Quality improvement in the care of patients with inflammatory bowel disease

A study with special reference to patients’ experiences, clinical redesign and performance measurements in a population-based setting

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To those who suffer from inflammatory bowel disease
# Table of contents

Table of contents ................................................................. 4  
Abstract .................................................................................... 6  
List of papers ............................................................................. 8  
Abbreviations ............................................................................ 9  
Definitions ................................................................................ 10  
Introduction .............................................................................. 12  
Background .............................................................................. 13  
Quality and Quality improvement ............................................. 13  
Quality improvement in healthcare .......................................... 14  
Quality improvement in healthcare .......................................... 15  
Models for understanding the particular context ..................... 16  
Measurement in Quality improvement ...................................... 17  
Inflammatory bowel disease ..................................................... 18  
Diagnosis, treatment and effects of IBD .................................. 19  
To experience living with IBD .................................................. 20  
Outcome in healthcare ............................................................ 21  
Outcome in IBD care ............................................................... 22  
Aim and Objectives ................................................................. 24  
General aim ............................................................................. 24  
Specific aims ............................................................................ 24  
Methods ................................................................................... 25  
Setting ..................................................................................... 25  
Participants .............................................................................. 25  
Haemoglobin, medication, QoL and hospitalization ................. 26  
A framework for the research design ........................................ 26  
Methods ................................................................................... 27  
The quality improvement intervention ...................................... 27  
Methods for the study of the QII (I) ......................................... 28  
Methods used to create a quality framework (II) ...................... 29  
Methods in Study (III) ............................................................. 29  
Methods in Study (IV) ............................................................. 29  
Statistics .................................................................................. 30  
Ethical considerations ............................................................. 31  
Rigour of the research ............................................................. 31  
Results ..................................................................................... 32  
Participants .............................................................................. 32  
The study of the QII (I) ............................................................ 32  
A framework for the evaluation of IBD care (II) ....................... 35  
Anaemia in IBD care (III) ......................................................... 37  
Living with IBD – the patient perspective (IV) ......................... 39  
The experience of being affected by the disease ..................... 40  
The accompanying consequences of the illness ................... 40  
Adaptation required to restore one’s normal life ................. 41  
Discussion ............................................................................... 42  
Main contributions of the thesis ............................................. 42  
The quality improvement intervention .................................... 43  
The applied models ............................................................... 44  
Self-management, IBD and the QII .......................................... 45  
Performance measurement for IBD ........................................ 46
Haemoglobin .................................................................................................................... 47
Medication .................................................................................................................. 48
Quality of life and hospitalization ................................................................. 49
A framework for IBD care ...................................................................................... 49
Comparison of the local and national IBD registers ........................................ 50
Patients’ experiences of living with IBD ............................................................. 51
Limitations ................................................................................................................. 53
Concluding remarks ............................................................................................... 56
A “quality formula” for IBD care .......................................................................... 56
Future research .......................................................................................................... 57
References .................................................................................................................. 62
Appendix .................................................................................................................... 69
Abstract

A range of studies have supported the existence of a gap between what medicine could possibly deliver and what it actually does deliver. This is also true for the delivery of care to patients with inflammatory bowel disease (IBD) and several international stakeholders have called for action. The aim of this thesis was to describe, study and evaluate a quality improvement intervention (QII) in the care for patients with IBD in a population-based setting, with special reference to clinical redesign, performance measurement and patient experience.

The patient population on which this thesis is based was recruited from the gastroenterological unit at the Department of Internal Medicine, Highland Hospital, in Eksjö, Sweden. The QII was implemented through iterative improvement cycles in the early years of the 21st century. Data from yearly check-ups of patients including identification, gender, disease duration, medication, four questions about quality of life (QoL) and laboratory results were entered into a local register created as part of the QII. In addition, data on admissions to hospital were retrieved. The interactions between staff and patients as well as the elements of the delivered care were analysed by applying the model of clinical microsystems (CMS) and the Chronic Care Model (CCM). The QII was studied using a retrospective, descriptive analysis with quantitative elements. A multidimensional quality tool, the Clinical Value Compass (CVC), was applied to assess the quality of care. Later, the CVC and the quality model by Donabedian (Df) were merged to create a quality framework for IBD, which was tested on already existing data in the local IBD register. In a study of patients’ experiences of living with IBD, a content analysis was applied to interviews with 20 purposefully sampled patients.

The main components of the redesign, described as a “patient- and demand-directed care”, were: - A specialist nurse staffed the outpatient clinic full time and could offer patients who contacted the clinic an acute visit at the outpatient clinic within two days. - Yearly check-ups to either the nurse or physician were offered, either as telephone calls or as traditional visits to the clinic. A letter preceded the contact and included a QoL questionnaire and instructions for laboratory testing of haemoglobin (Hb). The QII led to decreasing numbers of hospitalizations compared to national data and better access to care. The prevalence of anaemia in the population was 6% and was correlated to a risk of being admitted to hospital during the year. The analysis of the interviews showed several parallels to the experiences of
people who live with other chronic diseases than IBD. Consequences of living with IBD were associated with everyday life and the adaptations needed to restore one’s life. It was always shadowed by the person’s worry that he or she might potentially need a toilet.

The main contribution of this thesis is the overall example of how a quality improvement intervention including continuous performance measures and frameworks, as well as the study of patients’ experiences, can be applied in a local population-based setting. The understanding of the interactions between patients, staff and the healthcare system was described and analysed through the application of CMS and the CCM. As a whole, this thesis contributes to the international quest for quality improvement efforts to bridge the quality gap in the delivery of IBD care today.
List of papers

This thesis is based on the following papers, referred to in the text by their Roman numerals:


IV. Rejler, M., Kjeldmand, D., Hedberg, B. (2012) Always considering the potential need for a toilet: A content analysis of 20 interviews with persons living with inflammatory bowel disease. Submitted


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## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<td>CCM</td>
<td>Chronic Care Model</td>
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<tr>
<td>CD</td>
<td>Crohn’s Disease</td>
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<td>CMS</td>
<td>Clinical Microsystem</td>
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<tr>
<td>CVC</td>
<td>The Clinical Value Compass</td>
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<tr>
<td>Df</td>
<td>Quality model according to Donabedian</td>
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<tr>
<td>HRQoL</td>
<td>Health-Related Quality of Life</td>
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<td>IBD</td>
<td>Inflammatory Bowel Disease</td>
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<tr>
<td>ICD</td>
<td>International Classification of Diagnosis</td>
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<tr>
<td>IoM</td>
<td>Institute of Medicine</td>
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<td>JCC</td>
<td>Jönköping County Council</td>
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<tr>
<td>PREM</td>
<td>Patient Reported Experience Measures</td>
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<td>PROM</td>
<td>Patient Reported Outcome Measures</td>
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<tr>
<td>QI</td>
<td>Quality Improvement</td>
</tr>
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<td>QII</td>
<td>Quality Improvement Intervention</td>
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<td>QoL</td>
<td>Quality of Life</td>
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<td>SALAR</td>
<td>Swedish Association of Local Authorities and Regions</td>
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<td>SHS</td>
<td>Short Health Scale</td>
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<tr>
<td>SoS</td>
<td>Swedish National Board of Health and Welfare</td>
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<td>SRR</td>
<td>Swedish Rheumatoid Arthritis Register</td>
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<td>SWIBREG</td>
<td>Swedish IBD Registry</td>
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<tr>
<td>TQM</td>
<td>Total Quality Management</td>
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<tr>
<td>UC</td>
<td>Ulcerative Colitis</td>
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<td>US</td>
<td>United States</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Definitions

Anti-TNF-α  Anti-tumour necrosis factor. Prohibits the inflammatory response associated with clinical problems in autoimmune disorders.

5-ASA  5-aminosalicylic acid is an anti-inflammatory drug used to treat IBD.

Calprotectin  Measurement of faecal calprotectin; a biochemical test for IBD.

Clinical Microsystem  A small group of people who work together to provide care, as well as the individuals who receive the care. Has clinical and business aims, linked processes and a shared information environment, and produces services and care which can be measured as performance outcomes. These systems evolve over time and are embedded in larger healthcare systems/organizations.

Disease  Complication in relation to an individual’s health as seen from the healthcare professional’s perspective.

Health  A state of complete physical, mental and social well-being, not merely the absence of disease.

Illness  The disease as perceived by an individual in his or her societal situation.

PDSA  Plan-Do-Study-Act, a quality improvement method for the implementation of changes through minor iterative cycles.

STEEP  The report Crossing the Quality Chasm by the IoM in the US recommends that delivery of healthcare in the 21st century be based on six key concerns: Safety, timeliness, effectiveness, efficiency, equitability and patient-centeredness.

Safety  Concerns avoiding injury to patients from the care that is intended to help them.

Timeliness  Concerns reducing waits and harmful delays.

Effectiveness  Concerns providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.

Efficiency  Concerns avoiding waste.
<table>
<thead>
<tr>
<th>Equitability</th>
<th>Concerns providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographical location and socioeconomic status.</th>
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<tr>
<td>Patient-centeredness</td>
<td>Concerns providing care that is respectful of and responsive to individual patient preferences, needs and values.</td>
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Introduction

At the beginning of my internship as a junior doctor at the Department of Internal Medicine at the Highland Hospital, I reflected on the care we delivered to patients affected by inflammatory bowel disease (IBD). It also just so happened that my family had just bought our first car. The investment decision had been guided by multidimensional measures like engine characteristics, drivers’ satisfaction scores and cost. What if we had instead had to care for a disease which had struck someone in the family? What would the guiding quality measures have looked like? What expectations should we have had? What had others experienced in the same situation? My early and honest questions were: Why did there seem to be more information about the qualities of cars than the outcomes of care for IBD? What did the situation look like from an international perspective and how did we do in our place? Were there any visions behind the delivery of care? What did quality measures for IBD look like? It seems to have been a lucky coincidence that these questions of a junior doctor were shared by senior colleague and gastroenterologist Dr Tholstrup and Head of Department Dr Bojestig, together with many other staff. The work this thesis is based on also has to be understood in connection with the context of the County of Jönköping (JCC), one of the first counties in Sweden to apply quality improvement as its main management strategy. The Department received support from the Qulturum, the JCC’s quality improvement centre which was created to support quality as the main management driver for improving care and the JCC’s research unit, Futurum, encouraged and supported research evaluations of improvement initiatives. The Department of Medicine in Eksjö had some years ago started an improvement journey, led by Dr. Bojestig, who had just been appointed Head of the Department. Together this had resulted in several international collaborations with focus on improving healthcare delivery. One example was the redesign of the gastroenterology unit, led by Dr Tholstrup. Along with this change he struggled to find improvement tools that could be used to monitor the effects of the changes. Dr Tholstrup inspired me to systemize the data and evaluate the redesign. This later resulted in a paper (I) describing and studying the quality improvement intervention (QII) at the gastroenterological unit. An extension of these studies later paved the way for this doctoral thesis, which thus came to address several of the questions around the evaluation of care raised when I compared the information gap between getting care for a chronic disease and buying a car.
Background

Quality and Quality improvement

Quality originates from the Greek word “qualitas”, which means character, nature or constitution. A couple elaborations on the concept are included here to exemplify:

“...there are two common aspects of quality. One of these has to do with the consideration of the quality of a thing as an objective reality independent of the existence of man. The other has to do with what we think, feel or sense as a result of the objective reality. In other words, there is a subjective side of quality.” 3 Walter Shewhart

The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs. 4 ISO 9000:2000

At the beginning of the 20th century, there was an emphasis on surpassing the minimum level of quality, defined as quality assurance 5. This gave rise to methods and principles for assessing industrial production. It was based on applications of statistics to understand and control variation in production processes. One example is from the telephone manufacturing industry, where the statistical process chart was developed by Walter Shewhart 3. Both W. Edwards Deming and Joseph Juran learned from and elaborated on how to apply the statistics to process variation, and later these ideas were disseminated to thriving post-war Japanese manufacturers 6 7. Along with this small-scale testing as an approach to change, which later developed into the plan-do-study-act cycle (PDSA), was introduced. Demings 8 later lay the foundation for what was to be known as continuous improvement 9. This was developed in the management philosophy of total quality management (TQM), closely connected to management theory 10. Dean and Bowen saw TQM as a philosophy characterized by its principles, practices and techniques combined with a focus on the customer, continuous improvements and teamwork 10. The overall goal of TQM is to fulfil the needs of the customer through improvements. According to Dean and Bowen, it consists of the categories of leadership, information and analysis, strategic quality planning, human resource development and management, management of process quality and customer focus and satisfaction. An example of the cultural part of quality improvement was Deming’s 14 points, with imperative statements like “improve constantly and forever”, “institute training on the job” and “drive out fear” 11.
Quality improvement in healthcare

Quality improvement (QI) is not a new idea in healthcare, even if this label was not used in earlier days. An early example was Semmelweis, who in the early 19th century in Vienna observed that there were higher rates of perpetual fever at one of two wards of the hospital. He observed physicians who had been performing autopsies moving into the labour unit of the ward containing patients with higher rates of fever. Based on this observation he suggested that physicians were to wash their hands before assisting in delivering babies, which resulted in a prompt decrease in the devastating fever. Florence Nightingale, who performed statistical analysis of wound infections during the Crimean War and Ernest Codman, a surgeon who systematically reported patient outcomes in surgery, are other examples. Unfortunately, both Semmelweis and Codman were forced from their chairs for pointing to the potential threat of challenging existing habits and outcomes.

In 1982 Deming suggested that complementary knowledge domains were important in improving quality, known as improvept knowledge or “Profound Knowledge”. This inspired Batalden and Stolz to create a translation to the healthcare context. They suggested that traditional improvement driven by intellectual disciplines and professional values differed from improvement knowledge based on knowledge about systems, variation, psychology and theory of knowledge. They suggested that it was actually the combination of both these knowledge systems that could help improve care continuously.

Batalden and Davidoff have suggested a definition for quality improvement in healthcare:

“The combined and unceasing efforts of everyone—healthcare professionals, patients and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning).”

“This definition arises from our conviction that healthcare will not realise its full potential unless change making becomes an intrinsic part of everyone’s job, every day, in all parts of the system. Defined in this way, improvement involves a substantial shift in our idea of the work of healthcare, a challenging task that can benefit from the use of a wide variety of tools and methods.”

A range of studies supports the existence of a gap, or even a chasm, between what medicine could possibly deliver and what it actually delivers. The challenge to bridge this gap has been taken on by many stakeholders. One of these is the Institute of Medicine (IoM) whose reports “Crossing the Quality Chasm” and “To Err is Human”, have served as eye-
openers nationally and internationally. As the quality problem of under-, over- and misuse was noted by IoM, a vision was launched, summarized in the mnemonic STEEEP, which stands for safe, timely, effective, efficient, equitable and patient-centred care \(^\text{16}\). For a further description, see definitions on page 10. The STEEEP vision provides a framework for the improvement of care. In Sweden, the National Board of Health and Welfare has adopted this vision in a document “Good Care” \(^\text{18}\) and used it as a guide in linking the patient perspective with the management perspective for all healthcare institutions in the country.

**To study Quality improvement**

They studying of whether a change was an improvement or not is challenging! In a paper “What is ‘quality improvement’ and how can it transform healthcare?” \(^\text{14}\), Batalden and Davidoff presented an effort to combine different systems of knowledge to understand how this combination brings about improvement. In a formula, they combined existing knowledge about the science of disease, with the setting in which care was actually delivered, i.e. context, and sophisticated measures of the outcome over time. The knowledge systems at work were 1) generalizable scientific knowledge, 2) particular context awareness, 3) performance measurement, 4) plans for change and 5) execution of planned changes.

![Formula for quality improvement](image)

The formula provides a framework for the connections of the knowledge systems needed for the improvement of care. The study of whether and how a particular change was an improvement has been placed under several terms such as implementation science, translational research, quality improvement science and science of improvement. Lately, a discussion to carry this further suggests an umbrella term where all these science areas and others contribute which can be called “improvement science” \(^\text{19}\). The intent is to include all aspects of research investigating the improvement of healthcare, systems, safety and policy with a starting point in the healthcare setting. The Health Foundation has suggested a definition: “Improvement science describes how to reduce the gap between what is actual and what is possible. It focuses on exploring what works, the best ways of measuring it and its dissemination within healthcare. It will also see the learning along with the interventions.” \(^\text{19}\)
Models for understanding the particular context

The concept of Clinical Microsystems (CMS) was first presented in the later 90s, using the term “microunits” 20, with a starting point in the key elements and core processes forming the care delivery within healthcare systems. The work focused on the daily care for patients by frontline staff, to provide a language for the organization and to offer a framework to use for understanding and improving care21. It was based on Sir Brian Quinn’s concept of smallest replicable unit22 23. Later research turned to how to improve the functioning of these units using QI methods in relation to the local context, the information environment and interactions between caregivers as well as between the clinical unit and the larger system 24. The CMS model provides a conceptual and practical framework for thinking about the interaction between patients and staff as the delivery of care is created. It is defined by Nelson et al. as follows 25:

“A clinical microsystem is a small group of people who work together on a regular basis to provide care to discrete subpopulations of patients. It has clinical and business aims, linked to the processes and a shared information environment and it produces performance outcomes. Microsystems evolve over time and are often embedded in larger organizations. They are complex adaptive systems and as such they must do the primary work associated with core aims, meet the needs of their members and maintain themselves over time as clinical units.”

Nelson et al. used the results from a study of 20 high-performing microsystems to define the anatomy of the CMS said to consist of the five Ps: patients, purposes, processes, professionals and patterns 23 26 27. Clinical Microsystems always have a individual at their centre, but evolve over time as living units. The research on CMS builds on the ideas developed by Deming 9, Senge 28 and Wheatly 29, among others, who have applied system thinking to organizational development, leadership and improvement. One CMS connects to another over the care cycle of a patient 30 which together constitute the meso-system together predicting the overall outcome of care on a macrosystem level. In the words of Deming, working as “a system is defined as a network of interdependent components that work together to try a specific aim” 6. The Chronic Care Model (CCM), developed by Wagner et al. 31 identifies essential elements of healthcare systems as care for chronic diseases are delivered. The model links the best possible knowledge, evidence-based medicine (EBM), at every level of healthcare to mutual cooperation with an active patient, resulting in improved outcomes. This model has four
elements: 1) self-managed care, 2) delivery systems design, 3) decision support and 4) clinical information systems. To the best of our knowledge, no published applications of this model to IBD care or any other general scientific description or evaluation of an IBD care system were available at the initiation of this thesis.

Patients with chronic diseases make decisions associated to their illness every day as they self-manage their disease. Self-management offers a strategy for individuals affected by chronic illness to take control in the struggle to regain and maintain life. Policy-makers and professionals have shown a growing interest in self-care and lay-led self-management as a mean to meet transformations of public health and healthcare systems due to epidemiological, economic and demographic transitions in the surrounding society. Today self-management is seen as a major component of healthcare policy in Britain and elsewhere. At the initiation of this thesis, experiences from self-management in IBD care were marginal. This was true for the other elements of CCM, decision support and clinical design, as well.

Measurement in Quality improvement

In definitions of QI, the importance of performance measures is underlined. On the other hand, the concept of performance measures is not always elaborated. Neely et al. define it as follows: “Literally it is the process of quantifying action, where measurement is the process and action leads to performance”. In one way, organizations achieve their goals by satisfying their customers’ requirements through greater effectiveness and efficiency. Here, effectiveness is the extent to which customers’ needs are met and efficiency is how economically the organization’s resources are utilized. Based on this, Neely et al. suggest that:

- Performance measurement can be defined as the process of quantifying the efficiency and effectiveness of actions.
- A performance measure can be defined as a metric used to quantify the efficiency and/or effectiveness of an action.
- A performance measurement system can be defined as the set of metrics used to quantify both the efficiency and effectiveness of actions.

The design of performance measurements can be traced at three levels: the individual, the system and the intersection at which the system meets the environment. Performance measures and the systems connected to them are increasing in importance for most
organizations. They support a variety of clinical and managerial purposes as means to improve organizational performance and play a significant role in the coordination of organizational activity, decision-making, prioritization, comparisons and the initiation of improvement processes. Their use is multilayered, as they may also work as tools for controlling, budgeting, motivating, or improving the care.

