality improvement actions including organizational rearrangements such as more time per colonoscopy, letting the most successful endoscopist perform more procedures, retraining the less successful and even advising some to give up colonoscopy completely. (117) The impact on quality was impressive with an increase in CIR from 60% to 94%. (116) Also Imperiali et al. managed to improve the CIR from 84.6% to 93.1% by applying 6-monthly audit cycles. (118) Also Kahi et al. showed in a small study improvement of CIR (increase from 95% to 98%) and ADR (increase from 44.7% to 53.9%) by using a quarterly report card for endoscopists. (119) Although the quality feedback system was similar, Gastronet results did not confirm these positive effects on CIR and PDR which remained unchanged during a decade.

In 1994, the health authorities of the United Kingdom established the Joint Advisory Group (JAG), a quality assurance initiative for improvement of services related to gastrointestinal endoscopy (www.thejag.org.uk). The group was designed to define professional consensus and agreement on standards in endoscopy. These standards included training and education as well as endoscopy unit accreditation. The group arranges endoscopy training courses with certification for all levels of endoscopist competency. In particular, trainees are supported in their endoscopic training by means of an electronic portfolio, a record of endoscopic progress and experience. This tool provides a valuable assessment and feedback of what level of competency a trainee has reached both for the trainee him/herself and the trainer and centre lead. The JAG implements an assessment tool, called Global Rating Scale (GRS), for evaluation of quality (www.globalratingscale.com). (120) The study of Gavin et al. documented that
through nationwide JAG audits, British colonoscopy services have achieved a high quality standard in accordance with international recommendations. (100)

In contrast to the UK, a study of Radaelli et al. revealed that colonoscopy service in Italy was below accepted quality standards. (121) This feedback of unsatisfactory quality is now regarded as a challenge for the Italian health authorities to initiate nationwide quality improvement measures.

The issue of feedback, i.e. information about measured performance quality which is given back to the performer, has been analyzed in different medical settings outside gastroenterological endoscopy. The studies of Leopold et al. and Kruger and Dunning concluded that performers are prone to overestimate their own performance. (122, 123) Further studies of Johnson et al., Barnsley et al. and Gordon explored self-assessed performance and feedback and concluded that they were not correlated. (124-126) Carter et al. point out the necessity of correct and objective feedback because biased, difficult to recognize and otherwise flawed feedback might hinder the recognition of suboptimal performance. (127)

In contrast to these studies demonstrating either a performer`s overestimation or a lack of correlation between self-assessment and feedback, it is remarkable that in our third study on self-assessment the average of all endoscopists shows underestimation of performance. (2) Especially less experienced endoscopists underestimated their performance but it was beyond the scope of our study to explore if other factors, for example cultural aspects, might influence the Gastronet results. In our study on time trends of quality indicators, a continuous decrease of the mean rate of procedures with severe pain from 14.8% to 9.2% was observed. (6) It remains to be seen if Gastronet
feedback supports this trend any further in the future. A complete eradication of severely painful procedures, however, may possibly not be achievable due to the invasive nature of colonoscopy.

Quality improvement strategies in medicine through audit and feedback have been shown to be effective. Still, there are important flaws connected to them which need to be targeted. These strategies often lack a theoretical framework which is standard in behavioural science. At least 25% of them are either ineffective or minimally effective. (128) A lack of theoretical framework may make it difficult to assess disparity between various trial results. An ineffective quality improvement measure may challenge any current strategy both from the patient point of view and from that of health care providers.

Audit and feedback measures depend greatly on the quality of guidelines which deliver clear definition of target quality. In a large review, it was stated that the quality of studies which constitute the evidence base for guidelines, is generally low. (129) The average gain of improvement after audit and feedback was only 7%, which represents a rather low quality improvement effect. In addition, there are hardly any guidelines including studies that weigh the financial cost of running a quality register against the profit of improved quality for the patient and the health care delivering system. In an era of scarce resources both effect and positive cost-benefit ratios are essential to vindicate resource consuming quality improvement initiatives.
10 Methodological considerations

Strengths of our studies on data from Gastronet are that they are based on large numbers of colonoscopies, the multi-centre design, the clinical routine setting and the prospective analysis.

A general drawback of studies related to the Gastronet quality registry is the nature of it being incomplete because although health care providers are obliged to participate in national registries, they do not face punitive measures if they do not. So far, there is no systematic registration of colonoscopies not being reported to Gastronet and their characteristics. This pool of missed procedures clearly represents a potential for bias which is not further explored.

Along with the nature of a quality register follows the drawback that none of our studies have a control group. This deprives research in Gastronet from the opportunity to make conclusions on the causality between participation in Gastronet and effects on quality.

10.1. Methodological considerations of study 1

A strength of our first study is that it encompasses a long period of time, i.e. a decade.

(6)A weakness of this study is that while two of the quality indicators (CIR and severe pain) were registered over a period of 10 years, the third indicator (number of polyps ≥ 5 mm) was only registered over a period of seven years (since 2006).

Another disadvantage is that many of the centres and endoscopists are recruited during the study period and therefore not followed through the whole period. Thus, the
number of endoscopists and procedures per Gastronet year decline substantially from
the first year of registration to the tenth year of follow up.

In a study like this extending over such a long time span, it would clearly be desirable to
link colonoscopy quality data to other relevant outcome data such as colorectal cancer
incidence. Gastronet has already been granted permission by the Ministry of health in
2014 to link Gastronet data regularly with other registry data, including data from the
Cancer Registry of Norway. Due to legislation, this permission must be confirmed by the
Norwegian Data Protection office. Unfortunately, this confirmation is still pending more
than two years of appeals after the initial application.

In this study, complications observed before the patient left the outpatients’ department
were registered in 0.6% of colonoscopies. This number comprises the whole range from
trivial complications like vasovagal reactions with no need for therapeutic intervention to
severe complications requiring admission to hospital. In 22% of the procedures, the
endoscopist omitted to tick off in the boxes for complication or no complication,
respectively. Therefore, it is likely that even “on site” complications in Gastronet are
underreported. Consequently, we did not focus on complication in this study. In a recent
paper on colonoscopy screening in Germany, the authors concluded that complications
related to colonoscopy, including those occurring after the patient had left the
endoscopy suite, are not reliably documented and there is much to be gained by
including patient feedback to capture the full picture of complications. (130)

Unpublished data from Gastronet analyzing colonoscopies from 2015 based on both
endoscopist and patient feedback revealed that serious complications occurred in 0.16%
of procedures. A recent study on screening colonoscopies from Austria showed a
comparable complication rate of 0.2%. (75) Gastronet is now preparing structural changes to secure more reliable registration of complications by making it easier for the patient to report adverse events.

So far, Gastronet has no authority to link Gastronet colonoscopy data to the Norwegian Cancer Registry, the Norwegian Patient Registry or hospital patient records. Consequently, it is not possible to identify patients diagnosed with a colorectal cancer who have had a recent colonoscopy failing to detect cancer in a defined time window suggesting overlooked cases of CRC. Although the link between Gastronet and the Norwegian Cancer Registry does not exist yet Gastronet requested accumulated data from the Norwegian Cancer Registry encompassing rates of diagnosed CRC-cases in the period from 2011 to 2013 in which the patient had a cancer-negative colonoscopy only 6 to 36 months prior to the procedure revealing a malignant tumor. According to this definition and data base 5.6% of patients with a CRC-diagnosis actually had an interval cancer which was overlooked in the preceding colonoscopy. This figure is only a rough estimate and, therefore, cannot serve as a robust steering tool for quality improvement policies. In addition, this data extraction service provided by the Norwegian Cancer Registry was rather costly entailing a bill of about 10.000 Norwegian kroner (approximately 1.110 €). There is no doubt that interval cancer frequency will constitute an important quality indicator for endoscopy centres as soon as reliable data extraction systems are established.

Another weakness of study 1 is the fact that the composition of participating centres and endoscopists were not identical for each year in Gastronet because some centres joined
Gastronet after the initial year 2003 and others opted out before the final year 2012 of the present study. This variation in centre participation is a challenge to interpretation of results. Therefore, we performed a sensitivity analysis which comprised only colonoscopies from the eight centres that participated through the entire study period. This selection reduced the number of colonoscopies from 73,522 to 41,772 procedures. The resulting bar chart displaying quality indicators cecal intubation rate, severe pain and PDR-5mm shows results which are very similar to the results including all participating centres in study 1: A stable cecal intubation slightly above 90%, stable PDR-5mm slightly above 20% and a gradually falling rate for severely painful procedures from 12.5% to 8.9%. See figure 11 in the appendix section. A logistic regression model equivalent to the one in study 1 provided comparable results with regard to cecal intubation, i.e. no change of CIR with increasing period of time. But the reduction of pain lost significance level (OR 0.91, p-value 0.066) and PDR-5mm turned to a significant improvement of polyp detection (OR 1.08, p-value 0.004). The clinical importance of these statistical variations may, however, be questioned. It should also be born in mind that centres may have participated throughout the study period, but the entire group of active endoscopists may have been changed or their percentage contribution altered. For centres with few endoscopists, this may have the same effect as one centre opting out and another joining during the study period.