To meet clinical and managerial purposes performance measures may be presented in different ways and the Clinical Value Compass (CVC) and the quality model of Donabedian (Df) were applied to the QII in this thesis. The CVC was derived from a management customer area and originates from the Balanced Score Card. It offers a flexible framework in which the outcomes of healthcare are perceived in four dimensions: clinical, functional, satisfaction and cost. The Df derives the quality of care from the components structure, process and outcome. Structure denotes the attributes of the setting and includes the facilities, equipment, human resources and organizational structure. Processes are defined by what is actually done in delivering and receiving care, while outcome denotes the effects of care on the health status of patients and populations. It conveys a production management perspective and frames a delivery-focused approach to the organization. Altogether the Df offers a logistic, productive perspective on the studied case. Few individual or process measures nor quality frameworks were at hand within the care for IBD when this thesis was initiated.

**Inflammatory bowel disease**

Gastroenterology is the field of internal medicine involving the digestive system, which includes the five- to ten-metre long digestive tract, liver, pancreas and gallbladder. What is included in the clinical speciality differs between countries. In Sweden, gastroenterology care primarily serves patients with inflammatory bowel disease (IBD) celiac disease, peptic ulcer disease and certain liver conditions.

IBD refers to a group of disorders that causes the intestine to become inflamed. Disease onset is most common between the ages of 10 and 30 years, with a smaller peak between 50 and 60. Its cause is not fully understood, but research presents evidence suggesting an inappropriate immunologic response to intestinal microbes in genetically susceptible individuals as the main pathogenesis. IBD mainly consists of ulcerative colitis (UC) and Crohn’s disease (CD) which are both characterized by periods of active disease, relapses, alternating with remission. Symptoms common to both conditions include diarrhoea, rectal bleeding, urgent bowel movements, abdominal cramps, pain, fever and weight loss.
Inflammation in the intestinal tract can also cause symptoms in other organs, including red eyes or blurred vision, joint pain or swelling and skin rashes or ulcers 49. Patients with IBD with an inflammation of their colon extending beyond the left flexure at any time are at higher risk for colon cancer 50. In ulcerative colitis, inflammation is confined to the mucosa of the intestine wall and involves the rectum and may affect part of the colon in an uninterrupted way. In Crohn’s disease the inflammation is transmural, which may lead to complications not seen in ulcerative colitis, e.g. strictures or fistulas. It involves single or multiple sections of inflammation anywhere along the digestive tract from the mouth to the anus, though the distal part of the small intestine and colon, separately or in tandem, are most commonly affected. The life expectancy is in line with a healthy population.

**Diagnosis, treatment and effects of IBD**

Different investigations, assessments and tests are used to diagnose IBD, including laboratory blood tests for anaemia, white blood cell count and nutrient levels. Examination of the bowel is performed using endoscopy, which involves inserting a flexible tube with a video lens at the end of it into the intestine. This allows ocular assessment, which is supplemented with biopsies. Furthermore CT scans and MR can add valuable information in the diagnose and evaluation. Treatment generally includes long-term anti-inflammatory drugs such as aminosalicylates combined with optional treatments involving corticoid steroids, immunosuppressive and biological medication for more severe disease 51 52. Patients not responding to drug therapy, or who experience precancerous or cancerous changes in the colon, undergo surgery to remove all or parts of the colon. In the near aftermath of the colectomy patients are left with a stoma, requiring them to wear external bags to drain stool. If a permanent stoma is not acceptable to the patient a more permanent solution is arranged after some months. The small bowel may then be connected to the rectum in an ileorectal anastomosis, or a reservoir may be created by connecting the lower small bowel to the anal region. Anaemia associated with IBD is caused by a combination of the bone marrow suppressive effect due to chronic inflammation and blood loss from intestinal bleeding 53 54. The prevalence of anaemia associated with IBD varies from 8.8% to 73.7% in studies of both ambulatory and hospitalized patients 55. The individual may experience anaemia as loss of energy levels and overt blood in the stools 53 56. It is treated in the short run by oral or intravenous iron 57, blood transfusion or by raising the intensity of the preventive medical treatment 58.
The prevalence of IBD was close to 0.5% in high-incidence populations, but there is great variance both in a north/south gradient as well as between continents. This means that more than a million people in the US have IBD, accounting for 700,000 physician visits per year and 100,000 annual hospitalizations. In Sweden, approximately 45,000 individuals have IBD, with roughly 6,000 hospitalizations concentrated among 4,000 patients with IBD in 2007. The cost of the disease is derived from in- and outpatient care as delivered by the healthcare system, medication, work losses for the individual patient as well as societal costs such as work disabilities. Blomqvist et al. found that one-forth of patients accounted for 48% of hospitalizations in Sweden 1994 and figures from the Swedish Patient Registry showed a stable hospitalization rate for IBD patients 1998 to 2006. In Canada the hospitalization rate for IBD 1994 to 2001 was stable, 41.8 to 40.2 hospitalizations per 100,000 inhabitants, with an average length of stay 1994 to 2001 of 10.3 days to 9.1, according to Bernstein et al.

Few reports from a local population-based settings studying hospitalizations, rate of readmittances and length of stay had been presented at the time for our local QII. Patients with IBD in the local setting at the Highland Hospital were followed once a year by a visit to the outpatient clinic, which often included an endoscopy and proceeded by laboratory testing. In the Swedish healthcare system, patients with suspected IBD were referred from primary to secondary care to be cared for, with the exception of distal ulcerative colitis in some settings. However, no general model for follow-up care was available at the initiation of this thesis.

**To experience living with IBD**

The concept of health is multidimensional. In English, illness as from an individual perspective, sickness as deprived status from a societal perspective and disease as from the profession’s perspective reflect some of the complexity in expressing health from different perspectives. The perspectives on the concept of health can be simplified into mainly two: the disease-orientated defining health as lack of disease and the holistic perspective defining health as more than the lack of disease. The latter definition was proposed by the WHO in 1948: “We conceive health as being a state of complete physical, mental and social well-being, not merely the absence of disease or infirmity.”

A chronic illness is a medical condition of long duration, intertwined with the individuals life it affects. The use of “chronic” derives from the passing of time itself and “illness” is a concept covering a wider meaning including the experiences and psychosocial contexts of
those who live with it. The experiences of chronic illness develop from both manifest experiences of how a disease affects and changes a person’s life as well as latent ones, concerning identity, relationships and the understanding of the disease.

Health-related quality of life (HRQoL) is a measure of how patients experience their chronic disease and its impact on their life. Several questionnaires have been used within IBD care as means to analyse individuals and groups. One of them, the Short Health Scale (SHS), has been developed for IBD and consists of four questions associated with symptoms of the bowel disease, impairment of daily function caused by the bowel disease, disease-related worries and general well-being. It was showed to be sensitive and responsive to changes in disease activity in all its dimensions. Results are presented as individual scores for each question and has been used in the Swedish IBD Quality Register (SWIBREG) and was applied to the local IBD register as well as a means to detect patients with a deteriorating health.

Qualitative research is a means for exploring and understanding a human or social phenomenon by studying texts, experiences, thoughts, expectations and motives. In contrast to the well explored medical condition of IBD, few studies have reported on its sociological, psychosocial and practical issues and perspectives as experienced by the patient. Thus, there was a need to extend current knowledge.

Outcome in healthcare
There is a rich general knowledge of population health, wealth and well-being in relation to healthcare systems. In addition knowledge is available about to what extent healthcare systems contribute to the prevention of deaths from certain diseases. On the other hand there is a lack of systematic information from many countries about the extent to which evidence-based healthcare is delivered to the individual patient or groups of patients. However, McGlynn et al. reported from the US that 55% of the patients received the recommended care and that adherence to recommended procedures varied from 79% in senile cataract to 11% in alcohol dependency. The authors concluded that this poses a serious threat to the health of populations and thus joined those calling for better follow-up and improvement of the quality of care delivered.

Sweden, with a population of nine million, has achieved universal access to healthcare through a decentralized, tax financed system. The Health and Medical Service Act, Sweden’s
core healthcare legislation, assigned the responsibility for healthcare financing and delivery to the country’s 21 county councils or regions. The counties ranging in size from 60,000 (region Gotland) to nearly two million inhabitants (Stockholms County Council), fund primary and acute care services and have considerable autonomy to pursue their own healthcare strategies and priorities. In 2008 Sweden spent 9.4% of its GDP on healthcare, compared to over 15% in the US, 11.1% in Germany, 8% in the UK and 7.4% in Finland.

The Swedish healthcare system has in the past been recognized internationally due to its inclusion of all residents and its equal distribution of care. At the beginning of this millennium, “open comparison” of process and outcome data from healthcare began on a national level in Sweden, conducted by the Swedish Association of Local Authorities (SALAR) and the Swedish National Board of Health and Welfare (SoS). From the start, great variation was detected in the distribution as well as the consumption of care in the country. The reports showed problems with access, safety and patient involvement. This was detected in different areas of care such as hip fracture, acute myocardial infarction and cancer. Data in open comparison were partly derived from clinical quality registers, which often had been initiated and developed by clinicians in national cooperation. To further enhance the development of outcome measures through the quality registers an agreement about considerable financial support was made between the government and SALAR.

**Outcome in IBD care**

Internationally a wide range of stakeholders reported a gap between the best possible care and the care delivered at the time. Some examples were the reports from McGlynn as mentioned above, the “Quality Chasm” presented by IoM and clinical registers and open comparison in Sweden. More practical suggestions were offered by the American Gastroenterology Association who stressed the need of the development and implementation of evidence-based quality measures in the management of GI disease, standardization of data collection and dissemination of best practices. However, few reports of this kind were to be found in the literature of outcomes and IBD. Reddy argued that the current state of IBD care was as follows in 2005:

> “patients with IBD often do not receive optimal medical therapy. In particular, there is suboptimal dosing of 5-ASA and immunomodulatory medications, prolonged use of corticosteroids, failure to use steroid-sparing agents, inadequate measures to prevent metabolic bone disease and inadequate screening for colorectal cancer.”
Several representatives of the IBD society have focused on this mission, but the practical implementation has shown to be difficult. Steps have been taken, however. Siegel et al. suggested applying the STEEEP vision to IBD care, as stated in an editorial in Inflammatory Bowel Disease. Further practical suggestions have been offered by Kappelmann i.e. to apply the Donabedian quality model in monitoring the quality of IBD care. Along with this, he suggested possible outcome measures to include: disease activity/remission rates, surgery, hospitalization, steroid exposure, QoL, disease complications, nutritional measurements and growth and development. Some of these measures are further explored, tested and evaluated in this thesis.

A main driver for the improvement efforts and this research was that in 2000, there was a frustration at the traditional outpatient clinic for gastroenterology at the Department of Internal Medicine since waiting times for patients were long for both planned and acute visits and as access was poor leaving patients with the sole alternative of seeking help at the Emergency Department resulting in short admittances to hospital. This situation did not meet the needs of the patient who did not experience the continuity of care they were entitled to. In addition, there was no system available to monitor processes or results of the care delivered.
Aim and Objectives

General aim
The aim of this thesis is to describe, study and evaluate a quality improvement intervention in the care for patients with IBD in a population-based setting, with special reference to clinical redesign, performance measures and patient experience.

Specific aims

- To describe, study and evaluate the transformation from traditional, mainly physician-focused, IBD care to patient- and demand-directed care. (Study I)

- To create a framework for quality assessment of the care for IBD, based on two generally held quality frameworks; and to apply, study and evaluate its application in a local clinical IBD care setting. (Study II)

- To analyse the prevalence of anaemia in ambulatory as well as hospitalized patients diagnosed with IBD in the Highland Health Care District, Jönköping County, Sweden. (Study III)

- To explore patients’ experiences of chronic illness in the case of IBD. (Study IV)
Methods

Setting

Jönköping County is located 320 km southwest of Stockholm and has a population of 333,000 inhabitants. The county’s healthcare system employs over 9,000 workers and is divided into three health areas, each of which includes a county-run hospital and a mix of publicly and privately run primary care centres. The healthcare system covers the whole population and is financed by taxes and a small out-of-pocket payment. One of the three health areas in Jönköping County, the Highland health area, is responsible for providing primary and secondary healthcare services to 110,000 residents across six municipalities. In 2008 the Highland health area was the largest local employer, with a staff of 2,200 clinicians and administrative personnel.

The Highland District County Hospital is located in the small city of Eksjö, a historic military town of 10,000 residents. It is the only hospital in the healthcare area. During its first year of operation in 1867, Highland Hospital admitted one patient. In 2008, the 280-bed hospital admitted 15,842 patients and employed 1,700 salaried health professionals and administrative staff. The gastroenterological unit, part of the Department of Internal Medicine at Highland Hospital, is responsible for all patients diagnosed with IBD in the area. The unit includes an outpatient clinic, a ward with 15 beds and an affiliated unit for endoscope procedures.

Participants

The patient population is this thesis was recruited from the gastroenterological unit at the Department of Internal Medicine, Highland Hospital, in Eksjö and are presented in Table 6. In Studies (I–III), all known patients with IBD were included. In Study (IV), a purposeful sample of the population was performed.

All patients diagnosed with IBD at the unit were recorded in a local register from 2001 and onwards, as shown in Figure 1. The register included name, gender, year of debut, disease duration and diagnosis for all patients. All diagnoses in the register were confirmed by a senior gastroenterologist. UC was subtyped into “extensive”, “left-sided”, “proctitis”, “previously surgically treated” and “unclear extension”, while CD was subtyped into “colon”, “small bowel”, “colon and small bowel” and “unclear extension”. Patients with “unclear extension” were excluded from the analyses of subgroups due to the small number (UC, n=3;

25
Data from the yearly follow-up were added to the register by the nurse or physician at the time of the contact.

**Haemoglobin, medication, QoL and hospitalization**

The cut-off point for haemoglobin (Hb) levels representing anaemia was defined as <120g/l for both men and women in Studies I and II. In Study III, anaemia was defined as Hb <130 g/l in men and <120g/l in women, according to WHO standards 57,92. Severe anaemia was defined as Hb < 100 g/l, in both men and women (I, II, III).

The patients’ medication related to IBD was recorded in the register and classified as 5-ASA, continuous cortisone, immunosuppressives or anti-TNF-α (I, II and III).

Quality of life (QoL) was measured by using the Short Health Scale (SHS) 77,78. The SHS items were evaluated according to a six-point Likert scale, with a score of 1 to 3 (no, light or moderate symptoms/function/worries/well-being) indicating that the goals for patient care has been achieved and a score of 4 to 6 (rather severe, severe, very severe symptoms/function/worries/well-being) indicating that the goals had not been achieved (I, II and III).

Data regarding hospitalization were collected by searching the hospital-based computerized case record system for UC and CD (ICD codes K50 and K51) in the first, second or third diagnosis heading of the discharge notes from the Departments of Medicine and Surgery. All notes were evaluated by the author of this thesis. Only hospitalization related to IBD was included (I, II, III). In addition, Hb count on the day of admittance was collected from the case records (III).

**A framework for the research design**

The presentation of the research design of this thesis is inspired by a framework presented by Creswell 93. The framework describes how different research designs relate to and interact with different worldviews, strategies of inquiry and research methods. Taking all the four papers together, they draw on a mixed methods approach in a sequential design inspired by a pragmatic worldview 93. Quantitative strategies of inquiry include experimental and non-experimental designs. Experiments seek to find a causal effect of a treatment, for example, while non-experimental approaches rely on surveys, cross-sectional and longitudinal questionnaires and structured interviews for data collection. Qualitative strategies of inquiry include the study of a phenomenon and other examples are case studies, which explore a programme in depth by collecting detailed various information over a bounded timeframe as
the case presented in the appendix. Research methods involve data collection, analysis and interpretation. These are found along a continuum from quantitative methods using instrument-based questions, often examined through statistical analysis, to qualitative methods involving interviews or text and document material, often analysed through interpretation for themes or patterns.

Table 1 offers an overview of the research designs and the associated strategies of inquiry, research methods, data collection, analytical approaches, studied population and time frame of this thesis.

<table>
<thead>
<tr>
<th>Study</th>
<th>Selected strategy of inquiry in the research design</th>
<th>Research Methods</th>
<th>Studied population</th>
<th>Time range of the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.</td>
<td>Descriptive qualitative case study and non-experimental-based survey</td>
<td>Data collection: Instrument-based questions applied to QII and performance data from hospital based computer system were collected over time</td>
<td>Analysis and interpretation: Case study analysis and retrospective descriptive trend analysis combined with statistical analysis</td>
<td>A population of all patients affiliated to the gastroenterological unit</td>
</tr>
<tr>
<td>II.</td>
<td>Qualitative theory building and non-experimental survey</td>
<td>Data collection: Two quality models were merged into a framework. Performance data from the local IBD register and computer based system.</td>
<td>Analysis and interpretation: Test of framework, a qualitative interpretation. Descriptive analysis combined with statistical analysis</td>
<td></td>
</tr>
<tr>
<td>III.</td>
<td>Non-experimental survey</td>
<td>Data collection: Performance data from the local IBD register and computer based system.</td>
<td>Analysis and interpretation: Retrospective descriptive analysis combined with statistical analysis</td>
<td></td>
</tr>
<tr>
<td>IV.</td>
<td>Qualitative</td>
<td>Data collection: Semi-structured interview data</td>
<td>Analysis: Content analysis</td>
<td>A purposeful sample of twenty patients with IBD affiliated to the gastroenterological unit</td>
</tr>
</tbody>
</table>

**Table 1.** An overview of the research designs and the associated strategies of inquiry, research methods, data collection, analytical approaches, studied population and time frame of this thesis.

**Methods**

**The quality improvement intervention**

The situation at the gastroenterological unit in 2000 called for a change because of long waits, no continuity of care, unnecessary hospitalizations and lack of a system for quality assessment of the care. It started with an invitation of all staff at the unit to join a week-long conference.
There, time was provided to reflect on the ethical and moral foundation of the care delivered and suggestions for new solutions were requested. The situation inspired the initiation of a redesign of the outpatient unit into being more patient- and demand-directed. A major redesign was launched, with a focus on increasing the value of the delivered care at the right level, at the right time, by creating a trustful and long-term relationship with the patient. Staff were further to act as consultants to the patient in their mutual responsibility for the chronic disease. The main components of the redesign were:

- A specialist nurse and her assistant staffed the outpatient clinic full time on weekdays.
- The nurse could offer patients who contacted the clinic an acute visit at the outpatient clinic within two days.
- Yearly check-ups were offered as either a telephone call or a traditional visit to the clinic.
- A letter to the patient preceded the yearly check-up and included a QoL questionnaire as well as instructions for laboratory testing of Hb.
- The application was iterative and interactive following the PDSA methodology.

The quality improvement intervention (QII) is described in detail in the Harvard Business School study case: Gastroenterology Care in Sweden\(^2\), presented in the appendix 1.

**Methods for the study of the QII (I)**

The overall research design of Study I was descriptive, with quantitative elements. It applied a non-experimental strategy of inquiry to a population of all known patients affected by IBD who were affiliated with the gastroenterological unit in the healthcare area. It applied a multidimensional quality tool to assess the quality of care. The applied Clinical Value Compass (CVC) included four clinical outcome dimensions; clinical, functional, satisfaction with care and resources or cost\(^95\). Added to the CVC were already existing measures. The chosen measures were defined as follows; *clinical* - laboratory tests of haemoglobin, *functional* – SHS, *satisfaction* – service survey of the outpatient clinic and *resources / cost* - hospitalization. The yearly collected data were entered into a computerized local IBD register. Data on access, waiting lists and hospitalization were registered yearly. The Study applied a retrospective, descriptive trend analysis combined with a statistical analysis. The time frame of the data was 1998 to 2006.
Methods used to create a quality framework (II)

In Study II two quality models, the Clinical Value Compass and the quality model of Donabedian (Df)\(^6\), were merged to create a new quality framework for IBD. The framework functioned as a pedagogical tool to better understand the dimensions and components of clinical care. In the evaluation it was found to reflect important parts of the IBD care delivery system in a local setting.