To further explore the relative importance of centre versus endoscopist participation, I examined if the observed decrease in painful colonoscopies was mostly related to the individual endoscopist or to the endoscopy unit. In other words, is it more important what characteristics the individual endoscopist with his or her talents and attitudes has or is it more important to be working at an endoscopy centre with favorable quality
characteristics? For this reason I re-ran the same logistic regression with identical
correction for confounding factors but instead of correcting for individual endoscopist
clusters (one cluster comprising all procedures performed by the same endoscopist), the
correction was made for endoscopy units (one cluster comprising all procedures
performed at the same centre). The results remained unchanged. Severely painful
procedures decreased significantly (adjusted OR 0.94 instead of 0.92 and p-value 0.01
instead of 0.045). The probability that different hierarchies of analysis (individual
endoscopist versus endoscopy units) display different results can therefore be regarded
as small. The same conclusion is valid for cecal intubation rate and polyp detection. Both
remain stable over time independent of the hierarchy.

10.2 Methodological considerations of study 2

The second study explored if withdrawal time and the degree of polyp findings was
correlated.

Polyp detection rate is one of the main quality indicators in Gastronet. Two
cornerstone trials published in the New England Journal of Medicine showed an
inverse association of adenoma detection rate with interval cancer. In other
words, a patient exposed to an endoscopist with a low adenoma detection rate
runs a high risk of future colorectal cancer.(28, 29) In the youth of Gastronet, the
obvious need to measure adenoma detection rate rather than polyp detection
rate was discussed and rejected. The detection of a polyp is purely visual and
available at colonoscopy when the Gastronet form is filled in, while registration of
an adenoma requires waiting for a histology report and a new round with the Gastronet form. Endoscopy centres would not accept this extra workload in view of the large volume of colonoscopies to be handled by most centres in Gastronet. Previous studies have shown a strong correlation between adenoma detection rate and polyp resection rate which is equivalent with polyp detection rate because routinely all polyps are removed. (55-57, 131) Another two studies confirmed a strong correlation between adenoma and polyp detection rate. (58, 132) As polyps with a diameter of ≥5mm have been shown to be adenomas in more than 80%, Gastronet used detection rate of polyps ≥5mm as a surrogate for adenoma detection rates. (133, 134). A recent study confirmed an inverse association between PDR and interval colorectal cancer. (48)

It is, however, not compulsory to provide photo documentation with a measuring scale. Thus, size estimates are subjective and polyp detection rate is prone to bias as a surrogate for adenoma detection rate. The convenience of immediate availability and practicality of polyp detection rate is hampered by the fact that polyp detection rate is possibly more corruptible than adenoma detection rate, with the potential for endoscopists to artificially inflate their polyp resection rate by removing insignificant diminutive polyps. (57)

Recent literature showed that variation in patient mix does not have significant impact on an endoscopist’s performance level on condition that the endoscopy centre operates in a normal population setting. (135, 136)
Another weakness of the study is that the centres and endoscopists could freely choose the method for measuring time to insert or withdraw the scope. Inaccuracies due to clocks without a second hand are expected to balance. A convenient way to measure time with whatever method available (wrist watch, wall clock with or without second hand, stopwatch or others) has been preferred in order to lower the threshold for participation among centres and endoscopists. Higher demands with regard to precision of time measurement may be applicable in the future if quality assurance develops into a more natural and obligatory part of health services.

Although our results discard withdrawal time as a quality indicator, individual endoscopists might still profit from feedback on mean withdrawal times. If, for example, polyp detection is low, it might be of interest to see if the endoscopist also uses relatively short time on inspection. For this endoscopist, spending more time on withdrawal might still be a starting point to improve polyp detection. If withdrawal time is long, other causes for poor polyp detection have to be evaluated.

A large number of exclusions due to delayed return of questionnaires (3290 colonoscopies from an initial pool of 10051 procedures) could possibly represent a selection bias with the potential of impact on results. Therefore, a sensitivity analysis which now also included procedures with delayed return was performed and it showed comparable results. There was no significant difference between procedures performed by endoscopists with median visual withdrawal times under 6 minutes compared to those with 6 minutes or longer.

In general, the problem of low coverage of procedures in Gastronet is a problem related to centres not participating in Gastronet rather than individual endoscopists omitting to
fill in and send the form. Therefore, low coverage of registration at hospital level is less important for selection bias on individual endoscopist level.

10.3 Methodological considerations of study 3

A strength of this study is that it covers an issue within gastrointestinal endoscopy which has not been explored before. How well or poorly does a colonoscopist believe he or she performs? (2) As a basic principle, a quality register would be obsolete if endoscopists (in an ideal world) already had an adequate understanding of their own performance with sufficient trust to act upon their intuitive understanding of own performance. In our “not-so-ideal-world” it would still be of interest to see how good or poor own intuition may be and in which direction (if any) a grading of own performance may veer.

In this study, each endoscopist is his/her own control, but still there is a limitation that only 39 out of 99 invited endoscopists responded to the request to fill in and return a questionnaire. Gastronet does not have any data on those endoscopists not responding to the initial invitation and a following reminder email. When there was still no response, Gastronet accepted that the endoscopist was not willing to participate and no further efforts were made to include non-compliers. The low participation rate makes our study susceptible to selection bias, but the principle hypothesis could be tested since each endoscopist was his/her own control.

Another limitation in this study is related to the high proportion of inexperienced endoscopists (56%) with a pre-study colonoscopy volume of less than 300 procedures. Due to lack of registration, it is not known to what degree young endoscopists received
help from senior endoscopists in a situation when they got stuck during the procedure. This unrecorded help also represents a potential source for bias influencing the results of inexperienced performers.

10.4. Methodological considerations of study 4

A strength of this study is that the problem of postcolonoscopy fluid leakage, incontinence from the back passage or soiling has not been investigated in the literature before. (94) Anal incontinence and fecal incontinence are used synonymously. This condition is usually defined as the involuntary passage of fecal matter through the anus or the inability to control the discharge of bowel contents. (137) Anal or fecal incontinence is a common problem with high prevalence in the population. According to two recent review papers the prevalence reaches up to 15% to 19.6%. (138, 139) In contrast to anal incontinence due to pathological and chronic conditions in the anus or rectum the term anal incontinence in our study is related to involuntary passage of laxative fluid or faeces of fluid or solid consistency. It has to be emphasized that anal incontinence in our study is neither a genuinely pathological nor a chronic condition. It is instead caused by implementation of effective cleansing formulations in unphysiologically high doses and carbon dioxide insufflation applied with the intention to obtain optimal emptying and inspection of the bowels. As the prevalence of fecal incontinence can reach as high as 19.6% of the population there may be a possible risk for bias in our study because the patient form did not explore if fecal incontinence was already existing before the patient started the bowel cleansing process. (138) We do,
however, regard it as unlikely that there was a significantly skewed distribution of patients with pre-existing fecal incontinence in the two groups (air/CO2).

The estimate of 5% for patients experiencing fluid leakage after colonoscopy with air insufflation was regarded as a rough estimate. It was based on the feedback in the free-text space of the patient form returned to Gastronet the day after the procedure. As this was the first study ever to address this problem it was not possible to base our estimate in the power calculation on results from other comparable studies.

A limitation of this study was that postcolonoscopy incontinence was not graded in the patient form. Thus, it was not possible to explore the range of impact of postprocedure fluid leakage which can vary from trivial moisture to overly embarrassing volumes.

Another weakness of the study was the lack of randomization for type of gas, but the study groups proved comparable with regard to demographics, case mix and sedation practice.

Another weakness of our study is the fact that Gastronet did not collect information about the distance between the endoscopy suite and the patient’s home. For example, the county of Telemark in Norway covers a range of about 175 kilometers at its widest diameter. The term “on your way home” can, therefore, range from a short walk home just around the corner of only a few minutes to a long travel by car or other transport means taking up to three hours. Again, Gastronet chose to keep questions for the patient short and simple in order to gain highest possible participation. The downside of this approach is loss of detailed information. We regard it though as very unlikely that there might have occurred a selection bias due to uneven distribution of different types of insufflation gases at colonoscopy and varying distances between the examination premises and the patient’s home.
11 Conclusions

The colonoscopy quality indicators CIR and PDR-5mm remained unchanged, but a significant relative risk reduction of very painful procedures of 38% over the decade from 2003 to 2012 was observed. Still, 9.2% of colonoscopies being severely painful in the tenth year of Gastronet is far from an ambitious aim of zero at the start of Gastronet. It remains to be seen if this improvement continues beyond the first ten years. The responsibility of local quality assurance lies in the hands of endoscopy centre leads. Gastronet can only provide supportive data and assistance in this process.