Corresponding data on the whole population of patients affected by IBD affiliated with the gastroenterological unit during 2008 were collected and applied to the framework. The overall research design of Study II was a sequential mixed method and applied qualitative theory-building and a non-experimental strategy of inquiry.

Methods in Study (III)

Data from two sources were used. The first source was the local IBD register and its data from the yearly check-up which consisted of laboratory testing, QoL, currently prescribed medication and an estimate of the number of relapses of the disease since last check-up. The second source was the hospital-based computerized case record system from were data about hospitalizations and Hb at admittance was retrieved. The analytical approach was retrospective, descriptive analysis combined with a statistical analysis. The overall research design of Study III was quantitative. It applied a non-experimental strategy of inquiry to a population of all patients affected by IBD affiliated with the gastroenterological unit during 2008.

Methods in Study (IV)

The overall research design of Study IV was qualitative. It applied qualitative interviews to a purposeful sample\(^7\) of 20 patients selected from the local database during 2007 to 2008. This allowed the experiences of men and women, with different ages, diagnoses and medications as well as durations of disease to enrich the narratives. They were invited to take part in the study by a formal letter, which explained the purpose of the study, the meaning of consent, confidentiality and assured anonymity in future presentation and informed them of their option to withdraw from the study at any time without giving a reason. They accepted the invitation by replying with a prepaid envelope, which was sent to one of the researchers who had never worked at the current care unit. This researcher checked in the electronic records for any previous contact between the informant and the author of this thesis in the electronic records. If there had been previous contact the informant was interviewed by the researcher not working at the outpatient clinic. After a second inclusion phase to further enrich the
material, additional informants were offered an interview, providing a total of 20 informants who were included in the study. With a few exceptions, the interviews were held at the home of the informant. The informants were asked to tell about their experiences with the illness and to provide narrative episodes. An interview guide outlined broad, open-ended questions, which allowed informants to describe their perceptions and experiences of their disease. The interviews were recorded in Swedish and were transcribed verbatim. After each of the two inclusion phases, the interviews were replayed and discussed by the researchers. As the aim was to study the manifest experiences of the lived experiences of patients with IBD, a qualitative content analysis was chosen. The analysis was conducted through systematic text condensation, inspired by Malterud. Preliminary themes were identified and revised, starting with listening to and reading all interviews to obtain a good grasp of the entire content, with the intent of restraining preconceptions. Secondly, units of meaning representing different aspects of the participants’ experiences of living with IBD were identified and coded. The coding was done by the author of this thesis and the findings were constantly modified and compared as the analysis continued. Thirdly, each coded group was condensed and its contents summarized. Fourthly, the emerging generalizing concept of the experience of what it means to live with IBD was formed.

**Statistics**

Descriptive statistics were applied to describe the population and sub populations (I-III). No age adjustment was made (I, II and III). SPSS 19.0 was used for statistical analysis. Unbalanced ANOVA was used to test for differences between groups and multiple statistical analysis was compensated for by Scheffe. Chi-squared test was used to test for differences between groups with ordered categorized data. A p-value lower than 0.05 was considered statistically significant.
Ethical considerations

In this thesis I have made an effort to conduct research according to the Declaration of Helsinki. This included written and verbal information to informants included (IV). Signed consents were used as presented above and efforts have been put into guaranteeing that informants cannot be recognized in the material. The studies were approved by the ethical committee at the University of Linköping.

Rigour of the research

The assumption of trustworthiness is the same irrespective of the applied research design. It is based on research values which are the same, but are different in linguistic terms (Table 2).

| Terms used in the assessment of the concept of trustworthiness of research |
|-----------------------------|-----------------|---------------------|
| Quantitative               | validity        | reliability         |
|                             | generalizability|
| Qualitative                | credibility     | dependability       |
|                             | transferability |

TABLE 2. An overview of the relationship and terms used in the assessment of the concept of trustworthiness of research.

Validity or credibility is a question to raise at every phase of the research plan and its relevance can be noted in several ways. Kvale suggests the questions of “What? Why? and How?” as to be companions throughout the research. Validity and credibility take into consideration the current correspondence to previous findings as well, questioning whether standardized units have been used or whether a survey has been tested for cultural differences and language. In qualitative work, credibility is even more challenging as data are communicated in a cultural and societal setting. This challenges the judgment of the researcher in explaining the design, goals and processes. There is also an expectation of science to be reliable or dependable. This is built on the accuracy in collecting data, whether alternative ways have been considered and whether the analysis and conclusions are actually grounded in the empirical data. This is best achieved by making an informed companion of the interested reader of the paper and thus attaining inter-subjectivity. The concept of generalizability or transferability can be discussed as an issue of applicability in both quantitative as well as qualitative designs. In what context are the results useful and applicable? Further, one should not forget to reflect on the originality of the research; if similar studies have been performed, it may be better to turn to other interesting areas.
Results

Participants
The inclusion of patients in the register started in 2002, as shown in Figure 1. The prevalence of IBD, 441/100000, was slightly lower than expected, including a cautious overweight of men. Patients with CD showed significantly longer disease duration and a lower body mass index (BMI) compared to UC. A total of 485 patients with IBD had been registered at the gastroenterology unit by the end of 2008.

The study of the QII (I)
The QII as designed by the interprofessional IBD care team included the following new services: A direct telephone line for patients to a specialized nurse available during working hours; appointments scheduled in accordance with expected needs and acute appointments available daily; traditional follow-ups of patients with IBD were replaced with yearly telephone contact with a specialized nurse.

As shown in Figure 1, the IBD register grew over the years to stabilize as the study was completed. In 2006, 338 patients with UC or CD were included in the register. Figure 1 shows the time of implementation of other parts of the QII as well.

The waiting times for patients referred to the unit and for gastroscopy were as shown in Figure 2. This measure of access was used as a proxy for patient satisfaction.

The total number of unique patients and the total numbers of patients with IBD, admitted to the ward, i.e. hospitalization, was used as a proxy for the cost dimension decreased, as shown in Figure 3a and 3b. Compared to national data, the decrease in unique numbers of individuals admitted and the numbers of occasions of inpatient care were greater at Highland Hospital than nationally, as shown in Figure 3a and 3b. Observations about the route of admittance to hospital showed a shift from unplanned to planned hospitalizations via the outpatient clinic, which was interpreted as an effect of the improved access to clinic visits.

The proportion of patients with Hb above 120 g/l and scores from 1 to 3 in the SHS are shown in Table 4a and 4b. Except for questions on “function” and “worry” regarding CD patients which showed no less than 84% any year, more than 92% of the patients scores from 1 to 3 on a Likert scale for QoL and > 120 g/l for Hb. During 2004/2005 both the UC and CD population reached above 95% having Hb > 120 g/l. Haemoglobin and SHS showed stable
FIGURE 1 A visualisation of the time when assessment of numbers of hospitalizations or inpatients, the introduction of a patient- and demand-directed care, the start of the local IBD register and its growth over time and of the introduction of patient surveys were implemented.

FIGURE 2. Waiting times for patients referred to the unit for an assessment at the outpatient clinic and for gastroscopy at the gastroenterological unit at the Department of Internal Medicine at the Highland Hospital, Eksjö, Sweden.

FIGURE 3. Waiting times for referrals and gastroscopies.
FIGURE 3a and 3b. The total number of unique patients and the total numbers of patients with inflammatory bowel disease admitted or hospitalized at the Medical or Surgical Department at the Highland Hospital, Eksjö, Sweden, compared to national data as normalised to 1998 years level.

TABLE 4a and 4b The proportion of patients achieving the goals of care with Haemoglobin above 120 g/l and Quality of Life scores from 1 to 3 in the Short Health Scale at the yearly check-up at the gastroenterological unit at the Department of Internal Medicine at the Highland Hospital, Eksjö, Sweden.
processes on group level over the years. The results of the service survey from the outpatient clinic was representing the satisfaction dimension in the value compass and showed no change over time.

A framework for the evaluation of IBD care (II)

This study presents how two generally held quality models with integrated clinical quality measures could be merged to create a quality framework. The framework was then tested in clinical practice to a local area-based IBD population. The main outcome was that the evaluation of the framework proved to be helpful in organizing quality measures when applied to IBD care, as shown in paper 1, page 1088 in the back of this thesis.

The framework created a pedagogical tool for understanding the balance between the components of clinical outcome through the Donabedian quality model (Df) and the dimensions of clinical care in the Clinical Value Compass (CVC). The combination of the two frameworks reflected important parts of the IBD care delivery system in a local setting. Further individual quality measures, such as haemoglobin and number of hospital admittances, could be retrieved from existing data sources and integrated into the framework. The selected quality measures and the framework are presented in Table 5.
TABLE 5 Selected quality measures from 2008 reflected important parts of the IBD care delivery system in a local setting at the gastroenterological unit at the Department of Internal Medicine at the Highland Hospital, Eksjö, Sweden.

<table>
<thead>
<tr>
<th>Patient data</th>
<th>Quality measures from 2008</th>
<th>Crohn’s disease</th>
<th>Ulcerative colitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnose</td>
<td>194</td>
<td>261</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td># woman: man</td>
<td>44%:56%</td>
<td>42%:58%</td>
</tr>
<tr>
<td>Age</td>
<td>Mean (SD)</td>
<td>53(±15)</td>
<td>53(±15)</td>
</tr>
<tr>
<td>Range</td>
<td>18-90</td>
<td>20-91</td>
<td></td>
</tr>
<tr>
<td>Disease duration</td>
<td># Years since time of diagnose</td>
<td>20(±13)</td>
<td>14(±10)</td>
</tr>
<tr>
<td>Laboratory measures</td>
<td>Hemoglobin, Mean(SD)</td>
<td>140(±12)</td>
<td>143(±13)</td>
</tr>
<tr>
<td></td>
<td># normal ≥120 g/l</td>
<td>95%</td>
<td>96%</td>
</tr>
<tr>
<td></td>
<td># anaemia 100 -119 g/l</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td></td>
<td># severe anaemia &lt; 100 g/l</td>
<td>16%</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td># missing</td>
<td>16%</td>
<td>17%</td>
</tr>
<tr>
<td>Medication</td>
<td>Prescribed medicine</td>
<td>43%</td>
<td>56%</td>
</tr>
<tr>
<td></td>
<td># 5-ASA</td>
<td>10%</td>
<td>4%</td>
</tr>
<tr>
<td></td>
<td># cortisone</td>
<td>34%</td>
<td>12%</td>
</tr>
<tr>
<td></td>
<td># immunosuppressives</td>
<td>8%</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td># anti-TNF-alpha</td>
<td>31%</td>
<td>40%</td>
</tr>
<tr>
<td></td>
<td># no medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical interventions</td>
<td>Incidence of surgery</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Type and numbers of surgical interventions:</td>
<td># colectomy</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td># hemi colectomy</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td># loop colectomy</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td># perianal/fistula/stricture incision</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td># revision abdominal scar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tumor incidence</td>
<td># Number and type of intestinal tumours associated with IBD</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>according to diagnosis in records as ICD code</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Quality of life</td>
<td>The Short Health Scale: WHS</td>
<td>95%</td>
<td>98%</td>
</tr>
<tr>
<td>Percent scoring 1 to 3 representing that the goal of the care was reached</td>
<td># symptoms</td>
<td>88%</td>
<td>95%</td>
</tr>
<tr>
<td></td>
<td># functioning</td>
<td>93%</td>
<td>94%</td>
</tr>
<tr>
<td></td>
<td># worry</td>
<td>97%</td>
<td>96%</td>
</tr>
<tr>
<td>Access to care</td>
<td>Waiting time</td>
<td>Number of days from the referral being sent from the primary care physician until the patient received a scheduled consultation at the outpatient clinic</td>
<td>&lt; 3 weeks</td>
</tr>
<tr>
<td></td>
<td>The clinic’s ability to offer an acute visit within two days after contact for known patients with IBD</td>
<td>&lt; 2 days</td>
<td>&lt; 2 days</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>ERS documented ICD code for IBD and hospitalization</td>
<td>29</td>
<td>17</td>
</tr>
</tbody>
</table>
Anaemia in IBD care (III)

Characteristics of the patients with IBD at the outpatient clinic in 2008 are presented in Table 6. The mean Hb level of patients with CD was significantly lower than that of patients with UC at the yearly assessment in 2008. This significant difference was not found in the studied subgroups of the disease. Concomitantly, the prevalence of anaemia was 5% for patients with UC and 9% for those with CD.

Anaemia at the annual check-up was more common in patients requiring inpatient care during anytime during the year (19.0% vs. 5.7%, p=0.015). When a sub-analysis was performed regarding UC and CD, there was a trend for more anaemia seen in patients with CD but not with UC (CD 25.0% vs. 8.2%, p=0.055; and UC 11.1% vs. 4.3%, p=0.340). The number of patients in this analysis was small, however, so results should be interpreted with caution.

Patients who received treatment with anti-TNF-α had a higher prevalence of anaemia than those without this treatment (25.0% vs. 5.4%, p<0.01), probably owing to more severe disease in patients who were recommended this treatment. The same result, regarding anaemia and anti-TNF-α treatment, was found when anaemia in UC and CD were analysed separately. In patients who received other IBD medications, such as 5-ASA, continuous cortisone and immunosuppressives, no correlation with anaemia frequency was found, neither in IBD in total nor when the diagnosis were subdivided into CD and UC.

In patients with CD, anaemia was connected to a worse SHS score; i.e. fewer patients with anaemia reached the set goal regarding well-being (33.3% vs. 5.5%, p=0.046). Functional measures showed a tendency towards a similar correlation (17.6% vs. 5.2%, p=0.058). No such correlations were found in patients with UC.
TABLE 6 Characteristics, self reported relapses, medication, SHS and hospitalisations of the patients with IBD at the outpatient clinic in 2008.

<table>
<thead>
<tr>
<th></th>
<th>Crohn’s disease</th>
<th>Ulcerative colitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>196</td>
<td>289</td>
</tr>
<tr>
<td>Prevalence (per 100 000)</td>
<td>178</td>
<td>263</td>
</tr>
<tr>
<td>Age, years (mean±SD)</td>
<td>53 ±15</td>
<td>51±15</td>
</tr>
<tr>
<td>Age, years (range min-max)</td>
<td>18–90</td>
<td>20–91</td>
</tr>
<tr>
<td>Female/male (%)</td>
<td>44 / 56</td>
<td>42 / 58</td>
</tr>
<tr>
<td>Disease duration, years (mean±SD)</td>
<td>20±13*</td>
<td>14±10*</td>
</tr>
<tr>
<td>Disease duration, years (range min-max)</td>
<td>0–58</td>
<td>0–53</td>
</tr>
<tr>
<td>BMI, kg/m2 (mean±SD)</td>
<td>25± 4*</td>
<td>26± 4*</td>
</tr>
<tr>
<td>Self-reported relapses in 2008 (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>70%</td>
<td>68%</td>
</tr>
<tr>
<td>1-2</td>
<td>18%</td>
<td>23%</td>
</tr>
<tr>
<td>3 or more</td>
<td>12%</td>
<td>9%</td>
</tr>
<tr>
<td>Haemoglobin (Hb), g/L (mean±SD)</td>
<td>140±12*</td>
<td>143±13*</td>
</tr>
<tr>
<td>Anaemia (%)</td>
<td>9%</td>
<td>5%</td>
</tr>
<tr>
<td>Hb missing</td>
<td>17%</td>
<td>10%</td>
</tr>
<tr>
<td>Medication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-ASA</td>
<td>44%*</td>
<td>56%*</td>
</tr>
<tr>
<td>Immunosuppressive</td>
<td>33%*</td>
<td>13%*</td>
</tr>
<tr>
<td>Cortisone</td>
<td>17%*</td>
<td>45%*</td>
</tr>
<tr>
<td>anti-TNFα</td>
<td>8%*</td>
<td>2%*</td>
</tr>
<tr>
<td>None</td>
<td>31%*</td>
<td>40%*</td>
</tr>
<tr>
<td>SHS (score of 1–3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom</td>
<td>93%</td>
<td>98%</td>
</tr>
<tr>
<td>Function</td>
<td>88%*</td>
<td>94%*</td>
</tr>
<tr>
<td>Worry</td>
<td>91%</td>
<td>94%</td>
</tr>
<tr>
<td>Well-being</td>
<td>97%</td>
<td>96%</td>
</tr>
</tbody>
</table>
Table 7 shows the number of individuals admitted to hospital and the total number of hospitalizations for the IBD population together with the anaemia rate on the day of admittance. Of the total IBD population, 6% (31/485) of the individuals were hospitalized in 2008. Of these, 30% (10/31) were readmitted any time during the year. In total, 44% of the hospitalized patients with IBD had anaemia including 4% with severe anaemia at admittance. Of the patients with UC admitted to the hospital 35% (n=6) had anaemia and of these one patient had severe anaemia. Of the patients with CD admitted to the hospital 50% (n=14) had anaemia and of these one had severe anaemia. No significant difference was observed between patients with UC and CD regarding anaemia frequency at admittance. Relatively few patients were hospitalized, however, so these results should be interpreted with caution.

<table>
<thead>
<tr>
<th></th>
<th>Inflammatory bowel disease (IBD)</th>
<th>Crohn's disease</th>
<th>Ulcerative colitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of hospitalizations due to IBD</td>
<td>46</td>
<td>29*</td>
<td>17*</td>
</tr>
<tr>
<td>Number of individual patients hospitalized (percent of all patients)</td>
<td>31 (6.4%)</td>
<td>18 (9.2%)*</td>
<td>13 (4.5%)*</td>
</tr>
<tr>
<td>Days in hospital (mean±SD)</td>
<td>3.9 ±4.2</td>
<td>2.8 ±2.7*</td>
<td>5.7 ±5.7*</td>
</tr>
<tr>
<td>Hb at admittance (mean±SD)</td>
<td>131±23</td>
<td>131±21</td>
<td>132±26</td>
</tr>
<tr>
<td>range (min-max)</td>
<td>64-166</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaemia at admittance#</td>
<td>44% (n=20)</td>
<td>50% (n=14)</td>
<td>35% (n=6)</td>
</tr>
<tr>
<td>Severe anaemia¤</td>
<td>4% (n=2)</td>
<td>4% (n=3)</td>
<td>6% (n=1)</td>
</tr>
</tbody>
</table>

TABLE 7 The number of individual patients admitted to hospital and the total number of hospitalizations for the IBD population together with the anaemia rate on the day of admittance to the Medical or Surgical Department at the Highland Hospital, Eksjö, Sweden.

Living with IBD – the patient perspective (IV)

The main finding of the analysis was the description of how living with IBD was experienced as “always considering the potential need for a toilet”. This description emerged from three main themes of the analysis: The experience of what it is like to be affected by the disease; the accompanying consequences of the illness; and the adaptation required to restore one’s normal life.
The experience of being affected by the disease

The results present a rich collection of narratives about how the destiny of the informant’s life was questioned when he or she was struck by the disease. The healthy and socially stable life situation of young adults was interrupted. This went along with experiences of denial and a delay of recognition of the growing disease:

“... Yes, I had an aching stomach and had to go to the bathroom all the time. In the end, I slept poorly and I couldn’t sleep all night as I had to go to the bathroom several times. But I did work, after all. I made it and went to work practically every day, except when I hadn’t slept at night.” (Informant #16)

The accompanying consequences of the illness

As daily life went on, there was also a need to be aware of the closest toilet. The consequences became overt as time passed. The main worry or concern presented in this study is the experience of a lack of control associated with the lack of predictability of one’s bowel function, as well as the physical distress connected with the intimidating feeling of being dirty. Physical needs could force the individual into the wild to find privacy. Others told of situations when failure left them with soiled underwear:

“... I certainly think that’s the worst: if you’re standing there and know you don’t have time...” and “Yes, I always bring extra underwear and trousers. And wipes so I can wash myself. Without this kit I go nowhere.” (Informant #18)

Further, the endoscopy assessment seemed to be a critical venue for determining future relations and trust. Over time, the informants learned to identify the early signs of a relapse, which could possibly subside without having a significant impact on their everyday life. When experiencing suspicious symptoms, most informants tended to try previously prescribed self-treatment so that contact with the clinic could be postponed. One reason for this was a more or less conscious wish to avoid an endoscopic examination, which was generally recommended by the staff in such situations. This examination was described as causing a diffuse, oppressive pain in the stomach combined with the feeling that one has to defecate the entire time. Some felt that the examination resulted in even more discomfort each time and dreaded the pain.

The situation was no better if the examination was experienced as being conducted in an abrupt and heavy-handed way. A few said that the unfamiliar devices in the examination room were frightening and did not want to be left alone there. Many felt that the discomfort that
arose in connection with the examination was minimized if they were given time by the staff and the examination was performed with great care. When treated in this way the examination was often carried out without much difficulty or pain and after rest and refreshments most informants felt like they could go home.

The greatest concerns were mainly about having surgery, a loss of energy and an altered body image, for instance if one had an enterostomy bag:

“After ostomy surgery my bowel habits became more normal, not having to run and locate toilets and always feeling on the go because you have to have a toilet nearby. So it was much easier even though you have to bring the stoma stuff. So, that’s the big difference really.” (Informant #6)

**Adaptation required to restore one’s normal life**

The informants told of the everyday work dealing with the consequences of the disease, associated with self-care, daily work tasks, the social situation and employment.

The adaptation to life after having experienced this striking disease with all its consequences led to the development of new attitudes and approaches to one’s own body, social situation and loved ones and the context often referred to as the healthcare system. Disease symptoms could often cause the informant to feel irritable and tired, which in turn led to nonparticipation in daily family life. In these situations, the informant’s life-mate and/or other adults in his or her life needed to step in with a helping hand and these people were experienced as invaluable during these periods. They could mostly manage the transition well and the situation often created a special closeness between the family and friends.

The disease itself was not experienced as having any higher meaning, though the illness did lead to a greater understanding of others in similar situations, with the result that the informants felt less sorry for themselves. In addition, they had learnt to accept help from their relatives.

“I haven’t had much trouble from the disease and really don’t mind taking medication regularly. It’s worth it to take medicine to prevent relapses. You have to try to actively take advantage of what you can do and try to enjoy life.” (Informant #8)

Knowledge about the disease was most often gained in contact with staff. Several informants said that the images on the monitor during the endoscopic examination provided valuable visual impressions, leading to a better understanding of the disease. Other sources of information were the Internet and friends.
Discussion

Main contributions of the thesis
The main contribution of this thesis is the overall example of how a QII including continuous performance measures and patient involvement can be applied to and studied in a local population-based setting. Further it responds to international calls for quality improvement efforts to bridge the quality gap in the delivered care of IBD (I-IV).

The focus of the study is on the clinical microsystem (CMS) in relation to the population, not the individual patient. However, in the future an individual perspective may take its starting point in the studied case, as it was an example of a CMS ready for and capable of change and redesign. Further, it followed the effects of a registry with balanced performance measures and strove to seek deeper insight regarding patients’ experiences of living with IBD.

The studied CMS at the local outpatient clinic for the care of patients with IBD was redesigned based on a local vision, and the redesign was implemented through iterative implementation cycles, thus exemplifying a quality improvement intervention (QII). To be able to learn from the implementation of improvement, the QII needed to be studied. First, a study of the redesign demanded the introduction of a local quality register. Secondly, simple, practical and already-existing measures were retrieved from existing data sources and applied to the clinical value compass model (CVC), which allowed the redesign to be monitored over time. Later, the CVC and the Donabedian quality model (Df) were merged into a quality framework (II), which was created to offer a tool for assessing the overall quality of care (II).

One of the performance measures, Hb, was studied to detect the prevalence of anaemia (III) as well as its relation to other measured dimensions. The last study took on the patient’s perspective of what it means to live with IBD, with the main finding that living with IBD was experienced as living with a constant awareness of the possible need for a toilet; another finding entailed opinions on care situations, for instance endoscopy which was burdensome (IV). The last study also provided inspiration for further redesign directed by patients’ experiences.
The quality improvement intervention
At the time of the redesign the QII represented an alternative approach to the care and follow-up of IBD. To meet predictable criticism of the patient- and demand-directed care, the responsible care team decided to create and use register data to monitor the quality outcomes of the intervention. No national or international consensus was at hand regarding what quality meant within the IBD care society, and relevant outcome measures were also difficult to define.

The content of the redesign was largely determined within the interprofessional staff group and was introduced as a QII without an initial plan for evaluative research. In the words of Batalden: it was set up to make improvements, not to study how the intervention was carried out or whether or not the changes were improvements. This is regrettable, as a deeper inquiry from the start would have deepened the understanding of the mechanisms of the redesign. It is also the main reason why three of the presented studies are retrospective. The QII was introduced in iterative cycles, and outcome measures were found to change but then stabilize over time. This probably reflects that the new processes of care were stable after the two intensive starting years of the redesign, which fits with the often quoted phrase “every system is perfectly designed to get the results it gets”.

The redesign (I) was named “a patient- and demand-directed care”, and we later discovered that the local principles had several similarities with the STEEEP vision set up by the IoM. One example is that access to care was a main driver for improving the processes; a more patient-centred approach is another. Our findings of high satisfaction with yearly check-ups via telephone is approved by Krier et al. reporting of similar patient satisfaction between telemedicine and clinical encounters. Examples of elements from the local QII and their connection to the “new rules” for healthcare which emerged from the Institute of Medicine’s STEEEP vision are presented in Table 8.
Previous approach | New rule | Examples from the redesigned care
--- | --- | ---
Care is based on visits. | Care is based on continuous healing relationships. | Open access to clinic.
Professional autonomy drives variability. | Care is customized according to patient needs and values. | Visits are offered at the clinic or by telephone.
Professionals control care. | The patient is the source of control. | Both parties are mutually responsible for taking contact.
Secrecy is necessary. | Transparency is necessary. | Mutual responsibility for the care of the disease.
The system react to needs. | Needs are anticipated. | New strategy for place and form of visits implemented.
Cost reduction is sought. | Waste is continuously decreased. | Fewer hospitalizations.

**TABLE 8** Examples of elements from the local QII and their connection to the "new rules" for healthcare which emerged from the Institute of Medicine’s STEEP vision.

The STEEP vision can be articulated, but how is it translated to care for individual patients and populations? The “five Ps” model, created by Nelson et al.\(^{105}\), suggests an anatomy of the context of care by identifying the patients, purpose, professionals, processes and patterns in the CMS. The CMS, together with five Ps, offers a model for understanding the relationship between the healthcare system, the individual patient and the context in which patients and professionals meet.

**The applied models**

The approach of having the patient as the starting point connects the CMS model to the studied QII in this thesis. As part of the local care model, professionals joined the patient in a mutual responsibility for the care of the disease. The care model stated that the professional with the best competence should be directed to meet the needs of the patient who contacted the clinic. The Ps, as described in the CMS, can be found in several parts of this thesis. The patient population was described (I and III), the purpose was redefined as guided by new rules (I), the redesigned processes were presented and studied (I), professionals adhered to the redesign (I), and individual performance measures formed patterns as they were tested in a framework (II-III). Together, they offered a model to better understand and to study the patient’s relationship with the surrounding healthcare system.

The Wagner Chronic Care Model (CCM)\(^{106}\) describes the delivery of care as a structural relationship between community resources and the healthcare organization. The delivery
further consists of four elements (self-management support, delivery systems design, decision support and clinical information systems) and thus shares some overlapping elements with the CMS. One of the aims of the redesign was that the staff were to act as consultants to the patients and that there was to be a mutual responsibility for the care. This is in accordance with the suggested support for self-management in the CCM. Self-management programmes have been studied in more general terms for other chronic diseases. These show variance in the format and outcome measures. In a review, Barlow et al. suggested:

“There is an increasing interest in understanding the value of self-management interventions for people with chronic conditions Collectively the literature suggests that self-management interventions have beneficial effects on the well being in the short term”.

Further, self-management promoted a better understanding of the patient’s life, tailored the management of the disease delivered to the patient and empowered the patient. In a critical essay, Newbould et al. stressed that there is a temptation to overstate the effectiveness of the programmes, which they found to be merely indicative. Still, evidence supports the notion that involving patients in the care contributes to changes in the delivered care.

Self-management, IBD and the QII

There are some reports on IBD and self-management. Robinson et al. conducted an RCT, assigning 203 patients to either traditional regular outpatient-based follow-up or patient-centred self-management training and follow-up on request (open access). The intervention was reported to reduce time to treatment, accelerate treatment provisions and reduce doctor visits in the self-management group. Their approach was further studied in a multi-centre cluster RCT, which showed that self-managing patients had fewer hospital visits without an increase in primary care centre visits and maintained their QoL. These findings are in accordance with ours. The redesign shares several characteristics with the compared open access approach, but the strategies differ in that the QII still offered yearly visits. We did not study time to medication, but from the interview study we learned that patients used self-medication to delay contacting the care unit. This probably means that they decreased the time to medication, as they would otherwise have had to wait to get a prescription at a scheduled visit. The two studies show consistency in the findings regarding open access that it might lead to fewer hospitalizations. A qualitative study further reported that open access better fit with patients’ self-management in view of their current condition and everyday routines, roles and responsibilities. It was found to be cost-effective as well, which corresponds to our...
findings in which fewer acute visits at the Emergency Department as well as fewer hospitalizations were noted. In our interview study, it was found that patients wished to decide themselves when, how and under what circumstances contact with the healthcare system was to be made.

Self-management is regarded as a major healthcare policy in Britain and elsewhere. From the presentation here, it seems that experiences from self-management in other chronic disease could be applicable in the care for IBD patients as well. The follow-up system introduced in the redesign was possible to describe, study and evaluate by applying the CMS and CCM models.

In a review of other chronic diseases such as diabetes, congestive heart failure and asthma, Bodenheimer 113 found that the inclusion of more than one of the above CCM elements resulted in improvements in either outcome or process measures. Is this true for IBD care as well? A recently published paper suggests that the implementation of CCM significantly decreases costs and healthcare utilization in patients with Crohn’s disease 114. In this thesis self-management is stressed, but it includes delivery systems redesign as well, as described by the QII, and decision support exemplified in the dedicated telephone line to the clinic. The contact of the QII in its relation to community resources is another aspect to develop in further redesign and improvement. The conclusion from others as well as this thesis is that CCM, applied together with a CMS approach, may decrease costs and healthcare utilization in combination with improved quality of care.

Performance measurement for IBD

Every organization has its plans or assumptions for internal or external outcomes connected to the organization itself. Gathering resources as well as planning, managing and assessing the efforts are a great challenge. Existing data from compilations, records, surveys, response cards and designed instruments are preferred, often presented as percentages, rates and ratios. Performance measures are best used when integrated into a system 115. When the selected performance measures are collected at timely intervals decision-making becomes more valid, performance is assessed and liability is enhanced. Measurement systems are the principal vehicle for observing, reporting and using performance measurements.

Data collection in our CMS began in 1998 and is presented over time until 2006. Results showed that the new design offered a more efficient outpatient clinic, where waiting lists were
markedly reduced although production rates remained the same. Data on hospitalization showed a significant decrease in comparison with national data, indicating that the new care was economically favourable. The clinical results regarding anaemia frequency in the IBD population were highly comparable with, or even better than, those found in the literature. In addition, the results regarding QoL were good, with more than 84% of patients achieving set goals.\textsuperscript{91}

**Haemoglobin**

The reported prevalence of IBD-associated anaemia in studies of both ambulatory and hospitalized patients varies from 8.8% to 73.7%.\textsuperscript{55} These studies include several loose or inconsistent definitions of anaemia, as well as suspected selection bias. In this thesis, the whole IBD population was included in the reporting on anaemia (I-III). In the most extensive study (III), the WHO definition was used. In a recent study conducted at six IBD centres in Scandinavia, anaemia, defined according to WHO, was found in every fifth consecutive patient seen at the outpatient clinics;\textsuperscript{116}, thus, a higher figure than in the present population-based study, where the prevalence was 6%.\textsuperscript{117}

As shown in Table 9, with less selection bias, less anaemia is found. Therefore, previously reported high levels of anaemia seem accurate for patients with active disease. With good control of disease activity in IBD, the prevalence of anaemia should be lowered and perhaps anaemia should not be accepted at all.\textsuperscript{118}

<table>
<thead>
<tr>
<th>Setting for study</th>
<th>anaemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schreiber et al\textsuperscript{55}</td>
<td>26%</td>
</tr>
<tr>
<td>Walker et al\textsuperscript{55}</td>
<td>13%</td>
</tr>
<tr>
<td>Bager et al\textsuperscript{119}</td>
<td>19%</td>
</tr>
<tr>
<td>Rejler et al\textsuperscript{117}</td>
<td>6%</td>
</tr>
</tbody>
</table>

**TABLE 9.** Reported anaemia in four different settings

Anti-TNF-\(\alpha\) is now an established therapy in more severe and complicated disease.\textsuperscript{120} This might explain the increased anaemia frequency at annual check-up seen in this study in this treatment group (II).\textsuperscript{117} For future research, a prospective analytical study could be interesting as a means to answer the question of whether following Hb in high risk groups of IBD patients, for example every month, could be predictive of increased disease activity.
Added to this approach could then be telephone calls, further laboratory testing and endoscopy, which together may prevent anaemia and hospitalization.

**Medication**

Pharmacological therapy in IBD is well agreed upon in guidelines \(^{52}\), but its implementation raises several concerns. At an American metropolitan hospital, Reddy et al. studied 67 consecutive patients. Of these, 64% did not receive maximum doses of 5-ASA. In 16 of 27 (59%), there was no attempt to start steroid-sparing medications. However, this was a small study. Knowledge about adherence to guidelines in the prescription of medication in patient populations with IBD is sparse. A Norwegian prospective study for newly diagnosed patients with IBD (IBSEN) \(^{122}\) \(^{123}\) and a Canadian study \(^{124}\) were used for comparison with our results. The IBSN study and Study III in this thesis are both population-based. In our study there was a higher frequency of prescribed immunosuppressive drugs and a lower rate of cortisone use, probably because of the longer disease duration in our population. This might indicate that the annual check-up represents a robust follow-up system for finding and following up patients with steroid-dependent disease and for enabling the introduction of immunosuppressive treatment in these patients. Table 10 shows the proportion of patients prescribed the various medications in the three settings. It also shows an example of how quality measures can be directly related to guidelines and thus offer important information about the quality of the care delivered \(^{52}\).

<table>
<thead>
<tr>
<th></th>
<th>5-ASA</th>
<th>Continuous cortisone</th>
<th>Immune suppressives</th>
<th>No medication</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ulcerative colitis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present study</td>
<td>56%</td>
<td>4%</td>
<td>12%</td>
<td>40%</td>
</tr>
<tr>
<td>Henriksen et al</td>
<td>50%</td>
<td>7%</td>
<td>1%</td>
<td>41%</td>
</tr>
<tr>
<td>Hilsden et al</td>
<td>74%</td>
<td>28%</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td><strong>Crohn’s disease</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Present study</td>
<td>43%</td>
<td>16%</td>
<td>34%</td>
<td>31%</td>
</tr>
<tr>
<td>Henriksen et al</td>
<td>54%</td>
<td>25%</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>Hilsden et al</td>
<td>54%</td>
<td>35%</td>
<td>24%</td>
<td></td>
</tr>
</tbody>
</table>

*Values expressed as percent of patient on respective medication.*

**TABLE 10. Proportion of patients prescribed 5-ASA, continuous cortisone and immunosuppressives in the three settings**
Quality of life and hospitalization

The SHS, as applied in the case, showed a stable outcome. Its main use was as a qualitative tool to find patients with a deteriorating disease at the yearly check-up.

Our study showed a correlation between risk of hospitalization and: self-reported relapse of disease during the past year; patients not meeting the set goals for SHS scores; patients prescribed continuous cortisone; and patients prescribed TNF-alpha medication. Furthermore, in the current study, patients with anaemia detected at annual check-up showed a higher risk of being admitted to hospital any time during the year. This is important to note, as it gives a hint of where to intervene to improve results as a means to decrease the need of hospitalization. In addition, the figures are interesting from an economic point of view. Hospitalization is the most costly form of care, and figures from the US show stable but, for CD, increasing rates of hospitalization. In addition, no immediate effect of biological medication on hospitalization is shown. Further research is needed to determine why 40/100,000 patients with IBD are hospitalized in our healthcare area compared to 100/100,000 in Wisconsin in the US, as presented by Ananthakrishnan et al. Increased attention to anaemia and a proactive approach in relation to signs of activated disease might offer a strategy for reducing future need for hospitalization and thus reduce both personal suffering and the healthcare system’s economic burden.

A framework for IBD care

The need for general assessment tools for IBD care has been emphasized several times over a number of years. When the redesign in our study was launched, no system for monitoring the quality of care was at hand, on either a local or a national level. At the time, the local redesign urged for the development of a quality assessment tool. The presented quality framework (II) was thus tested in a local population-based setting and was found to be instrumental in assessing the quality of care delivered to patients with IBD.

What is the difference between a register and a framework? A framework is the identification and characterization of the formal recording or collecting of data. A framework gives a register a theoretical foundation. Recent years have seen a promising establishment and use of clinical quality registers in several medical specialties. Sweden has been at the world forefront in this promising clinical quality management area, thanks to its uniform healthcare delivery system and its societal use of personal numbers, which allows the easy and valid identification of individuals over time.
Comparison of the local and national IBD registers

The selected quality measures in the framework provided information on less anaemia than in previously reported IBD populations, low hospitalization rates, low frequency of surgical interventions, and good access to the unit (I and III). In Table 11, data from the local register are presented together with comparable data from a national register. Since some years back, there have been efforts to build a national IBD register in Sweden, SWIBREG 130, with support from the SALAR. Annual reports have been issued, but no scientific papers discussing results have yet been published. One difference between ours and the national register is the share of included patients, whereby ours reflects an unselected total population and the latter a more scattered inclusion pattern. This probably impacts the results, as there is a lower portion of patients treated with immunosuppressives, anti-TNF-α and cortisone in the local register. However, importantly, the figures for medication prescribed for extensive disease in UC, which is partly a cancer-preventive strategy, are in correspondence between the two registers.

<table>
<thead>
<tr>
<th></th>
<th>Local IBD registry in Eksjö</th>
<th>SWIBREG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year</td>
<td>2008</td>
<td>2008</td>
</tr>
<tr>
<td># of patients tracked</td>
<td>481</td>
<td>6535</td>
</tr>
<tr>
<td>Expected prevalence in coverage area</td>
<td>550 cases (of 110,000 pop)</td>
<td>45000 (of 9 million pop)</td>
</tr>
<tr>
<td>Estimated registry coverage</td>
<td>&gt;95%</td>
<td>19%</td>
</tr>
<tr>
<td>% men included</td>
<td>43%</td>
<td>50.4%</td>
</tr>
<tr>
<td>% women included</td>
<td>57%</td>
<td>49.4%</td>
</tr>
<tr>
<td># IBD-related visits per year</td>
<td>Not tracked except yearly follow-ups</td>
<td>Tracked</td>
</tr>
<tr>
<td>Cause of visit: increased/worse symptoms, planned visit, unknown cause?</td>
<td>Not tracked</td>
<td>8.3% worse symptoms 91.7% unknown/ unregistered 71.7% planned or unknown</td>
</tr>
<tr>
<td>Any IBD-related sick days this year?</td>
<td>Not- tracked</td>
<td>8.5%</td>
</tr>
<tr>
<td>% with IBD hospitalizations this year</td>
<td>7.4%</td>
<td>4.8%</td>
</tr>
<tr>
<td>% undergone IBD surgery at any time</td>
<td>Not tracked</td>
<td>19.4%</td>
</tr>
<tr>
<td>% undergone surgery during past year</td>
<td>2.1%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Short Health Scale</td>
<td>Tracked</td>
<td>Tracked</td>
</tr>
<tr>
<td>Smoking</td>
<td>Not tracked</td>
<td>24.6% non-smokers 3.6% smokers 71.8% unknown/unreg</td>
</tr>
</tbody>
</table>
Ulcerative colitis
Crohn’s disease
Ulcerative colitis
Crohn’s disease
% of patients on medication
Local IBD registry in Eksjö
SWIBREG
5-ASA (all pat) 56.0% 43.0% 47.2% 32.4%
5-ASA (pat with extensive UC) 70% N/A 67% N/A
Immunosuppressives 12.0% 34.0% 25.9% 35.6%
Cortisone 4.0% 16.0% 12.4% 14.0%
Anti-TNF-α 2.0% 8.0% 4.8% 8.9%

TABLE 11. Data from the local IBD register presented with comparable data from the national IBD register, SWIBREG, from 2008.