According to Gastronet results, withdrawal time is a poor quality indicator in routine colonoscopies based on Gastronet data.

Endoscopists participating in Gastronet have a tendency to underestimate their own performance with regard to CIR, PDR-5mm, withdrawal time and severe pain associated with the procedure. There is, however, a wide variation from overestimation to good estimation and underestimation among colonoscopists enrolled in Gastronet between 2008 and 2013. Consequently, self-assessed quality of colonoscopy performance may not be a satisfactory substitute for systematic registration of quality.

Postcolonoscopy incontinence or fluid leakage was reported in 5.5% of the patients who underwent colonoscopy registered in Gastronet in 2009. By converting from air to carbon dioxide, the risk for incontinence or fluid leakage was reduced by 60%, i.e. from 5.5% in the air group to 2.1% in the carbon dioxide group.
12 Discussion of results

This doctoral thesis focuses on quality related to colonoscopy, an invasive examination of the rectum and the large bowel by means of a flexible videoendoscope. For the patient, it is often considered as an inconvenient and embarrassing procedure. In this thesis, medical technical aspects, endoscopists’ self-assessment of quality and factors associated with the patient’s experience are highlighted.

Medical technical aspects include rate of completed procedures, detection of polyps, amount of time used on withdrawal of the endoscope for inspection and therapy and effect of different types of gases used to inflate the bowels. Patient experience covers feedback on pain inflicted on the patient under the procedure and degree of involuntary fluid or stool leakage after the procedure. The endoscopist is challenged to try and guess how good his or her own performance actually is.

The average cecal intubation rate in Gastronet has been consistently above 90% over a period of 10 years in line with international guidelines in Western countries. This has been discussed in chapter 5.5. The cecal intubation rate in Gastronet was, however, consistently below 95%. The recently updated ESGE guidelines define a target level of 95%. (35) In a recent large European trial exploring colonoscopy screening for colorectal cancer, it has been shown that average cecal intubation rate can reach as high as 97.2%. (98) All four participating countries reached a level above 95%. This clearly challenges the performance registered in Gastronet. If, however, increased demands with regard to cecal intubation necessitate a more dedicated colonoscopy training the health care authorities might experience a prolongation of the endoscopist training process entailing a decrease of endoscopy personal available for routine examinations. The balance
between highest possible performance demands for endoscopists and availability of
enough skilled endoscopist personal needs to be defined in the future.

Large screening trials have provided solid evidence that a high adenoma detection rate is
associated with a low risk for interval colorectal cancers and death. (29) (28) The recent
ESGE-guidelines define this evidence level as moderate to high, (35) but why do these
guidelines also define a polyp detection rate of 40%? The evidence for this is only
described as low. The weakness of the adenoma detection rate is its cumbersome
provision with the need to correlate histological results and endoscopy reports.

Therefore, in everyday life conditions outside screening settings, there is probably hardly
any endoscopist who actually knows his or her adenoma detection rate. There is now
emerging evidence that also polyp detection rate is inversely associated with interval
colorectal cancers. (48) This supports Gastronets policy to use polyp detection rate
rather than adenoma detection rate – at least until Gastronet and pathology reports may
become integrated with the electronic medical records in routine clinics. In order to
vindicate the continued use of polyp detection rate, Gastronet may in the future need to
provide answers to the following questions: is the polyp detection rate in Gastronet also
inversely correlated to interval cancer? This necessitates linkage of Gastronet data to the
Norwegian Cancer Registry, Norwegian Patient Registry and hospital records.

Longer withdrawal time in colonoscopies without biopsy sampling or therapy did not
show a significant association with increased detection of polyps with a diameter of 5mm
or larger. (5) Another study including both screening and clinical procedures concluded
the same: increased time on inspection did not yield a better detection of polyps of all
sizes. (85) A recent study of more than 76,000 screening colonoscopies revealed highly
significant associations between longer time used on inspection and higher rates for
detection of adenomas and lower risk for interval cancers. The pendulum might finally be swinging in favour of using withdrawal time as quality indicator. The ESGE-guidelines evaluate the evidence supporting withdrawal time as quality indicator as moderate. They define 6 minutes as minimum and 10 minutes as target. They do, however, recommend that withdrawal time should only be measured in case of insufficient adenoma detection rates. (35) In Gastronet, it might be worthwhile to explore the meaning of withdrawal further, especially with regard to accuracy of time measurement. Is it possible that the study on withdrawal time and polyp detection was confounded by inaccurate time measurements because a significant number of endoscopists actually guess very roughly how many minutes they use on withdrawal rather than really measuring it by means of a clock of any sort? Current huge studies explore the effect of colonoscopy screening on the incidence of colorectal cancer in several European countries. (98) If the results support the effect of screening, one can expect that the number of screening colonoscopies will increase immensely in the future. This will enable Gastronet to explore its performance parameters in the setting of screening.

From the patient’s point of view there is no doubt that colonoscopy can be quite unpleasant and even painful. A recent study in Gastronet documented that 33% of the patients describe the experienced pain during a colonoscopy as either moderately or severely painful. 41% of those were women and 24% men. (140) Apart from the American guidelines not proposing any form of patient feedback and Australian guidelines recommending that less than one in hundred colonoscopies should inflict adverse events that entail hospital admission, all other guidelines from the ESGE, Britain, Canada and the Netherlands recommend to record self-reported patient feedback especially with regard to discomfort and pain. (3, 35, 37, 41, 43, 45) In Europe, two
registers using validated questionnaires for patient feedback are established, the Global Rating Scale and the Gastronet. (79, 141) The use of sedative and analgesic medication can reduce pain and discomfort. (142) This, however, has little effect on pain occurring after the procedure. (98) Increased use of sedatives and analgesics is associated with an increased risk of complications. (143) The optimal balance between maximum ease of discomfort for the patient and least possible risk for procedure related adverse events is yet to be defined. In a study comparing routine use of fentanyl, an opioid analgesic agent, and use only on demand concluded that routine use of fentanyl did not provide better results. (144) The gradual decline of severely painful colonoscopies in Gastronet will hopefully continue, but it is unlikely that severe pain can be completely eliminated. (6) The future challenge for Gastronet will be to identify modifiable factors that can help to get the rate of painful procedures as close to zero as possible. The extent of involuntary leakage of stool or fluid was significantly reduced by 60% in patients when carbon dioxide was used instead of air for bowel inflation. (94) To my knowledge, there is no other study exploring this issue. Consequently, it is so far not possible to compare Gastronet results with others. Reducing the post-colonoscopy risk of leakage by using carbon dioxide rather than air adds to the post-colonoscopy pain reduction and elimination of the rare risk of intracolonic gas explosion by using carbon dioxide for insufflation. (145-147)

Gastronet explored if endoscopists were capable of estimating their own performance purely on the background of previous colonoscopy experience. (2) It is a known phenomenon that people’s perception of their own competence often diverges from their true level of competence. (127) It is not surprising that the self-estimates comprised underestimation, good estimation and overestimation. It is, however, a
surprise that the mean numbers for all endoscopists indicate a general underestimation of performance. On average, more colonoscopies were completed, more polyps found, more time was used for inspection and fewer patients reported severe pain than the endoscopists estimated. These results did not change when corrected for pre-study endoscopy experience of endoscopists either. Self-estimation appeared to be equally difficult for experienced endoscopist as it was for less experienced young doctors. The differences between the mean estimated and registered results were small and it is difficult to say to which extent they are clinically relevant. They may just reflect an attitude of modesty among endoscopists embarking on a new quality assessment initiative. It is not yet clarified if self-estimation is an element that can contribute to quality improvement. In a systematic review on self-assessment of performance among physicians, the authors concluded that physicians have a limited ability to accurately self-assess. A number of studies found the worst accuracy in self-assessment among physicians who were the least skilled and those who were the most confident. (148) Is it possible that endoscopists who estimate their performance as good, but whose registered results document unfavorable levels, may constitute a target group with need for extra attention and improvement measures? To answer this question, larger studies in Gastronet are necessary. It would also be important to gain higher participation rates as the results in Gastronet are hampered by the fact that only 39% of invited endoscopist responded to the invitation.
13  Future perspectives

Robertsen et al.(60) recommend a framework for a universal, basic colonoscopy curriculum for colonoscopy screening of colorectal cancer including knowledge teaching, technical skills training and non-technical skills training. Methods of adult teaching, training aids and semi-objective competency assessment tools to facilitate acquisition of skills, upskilling courses and `train-the-trainer`courses should be part of this framework.(60) The future will show if this tailor-made structured training for screening endoscopists may also be applicable for colonoscopists in a routine clinical setting.(6)

Aiming at general availability of high quality colonoscopy to as many patients as possible, health care providers and authorities have to address quality assurance not only on a local hospital level(149), but also on a nationwide level as seen in the JAG/GRS initiative in the UK.(100) The European Society of Gastrointestinal Endoscopy and the United European Gastroenterology have recently promoted a framework for improvement of endoscopy in Europe. (150, 151)

Apart from the issue of pre-procedure bowel preparation quality there has been little focus on colonoscopy quality in hospitalized patients .(152) (153, 154) This problem was discussed in detail in chapter 5.4. It remains to be seen if this group of patients will receive more attention with regard to quality audit in the future.

The impact of high ADR on the reduction of colorectal cancer detected after a recent negative colonoscopy, also called interval colorectal cancers,(29) has entailed efforts to refine this quality measure further. Lee et al. proposed to calculate the mean number of adenomas an endoscopist finds per procedure or per procedure with one or more adenomas.(135, 155) These indicators would reflect the absolute number of detected adenomas rather than the ADR as rate of colonoscopies with an undefined number of
adenomas. This might give additional insight into endoscopist performance. In a recent study of le Clercq et al. temporal trends of mean adenomas per procedure rates were analyzed. (156) In addition, more refined detection rates (proximal ADR, detection rates for nonpolypoid adenomas and for serrated polyps) were applied. A significant improvement over time was observed for ADR, mean adenoma per procedure rate and proximal ADR.

Another important issue related to adenoma resection has emerged in recent years. Neoplastic polyps are often incompletely resected, and the rate of incomplete resection varies widely among endoscopists. This might contribute to the occurrence of interval cancers. (157)

High production pressure in colonoscopy services can influence and result in deterioration of quality. (158, 159) It has therefore been suggested to provide financial incentives for quality, for example rewarding endoscopists with ADRs higher than average. (158) This principle of value-based purchasing or pay for performance have been proposed in other contexts (160) and it remains to be seen if it will be implemented in endoscopy services.

Previous studies in Gastronet have shown that colonoscopists` report coverage has decreased in the period from 2004 to 2006. (161) The authors suspected increased work load for the endoscopists as a possible reason. In order to minimize additional work load, an electronical medical colonoscopy record as integrated part of an electronical patient journal was developed for use in large screening trials in Europe. (162) By means of this system all data relevant for quality assurance analysis can be automatically extracted from the patient journal and the endoscopist is freed from the need to fill in a paper form. A similar prototype for integration with hospital medical records will soon be ready.
for testing in routine clinics in Norway. This might lower the threshold for endoscopists to register in Gastronet, increase participation and reduce the likelihood of bias due to omission of filling in an endoscopy form.

Provided a successful framework for extraction of data from electronic patient records and adequate funding with wide acceptance among health care providers and political authorities, then the scenario summarized in figure 12 might emerge for Gastronet in the future.

Data extraction from electronic patient records combined with substitution from active patient consent to presupposed consent and patient`s right to reserve against registration could facilitate complete registration of all procedures. This might ease concerns about reporting bias in registries. Administrative claims to register endoscopy procedures in Gastronet for institutional billing rights would support complete registration further.

Besides presentation of results to centres and individual endoscopists, Gastronet could become responsible for defining minimum and target quality standards for endoscopy. It could also develop guidelines for implementation of new procedures suitable for quality assurance measures. Gastronet could function as a hub for coordination of gastrointestinal endoscopic upskilling courses covering various levels of competency. Gastronet could provide quality feedback results to centres with a frequency of, for example, six month intervals or, if desirable, at even shorter intervals, which would approach a continuous real-time quality assessment. For centres, the quality indicators
ADR, the rate for interval cancers and the frequency of painful colonoscopies at centre level would probably gain major importance as they presumably will attract a high level of attention in the public and media.

According to centres, the individual endoscopists could receive repetitive quality feedback at similar frequencies. The possibility of comparing personal results with results
of anonymized peers at close to real-time pace might effectively increase personal ambition to improve.

Endoscopist novices who recently have started a career as endoscopist are clearly a group that could profit from Gastronet being allocated the responsibility to secure proper local supervision. Gastronet could coordinate participation in initial colonoscopy simulator training courses. It could create a curriculum for novices and document learning curves for different quality indicators. Ultimately, it might be possible that Gastronet develops an audit and certification process for colonoscopy which would help centre leads to decide when a young endoscopist has reached a competence level allowing independent endoscopy without supervision.

Finally, Gastronet might turn into an institution entitled to contact centres or possibly also individual endoscopists if alarming quality deficits are found repetitively over time. Gastronet might arrange confidential meetings with centre leads or endoscopists to discuss problems and try to find ways for improvement. It might recommend upskilling training courses or train-the-trainer courses.

During the last decade colonoscopy has developed at an enormously rapid pace. This accounts both for the procedure in general and polypectomy in particular. (27, 163, 164) These innovations are for example a small device like endocuff, which is mounted on the tip of a colonoscope to help flatten the colonic folds during withdrawal. An increase in ADR compared to standard colonoscopy has been shown. (165, 166) They also encompass a Peerscope system, a high resolution endoscope with a surround view up to 330°. (167) Even robotic self-propelling colonoscopies have been developed. (168) It
remains to be seen if this sophisticated device will vanish into oblivion or if it will develop into a diagnostic method with the potential to replace colonoscopy steered by human hand.

The success of a quality registry depends on different factors of various tiers. Both patients, physicians/nurses and hospital administrations have to contribute substantially to accomplish effective quality improvement through quality registries.

Quality registries have to focus on key parameters. It must be possible to define actions that can impact performance measured, especially performance that is below standard. It is crucial to identify areas with the largest need for improvement. (169) Registries must be considered relevant and applicable in the local context. (170) Automated capture of data from electronical patient records will minimize work load related to data collection and allow focus on clinical improvement work. (171) A multi-faceted approach with a combination of different ways of feedback (as for example result feedback to individuals combined with participation in peer meetings in Gastronet) has proved to be more efficient than single intervention feedback. (78, 172) Timeliness of feedback with least possible delay after result acquisition is important. Data collection must derive from registries especially designed for the purpose in focus and not extracted from registries with originally different purposes. Adherence to protocols supports the quality of a registry. High quality of data is known to be motivating for recipients.

It is crucial to recruit doctors and nurses with a high level of engagement. (173) Feedback management and support by peers and coworkers is important. (171) Hospital leads play an important role in quality improvement. They are responsible for what actions are initiated and what level of motivation among participants is reached. (171, 173) It is, though, remarkable that there are only few studies that support
observational evidence with regard to importance of leadership. The associations between leaders influence and improvement are regarded as weak. What exactly a leader should do is less certain. (173) Identifying and influencing `opinion leaders` to promote quality improvement appears to be one successful way to gain involvement, but other actions are needed such as providing time, resources, data, evidence of results and incentives. (173)

Summarizing tables for recruitment and retaining participants in quality registries are given in table 9 in the appendix section.
14 References


44. Australia CC. Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up; following curative resection of colorectal cancer; and for cancer surveillance in inflammatory bowel disease, December 2011.


112. Loberg M, Kalager M, Bretthauer M. "Randomize, then Consent", or "Consent, then Randomize"? Revitalizing the issue of pre-consent randomization. Epidemiology. 2016.


### Appendix

**Figure 4: Patient form, colonoscopy (original Norwegian version)**

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<th>Spørsmål om undersøkelsen</th>
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<th>Ja</th>
<th>Litt</th>
<th>Middels</th>
<th>Stort</th>
</tr>
</thead>
<tbody>
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<td>1. Var undersøkelsen smertefull?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Har du hatt luftaner eller annet ubehag etter undersøkelsen?</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Er du fornøyd med behandlingen som ble gitt?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Er du fornøyd med informasjonen du fikk om undersøkelsen?</td>
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<td>Nei</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Har du hatt noen uforvillige &quot;lekkasjer&quot; på hjemvei?</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Spørsmål om tarmstomningen</th>
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<th>Litt</th>
<th>Middels</th>
<th>Stort</th>
</tr>
</thead>
<tbody>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Smakte tømmingens wasken vondt?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Medførte toningen av tarmen magesmerter?</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Medførte toningen av tarmen kvalme?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Medførte toningen av tarmen oppblåsthet?</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Medførte toningen av tarmen hodepine?</td>
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<td>Nei</td>
<td></td>
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</tr>
<tr>
<td>12. Medførte toningen av tarmen andre plager?</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*Hvis ja, vennligst spesifiser plagen (Bruk gjerne baksiden av arket):*

*Andre kommentarer (Bruk gjerne baksiden av arket):*

---

#### Tilbakemeldingsskjema, koloskop, dal 1
Dette skjemaet skal du fylle ut dagen etter undersøkelsen og returnere i vedlagte svaraksept hånd dagen etter undersøkelsen. (versjon 090413)

<table>
<thead>
<tr>
<th>Skjemaar</th>
<th>Senter</th>
<th>Us dato</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

101
Figure 5: Endoscopist form, colonoscopy (original Norwegian version)
Figure 6: English translation of the patient colonoscopy form

Patient report form, colonoscopy, part 1

Kindly ask you to fill in the questionnaire on the day after the procedure and return it in the attached pre-paid envelope.