The previous lack of quality register reports from the IBD society has in part been filled by the ImproveCareNow network. This network is based in the Paediatric IBD Network in the US, and has presented results from their paediatric IBD register. The register includes weight and height at patient follow-up, and collected data on whether the thiopurine activity was tested before prescribing immunosuppressives and whether continuous cortisone was prescribed. All these data are recorded over time.

Patients’ experiences of living with IBD
This study conveys a wide range of experiences of what it is like to live with a chronic illness, in this case IBD. Our interviews offer a rich collection of narratives on how patients questioned their future when the disease struck, how it interrupted the lives of healthy adults with a formerly socially stable life situation. The informants experienced denial, which resulted in a delay in acknowledging the disease. With time, a need to locate the closest toilet became a routine objective of daily life.

From studies of other chronic illnesses, we learn that they are not simply a medical issue. Considering the findings in Study IV, this seems to be true for IBD as well; several of the findings indicate that IBD shares many experiences with other chronic illnesses.

Corbin and Strauss described that a chronic illness requires the patient to deal with a disease which occurs in a series of stages, including managing a medical crisis, controlling symptoms and normalizing social interactions and everyday life. In the late 1980s, they wrote that living with a chronic illness is accomplished at home, not without a degree of difficulty and a great deal of work:
“...but the majority of the chronically ill live at home, where they attempt to manage their illnesses, often with the help of advanced medical technology (drugs, medical machinery, procedures). At the same time, they must carry on with other aspects of their lives...and a great deal of work [is required] on the part of all who live therein” 134.

Additional consequences of the illness came to light. Previous research has identified the main concerns of IBD informants as: loss of energy, loss of control, change in body image, isolation and fear, not reaching their full potential, feeling dirty and lack of communication 136. The main worry or concern presented in this study was lack of control, associated with the unpredictability of the disease and one’s bowel function. The first signs of an impending relapse were often difficult to distinguish from an irritable bowel, which may mimic diffuse symptoms associated with IBD. The degree to which control was experienced was in direct relation to the physical distress associated with the intimidating feeling of being dirty. This required the individual to carry an “intimacy safety kit”. This need was strongly stressed in narratives in which the informant’s physical needs forced him or her into outdoor settings in order to find privacy, as well as from situations when failure resulted in soiled underwear.

Others have found that the greatest concerns were mainly about having surgery and an altered body image, such as having an enterostomy bag 137 138, which is in accordance with our study.

Our findings have parallels with previously published papers, which show how people with different chronic illnesses share fundamental concerns about their functional abilities and strategies for maintaining “normal” lives 34. Previous research by Hall et al. has reported on the “fight for health-related normality” while living with IBD 139, and Cooper et al. reported the main theme to be a “reconciliation of the self in IBD” 140. In this adaptation, help from close friends and loved ones was very important.

Several negative consequences of IBD originate from the endoscopic examination, which seems to be a critical venue for determining future relations with and trust for healthcare professionals. Patients had experienced rough examinations, which sometimes exposed them to intimidating or intolerable pain and embarrassing exposure. Similar patient experiences have been reported previously 141.

The adaptation required to restore one’s life after having experienced IBD with all its consequences led the informants to develop new attitudes and approaches. The affected body needed time to recover, social situations were solved with help from people who would become close friends, loved ones needed to adapt to needs for transportation and food, and the healthcare system had to cope with patients who hesitated to make contact because of the

52
threat of endoscopic assessment. This adaptation led patients to create a new biography, as Corbin and Strauss have described it for other chronic illnesses. This could be relatively uncomplicated if the informant’s health was easily regained, but for others the biography was repeatedly torn apart due to medical and social interruptions.

Patients described how they hesitated to contact the clinic. The negotiation of whether or not to contact the outpatient clinic can be understood as the struggle between maintaining normality and realizing that the severity of the relapse might lead to an endoscopic assessment. Physicians can do several things to help patients accept the examination, e.g. introduce themselves before seeing the informant stripped and placed on the assessment table, give timely medication, have an empathetic approach during the examination and use a gentle technique. Furthermore, staff need to always be prepared to adjust their attitude and actions according to the situation. The main duties of the staff are to encourage and support, avoid intimidating situations and provide advice that will help the patient adapt and restore a sense of normalcy to his or her life. This finding needs to be understood in relation to the QII. One of its foundation was the inspiration from patient centered care\textsuperscript{142}. Still the findings stresses that staff needs to improve the interaction so the goal of a mutual responsibility of the chronic disease is met\textsuperscript{143} \textsuperscript{144}. It stresses even more the need to monitor the quality of care by including the patients as partners in the challenge to improve it.

This study shows that there are many parallels between the experiences of people living with IBD and those of people living with other chronic conditions. Experiencing the consequences of the illness is associated with everyday life, and the adaptation needed to restore one’s life is associated with the need for biographical work, all of which is guided from the social and cultural context of the patient. In the words of Corbin and Strauss, these three perspectives are “inextricably linked and reciprocally interactive” \textsuperscript{145}. To be added from the results from our study is that they are always shadowed by the person’s worry that he or she might potentially need a toilet.

**Limitations**

This thesis not only represents a mixed methods approach; the individual studies are examples of the distinction between enumerative and analytical studies. Study I is an analytical retrospective study of outcomes over the years 1998 to 2006. Study III is an enumerative study, in which estimates of the frequencies of anaemia in the population were calculated.
The redesign of the outpatient clinic was a QII. A study of this intervention was not planned from the beginning, but arose from an urge to learn more from what had been accomplished (I). This had implications on the methodology, which came to be mainly descriptive in combination with the collection of retrospective data. A prospective design would have been preferable. During the work with this thesis the QI methodology in healthcare has improved through the increased application of statistical process control \(^{146}\), the use of bundles when analysing performance measures, and experimental designs consisting of carefully chosen subsets of experimental runs with factorial design \(^{147}\).

In Studies I to III, all known patients affected by IBD were included. To get an idea of whether there were patients with IBD not referred to the hospital-based IBD outpatient clinic, three out of six primary care areas were contacted. Colleagues were asked by email if they knew of patients they not had referred to secondary care. No new unknown patients were identified this way. Over the years there have been a few patients admitted to hospital care for other reasons who have had a quiescent IBD disease for many years, in which medication or endoscopy surveillance was not indicated. The prevalence of IBD was slightly lower than expected, which might be explained by the relatively older population in the studied area \(^{148}^{149}\).

In Study III patients who dropped out were identified in terms of numbers of patients missing the yearly examination in the entire IBD population during 2008. These patients constituted 2.9\% (n=14/485) of the population. Four received their diagnoses late in the year, so their follow-up occurred the following year. Four declined to participate in the study, and five missed the annual follow-up examination. One patient was excluded from the study due to a severe disease that resulted in more or less continuous hospitalization. A total of 16\% of the IBD patients failed to provide an Hb test at the annual check-up, despite reminders. Analysis of this group of “Hb dropouts” showed that they were younger and had a shorter disease duration than patients providing an Hb test. In the case of UC, 72\% had either proctitis or left-side colitis, i.e. a less extensive disease. Regarding CD, 84\% had involvement of only the small intestine or the colon. None of the Hb dropouts were prescribed anti-TNF-\(\alpha\) or continuous cortisone. In addition, they had significantly less 5-ASA and immunosuppressives medication prescribed. The analysis of the Hb dropouts indicates that these patients were healthier and less affected by their IBD and thus probably did not have lower Hb than the figures we report.

The last study in this thesis was decided on when the research group realized that the experiences of the patients were not addressed in the first three studies. To meet this need,
Study IV was planned. The participants were selected in a purposeful way. A second inclusion was done after the first ten interviews, in order to receive rich material representing all experiences of how it is to live with IBD.

The author of this thesis worked at the outpatient clinic during the whole research project. In Study IV, several steps were taken to protect the patient integrity. The selection of who was to interview whom was done by the researcher (DK) not working at the department. The main goal was to avoid previous patient-physician contact before the interview. In addition, an offer was made to allow the patient’s future visits to be with a gastroenterologist not involved in the study. The only exception would be the need of an acute assessment, whereby the schedules determined who was on call. The researcher’s regular contact with the studied setting may have had positive effects owing to deep insights into the processes of care, but could also have placed bias and blind spots into the analysis and interpretation. During this study, as well as the three others in a broader sense, this was balanced by the other participating researchers, who had their professional lives in other settings and fields.
Concluding remarks

This thesis has presented, studied and evaluated the efforts to improve the quality of care for patients with IBD. Findings have outlined new insights that living with IBD means living with the constant thought in mind of the possible need for a toilet. The redesign of the outpatient clinic can be seen as an example of the worldwide movement to improve healthcare and several of the STEEEP goals were shown to have been met through the application of a quality framework.

Also noteworthy are the encouraging reports, such as a review by Mikocka et al. 150, presenting common features of integrated models of care for IBD from IBD centres at the Bart and London NHS Trust, the Milan Model and the Winnipeg Model, among others. The common features are: Patient-centred care and the involvement of patients in the service development, a mechanism for active follow-up of patients, patient education, comprehensive assessment of biopsychosocial functioning, and a significant role of dedicated IBD nurses.

A “quality formula” for IBD care

Batalden and Davidoff have suggested that quality improvement is based on several interacting knowledge systems 13. For the care of IBD this formula may be translated as follows. Quality improvement forms a link between the study of disease (science) and clinical care (management) 14. The results in the studies (I-IV) in this thesis represent different knowledge systems, which together can create a “quality formula” for IBD care 102. A short overview of the most interesting findings follows.

1  To the generalizable scientific evidence, additional knowledge has been added regarding the lived experienced of the disease (IV).
2  The application of the CMS and the CCM to the redesigned care unit added knowledge in the understanding of the particular context (I).
3  Performance measurements added knowledge about outcome of care for patients with IBD (I and III).
The proposed quality framework applied to the local IBD was shown to be helpful as a means to connect generalizable scientific evidence with the particular context (II).

Will, ideas and execution made the redesign successful, founded in an accepting culture, a proactive follow-up programme and dedicated leadership (I).

The conclusions embedded in the improvement formula point to several important experiences and new knowledge to be tested, evaluated and refined further within the gastroenterological society in collaboration with patients. The approach of applying the “quality formula” to population-based care may also be of interest in the care for patients with other chronic illnesses.

**Future research**

An inspiring QI attempt was recently published by the Cincinnati Children’s Hospital Medical Center. The hospital formed a QI team, introduced significant QI interventions including EBM guidelines, joined a national QI collaborative and initiated pre-clinical planning and laboratory testing. They reported of less steroid usage and improved clinical remission rates. Further patient-reported outcome measures (PROM) were used, and interesting findings regarding use of calprotectin as a surveillance marker were presented. A future challenge is the development of an index to be used as a prognostic tool. It is important to note that these improvements are not due to new medication or expensive treatment options.

The need to link the results in this study mainly resulting from a population level to the care of individuals is a challenge to be undertaken in future research. Inspiring results have already been achieved within care for Rheumatoid Arthritis (RA), including the Swedish Rheumatoid Arthritis Register (SRR). The SRR is based on patients adding data from a self-evaluation of tenderness and swelling of joints as well as pain and overall health. The PROM, together with patient-experienced outcome measures (PREM), are then fed forward to the physician, whose assessment is added. When a patient visits the clinic, the professionals and the patient can then share common data for the evaluation of current state and planning future care. The situation can be evaluated based on previous and current medication, as well as social parameters such as the ability to work. This register serves as an inspiring challenging example of what IBD care could look like in the future!
Svensk sammanfattning


Förbättringsarbetet genomfördes med hjälp av upprepade förändringscyklar under några år i början av 2000-talet. För att studera vårdförmågan hämtades data från patienternas årskontroller som inkluderade information om personens identitet, kön, sjukdomsduration, medicinering, livskvalitet samt laboratorieresultat och sparades i ett lokalt IBD register. En gång om året inhämtades dessutom uppgifter rörande sjukhusinläggningar som var associerade med tarmsjukdomen. Samspelet mellan patienten, personalen och mottagningen studerades genom att applicera en modell för kliniska mikrosystem och en modell som beskrev uppväggnaden av vård av kronisk sjuka. Förbättringsarbetet som helhet studerades med hjälp av en retrospektiv, deskriptiv analys med kvantitativa inslag. Ett flerdimensionellt mätverktyg, Värdekompassen, och Donabedians ramverk för mätning av kvalitet lades senare samman för att skapa ett kvalitetsramverk för utvärderingen av vården för patienter med IBD. Ramverket testades med hjälp av befintliga data från det lokala IBD-registeret. Slutligen intervjuades tjugo patienter om sina upplevelser av att leva med IBD.

Förbättringsarbetet gav upphov till flera förändringar i utformningen av uppföljningen av patienterna: - En specialistsjuksköterska bemannade mottagningen under dagtid och kunde erbjuda patienter som kontaktade kliniken en tid på mottagningen inom två dagar. - Årliga kontroller erbjuds via telefonsamtal från en sjuksköterska eller läkare eller som tidigare vid ett besök på mottagningen. Årkontrollen förebereddes genom ett brev, som inkluderade ett livskvalitetsfrågeformulär och instruktioner för provtagnings av blodvärden.

Sammantaget ledde förbättringsarbetet till ett minskat antal sjukhusvistelser jämfört med övriga Sverige. Förekomsten av anemi i patientgruppen, 6%, var låg i jämförelse med tidigare rapporter och korrelerade med en ökad risk för inläggning på sjukhus. Erfarenheterna av att leva med IBD visade på flera paralleller till andra kroniska sjukdomar. Att leva med IBD var associerat med komplikationer i vardagen och att individen anpassade sig i väntan på
att återvinna sitt tidigare liv. Allt överskuggades dock hela tiden av en oro för att han eller hon eventuellt skulle behöva en toalett.

Det viktigaste resultatet av denna avhandling är det övergripande exempel den ger på hur ett förbättringsarbete kunde appliceras i ett lokalt klinisk sammanhang och studeras med hjälp av modeller för kliniska mikrosystem och en modell för uppbryggnaden av vård av kronisk sjuka. Den inkluderade vidare förslag till mätetal och ett ramverk för kvalitetsuppföljning för IBD vård samt redovisade patienters erfarenheter av att leva med IBD. Som helhet är denna avhandling ett bidrag till att möta internationella strävanden att överbrygga gapet mellan den bästa möjliga och den idag givna vården för patienter med IBD.
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References

100. Declaration of Helsinki- Ethical Principles for Medical Research Involving Human Subjects. Published and adopted by the 18 th World Medical Association, General Assembly in Helsinki, 1964.
Appendix
Highland District County Hospital: Gastroenterology Care in Sweden

In spring 2009, Dr. Jørgen Tholstrup, head of the gastroenterology unit at Highland District County Hospital in Eksjö, Sweden, reflected on the restructuring process his team had undergone over the past eight years. In 2001, when he had been the hospital’s sole gastroenterologist, wait times for nonurgent follow-up appointments were as long as two years. Inpatient and outpatient gastroenterology care had been delivered in separate parts of the hospital. By 2009, Tholstrup led a team of four physicians and over 20 nurses and nurse assistants. Wait times were dramatically lower, and a brand new gastroenterology unit co-located inpatient and outpatient care.

Throughout the process, Tholstrup had initiated a number of modifications aimed at integrating care delivery for inflammatory bowel disease. Tholstrup knew that some of the changes were considered unconventional, and felt that measuring and demonstrating improved results would be key to clinician acceptance of future initiatives. He was also concerned about recent trends toward productivity-based reimbursement for care elsewhere in Sweden. If similar systems reached Eksjö, how would they affect the gastroenterology unit?

Gastroenterology and Inflammatory Bowel Disease

Gastroenterology was the field of medicine involving the digestive system, which included the 25-foot digestive tract, liver, pancreas, and gallbladder (see Exhibit 1). In the U.S., gastroenterologists treated pancreatitis, gallbladder disease, appendicitis, liver cirrhosis, celiac disease, peptic ulcer disease, viral hepatitis, colorectal cancer, irritable bowel syndrome, and inflammatory bowel disease (IBD). In Sweden, many of these conditions were handled by surgeons, while gastroenterologists primarily saw patients with IBD, celiac disease, peptic ulcer disease, and certain liver conditions.

Inflammatory bowel disease referred to a group of disorders that caused the intestines to become inflamed. The two major types of IBD were ulcerative colitis and Chron’s disease, both of which involved periods of active disease alternating with remission. In ulcerative colitis, inflammation was confined to the inner lining of the intestine wall. As inflammation was limited to the colon, ulcerative colitis could be cured in some patients through surgical removal of the entire colon and rectum.

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1 The Swedish name of “Highland Hospital” was Hoglands sjukhuset I Eksjö. The English translation was used in this case for ease of reading by non-Swedish audiences.
Chron’s disease could involve multiple sections of inflammation anywhere along the digestive tract from the mouth to the anus, though the lower small intestine and colon were most commonly affected. The condition could also affect all layers of the intestine wall, leading to complications not seen in ulcerative colitis. The condition was usually incurable, as recurrence appeared in the vast majority of patients within 10 to 15 years of surgery. As a result, most Chron’s surgeries were performed for complications of IBD (e.g., fistulae, bleeding) rather than to treat the disease itself.

Symptoms common to both conditions included diarrhea, rectal bleeding, urgent bowel movements, abdominal cramps, pain, fever, and weight loss. Inflammation in the intestinal tract could also cause symptoms in other organs, including red eyes or blurred vision, joint pain or swelling, and skin rashes or ulcers. Some IBD patients were also at higher risk for colon cancer.

Disease onset most commonly occurred between the ages of 10 and 30, with a smaller peak between 50 and 60. Although the exact cause was unknown, IBD risk was at least partly hereditary and varied across ethnicities. Environmental factors were also believed to play a role, and the disease seemed to be more common in wealthier countries and colder climates. Smokers were more likely to develop Chron’s disease, and were also at higher risk for a more aggressive form of the condition.

More than one million people in the United States had IBD, accounting for 700,000 physician visits per year and 100,000 annual hospitalizations. In Sweden, approximately 60,000 individuals had IBD, with roughly 6,000 hospitalizations concentrated among 4,000 IBD patients in 2007.4

Many diagnostic procedures and treatments were used for both ulcerative colitis and Chron’s. Measures used to diagnose and monitor IBD included blood tests for anemia, high white blood cell count indicating inflammation or infection, and low nutrient levels. Diagnosis was normally confirmed with an endoscopic procedure that involved putting a tube with a light at the end of it into the intestines. Barium x-rays and CT scans were also used in diagnosis and evaluation.

Treatment generally included long-term anti-inflammatory and steroid drug regimens. Some patients who did not respond to drug therapy or who experienced precancerous or cancerous changes in the colon underwent surgery to remove all or part of the colon, and in some cases the rectum. Historically, some patients had to have permanent stomas requiring them to wear external bags to drain stool. In 2009, a pouch procedure was often used to create a reservoir out of the lower small intestine that connected to the anal region so that a stoma was not needed. Complications of the pouch procedure included incontinence, impotence, and IBD relapse in the remaining intestine.