(Version 090435)

Name tag

Quest. No Centre. No Exam date

Questions about the examination

1. Was the examination painful?
   - No
   - Yes, a little
   - Moderately
   - Very painful

2. Have you had bloating or other discomforts afterwards?
   - No
   - Yes

3. Are you satisfied with the treatment?
   - No
   - Yes

4. Are you satisfied with the information you got?
   - No
   - Yes

5. Have you had involuntary leakage on your way home?
   - Yes
   - No

Questions about the bowel cleansing

6. Was the instruction for bowel cleansing difficult to understand?
   - No
   - A little
   - To some degree
   - Very

7. Did the cleansing fluid taste bad?
   - No
   - Yes

8. Have you had pain during the cleansing process?
   - No
   - Yes

9. Have you had nausea during the cleansing process?
   - No
   - Yes

10. Did you feel bloated during the cleansing process?
    - No
    - Yes

11. Have you got a headache during the cleansing process?
    - No
    - Yes

12. Have you had other complaints during the cleansing process?
    - No
    - Yes

If yes, please specify what exactly (use back page if more space is needed)

Other comments (use back page if more space is needed)

MD1 MD2 Nurse 1 Nurse 2
Figure 7: English translation of the endoscopist report form
Figure 10:

Questionnaire in study 3 for self-estimation of colonoscopy quality which was emailed to new endoscopists who requested participation in the Gastronet project (original and English version)

a) Original version in Norwegian

Noe av nytten med Gastronet er å bli mer bevisst på ens egen utførelse av skopier og eventuelt bruke den kunnskapen som et verktyg til egenutvikling som skopør. Vi vet egentlig ikke i hvilken grad tilbakemeldinger til den enkelte skopør bidrar med kunnskap og innsikt som skopøren kanskje allrede har. For å vite noe om dette, hadde det vært fint om dere kunne svare på noen spørsmål på noen e-mailen til meg. Deretter sender jeg nøkkel for skopørkodenummer i individuelle e-mailer til hver av dere for at hver enkelt skal kunne sammenligne sin koloskopistatistikk med alle andre anonymiserte skopører i de vedlagte tabellene fra Gastronet.
Ta kontakt hvis det er noe dere lurer på.

Her er spørsmålene:

1) Har du deltatt i kvalitetssikringsundersøkelser for koloskopi de siste 5 år?
   Svar: (ja, nei, vet ikke) ……………………………
2) I hvor mange present av koloskopundersøkelsene tror du at du når caecum?
   Svar (ca. angivelse av antatt present) ……………………………
3) Har du noen gang gjort en oppptelling av i hvor mange present av koloskopiene du
   når caecum?
   Svar: (angitt present hvis du har gjort en oppptelling) ……………………………
4) Hvis ja I svaret ovenfor, når var det sist du gjorde en slik oppptelling?
   Svar: (ca. årstall) ……………………………
5) Hvilket år begynte du å koloskopere?
   Svar: (ca. årstall) ……………………………
6) Hvor mange koloskopundersøkelsene har du gjort hittil?
   Svar: (ca. antall) ……………………………
7) I hvor mange present av koloskopundersøkelsene tror du at du finner polypiper
   på 5 mm eller større?
   Svar: (ca. angivelse av present) ……………………………
8) Hvor lang tid tror du at du bruker i gjennomsnitt for en diagnostisk koloskopi?
   Svar: (anslått gjennomsnitt minutter for hele undersøkelsen fra anus til caecum og tilbake) ……………………………
9) Hvor lang tid i snitt tror du at du bruker for å skopere fra caecum og ut?
   Svar: («withdrawal time» i minutter) ……………………………
10) Hvor stor andel av koloskopipasientene dine tror du har henholdsvis sterke
    smerter eller ingen smerter under koloskopien?
    Svar prosent med sterke smerter ……………………………
    Svar present uten noen smerter ……………………………
b) Translation of the questionnaire into English

One aspect in Gastronet is to help endoscopists reflect upon the quality of the endoscopy procedures they perform. Feedback information from Gastronet can be used as a tool to support improvement of endoscopy quality. We do not really know if the information about quality issues conveyed from Gastronet to endoscopists actually is new to the person concerned or not. Is it possible that an endoscopist can estimate his or her own quality? To find out about this we would like to ask you to answer some questions and return them to me. Afterwards I will send the endoscopist code in individual e-mails to each one of you. This gives you the opportunity to compare your personal colonoscopy results with anonymized results from other endoscopists which are available in the attached table from Gastronet. If you have any questions, do not hesitate to contact me. And here are the questions:

1) Have you ever participated in quality assurance initiatives for colonoscopy within the recent 5 years?
   Answer: (yes/no/I do not know) ……………………..

2) In how many percent of your colonoscopy procedures do you believe you reach the cecum?
   Answer: (approximate guess of percent) ……………………..

3) Have you ever made calculations on your rate for complete colonoscopy?
   Answer: (percent if you made calculations previously)

4) In case of “yes” in the previous question, when did you make your last calculation?
   Answer: (approximate year) ……………………………..

5) Which year did you start to perform colonoscopy?
   Answer: (approximate year) ……………………………..

6) How many colonoscopy procedures have you performed so far?
   Answer: (approximate number) ……………………………..

7) In how many percent of your colonoscopy procedures do you believe you find polyps with a diameter of 5 mm or larger?
   Answer: (approximate percent) ……………………………..

8) How many minutes do you believe you need to perform a diagnostic colonoscopy?
   Answer: (approximate average of minutes for the entire procedure from anus to cecum and back) ……………………………..

9) How many minutes in average do you need to retract the scope from the cecum to the anus?
   Answer: (withdrawal time in minutes) ……………………………..

10) In how many percent of your colonoscopies do you believe the patient experiences severe pain or no pain during the procedure?
    Answer: (percent with severe pain) ……………………………..
    Answer: (percent with no pain) ……………………………..
Figure 11:

Development of quality indicators (PDR >=5mm, severe pain, completed colonoscopy) in GN as mean% of all participating endoscopists’ colonoscopies per year. This diagram contains only colonoscopies from the eight centres that participated through the entire study period 2003-2012.
### Table 4:

Number of colonoscopies and percentage of total per endoscopist in study 1

<table>
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<tr>
<th>Endoscopist</th>
<th>Procedure volume</th>
<th>Percentage of total</th>
<th>Endoscopist</th>
<th>Procedure volume</th>
<th>Percentage of total</th>
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Table 5: Number of colonoscopies and percentage of total per endoscopy centre in study 1

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Table 6:
Number of colonoscopies and percentage of total per endoscopist in study 2

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Number of colonoscopies and percentage of total per endoscopy centre in study 2

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Table 9  

Keys to recruiting and retaining participants in the quality registry (Hospital recruitment, physician recruitment and patient recruitment (169))

Keys to hospital recruitment:
- The condition being studied satisfies one of the hospital’s quality assurance mandates. Sufficient funds, data, or other benefits will be realized to justify the effort required to participate.
- The confidentiality of the hospital’s performance data is ensured, except to the extent that the hospital elects to report it.
- Clinically relevant, credible, timely, and actionable self-assessment data – ideally, data that are risk adjusted and benchmarked – are provided back to the hospital to help it identify opportunities for enhancing patient care outcomes.
- High-profile hospitals (regional or national) are participating in the registry.
- Burden is minimized
- Participation assists the hospital in meeting coverage and reimbursement mandates, gaining recognition as a center of excellence, or meeting requirements for pay-for-performance initiatives.

Methods of hospital recruitment:
- Identify eligible hospitals from the American Hospital Association database.
- Use stakeholder representatives to identify potentially interested hospitals.
- Enroll hospitals through physicians who work there and are interested in the registry.
- Use invitation letters or calls to directors of quality assurance or the chief of the clinical department responsible for the condition targeted by the registry.
- Ask physician members of an advisory board (if applicable) to network with their colleagues in other hospitals.
- Reach out to physicians or hospital administrators through relevant professional societies or hospital associations.
- Leverage mandates by external stakeholders, including third-party payers, health plans, or government agencies.

Keys to physician recruitment:
- The condition being studied is part of the physician’s speciality.
- The registry is a valuable scientific endeavor.
- The registry is led by respected physician opinion leaders.
- The registry is endorsed by leading medical, government, or patient advocacy organization(s).
- The effort needed to recruit patients and collect and submit data is perceived as reasonable.
- Useful practice pattern and/or outcome data are provided.
The registry meets other physician data needs, such as maintenance of certification requirements, credentialing requirements, or quality-based, differential, reimbursement payment programs (pay-for-performance).

Methods of physician recruitment:
- Purchase mailing list from physician specialty organization
- Ask opinion leaders in the field to suggest interested colleagues.
- Partner with local and national medical societies or large physician hospital organizations.
- Use stakeholder representatives to identify interested physicians.
- Recruit and raise awareness at conferences.
- Advertise using email and the Web
- Register in the Registry of Patient Registries (RoPR) to increase awareness.
- Leverage practice-based research networks.

Keys to patient recruitment:
- Recruit through a physician who is caring for the patient.
- Communicate to the patient that registry participation may help to improve care for all future patients with the target condition.
- Write all patient materials (brochures, consent forms) in a manner that is easily understandable by the lay public.
- Keep the survey form short and simple.
- Provide incentives. These can be nonmonetary, such as functions relevant to the patient’s care (reports) or community (newsletters, portals). In some cases, monetary incentives can be offered if approved by the institutional review board.
- Actively plan how to include minorities or other populations of interest.

Methods of patient recruitment:
- Noninstitutionalized residents of the general U.S. population:
  - Recruit via letter survey, telephone, or email.
  - Recruit during well-patient visits to outpatient clinics.
  - Recruit via patient advocacy and support groups, health information Web sites, etc.
  - Register in the Registry of Patient Registries (RoPR) to increase awareness.
- Outpatients attending the clinic of a physician who is participating in the registry
  - Recruit through the patient’s physician.
  - Recruit via brochures placed in physician’s office.
- Hospital inpatients who are hospitalized for treatment of a condition that is the subject of the registry:
  - Recruit through the patient’s physician.
  - Recruit through hospitalists or consultant specialists.
  - Recruit through a hospital research coordinator.
- Residents of nursing homes and similar long-term care facilities:
  - Establish a relationship with the nursing home and staff.
16 Errata

- Study 1, p. 6, Figure 4b: the scatterplot diagram for colonoscopies with severe pain includes a red line marking a level of twelve percent colonoscopies with severe pain. This line was added by mistake. As described in the legend of figure 4 this diagram should be without red line. The twelve percent represent the mean for endoscopists’ pain level registered in Gastronet and was meant to be an orientation for endoscopists when comparing their own level with others. But, clearly, every endoscopist’s target should be a pain level as close to zero as possible.

- Study 3, figure 1 a: five inexperienced endoscopists (blue circles) estimated their CIR below 90% while registered values confirmed a CIR of 90% or higher. In the study period Gastronet did not register if an endoscopist needed help from a senior endoscopist to accomplish cecal intubation. Therefore, the degree of underestimation of CIR, especially among inexperienced colonoscopists, might in fact be lower than registered in Gastronet. A young endoscopist might have guessed his or her CIR without help from senior staff, while Gastronet registered cecal intubation independent of whether assistance from a senior doctor was needed or not. Therefore, we do not know if correction for “assisted” cecal intubation might have changed our results.
17 Papers
An explorative study from the Norwegian Quality Register Gastronet comparing self-estimated versus registered quality in colonoscopy performance

Authors
Volker Moritz1, Oyvind Holme2, Marissa Leblanc3, Geir Hoff4

Institutions
Institutions are listed at the end of article.

Background and study aims: The value of a colonoscopy quality assurance (QA) register may be questioned if it brings no new information on which to act for quality improvement, e.g. if self-assessed quality of colonoscopy performance correlates perfectly with registered performance.

Patients and methods: In this explorative study, 39 (33 Norwegian and 6 Swedish) out of 99 new endoscopists joining the Norwegian QA register Gastronet from 2008 to 2013 responded to an invitation to fill in a questionnaire for self-assessment of cecal intubation rate, polyp detection rate for polyps ≥ 5mm (PDR-5mm), withdrawal time, total examination time, and rates for severely painful and pain-free colonoscopies before receiving their first-time feedback of actually registered results from Gastronet. A linear regression analysis was applied to explore the correlation between experience level and quality of estimation.

Results: We included 2654 colonoscopies in our study. Endoscopists underestimated their cecal intubation rate (estimated 88.8%, registered 93.1%, P<0.001), total procedure time (estimated 31.7 minutes, registered 37.2 minutes, P=0.014), withdrawal time (estimated 9.8 minutes, registered 14.4 minutes, P=0.006) and the rate of pain-free procedures (estimated 18.3%, registered 24.5%, P=0.001). Pre-study colonoscopy experience was not correlated with estimated quality for any of the indicators.

Conclusions: Apart from overestimation of severely painful examinations, endoscopists most often underestimated their colonoscopy performance. Self-assessed quality of colonoscopy performance may not be a satisfactory substitute for systematic registration of quality and not sufficiently valid to be acted upon.

Introduction

Colonoscopy is currently regarded as the gold standard for diagnosis of colorectal conditions, including polyps and cancer. Demographic changes with an older population in many countries call for efforts to meet increasing demands for endoscopy services. Along with a steady increase in the number of colonoscopies performed, there has been a growing concern about the quality of colonoscopies. In recent years, European and American guidelines for quality of colonoscopy have been established giving both center leads and individual endoscopists a tool to assess quality of performance and service provided, [1,2] in addition to several quality assurance (QA) programs [3,4].

To our knowledge, there have been no studies exploring the ability of individual colonoscopists to self-assess or guess the quality of their performance compared to actually measured performance results.

In Norway, the Gastronet QA program was launched in 2003 [4]. Participation has been voluntary. Endoscopic retrograde cholangiopancreatographies (ERCP) (1,076 from 11 Norwegian centers) and colonoscopies (15,423 from 25 Norwegian centers) were reported to Gastronet in 2014. In addition 3,123 colonoscopies from 3 Swedish clinical center and 5 Norwegian screening project sites were registered last year. Previously, gastroscopies were also reported but due to limited resources in the Gastronet secretariat and work load for the endoscopists, gastroscopy registration was ended.

Both center leads and individual endoscopists receive feedback on different indicators capturing quality of colonoscopy (rate of completed colonoscopies, polyp detection and colonoscopies described as severely painful by the patient – in addition to the rate of procedures performed with...
sedation/analgesia and degree of patient satisfaction with the service). Registrations are paper-based using one form to be filled in by the endoscopist immediately after the colonoscopy and another to be filled in by the patient on the day after the procedure. Both forms are then returned to the Gastronet secretariat by mail. The aim of this study was to explore to what degree endoscopists (both experienced and inexperienced) were capable of estimating their own colonoscopy performance. These self-estimates were then compared with the results from actually registered quality indicators in Gastronet.

**Patients and methods**

Endoscopists from Norway and Sweden who registered in Gastronet for the first time between 2008 and 2013 were eligible for this explorative study. Shortly after enrollment in Gastronet they were mailed a questionnaire and asked to estimate their colonoscopy performance on the basis of their colonoscopy experience so far. Those who responded and returned the questionnaire before they received individual feedback information from Gastronet for the first time were registered for this study.

We focused on the following four aspects of colonoscopy: rate of completed procedures, rate of polyp findings, duration of the procedure including insertion and withdrawal times, and subjective perception of pain reported by the patient by means of a four-point verbal rating scale (no, slight, moderate or severe pain). The patient filled in the questionnaire the day after the procedure and returned it to Gastronet in a prepaid envelope.

The endoscopists estimated the percentage of procedures during which colonoscopy was completed (cecal intubation rate [CIR]), the percentage of procedures during which polyps measuring at least 5 mm were found (polyp detection rate for polyps ≥5 mm [PDR-5 mm]), and how many minutes, on average, were needed to perform a full procedure and to withdraw the endoscope from the cecum to the anus while inspecting the colon mucosa for pathological findings. Total examination time and withdrawal time were restricted to diagnostic colonoscopies without therapeutic interventions. The insertion time from anus to cecum was calculated by subtracting withdrawal time (WT) from total procedure time. The endoscopists were also asked to estimate what percentage of their patients experienced severe pain and no pain, respectively, during the procedure. After returning the form with individual performance estimates, the endoscopists then received individual feedback on their performance results based on registrations in Gastronet. The results from self-assessment were then compared with registered performance data in Gastronet. We also explored whether differences were dependent on endoscopist experience or gender. Inexperienced endoscopists were defined as having performed fewer than 300 colonoscopies.