**The Swedish Health Care System**

Sweden, with a population of nine million, had achieved universal access to health care through a decentralized, government-administered system. The Health and Medical Service Act, Sweden’s core health care legislation, assigned responsibility for health care financing and delivery to Sweden’s 18 county councils or *landsting*, two health care regions (Skåne and the Västra Götaland region), and 290 municipalities, one of which functioned administratively as a *landsting*. *Landsting* were further subdivided into Health Areas consisting of multiple municipalities. Unlike *landsting* and municipalities, Health Areas had no political or administrative functions unrelated to health care.

The *landsting* (and other regions functioning as such), ranged in size from 60,000 to nearly 2 million inhabitants, funded primary and acute care services, and had considerable autonomy to pursue their own health care strategies and priorities. *Landsting* were not usually legally obligated to provide care to residents of other counties, and many providers refused to see nonresident patients due to capacity and funding concerns.
Sweden spent 9.4% of GDP on health care, compared to over 15% in the United States, 11.1% in Germany, 8% in the United Kingdom, and 7.4% in Finland. More than 70% of Sweden’s health care costs were financed through income taxes collected by landsting, and to a lesser extent by municipalities. The Swedish government estimated that 90% of landsting activities were related to health care. To minimize the effects of demographic differences across regions on access to care, the central government issued grants to landsting and municipalities based on demographic, geographic, and socioeconomic factors. National grants covered roughly 20% of health care costs in Sweden.

Fewer than 1% of Swedes subscribed to private health insurance plans. As the public system covered virtually all medical care, many Swedes opting for private coverage did so to receive faster access to services, since private providers often had more available capacity than public facilities.

Landsting and municipalities directly delivered about 90% of health care services to their residents through publicly owned and managed providers. The balance of care was delivered by private providers, including 15% to 25% of primary care.

In 2005, amid long wait lists for many types of nonurgent care, an expanded national maximum wait time guarantee allowed patients flexibility to see providers throughout Sweden. The guarantee covered all elective care and promised patients immediate access to the health care system (contact in 0 days), a consultation with a primary care physician within seven days, an appointment with a specialist within 90 days, and a wait of 90 days or less between the specialist appointment and receipt of treatment (the so-called “0-7-90-90” rule). If a patient’s own landsting could not meet the guarantee, the landsting was obliged to offer to refer the individual for care elsewhere in Sweden.

In 2009, pending national legislation would require all landsting to allow patients to choose their primary care providers within their counties by 2010. Some landsting, including Stockholm and Halland, had already implemented the policy, known as “Vårdval” or “Patient Choice.” Early indications suggested that most residents of landsting with Patient Choice programs continued to seek primary care within their local Health Areas, but that patient satisfaction had improved.

**Primary care** Most primary care was delivered by more than 900 public and 300 private local primary care centers (PCC), typically staffed by nurses and one or more physicians. Each municipality contained at least one PCC, with some larger urban municipalities operating multiple public and private centers. Many PCCs either employed physical therapists, psychologists, and gynecologists, or arranged for clinicians from local hospitals to offer those services at the centers on a part-time basis. District Nurses based at the PCC typically coordinated clinical home care for the elderly, while nonclinical support (e.g., assistance with activities of daily living) was delivered by nurses based elsewhere and employed by the municipality. Pediatric care was often delivered at primary care centers, although some municipalities offered separate pediatric outpatient clinics.

Each landsting decided whether to impose “gatekeeper” rules requiring patients to visit primary care providers before seeking specialty services. Public primary care physicians were largely salaried landsting employees. As of 2003, nearly half of outpatient consultations occurred in hospitals, and fewer than 40% of Swedish physicians worked outside of hospitals, versus 55% in Finland, and over 80% in the U.S. (excluding private physicians with hospital admitting privileges).

**Hospital care** Swedish hospitals were generally organized by traditional medical specialties, each with its own scheduling and administrative functions. Most hospitals offered a broad range of services. Multiple hospitals within each landsting typically offered a particular service or procedure.

Sweden had three types of public hospitals, classified according to the scope of specialties offered, sophistication of care, and geographic coverage area. Most Health Areas contained at least one of
Sweden's approximately 40 District County Hospitals, which were roughly equivalent to community hospitals in the U.S. and provided inpatient, outpatient, and emergency care for most basic conditions. Most landsting also had at least one larger Central County Hospital, serving mainly as a referral hospital for a defined geographic area. These hospitals typically offered 15 to 20 specialties, and served the majority of residents' acute care needs.

Sweden was divided into six medical regions for specialized and complex hospital care. Each region was comprised of multiple landsting and housed at least one of the country's eight large Regional Hospitals. Like the smaller Central County Hospitals, Regional Hospitals were owned by the landsting in which they were located. In addition to complex care, they also provided general acute and outpatient care for local residents.

**Pharmaceuticals** All drugs and medical devices had to be registered with the national Medical Products Agency, which evaluated them on the basis of safety, quality, and cost-effectiveness. After a drug had secured MPA approval, the Pharmaceutical Benefits Board (LFN) decided whether to include it in Sweden's drug benefits program for provision on an outpatient basis.

The National Corporation of Swedish Pharmacies (Apoteket AB), a state-owned organization, maintained sole authority to sell pharmaceuticals to the public through community pharmacies, although it was scheduled to lose monopoly status in 2009. The Corporation also operated most hospital-based pharmacies under one-year contracts with the landsting.

**Reimbursement** Landsting had wide discretion to organize and compensate providers. Public primary care was most often funded through capitated payments covering all primary care services, or based on global budgets set at the clinic level. Amid long wait times, some landsting had begun to implement productivity-based primary care reimbursement, often together with the “Patient Choice” reforms. For example, Stockholm County had adopted a pay-per-visit model coupled with a per capita (i.e., capitated) payment from the landsting for each patient designating a particular center as his or her main source of primary care.

For public hospital care, prospective global budgeting based on patient volume by diagnosis related group (DRG) was the most common payment arrangement. In many landsting, county purchasing organizations negotiated with hospitals to establish DRG-based reimbursement contracts, particularly for acute inpatient care. Multiple DRG systems were employed throughout the country, although the most common system was used by 80% of landsting.12 At the request of landsting, the Ministry for Health and Social Affairs had created a center to coordinate national DRG standards.13 Fee-for-service arrangements and global per patient capitation (i.e., a set per patient amount, not according to DRGs) were also in use.

The global budgeting systems used by most large hospitals aimed to control costs by limiting annual procedure volume. Care exceeding the pre-determined rate was typically not reimbursed. If, for example, a hospital budget included 350 knee replacements for a calendar year and the hospital performed all 350 surgeries by August, the provider would not be reimbursed for additional knee

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2 Capitation referred to fixed per patient payments issued to a provider. The same amount was paid for each person served (though payments could be risk-adjusted), and did not vary according to the quantity of services actually delivered.

3 DRG-based reimbursement systems classified patients into groups according to their clinical diagnoses, type of care required, and initial patient conditions (e.g., age, gender, comorbidities). Care for patients within the same DRG was, on average, expected to require similar amounts of resources. A DRG payment typically covered an inpatient “episode” of care, including, the majority of services delivered within a single hospital admission.
replacements until the following January. The provider would typically keep pending patients on a wait list until the new contract began. Many providers attempted to space patients such that they would not “run out” of procedures until the end of their contracts.

Most private providers contracted with landsting to reimburse care delivered to public patients, usually in the landsting in which they were located. The terms of private care contracts typically allowed providers to perform a variety of procedure types up to a pre-determined reimbursement cap, or to perform a set number of procedures at a fixed per procedure price. Per procedure prices were rarely risk adjusted. Agreements usually lasted from one to five years, with options to renew.

**Measurement** Health IT was employed to varying degrees across landsting, municipalities, and health care providers. While most records in Sweden were kept electronically, including nearly all primary care records and 80% of specialty care documentation, there was no national standard or template for their integration or maintenance. In 2006, Sweden announced a National Strategy for eHealth identifying national priorities for health information technology that included creating common information and technical infrastructures; facilitating interoperable systems; and improving accessibility of information across organizations and to patients themselves. Implementation was underway in 2009, with financing of IT investments proving to be a significant issue.

Sweden maintained nearly 70 national quality registries, with more in the planning stages. Each registry collected and recorded information on patient characteristics, diagnoses, and care processes for a particular condition (e.g., cataracts) or medical procedure (e.g., hip replacement). For example, the National Stroke Registry recorded structure and process measures believed to improve stroke care, such as time to hospital, treatment in a stroke unit, and provision of hypertension and lipid-lowering therapies. Many registries also tracked some quality of care and outcome indicators. Provider reporting to the registries was voluntary, yet participation rates often exceeded 90%.

In 2007, the Swedish Association of Local Authorities and Regions (SALAR), the national organization representing the country’s landsting and municipalities, assumed primary responsibility for the operation, development, and financing of the registries. As of 2009, however, the registries continued to be initiated and managed by members of the professional groups that used them. New registries were usually initiated by one or more physicians who gained support through discussions with other experts in the field to agree upon measures and secure provider participation. Upon achieving consensus, the physician leader usually created the registry within his or her academic or medical department, often with public funding.

**Jönköping County’s Health System**

Jönköping County (pronounced YAWN-che-ping), located 200 miles southwest of Stockholm, encompassed a 6,500-square-mile area with a population of 333,000 (see Exhibit 2). The County's health care system employed more than 9,000 workers and was divided into three Health Areas, each of which included a County-run hospital and a mix of public and private primary care centers. Since the 1990s, the County had engaged in a number of health care safety and process improvement efforts that had attracted national and international attention. In 2000, Jönköping became the first Swedish county to create its own center for health care quality improvement, known as Qulturum, which maintained close connections with like-minded organizations including the U.S.-based nonprofit Institute for Healthcare Improvement and Dartmouth Medical School.

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4 A small number of procedures above the limit were usually allowed (under 5%), reimbursed at a reduced rate.
The Highland Health Area, one of the three within Jönköping County, spanned nearly 2,500 square miles and was responsible for providing primary and secondary health care services to 110,000 residents across six municipalities. The Highland Health Area was the largest local employer, with a staff of 2,200 clinicians and administrative personnel.

Around 63% of the Health Area’s 2008 budget of €156 million (US$234 million) was for staff salaries, with 16% for drugs, 12% for facilities and equipment, and 9% for other materials and services. Hospital-based inpatient and outpatient care accounted for €86 million of the Health Area budget, followed by primary care at €51 million, psychiatric care at €12 million, ambulance services at €4 million, other transportation at €2.2 million, and €.8 million in other health care expenses. The Health Area achieved a 2008 budget surplus of €16 million (over US$24 million).

Primary care was delivered by six Primary Care Areas corresponding to the six municipalities within the Health Area’s borders. Each Primary Care Area contained one or two primary care centers. Eight of the Highland Health Area’s 11 PCCs were publicly owned and run. Each center included approximately one physician per 1,500 patients, along with nurses and nurse assistants. District nurses with advanced training were based at the centers and coordinated home care for elderly or disabled patients, with the help of nurse assistants. Nurses typically conducted the home visits themselves, which ranged from occasional visits to nearly full-time care for patients requiring palliative or end-of-life care. In addition to adult and pediatric checkups and physician visits, each center also offered appointments with a gynecologist employed by Highland Hospital who divided his time between the hospital and local primary care centers. The PCCs employed psychologists as well as a physiotherapist to deliver outpatient rehabilitative care for conditions including back pain and stroke. Rehab clinicians also assessed whether patients required rehab equipment at home.

The three private PCCs contracted with the municipalities in which they were located for public reimbursement. Three private sole practitioners also delivered primary care in the Highland Health Area, but did not qualify as formal PCCs due to their small size. In 2009, municipalities no longer contracted with new centers staffed by fewer than two or three physicians, plus support staff.

Most patients requiring hospital care were directed to the County-owned and operated Highland District County Hospital, the Health Area’s only hospital. Jönköping County required all three of its Health Areas to direct patients requiring care for certain complex conditions including acute invasive cardiology procedures, inpatient or emergency ear nose and throat care, scintigraphic procedures (imaging using radioisotopes), and acute psychiatric care to Ryhov Central County Hospital.

Jönköping County had identified a single electronic medical record system, “Cosmic,” for use by all of its public hospitals and PCCs. The landsting issued the system to providers with no up-front charge, and adjusted each provider’s IT budget accordingly. In 2009, providers were in the process of implementing the system, which included patient medical records, a computerized physician order entry system for prescriptions, and lab test order entry and test results.

Highland Hospital

Founded in 1867, the Highland District County Hospital was based in the small city of Eksjö (pronounced EK-cho), a historic military town of 10,000 residents with many buildings dating to the 1600s. The city of Eksjö was located within the 16,500-resident Eksjö municipality.

During its first year of operations, Highland Hospital admitted one patient. In 2008, the 280-bed hospital admitted 15,842 patients and employed 1,700 salaried clinicians and administrative staff. A survey conducted by an association of Swedish physicians ranked Highland as the country’s second-
best training hospital. The hospital also belonged to the World Health Organization’s “Health Promoting Hospitals” network of international providers committed to improving the quality of care.

In addition to its main facility in Eskö, Highland Hospital operated a second site in Nässjö, roughly 20 minutes from Eskö by car. The Nässjö facility had been a full-service hospital when it merged with Highland Hospital in 1974. It was considered politically impossible to close the Nässjö facility, so most services were gradually shifted to Eskö over the following 30 years. In 2009, the Nässjö site offered primarily rehabilitation services for elderly patients and a mammography clinic.

Inpatient and outpatient care was organized into 14 clinical departments, most of which were common across the County’s three hospitals: Medicine; Surgery; Orthopedics; Gynecology; Radiology; Anesthesiology; Pediatrics; Ophthalmology; Ear Nose, and Throat; Psychiatry, Infectious Disease; Clinical Physiology; Pathology; and Rehabilitation (see Exhibit 3).

Most clinical departments offered both inpatient and outpatient services. Inpatient care was administered in wards located throughout the hospital campus, while outpatient care was delivered in separate locations known as “clinics.” Many outpatient clinics were located in the same building, and increasingly on the same floor, as their corresponding inpatient wards.

The Department of Medicine operated five inpatient wards and six outpatient clinics that were organized around the clinical subspecialties falling under the Department’s purview (e.g., gastroenterology, hematology). Many Department of Medicine subspecialties had co-located their outpatient clinics and inpatient wards to form a single unit occupying a dedicated hallway or portion of a corridor. Some Department of Medicine inpatient wards were shared by two subspecialties, while other subspecialties had their own. However, most patients did not have conditions related to their wards’ subspecialties. For example, on average, 12 of the hematology ward’s 15 beds were occupied by patients with conditions unrelated to hematology. These patients were considered “general” patients, often elderly individuals who did not require hematologic care but were seriously ill from other diseases handled by the Department of Medicine, (e.g., infection, congestive heart failure).

Historically, the hospital had set each Department’s inpatient budget separately from its outpatient clinic budget. Beginning in 2001, the hospital issued to each Department a single budget that covered both inpatient and outpatient care. For the Department of Medicine, each subspecialty unit (e.g., the gastroenterology unit) also received its own budget including both inpatient and outpatient services. The €1.6 million (US$2.4 million) gastroenterology budget, for example, included nonphysician staff salaries, imaging, labs, and inpatient drug costs (see Exhibit 4).

Separately, the hospital issued a single Department of Medicine budget that was equal to a sum of the subspecialty unit budgets, plus Department of Medicine physician salaries. The Department budget also included its share of hospital facilities and IT. While many hospitals budgeted separately for pharmaceutical costs, each Highland Department budget combined drugs with care and staffing costs. Budget amounts were largely based on historical costs, with adjustments to reflect expected patient volumes. Each Department submitted written requests for new equipment for approval.

**Gastroenterology Care at Highland Hospital in 2001**

In early 2001, IBD care at Highland Hospital was representative of typical IBD care in Sweden. Dr. Tholstrup, the Department of Medicine’s sole gastroenterologist, led the inpatient and outpatient diagnostic and treatment efforts for nearly all of the hospital’s gastroenterology patients, including individuals with IBD, celiac disease, microscopic colitis, and certain liver diseases. Tholstrup treated
patients with the support of one junior physician (who was in gastroenterology training), nurses, and administrative staff. Tholstrup also received support from various generalists or other sub-specialists in the Department of Medicine on an as-needed basis. Care for a handful of patients with longstanding IBD was managed by a surgeon, as IBD had historically been treated primarily through surgery and some older patients wished to maintain the same physician.

Tholstrup handled diagnosis and treatment for all Highland Health Area patients with new or acute IBD symptoms at the Department of Medicine outpatient clinic (see Exhibit 5). That clinic also saw patients with other conditions including heart disease, neurological conditions, and diabetes. One room in the clinic was dedicated solely for rectoscopies, a type of endoscopy that used a rigid tube to examine the rectum, and other types of endoscopic procedures. The other exam rooms and administrative space were shared across subspecialties.

Full-time clinic staff included three nurses, four nurse assistants, and two clinical physiologist technicians who were shared across subspecialties. Three administrative assistants were housed in a separate office in the same building, and served all Department of Medicine clinicians across inpatient and outpatient settings. Department of Medicine physicians divided their time between the outpatient clinic and the Department’s inpatient wards. Tholstrup generally saw gastroenterology patients at the outpatient clinic one morning and two afternoons per week.

Since the mid-1990s, each outpatient clinic nurse had been paired with a nurse assistant to create informal teams. Together with the appropriate physicians, each nursing team was responsible for most of the patients with conditions falling under a particular Department of Medicine subspecialty. For example, one team specialized in gastroenterology and hematology patients, while another focused on neurology and nephrology. Roughly 30% of the patients seen by each team had conditions related to that team’s subspecialty concentrations, and all nurses continued to care for various types of clinic patients.

Inpatient care for IBD patients was concentrated within ward 10, located on the third floor of a building adjoining the outpatient clinic. Ward 10 was one of five 24-bed wards used by the Department of Medicine, and was shared by the gastroenterology and hematology subspecialties. While most patients were “general” patients with conditions related to neither subspecialty, gastroenterology patients were grouped on one side of the ward and hematology patients were on the other to facilitate subspecialist physician evaluations.

Referral to Highland Hospital

Most patients with symptoms consistent with IBD first visited their local primary care physicians. If the physicians suspected IBD, they either mailed paper referrals describing the symptoms to the Highland Hospital Department of Medicine, or contacted Dr. Tholstrup directly by letter or phone. Some primary care physicians also sent partial or complete copies of patient records and lab results.

Referrals were received by a Department of Medicine administrative assistant, who pulled the patients’ paper records. The assistant gave the referrals and medical records to a senior Department of Medicine physician who reviewed referrals for all medical conditions treated by the Department. The reviewing physician placed referrals representing gastroenterology-related diagnoses in Tholstrup’s hospital mailbox. Tholstrup read the referrals to confirm the preliminary diagnosis and decide which lab tests to order before the patients’ first visits to the Department of Medicine outpatient clinic. A clinic nurse or administrative assistant then called the patients and scheduled their appointments.
Patients waiting for their referrals to be assessed could call a general Department of Medicine outpatient clinic number used for all incoming calls. The line was staffed on a rotating basis by the clinic’s nurses and nurse assistants. If the nurse answering the phone could not resolve a patient’s question, or if the patient required a physician to renew a prescription, the nurse placed a written message in Tholstrup’s office mailbox. Tholstrup responded to the requests either by dictating letters to be sent to the patients or sharing his answers with a nurse, who would return the patients’ calls. Response times varied greatly.

Alternately, many patients experiencing severe, acute symptoms presented at the Highland Hospital emergency room. Some patients with milder IBD symptoms also reported to the emergency room for diagnosis to avoid three to four month wait times for outpatient clinic appointments.

The durations of inpatient stays depended largely upon whether Tholstrup was in the inpatient ward that day, as he split his time between the ward and outpatient clinic. Suspected IBD patients admitted during the weekend typically remained in the hospital without official diagnoses until Tholstrup returned to the ward on Monday.

Diagnosis and Treatment Initiation

Suspected IBD patients who did not present at the emergency room visited the Department of Medicine outpatient clinic for diagnostic exams. Upon reporting to the clinic, patients checked in with the receptionist and paid a copayment of 300 Swedish Kronor (around US$40). Before meeting the patient, Tholstrup picked up the patient’s medical records from a nurse assistant. Most newly referred patients had received advance notice to have certain lab tests performed at their local PCCs prior to their appointments, and Tholstrup was able to review results before the exams.