The thresholds for good performance in our study followed international guidelines. American and European guidelines recommend a cecal intubation rate of ≥90% [1,2]. During our study, American guidelines recommended an adenoma detection rate of 20% (25% for men and 15% for women) [5]. Because 80% of colorectal polyps ≥5 mm have been shown to be adenomas [6,7], the defined target in Gastronet was detection of polyps ≥5 mm of 20% or more (20% [0.8]). In recently updated American guidelines, recommended adenoma detection rates have been increased to 30% for male patients and 20% for females [1]. The guidelines also recommend a withdrawal time in negative-result screening colonoscopy of ≥6 minutes. In our study, endoscopists were asked to estimate their individual mean withdrawal time for diagnostic colonoscopies without any therapeutic interventions. There are no international recommendations for the duration of total procedure time or insertion time. Likewise, international guidelines do not recommend standards for patient feedback on pain during colonoscopy. The endoscopists’ average rate of procedures with severe pain for the patient registered in Gastronet ranged from 13% to 11.5% in the last 5 years (13% in 2010, 12% in 2011, 11.8% in 2012, 12.2% in 2013 and 11.5% in 2014). Therefore Gastronet recommends that endoscopists aim at a lowest possible rate with a maximum level of 12%. To our knowledge, there are no recommendations for the rate of pain-free colonoscopies.

**Statistical methods**

Paired-samples *t*-test was applied to compare self-assessed with registered performance. The width of the paired-sample *t*-test confidence intervals was used to assess the uncertainty in our estimates. To explore the importance of colonoscopy experience for the ability to self-assess quality, we performed a linear regression for each indicator (cecal intubation rate [CIR], PDR-5 mm, total examination time, insertion time, WT, severe pain, no pain). The predictor variable was the estimated number of colonoscopies performed by the endoscopist during his/her career before entering Gastronet. The dependent or response variable was the difference between estimated and calculated value for each indicator. The presumption was that the differences between estimated and measured values might decrease with increasing endoscopist experience (number of performed procedures). An independent two-sample *t*-test was applied to see if male and female endoscopists differ with regard to quality of self-assessment. All tests were two-sided, and *P* < 0.05 was considered statistically significant. All analyses were conducted with SPSS, version 21.

In order to evaluate the reliability of estimated compared with calculated (observed) values the intraclass correlation coefficient (ICC) was calculated for each quality indicator.

**Ethics**

The Regional Committee for Medical and Healthcare Research Ethics of the South Eastern Norwegian Health Board waived their need to evaluate the study protocol.

**Results**

In total, 99 endoscopists who registered for the first time in Gastronet between 2008 and 2013 were sent a questionnaire for estimation of their colonoscopy performance. Thirty-three (52%) of the 63 Norwegian candidates responded. Twenty-five (40%) did not respond and five (7.9%) were erroneously invited because they already had been registered in Gastronet and previously obtained their Gastronet results (non-eligible for the study). Six (17%) out of 36 Swedish candidate endoscopists responded (Table 1). The participating endoscopists in this study had greatly varying pre-study experience defined by the number of colonoscopies performed. The endoscopist with the lowest level of experience...
had only performed 30 colonoscopies before entering Gastronet. The most experienced endoscopist estimated his pre-study experience at 5000 procedures. Twenty-two endoscopists had performed fewer than 300 colonoscopies before Gastronet registration. Sixteen endoscopists estimated their previous experience at 300 or more colonoscopies. One participant did not give information about previous experience.

The number of colonoscopies registered in Gastronet in this study varied between 30 and 170 procedures for a single endoscopist. The median number was 59 procedures per endoscopist. In total, 2654 procedures were included. The results from the paired-sample Student’s t-test are summarized in Table 2.

Cecal intubation rate
Estimated CIR values ranged from 70% to 95% compared to 83.6% to 100% for registered CIR (Fig. 1a). The mean estimated CIR was 88.8%, compared to the registered CIR 93.1%, P value < 0.001. Only 26 participants estimated that they met the required 90% level of cecal intubation rate, while 30 endoscopists fulfilled the requirements according to registered results.

Polyp detection
The estimated PDR-5 mm detection rate ranged from 5.0% to 70%, and 3.2% to 54.8% for registered PDR-5 mm (Fig. 1b). The participants estimated their polyp detection rate (PDR-5 mm) to be slightly worse than registered (mean estimated 16.3%, mean registered 20.8%) but the difference did not reach statistical significance, P=0.07. The target of PDR-5 mm of 25% or higher was met by 11 endoscopists (29%).

Pain during colonoscopy
The estimated proportion of severely painful colonoscopies ranged from 1% to 60% and 5% to 50% for pain-free procedures. The corresponding registered results were 0% to 42% and 8.6% to 45.0%, respectively (Fig. 1c). The rate of severely painful colonoscopies was estimated slightly higher than actually registered, but not statistically significant (mean estimated 18.2%, mean registered 14.1%, P=0.018). Conversely, the endoscopists estimated their rate of pain-free procedures to be rather low (mean estimated 18.3%, mean registered 24.5%, P=0.001).

Duration of procedure
The range for estimated total procedure time was from 15 to 50 minutes and 3 to 15 minutes for withdrawal time. The range for registered results in Gastronet was from 13.4 to 86.2 minutes for total examination time and 3.8 to 49 minutes for withdrawal time (Fig. 1d). The mean estimated insertion time (21.7 min) was very close to the registered value (23.0 min), P=0.27. In contrast, the endoscopists underestimated the time they used for withdrawal and inspection in diagnostic procedures. The mean estimation was 9.8 minutes and the registered result 14.4 min-

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</tr>
<tr>
<td>Invited, responded</td>
<td>33 (52%)</td>
</tr>
<tr>
<td>Invited, no response</td>
<td>25 (40%)</td>
</tr>
<tr>
<td>Not eligible (already having received Gastronet results)</td>
<td>5 (7.9%)</td>
</tr>
<tr>
<td>Total</td>
<td>63</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Results of the paired-sample Student’s t-tests for the means of estimated and registered colonoscopy quality indicators for all included endoscopists.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESTIMATED</td>
<td>REGISTERED</td>
</tr>
<tr>
<td>Cecal intubation (min)</td>
<td>88.8</td>
</tr>
<tr>
<td>PDR-5 mm (%)</td>
<td>16.3</td>
</tr>
<tr>
<td>Total colon. time (min)</td>
<td>31.7</td>
</tr>
<tr>
<td>Insertion time (min)</td>
<td>21.7</td>
</tr>
<tr>
<td>Withdrawal time (min)</td>
<td>9.8</td>
</tr>
<tr>
<td>Severe pain (%)</td>
<td>18.2</td>
</tr>
<tr>
<td>no pain (%)</td>
<td>18.3</td>
</tr>
</tbody>
</table>

Abbreviations: Min., minimum; Max., maximum; SD, standard deviation; CI, confidence interval; ICC, intraclass correlation coefficient.
utes, \( P = 0.006 \). Accordingly, total examination time was also underestimated (estimated 31.7 minutes and registered 37.2 minutes, \( P = 0.01 \)).

**Colonoscopy experience**

The precision of self-estimates did not improve with increasing pre-study colonoscopy experience. In the linear regression model, none of the quality indicators reached significance level (lowest \( p \)-value 0.17 and highest 0.74, regression line and table not shown). In **Fig. 1a, 1b, 1c, and 1d**, four scatterplots for different quality indicators depict the range of self-assessment quality for inexperienced (blue circles) and experienced endoscopists (red circles).

**Endoscopist gender**

Female endoscopists estimated their insertion time to be 5.5 minutes shorter than registered values whereas their male colleagues estimated their insertion time to be 0.6 minutes longer than the registered values (95%CI 1.2 minutes – 10.9 minutes, \( P = \).
In the reliability of estimated compared to observed values was the most confident. among physicians who were the least skilled and those who associations. The worst accuracy in self-assessment was found an inverse relationship and only seven demonstrated positive as-
between self- and external assessment demonstrated little, no or to accurately self-assess. In this review, 13 out of 20 comparisons
Davis et al. [9] also concluded that physicians had a limited ability
mally influenced by external feedback. Another review article by
of self-assessed performance was found to be low to moderate. It improve or maintain quality. This explorative study suggests that self-assessed quality of colonoscopy performance is not a satisfactorily substitute for systematic registration of quality and not sufficiently valid to be acted upon. There was great variation in the ability to self-assess colonoscopy performance with a tendency for endoscopists to underestimate the quality of their performance. One exception was self-assessment from novice to expert performed polypectomy in simulated colonoscopy [14]. Each procedure was assessed by a structured assessment form both by the endoscopist himself or herself and by two expert assessors. They concluded that the correlation between assessors’ scores and self-assessment scores was weak. Different approaches have been explored to improve diagnostic methods and treatment of colorectal polyps. Gupta et al. tested a polypectomy competence assessment tool [Direct observation assessment tool] [15], Dawn et al. established a conversion factor to estimate the adenoma detection rate from the polyp detection rate [16]. Both authors concluded that their tools can contribute to improve the quality of colonoscopy services for treatment of polyps. Self-estimation of quality by endoscopists was not implemented in these two studies.