An assistant nurse escorted the patients to a multipurpose room where Tholstrup performed a general physical exam. Next, many patients received rectoscopies, which Tholstrup conducted with nurse assistance in the outpatient clinic room dedicated for endoscopic procedures.

Virtually all patients with suspected IBD required biopsies during their exams to confirm their IBD diagnoses and to distinguish between ulcerative colitis and Chron’s disease. Biopsies could be conducted during rectoscopies or other endoscopic procedures, which Tholstrup performed in the outpatient clinic endoscopy room. He then sent the samples to the hospital’s pathology department for review. Biopsy results were normally available within two to three weeks, and communicated to Tholstrup in paper copy via the hospital’s internal mail. Methods of sharing results with patients varied; Tholstrup told some patients that if they did not hear back, it meant that the results were fine or as expected. Other patients received letters or calls from the clinic confirming their diagnoses and the dates of their next clinic appointments. Typical diagnostic visits including a physical exam and rectoscopy with biopsy lasted around 40 minutes.

Tholstrup ordered flexible sigmoidoscopy procedures for roughly one quarter of new IBD patients. Like rectoscopies, flexible sigmoidoscopies were endoscopic procedures that allowed Tholstrup to view and examine patients’ distal colons. The procedures improved diagnostic accuracy, particularly for patients with severe disease, by allowing clinicians to advance roughly twice as far in the colon than with rectoscopies. As sigmoidoscopies had historically been handled by surgeons, and also required expensive equipment unavailable to the Department of Medicine at that time, the procedures were scheduled at the surgical outpatient clinic located across the hospital campus. Sometimes the five- to 10-minute procedures could be performed on the same day, while others required a second visit two to four weeks later when the equipment needed for the procedures was already in use.
When sigmoidoscopies could not be performed on the same day as physical exams, Tholstrup often had to decide whether to initiate or alter drug therapy without the procedure results to confirm diagnosis and disease severity. For that reason, Tholstrup frequently performed rectoscopies rather than sigmoidoscopies. Tholstrup handed paper prescriptions directly to the patients during their appointments. Patients could then fill the prescriptions at any pharmacy.

A handful of patients required diagnostic colonoscopies when it was necessary to view the whole colon. Tholstrup performed the colonoscopies at the hospital’s second facility in Nassjö, usually within one to two months after the initial diagnostic visit. The procedures lasted 20 to 30 minutes, and patients remained at the hospital for a few hours to recover from sedation.

Some patients, especially suspected Chron’s patients, underwent imaging procedures such as barium x-rays or CT scans in addition to (or instead of) endoscopies. Imaging was conducted at the hospital’s Department of Radiology, located at the Eksjö facility on the third floor of a nearby adjoining building to the Department of Medicine outpatient clinic. Imaging was generally performed during a separate visit within a few weeks after the clinical exam, and appointments were scheduled with the Radiology Department. Same-day imaging could be arranged for severe cases. Unlike endoscopic procedures, the Department of Medicine outpatient clinic budget was charged internally for imaging procedures and hospital lab tests performed on its patients, and was also charged for the analysis of lab tests performed externally by primary care centers.

Chronic Care Management

Patients diagnosed with conditions that did not require follow-up with a gastroenterologist were referred back to their local primary care physicians after their assessments. After Tholstrup shared these patients’ diagnoses with them, the outpatient clinic mailed letters to the patients containing their diagnostic exam and lab results to share with their primary care doctors.

Dr. Tholstrup continued to deliver care for patients with IBD, as they required ongoing gastroenterologist follow-up via regular checkups at the outpatient clinic. Like diagnostic appointments, regular exams often included rectoscopies or sigmoidoscopies and reviews of recent lab tests. Also as with diagnostic appointments, some patients required colonoscopies after their annual exams to screen for tumors or assess the effect of treatment. The procedures were performed at the Nassjö facility, and had to be scheduled separately. Tholstrup aimed to see all IBD patients for at least one annual exam, but wait lists often doubled the recommended time between visits.

Acute and Inpatient Care

Some patients experiencing acute flare-ups were able to secure emergency outpatient appointments by calling the Department of Medicine, but many reported to the emergency room for care. IBD patients presenting at the emergency room were typically seen by a junior physician specializing in internal medicine who took their vital signs, ordered basic lab tests, and eventually sent the patients for imaging at the hospital’s Radiology Department. These patients were frequently admitted to ward 10 for hospital stays. In many cases, at least two physicians including the emergency room doctor and the physician covering the inpatient ward saw the patient before Tholstrup. Patients with less severe symptoms were discharged once Tholstrup had examined them, while patients with very severe flare-ups remained in the hospital to stabilize their conditions.

Patient rounds for ward 10 were divided in half, with Tholstrup and a junior resident rounding on the 12-bed side of the ward designated for gastro patients, while a hematologist was responsible for the other 12 beds. Each day at 9am, Tholstrup met with the junior resident and nurse that would join him on rounds to discuss each patient’s status. The team visited each patient’s bedside, with most
rooms shared by two to four patients. If a clinical exam was needed, the team closed the curtains around the patient’s bed and conducted the assessment there. Some patients were uncomfortable speaking with the team in the presence of their roommates. When patients expressed such concerns, nurses attempted to arrange private consultations with the junior resident later in the day.

When Tholstrup was not covering the inpatient ward, such as on weekends or vacations, the gastroenterology patients were seen daily by the rounding Department of Medicine physician. That physician often did not address the patient’s IBD treatment plan, but monitored the patient until Tholstrup could conduct an in person evaluation or could be reached by phone for advice. In Tholstrup’s absence, the rounding physician could also call a gastroenterologist at Ryhov Central County Hospital or Linköping Hospital, the closest university hospital in the neighboring county of Östergötland, for advice if needed.

**Surgery**

Tholstrup recommended that a small minority of patients with severe IBD that did not respond to medical treatment undergo evaluations for surgery. Tholstrup either issued written referrals to Highland Hospital’s Department of Surgery, or more often discussed the patient in person with one of the two surgeons that performed most of the hospital’s gastrointestinal operations. The surgeons then examined the patients at the surgical outpatient clinic to determine surgical eligibility. Exams were prioritized based on urgency, and typically occurred within three weeks of referral.

IBD surgeries ranged from relatively simple procedures to extremely complex operations that rerouted much of the digestive tract (e.g., pouch surgeries). Very complex cases were referred to Linköping Hospital, which employed five or six surgeons specializing in complex IBD procedures. These surgeons received surgical referrals from three adjacent counties covering approximately one million residents, and rough estimates suggested they performed a total of 80 IBD surgeries per year.

### Preparing to Restructure IBD Care Delivery

In 2001, Highland Hospital had a nearly decade-long history of studying and modifying its internal processes to reduce the need for inpatient care and improve coordination. In 1998, Dr. Mats Bojestig, Chief of the Department of Medicine, together with other Health Area leaders, Qulturum, and the U.S.-based Institute for Healthcare Improvement, had initiated a project to address an increasing number of hospital admissions. The project was named “Esther” for a fictional 88-year-old patient living alone who represented the growing elderly population in Sweden. The Esther project considered hospital services within the full scope of patients’ care over time rather than as discrete episodes. As a result of Esther, a number of process improvements were introduced to improve care coordination and speed access to outpatient care to minimize unnecessary emergency room visits.

By 2001, the hospital’s inpatient occupancy had fallen, with more than 25 of 117 beds empty on a typical day, equal to an entire ward. While staff morale had improved, the hospital, and the Department of Medicine in particular, feared potential budget cuts for 2002. Historically, hospitals with empty beds had risked losing funding to other providers with higher inpatient volumes.

Bojestig was convinced that the reduced inpatient volume signaled clinical progress, and worried that budget cuts would hurt the hospital’s quality improvement efforts. With sustained budget funding, he believed Highland could redirect the funding freed up by the lower inpatient occupancy to improve care. Bojestig presented his case to Jönköping County leadership, including the County CEO whom he knew well through Esther initiatives. He asked the County to pilot a revised budgeting system for Highland Hospital that was not linked to inpatient capacity. The proposal was
approved, and Bojestig committed to reorient the Department of Medicine’s mission around outpatient care while improving continuity across inpatient and outpatient settings.

As part of the reorganization, the Department of Medicine agreed to close one of its five inpatient wards. It would also restructure the single general purpose outpatient clinic into multiple, separate sub-specialty outpatient clinics (e.g., gastroenterology, neurology). Each outpatient clinic would be affiliated with a corresponding inpatient ward, creating a single subspecialty unit. Each unit would have its own budget and, space permitting, inpatient and outpatient care would be co-located.

Once the units had been formed, each unit’s entire inpatient and outpatient teams, including both clinical and administrative staff, assembled for a weeklong off-site conference to develop and discuss their mission and outline care delivery goals. Tholstrup had begun to redesign gastroenterology care delivery in spring 2001, and continued those efforts under the new unit structure.

The physical restructuring took place over the following eight years, as relocation of subspecialty units depended upon space becoming available as the hospital was renovated. The gastroenterology inpatient ward and outpatient clinic were each moved through six temporary, separate locations before settling into a permanent, co-located space in March 2009.

**Gastroenterology Care at Highland Hospital in 2009**

In 2009, the gastroenterology unit was located on the hospital’s fifth floor (see Exhibit 6). The outpatient and inpatient portions of the gastroenterology unit were located within the same hallway. In addition to nine patient rooms, the inpatient ward contained common lounge and dining space for patients and their visitors. The outpatient space included a waiting room, three exam rooms, a specially outfitted endoscopy room (mainly for sigmoidoscopies), meeting space, and clinical and administrative offices (see Exhibit 7).

Dr. Tholstrup remained the senior Highland Hospital gastroenterologist and led the gastro unit with support from the same junior gastroenterologist on staff in 2001. Two additional gastroenterologists from Poland had joined the Department of Medicine in 2002 and spent approximately two-thirds of their time with the gastro unit. Most weeks, one gastroenterologist worked full-time at the outpatient clinic while another split the day between the outpatient clinic and inpatient ward. Each of the gastroenterologists was on call approximately one day per week for the Department of Medicine, during which time they could not schedule outpatient gastroenterology appointments.

The 15-bed inpatient ward was organized into three color-coded areas, each with its own nursing station. Each station was staffed by a nurse and nurse assistant team responsible for five patient beds. In total, more than 20 nurses and nurse assistants worked in the gastro unit, of whom two were dedicated to the outpatient clinic, three split their time between inpatient and outpatient care, and the rest delivered only inpatient care. Most nurses worked at least 25 hours per week, and typically spent all of that time with the gastro unit. Two full-time administrative assistants supported the unit, and a third was seated at the unit’s reception desk.

Tholstrup held a team meeting every Monday afternoon in a glass-walled room to plan the schedule for the following two weeks and discuss any issues and opportunities for improvement. All physicians on duty that week attended, as well as the nurses and nurse assistants dedicated to outpatient gastro care. Administrative staff also participated in portions of the meeting. The numbers of new referrals and upcoming follow-up visits were listed on a white board that served as a process control measure clearly visible to all staff throughout the day.
Tholstrup had introduced a number of care delivery modifications over the past eight years, and continued to review and revise the care delivery model according to three basic values that had guided the unit’s creation and operations since 2001. Tholstrup explained:

First, we should include patients as team members. Before, the physician-patient relationship was at the center of care delivery, but the physician lacked the time to properly engage the patient. Now the patient is not seen as a customer, but as the central member of a multidisciplinary team of clinicians. Second, all of the activities we conduct should produce positive value for individual patients. For years we tried to get the patient to fit in our system rather than individualize care to meet patient needs. Today, the patient helps the clinical team determine when care is actually needed. For example, we used to see all patients for scheduled visits once a year regardless of whether they needed them. Those appointments kept us so busy that we lacked capacity to see acute patients with flare-ups for unplanned visits. As a result, many of the acute patients’ diseases worsened and required more complex treatment than if we’d seen them right away. We realized that the patient himself was the best judge of when appointments were needed, not simply an annual timeline. So we looked for alternative ways to maintain regular contact with patients with stable disease while affording us the scheduling flexibility to see acute patients. And third, patients should feel safe and confident in the care they receive.

**Referral, Diagnosis, and Treatment Initiation**

Patients’ primary care physicians continued to submit paper referrals to the gastroenterology unit for suspected IBD patients. However the Department of Medicine as a whole was moving to electronic referrals via the new “Cosmic” IT system. Lab results were already available online, allowing Tholstrup and his team to immediately see the results of all lab tests ordered by patients’ primary care physicians anywhere in the County. Referrals were reviewed daily by the gastroenterologist covering the inpatient ward. However, some referrals were still sent directly to Tholstrup, as many area physicians knew him to be the senior gastroenterologist.

During most diagnostic appointments, a gastroenterologist performed a sigmoidoscopy, as well as a biopsy if needed, in the clinic’s designated endoscopy room, allowing the patient to undergo the procedures immediately. Due to the ease of conducting sigmoidoscopies in the dedicated exam space in 2009, many more patients underwent diagnostic sigmoidoscopies than in 2001. Rectoscopies were no longer used in the diagnostic process. A full diagnostic visit, including a sigmoidoscopy, lasted around 45 minutes, while a follow-up visit for an existing patient lasted around 30 minutes.

Diagnostic and follow-up imaging remained similar to 2001, but with shorter wait times due to new MR and CT equipment acquired by the hospital.

The gastro unit had installed a dedicated phone line for new and existing patients to call with questions about their conditions. The unit also received and answered patient questions by email.

**Chronic Care Management**

The gastroenterology clinic still aimed to touch base with every IBD patient at least once per year. Patients with unstable disease, intellectual handicaps, or requiring surveillance colonoscopies or treatment with immunosuppressive drugs continued to report for annual follow-up visits at the gastroenterology unit.

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5 For figures further outlining Dr. Tholstrup’s approach to conventional versus redefined “roles and rules” of patients and their clinical teams, see [www.isc.bbs.edu/pdf/tholstrup.pdf](http://www.isc.bbs.edu/pdf/tholstrup.pdf)
Patients with stable conditions were offered the option of an annual telephone appointment with a gastroenterology nurse instead of in-person physical check-ups, though all patients were given the option of in-person exams. Tholstrup commented:

One hundred years ago, my hometown had a population of 1,100, all of whom belonged to the village church. Today, the church has 60 members, and there might be two or three people at Sunday services. Yet they’ll never close the church because it’s a sacred house. Health care has many “sacred houses,” processes that physicians refuse to change. But when you step back and consider the lack of value – or even harm – these processes produce, it gets a little frightening. Introducing phone appointments instead of in-person visits for some patients was like closing a sacred house.

Prior to both telephone and in-person appointments, the nurse or gastroenterologist issued electronic referrals for lab work to be completed at the hospital or a local lab. The labs electronically entered the test results into the EMR, where they could be accessed by the gastroenterology team prior to patients’ appointments.

Clinic administrative staff also mailed a self-administered quality of life survey known as the Short Health Scale to both telephone and physical exam patients, which they completed before their consultations. The survey included four questions about symptoms, function, degree of worry, and general well-being. Physical exam patients brought their survey results to the clinic, while phone appointment patients reported their results during their exams or mailed the surveys to the clinic.

In 2009, roughly half of annual follow up exams were conducted by phone. The outpatient clinic nurse began each telephone exam by asking about the patient’s general health since the previous appointment. The nurse inquired whether the patient had experienced any flare-ups, developed new symptoms, or required prescription renewals. After discussing lab and quality of life survey results, the patient was given the chance to ask questions. The patient was also offered the opportunity to schedule a physical appointment at the clinic, and instructed to call with further questions.

In-person, physical exams lasted around 30 minutes, including a sigmoidoscopy if needed. Although sigmoidoscopies were commonly performed during annual exams, endoscopic procedures were no longer standard exam components. Instead, they were recommended on an individual basis for patients with active, severe, or worsening disease. The gastroenterologist typically determined whether a patient would need an endoscopic procedure prior to the appointment, although some patients experiencing flare-ups at the time of their exams did receive unplanned endoscopies.

Colonoscopies were also conducted for cancer surveillance for patients with extensive ulcerative colitis. The procedures were typically performed according to a fixed schedule beginning 10 years after diagnosis, after which point the procedures were performed every other year. Patients who had been diagnosed at least 20 years earlier received colonoscopies every year. Patients checked in at the gastroenterology unit and walked downstairs to the hospital’s new endoscopy unit, which contained five procedures rooms. The endoscopy unit budget was included within the Department of Surgery, but the unit was led jointly by a senior surgeon and Tholstrup.

Nurses were responsible for delivering in-person outpatient follow-up care for patients with stable disease. One nurse was training to perform colonoscopies on nonacute patients, which had involved academic coursework and clinical training. Tholstrup noted:

In our reviews, we discussed who was doing what on our team in the context of our three core values. We saw that we needed to better customize care to meet each patient’s needs, and more effectively engage and utilize the competence of the patient. We also needed to better define the boundaries between clinical professions, especially between nurses and physicians.
At that point, the nurses’ capacity to do more suddenly became very obvious. Today, physicians are primarily responsible for diagnosis and initiating treatment plans, while nurses conduct much of the follow-up for stable cases. Nurses are often better at performing colonoscopies and conducting follow-up than physicians, as nurses have more time to be thorough and address any patient questions or concerns.

On an ongoing basis, any patient could call or email the outpatient clinic phone line with routine requests, such as prescription refills, which were reviewed by a physician on a daily basis. Once a gastroenterologist approved a prescription or refill, the request was electronically sent to the pharmacy system using the computerized physician order entry system. All outpatient pharmacies in Sweden were run by the state-owned Apoteket AB and used a common IT system, allowing patients to collect their prescriptions at any local pharmacy.

**Acute and Inpatient Care**

Individuals requiring inpatient care for gastroenterological conditions were assigned to ward 10, located immediately adjacent to the outpatient clinic. On a typical day roughly two beds were filled by gastro patients, while other Department of Medicine patients occupied the rest of the ward.

Tholstrup had reorganized ward 10 rounds to shift their purpose from “standardized procedures” to “individualized planning meetings” between where patients and their clinical teams could jointly make treatment decisions. Unlike in 2001, when all patients were seen each day, in 2009 around two-thirds of gastroenterology ward patients were seen on daily rounds. The patients not seen were those with defined treatment or discharge plans (e.g., patients with firm plans for additional treatment or testing, patients waiting for lab or imaging results, patients scheduled for discharge). A white board listing all ward 10 patients included color-coded dots indicating whether each patient needed to be assessed on rounds (red), was ready for discharge (green), or stable with an existing treatment plan or awaiting test results (yellow), (see Exhibit 8).

Patients who were immobile or suffering from dementia were seen during bedside rounds, as in 2001. For most patients, however, the rounding process had changed. Instead of visiting each patient’s bedside, a gastroenterologist, medical resident (not belonging to the gastro unit), nurse, and nurse assistant remained in a “rounding room” within the ward that doubled as an outpatient exam room. The nurse assistant escorted each patient in for a private consultation, and relatives were welcome to attend if the patient desired.

Rounds included a physician assessment of the patient’s recent care and lab results, a physical exam if needed, and time for patient questions and discussion. The team displayed each patient’s record onto two large flat screen monitors, allowing everyone to view the information.

At the end of each rounding appointment, the team clarified each member’s duties moving forward. A senior gastroenterologist charged the medical resident with issuing any new referrals for tests or procedures (e.g., x-rays) and initiating new prescriptions or authorizing refills. The nurse was responsible for monitoring any prescription changes, and the nurse assistant was responsible for staying up-to-date on the patient’s schedule of tests or procedures as well as managing discharge planning. The “sitting rounds” were usually completed more quickly than walking rounds, and staff believed that they led to more focused decision-making and greater patient engagement. By 2009, other wards within the Department of Medicine had also adopted the sitting round model.