**Pain during colonoscopy**

By self-assessment, the endoscopists tended to overestimate the proportion of severely painful and underestimate painless colonoscopies reported by their patients. The mean estimate for severe pain was 18.2% compared to 14.1% reported (P=0.012). The self-estimated proportion of pain-free procedures was 18.3% compared to 24.5% reported by the patients as being pain-free (P=0.001). In line with the other indicators, there was a wide spectrum of estimations ranging from overestimation, good estimation approximating registered results to underestimation as depicted in Fig. 1a. In Gastronet, cecal intubation is registered as successful independent of whether the endoscopist needed help from a more experienced colleague or not. Therefore the CIR for endoscopists with very little pre-study experience might reflect a well-functioning master/apprentice cooperation rather than genuine unaided caecum intubation of the trainee.

**Intraclass correlation coefficient**
The ICC was low for all quality indicators. The highest ICC was for insertion time (0.611) and the lowest ICC was 0.013 for withdrawal time. The results are shown in Table 2. This indicates that the reliability of estimated compared to observed values was moderate for insertion time and low for all other quality indicators.

**Discussion**

Quality registers aim to provide information that is 1) not available otherwise and 2) valid for responsible persons to act on to improve or maintain quality. This explorative study suggests that self-assessed quality of colonoscopy performance is not a satisfactory substitute for systematic registration of quality and not sufficiently valid to be acted upon. There was great variation in the ability to self-assess colonoscopy performance with a tendency for endoscopists to underestimate the quality of their performance. One exception was self-assessment of severely painful colonoscopies which tended to be higher than registered.

In a review by Gordon [8] the author concluded that the validity of self-assessed performance was found to be low to moderate. It did not improve with time in training programs and it was minimally influenced by external feedback. Another review article by Davis et al. [9] also concluded that physicians had a limited ability to accurately self-assess. In this review, 13 out of 20 comparisons between self- and external assessment demonstrated little, no or an inverse relationship and only seven demonstrated positive associations. The worst accuracy in self-assessment was found among physicians who were the least skilled and those who were the most confident.

**Cecum intubation**
The mean self-assessed cecal intubation rate in our study was 43.3% less than registered CIR (self-assessed 88.8%, registered 93.1%, P<0.001). More endoscopists accomplished the desired level of CIR of ≥90% (30 endoscopists) than shown by self-estimated CIR (26 endoscopists). Incorrect self-estimation ranged from mild overestimation (one endoscopist estimated CIR to 90% while it was registered as 85%) to gross underestimation (one endoscopist with self-estimated CIR of 70% which was registered as 93%). Several studies have focused on learning curves for CIR among endoscopist trainees [10 – 13]. The number of colonoscopies needed to accomplish a CIR of 85 to 90% ranged from 150 to 280 procedures. None of the studies implemented a self-estimation by the endoscopist. From our data we can conclude that the participating endoscopist underestimated their completion rate and the capability to estimate the individual CIR varies greatly among endoscopists as depicted in Fig. 1a. In Gastronet, cecal intubation is registered as successful independent of whether the endoscopist needed help from a more experienced colleague or not. Therefore the CIR for endoscopists with very little pre-study experience might reflect a well-functioning master/apprentice cooperation rather than genuine unaided caecum intubation of the trainee.

![Fig. 2](image-url) Bar chart showing the endoscopists’ mean values for self-assessed and registered performance in Gastronet for each quality indicator (P values from paired-samples t-test) (39 endoscopists).
and nurses tended to overestimate the patients’ discomfort. However, in 9% of cases the level of patient discomfort was considerably underestimated by at least one member of the team. In our study, 16 endoscopists (41% of all) estimated their rate for severely painful colonoscopies to be less than the registered rate in Gastronet. For twelve of them (31% of all endoscopists) the registered rate for severely painful procedures was 5% or more above the self-estimated rate. This means that almost one third of the endoscopists reckon their performance with regard to pain is better than reported by the patients.

The wide range of estimation of quality in both studies reflects the high grade of subjectivity related to assessment of pain. In the context of clinical routine endoscopy, there is no direct objective measurement of pain. Consequently, from our point of view, subjective feedback from the patient himself/herself should define the amount of discomfort or pain perceived.

Procedure duration

The endoscopists in our study used more time both for the entire procedure and for withdrawal than reflected in their self-estimations of average time spent. The registered mean for total examination time and withdrawal time was significantly longer than estimated (total time 31.7 min estimated and 37.2 min registered, \( P = 0.01 \). WT 9.8 min estimated and 14.4 min registered, \( P = 0.006 \)). The estimated insertion time (mean 21.7 min) met quite well the registered value (mean 23.0 min), \( P = 0.27 \). We can conclude that the total procedure time is longer than estimated because the endoscopists use more time on withdrawal than they estimate themselves. American guidelines recommend a WT of at least 6 minutes in purely diagnostic procedures [1]. According to those guidelines, the endoscopists in our study were well within standards. Spending twice as much time on withdrawal and inspection than estimated by the endoscopists themselves may suggest an overzealous attitude by a highly motivated endoscopist embarking on a new QA program. This, however, goes beyond the scope of the present study.

Colonoscopy experience

One might expect that increasing colonoscopy experience would make it easier for an individual endoscopist to make a good guess about his/her own colonoscopy quality. But we did not see evidence of that in our linear regression model with a limited number of endoscopists. Thus, we cannot conclude that a higher number of pre-study colonoscopies (i.e. endoscopist experience) may reduce the difference between self- assessed and registered result. Studies with larger numbers of endoscopists are needed to analyze the correlation between experience level and self-assessment quality. Self-assessment of personal quality of performance, however, appears to have very limited value for and impact on QA work regardless of level of experience.

Endoscopist gender

Apart from a significant underestimated of insertion time by female endoscopists compared to male endoscopists, there was no significant difference between male and female endoscopists with regard to CIR, PDR-5 mm, total examination time, WT, or rates for severely painful and pain-free colonoscopies. Endoscopist gender, therefore, does not appear to be a major issue in self-assessment of colonoscopy performance.

Limitations

The response rate from invited endoscopists was low at only 39%. Accordingly the number of participating endoscopists was low with only 39 participants. Gastronet did not investigate why the response rate was low. In Norway 25 out of 58 eligible endoscopists (43%) and in Sweden 30 out of 36 eligible endoscopists (83%) did not respond to the invitation. Participation rates in the different centers ranged from only three out of 14 invited endoscopists (21%) in a tertiary center in Sweden to all out of six invited (100%) in a center in South Norway. We do not know why participation was low, particularly in Sweden.

We can only speculate whether the reasons for this might be high workload, embarrassment about giving a wrong estimation, a negative attitude toward quality improvement work, worry about being confronted with personal suboptimal performance or other unknown reasons. Analysis of non-participation goes beyond the scope of a quality assurance initiative. Given the high non-participation rate, we cannot exclude the possibility of selection bias affecting our results. This clearly represents a weakness in our study.

Apart from CIR, all quality indicators show rather wide 95% confidence intervals in the paired-sample \( t \)-test (Table 2). Indicators with a \( P \) value approaching the 0.05% significance level may reach significance in a larger endoscopist cohort, as for example PDR-5 mm with a \( P \) value of 0.066.

Conclusions

Endoscopists do not accurately estimate their own performance with regard to several colonoscopy quality indicators. There is wide variation ranging from overestimation, to good estimation, to underestimation. Experience level was not correlated with the quality of self-estimation in our data but that might be due to the low number of participants. Quality of self-estimation does not differ with gender of the endoscopist.

Competing interests: None

Institutions

1 Telemark Hospital – Department of Medicine Skien, Norway
2 Sarlandet Hospital Kristiansand – Department of Medicine Kristiansand, Norway and University of Oslo – Institute of Health and Society, Oslo, Norway
3 Oslo University Hospital – Oslo Centre for Biostatistics and Epidemiology, Research Support Services Oslo, Norway
4 Institute of Population-based Cancer Research – Clinical and registry-based research, Oslo, Norway

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References

7 Tsai FC, Strum WB. Prevalence of advanced adenomas in small and diminutive colon polyps using direct measurement of size. Dig Dis Sci 2011; 56: 2384–2388
9 Davis DA, Mazmanian PE, Fords M et al. Accuracy of physician self-assessment compared with observed measures of competence: a systematic review. JAMA 2006; 296: 1094–1102
17 Heuss LT, Sugantha SP, Degen LP. Endoscopy teams’ judgment of discomfort among patients undergoing colonoscopy: “How bad was it really?” Swiss Med Wkly 2012; 142: w13726