**Surgery** As before, most patients requiring surgery were internally referred to the Highland Hospital’s Department of Surgery. In 2008, 11 Highland Hospital IBD patients underwent surgery for their disease, one of whom had been referred to the university hospital in Linköping.
Measurement

In 2003, after failing to find a national or international IBD quality registry in which the Highland gastro unit could participate, Tholstrup launched an internal computerized IBD registry along with additional data collection efforts to facilitate results measurement and patient tracking. In 2009, the internal registry recorded quality information for IBD, microscopic colitis, and celiac disease patients. Measures were organized according to a “value compass” framework presented by Eugene Nelson and colleagues at the Dartmouth Institute of Health Policy and Clinical Practice, consisting of four dimensions: clinical, functional, cost, and satisfaction.26 (See Exhibit 9.)

The Highland IBD registry tracked a number of quality measures that Tholstrup and his team had identified based on scientific publications and their own experience. These measures fell primarily along the “clinical” dimension of the value compass, and included basic patient demographic and health (e.g., gender, height, weight, year of diagnosis), current IBD prescriptions, and lab results (e.g., hemoglobin levels).6 Registries also tracked “functional” measures via patient responses to four Short Health Scale survey questions administered prior to annual exams. Responses ranged from one to six, where scores of one were most positive, while six indicated the patient was not doing well.

To ensure that all patients were included in the registry, the junior gastroenterologist reviewed historical Highland Hospital IBD inpatient and outpatient lists and reviewed a random sample of IBD patient records from two local PCCs. According to those records, more than 98% of IBD patients in the Health Area had been seen at the outpatient clinic regularly and were captured by the registry.

The registry’s technical design had been undertaken by the Highland Hospital’s IT department. It was created as a Microsoft Access database accessible to gastro team members from their own hospital computers. Staff from other Highland Hospital Departments or outside providers could not access the database. Data was entered after each patient visit or phone appointment, generally by the nurse or physician conducting the exam. After data had been entered, a new page was automatically created in the patient’s account for the next planned appointment, and was auto-populated with the patient’s contact information, diagnosis, and other basic details. Drop-down menus appeared for most information fields, with free space for notes (see Exhibit 10). Patient medications were entered using check boxes listing the three most common drugs, as well as a “no medication” option.

The registry was separate from the Highland Hospital’s general IT system, although the hospital planned to connect them. Therefore, although lab results were accessible electronically within the hospital’s IT system, gastroenterology unit nurses (or physicians, if they had made the patient contact) manually entered the lab and other data into the IBD registry after each appointment. Many IBD patients had multiple medical conditions and were included in various internal and national registries, with data entry was conducted separately for each registry.

A “statistics” function within the Highland IBD registry allowed for simple, descriptive reporting of, for example, IBD patients by diagnosis (e.g., Chron’s, ulcerative colitis), gender, or age. To perform more advanced analysis, clinical staff pasted the data into a Microsoft Excel spreadsheet.

The Highland IBD registry had been adopted by the other two hospitals in Jönköping County, each of which maintained its own separate database. The County-wide rollout of the Cosmic IT system included plans to incorporate the IBD and other locally maintained patient registries, and allow data sharing across providers. Highland IBD registry results were not posted publicly, and the data was given to patients upon request. Tholstrup had no near-term plans to begin public reporting.

6 The use of hemoglobin levels as an IBD quality indicator was not widely accepted. Tholstrup chose to measure it based on several studies that indicated as many as 30% of IBD patients were anemic.
A surgeon at Linköping Hospital had also initiated a national IBD registry a few years after the Highland registry began. In 2009, the Highland gastro unit did not participate in the national registry, which included data for roughly 20% of Swedish IBD patients. While the national registry did not publish its results, the Highland team had access to the figures and could compare its performance for measures tracked by both registries. Tholstrup had been on the steering group for the national registry, but left due to concerns about low patient coverage and because he felt the national results were used more for research than improving patient care.

Discussions were underway to explore adapting the national rheumatoid arthritis registry, among Sweden’s most advanced, as a template for other chronic conditions. If adopted for IBD, the model would likely track patient costs, outcomes, and process measures. It was unclear whether a new national IBD registry would operate alongside or be combined with the existing national registry.

Separately from the internal Highland IBD registry, the Highland Hospital IT system monitored the number of its IBD patients referred for tertiary care at Linköping Hospital and the reasons for the referrals. The gastro team considered this a clinical measure, as such referrals indicated increasing disease severity, and annually searched the hospital database for this information.

The gastroenterology unit also tracked its aggregate costs using the general hospital IT system, and compared actual costs to the unit’s budget each month. Per patient costs were not tracked. As hospitalizations represented the greatest health care costs for most IBD patients at an average of €550 per inpatient day, the team’s junior gastroenterologist also monitored the frequency of IBD patient admissions to the hospital’s medical or surgical departments, annually measuring the total number of IBD hospitalizations and the number of unique IBD patient admissions.

The route of hospital admission was tracked as well, i.e., an unplanned admission from the emergency department versus a planned admission from the gastroenterology outpatient clinic. The junior gastroenterologist gathered the data by searching the hospital’s computerized case record system for the two ICD-97 codes corresponding to IBD. The Highland Hospital IBD patient data was then compared to corresponding raw (i.e., not risk-adjusted) national data collected by Sweden’s National Board of Health and Welfare.

In 2009, the Highland IBD registry was not capable of tracking surgical referrals, aggregate costs, and route of admission. The gastro team had chosen not to modify the internal registry until it was determined whether the national IBD registry would be updated based on or replaced by the chronic care template. Once the national registry format was decided, the team planned to overhaul its internal registry in order to collect the national measures.

The unit also tracked access measures including the number of pending new referrals and endoscopies, method of hospital admission, and wait times for appointments. Patient satisfaction was measured using quarterly satisfaction surveys, distributed in hard copy to five randomly selected patients per month during their outpatient appointments. Typical questions asked about patients’ experience of care, for example whether they had received the information they needed about their care and whether they had been treated with respect and integrity.

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7 The International Classification of Diseases (ICD) system, published by the World Health Organization, was used worldwide to classify diseases and other health problems, enabling data compilation and comparison. ICD-9 referred to the ninth edition of the classification (http://www.who.int/classifications/icd/en/).
Results

Tholstrup and the IBD team set goal levels for the clinical and functional (i.e., Short Health Scale) measures they considered most important. They aimed to achieve normal hemoglobin levels in more than 95% of patients; moderate or mild symptoms, impairment of function, and level of anxiety in more than 90% of patients (as measured by the Short Health Scale); and a good or better level of general well being in more than 90% of patients (also the Short Health Scale), (see Exhibit 11).

In 2008, 95% of Chron’s and 96% of ulcerative colitis patients achieved hemoglobin levels exceeding the unit’s goal of 120 g/l. Ninety-seven percent of Chron’s and 96% of ulcerative colitis patients had Short Health Scale scores indicating somewhat good or better general well-being, compared with 90% of Chron’s and 94% of ulcerative colitis patients in 2002-2003. Scores for patient worry and function remained roughly constant between 2002 and 2008, with a 1% and 3% improvement in symptom severity for Chron’s and ulcerative colitis patients respectively.

Based on widely accepted guidelines issued by the American Gastroenterology Association, the gastro team aimed to have at least 95% of its patients with extensive ulcerative colitis on the anti-inflammatory drug 5-ASA. In 2008, approximately 70% of these patients had 5-ASA prescriptions, versus 67% of patients tracked by the national IBD registry (see Exhibit 12).

The proportion of Highland patients hospitalized for IBD-related illness had decreased substantially. In 1998, nearly all Highland IBD patients were admitted to the hospital, comparable to national figures. By 2008, Highland admissions had fallen to 55%, while national IBD admissions were stable (see Exhibit 13). Over the same period, the proportion of planned (versus emergency) IBD admissions rose from 33% to 55%.

Wait times for new patient appointments decreased from nearly 70 days in 2001 to 32 days in 2003 and 23 days in 2008. Wait times for gastroscopies fell from 30 days in 2001 to 13 days in 2003 and 4 days in 2008 (see Exhibit 14).

Future

The phone appointments, sitting rounds, and other care delivery modifications had been well-received by patients and clinicians and Tholstrup hoped that internal IBD registry results would continue to empirically demonstrate improvements in patients’ health. Tholstrup also felt the unit’s new space would enable even faster implementation of improvements, and he continued to search for ways to “organize IBD care around the patient’s needs, rather than the system’s.”

In 2010, Jönköping County would introduce primary care budgeting and reimbursement reforms similar to those launched elsewhere in Sweden along with the Vårdval “Patient Choice” program. A productivity tracking system was already in place for hospital care in Jönköping, although it was not used to determine clinician salaries or hospital reimbursement. That system issued “points” for each outpatient hospital visit or intervention, with more points allocated for complex procedures. Telephone calls were not considered to be visits and did not command any points. Tholstrup wondered if Jönköping adopted a productivity-based reimbursement system for primary care, a similar system for hospital care might not be far behind.
Exhibit 1  Human Gastrointestinal Tract


Exhibit 2  Map of Sweden

Exhibit 3  Specialties Offered by Jönköping County’s Three Hospitals

<table>
<thead>
<tr>
<th>Department/Service Line</th>
<th>Highland Hospital</th>
<th>Ryhov Hospital</th>
<th>Varnamo Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicine</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Surgery</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Gynecology</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Radiology</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Anesthesiology</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>Outpatient</td>
<td>Yes</td>
<td>Outpatient</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>Outpatient</td>
<td>Yes</td>
<td>Outpatient</td>
</tr>
<tr>
<td>Ear, Nose &amp; Throat</td>
<td>Outpatient</td>
<td>Yes</td>
<td>Outpatient</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Infectious Disease</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Clinical Psychology</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Clinical Chemistry &amp; Pathology</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Rehab</td>
<td>Yes(^a)</td>
<td>Some(^b)</td>
<td>No</td>
</tr>
</tbody>
</table>

Source:  Organization documents.

\(^a\)Highland Hospital provided all rehabilitative care in Jönköping County, except for neurological rehab for patients older than 60.  Highland Hospital rehab facilities located in the municipality of Nässjö, 30 minutes from the main hospital facility in Eksjö.

\(^b\)Neurological rehab for patients younger than 60.

Exhibit 4  Highland Hospital Department of Medicine and Gastroenterology Unit Budgets, 2009

<table>
<thead>
<tr>
<th>Department of Medicine Budget</th>
<th>Euros (million)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff (physicians)</td>
<td>12.0</td>
<td>54.3%</td>
</tr>
<tr>
<td>Imaging</td>
<td>1.5</td>
<td>6.8%</td>
</tr>
<tr>
<td>Laboratory</td>
<td>1.7</td>
<td>7.7%</td>
</tr>
<tr>
<td>Drugs (inpatient)</td>
<td>5.5</td>
<td>24.9%</td>
</tr>
<tr>
<td>Facilities</td>
<td>1.0</td>
<td>4.5%</td>
</tr>
<tr>
<td>IT</td>
<td>0.4</td>
<td>1.8%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>22.1</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gastroenterology Unit Budget</th>
<th>Euros (million)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff (non-physicians)</td>
<td>1.07</td>
<td>66.9%</td>
</tr>
<tr>
<td>Imaging</td>
<td>0.18</td>
<td>11.3%</td>
</tr>
<tr>
<td>Laboratory</td>
<td>0.15</td>
<td>9.4%</td>
</tr>
<tr>
<td>Drugs (inpatient)</td>
<td>0.2</td>
<td>12.5%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1.6</strong></td>
<td></td>
</tr>
</tbody>
</table>

Source:  Organization documents.
Exhibit 5  Location of IBD Care at Highland Hospital, 2001

Exhibit 6  Location of IBD Care at Highland Hospital, 2009

Source: Organization documents.
Exhibit 7  Highland Hospital Gastroenterology Unit, 2009

The inpatient ward included nine patient rooms, common lounge and dining space. Each nursing area included one nursing station and five patient beds.

Source: Organization.

Exhibit 8  Gastroenterology Unit White Board

The outpatient clinic included a rounding room, three exam rooms, endoscopy room, waiting room, meeting space, offices.

Source: Organization.
Exhibit 9  Measures Tracked by the Highland Gastroenterology Unit, 2009

Clinical Measures:
1. Patient-reported number of relapses during the past year*
2. (Hb) levels, where normal defined as >120 g/l, anemia defined as <120 g/l, severe anemia defined as <100 g/l*
3. Albumin (assessing nutritional status) and CRP (signaling potential inflammation)*
4. Whether patients took certain preventive medications including 5-ASA, cortisone, or immunosuppressive therapies*
5. Number of Highland Hospital IBD patient referrals for tertiary care at Linköping Hospital and causes of referrals**
6. Number of gastrointestinal tumors for Highland Hospital IBD patients reported in the national tumor registry***

Functional Measures (measured by “Short Health Scale”):
1. Do you have any symptoms from your disease? (1 = no, 6 = very severe)*
2. Does your disease impair your daily function? (1 = not at all, 6 = to a very high degree)*
3. Does your disease worry you? (1 = not at all, 6 = to a very high degree)*
4. How is your general well-being? (1 = very good, 6 = extremely bad)*

Cost Measures:
1. Proportion of IBD patients requiring inpatient care in a given year, compared with national data***

Satisfaction Measures:
1. Number of days between PCP referral for IBD outpatient care and outpatient clinic appointment**
2. Proportion of IBD patients able to schedule outpatient clinic visits for acute flare-ups within 2 days**
3. Method of hospital admission for IBD patients (i.e. emergency room or outpatient clinic)**

*tracked by Highland Hospital gastroenterology unit IBD registry
**tracked by Highland Hospital general database
***tracked by the Swedish National Board of Health and Welfare

Source: Organization.
**Exhibit 10** Sample IBD Patient Registry Screen, Highland Hospital Gastroenterology Clinic

<table>
<thead>
<tr>
<th>Personal ID#</th>
<th>12345678-1234</th>
<th>Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Göran Johansson</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>Tallvägen 1 123 45 Eksjö</td>
<td></td>
</tr>
<tr>
<td>Gender:</td>
<td>Male</td>
<td>Age: 36</td>
</tr>
<tr>
<td>Diagnosis:</td>
<td>Ulcerative colitis</td>
<td></td>
</tr>
<tr>
<td>Date of onset:</td>
<td>2002-5-30</td>
<td></td>
</tr>
<tr>
<td>Entered in registry:</td>
<td>2002-11-25</td>
<td></td>
</tr>
<tr>
<td>Exited registry:</td>
<td></td>
<td>Reason for exit:</td>
</tr>
</tbody>
</table>


Symptoms described at visit:
- None

- Malfunction of bowel: Any symptoms now?
  - None
  - No

- Worry about IBD disease?: Flare ups within past year?
  - No worry
  - 1

- General well being?: Current disease intensity?
  - Good
  - None

IBD-related medications:
- X 5-ASA
- 
- Immunosuppressive/anti-body treatment
- 
- Continuous steroids
- 
- No medications

Source: Organization.
Exhibit 11  Clinical and Quality of Life Results for Highland Hospital Patients with IBD

Hemoglobin

Patients with hemoglobin > 120 g/L

Symptom Severity

Patients rating their IBD symptoms between 1 (none) and 3 (moderate) out of 6 on the Short Health Scale

Daily Functioning

Patients rating the degree to which IBD impaired their daily functioning between 1 (not at all) and 3 (to a moderate degree) out of 6 on the Short Health Scale
IBD patients rating their degree of worry about their disease between 1 (not at all) and 3 (to a moderate degree) out of 6 on the Short Health Scale.

**Degree of Worry**

IBD patients rating their general well-being between 1 (very good) and 3 (rather good) out of 6 on the Short Health Scale.

**General Well-Being**

Source: Organization documents.
Exhibit 12  Measures Tracked by National IBD Registry, vs. Highland Hospital Results (2008)

<table>
<thead>
<tr>
<th>Measures</th>
<th>National IBD Registry</th>
<th>Highland Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td># of IBD Patients Tracked</td>
<td>8,535</td>
<td>481</td>
</tr>
<tr>
<td>Expected Prevalence in Coverage Area</td>
<td>45,000 cases (of 9 million pop)</td>
<td>550 cases (of 110,000 pop.)</td>
</tr>
<tr>
<td>Estimated Registry Coverage</td>
<td>19%</td>
<td>&gt;95%*</td>
</tr>
<tr>
<td>% Men Included</td>
<td>50.4%</td>
<td>43%</td>
</tr>
<tr>
<td>% Women Included</td>
<td>49.6%</td>
<td>57%</td>
</tr>
<tr>
<td># IBD-related Visits per Year</td>
<td>Tracked</td>
<td>Not Tracked</td>
</tr>
<tr>
<td>Cause of Visit: increased/worse symptoms, planned visit, or unknown cause?</td>
<td>8.3% worse symptoms 91.7% unknown/unregistered 71.7% planned or unknown</td>
<td>Not Tracked</td>
</tr>
<tr>
<td>Any IBD-related Sick Days That Year?</td>
<td>8.5% of patients – yes</td>
<td>Not Tracked</td>
</tr>
<tr>
<td>% with IBD Hospitalizations That Year?</td>
<td>4.8%</td>
<td>7.4%</td>
</tr>
<tr>
<td>% Undergone IBD Surgery at Any Time</td>
<td>19.4%</td>
<td>Not Tracked</td>
</tr>
<tr>
<td>% Undergone Surgery in Past Year</td>
<td>2.9%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Smoking</td>
<td>Tracked (Unavailable)</td>
<td>Tracked**</td>
</tr>
<tr>
<td>Short Health Scale</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>24.6% non-smokers 71.8% unknown/unregistered</td>
<td>Not Tracked</td>
</tr>
<tr>
<td>% of Patients on Drug Therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-ASA (all patients)</td>
<td>47.2%</td>
<td>32.4%</td>
</tr>
<tr>
<td>5-ASA (patients with extensive Ulcerative Colitis)</td>
<td>67% N/A</td>
<td>70% N/A</td>
</tr>
<tr>
<td>Immunosuppressives</td>
<td>25.9%</td>
<td>35.6%</td>
</tr>
<tr>
<td>Cortisone</td>
<td>12.4%</td>
<td>14.0%</td>
</tr>
<tr>
<td>Anti-TNF (Antibody to Tumor Necrosis Factor)</td>
<td>4.8%</td>
<td>8.9%</td>
</tr>
</tbody>
</table>

*Expected IBD prevalence for Sweden and the Highland Health Area was estimated at 0.5% of the population. Estimated registry coverage was calculated by comparing the number of patients included in the registry to expected prevalence. Highland Hospital believed the true IBD prevalence in the Highland Health Area was below 0.5% due to its demographics (e.g. more elderly residents), and internal surveys suggested the Highland IBD registry included more than 95% of local IBD patients, rather than 87% using a 0.5% expected prevalence.

**See Exhibit 10.

Source: Organization documents.
Exhibit 13  Care Events and Hospital Admissions for Highland Hospital IBD Patients, 1999–2008

% Care Events = Percentage of hospital-based care events and admissions coded with ulcerative colitis or Chron’s disease as the primary diagnosis (not unique patients).

NP = Percentage of unique patients requiring hospital-based care events coded with ulcerative colitis or Chron’s disease as the primary diagnosis.

Source: Organization documents.

Exhibit 14  Wait Times for Gastroscopies and Outpatient Clinic Appointments for IBD Patients at Highland Hospital, 2001–2008

Source: Organization documents.
Endnotes


14 “Health Care Innovation Week” presentation by State Secretary Karin Johansson, Ministry of Health and Social Affairs, February 20, 2008.


18 Swedish Association of Local Authorities and Regions (SALAR), National Healthcare Quality Registries in Sweden, 2005.


22 Clinical physiology was a branch of physiology particularly dealing with functional disturbances in disease (pathophysiology) and the integrated function of the human body in disease against the background of normal function in healthy subjects, suitable physiological methods for the study of patients—particularly for diagnostic purposes—as well as for research, and the education of medical students and laboratory assistants in these fields. From: Linderholm, H., “Clinical physiology: an accepted branch of physiology,” Clinical Physiology and Functional Imaging, Vol. 10, Issue 3, 1990.

23 Histopathology was not needed to issue an IBD diagnosis for all patients, but was helpful in some cases.

