Getting Going on Getting Better:

How is Systematic Quality Improvement Established in a Healthcare Organization?

Implications for Change Management Theory and Practice

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Change is disturbing when it is done to us, exhilarating when it is done by us.

– Rosabeth Moss Kanter
ABSTRACT

Despite the widespread application of quality improvement (QI), there is enduring uncertainty about its effectiveness in healthcare as an approach to the inevitable, but challenging, task of managing organizational change. This uncertainty is due, at least in part, to our limited understanding of what it takes to apply QI fully in healthcare organizations as well as to the difficulties involved in evaluating QI efforts. Understanding the degree of application – both its depth and breadth – is key for assessing the impact of QI.

This thesis examines how QI was established in one large healthcare organization, Huddinge University Hospital (HUH) outside Stockholm, Sweden, between 1997 and 2001 (Studies I, II, and IV). The thesis also includes a systematic literature review of how Statistical Process Control, a key approach to QI, has been applied to healthcare QI (Study III). Together, the four studies and a review of related literature form the basis for a model of how QI is established in a healthcare organization.

Studies I, II, and IV rely on a case study of a natural experiment: the introduction of process management – an application of QI – at HUH. Drawing on participant observation and extensive documentation from over 1000 QI team sessions at the hospital, Study I examines how QI efforts were initiated through collaboration between multi-professional clinical teams and managers; Study II how QI facilitators helped such teams apply QI methods and principles in practice and improved their own approach as they went; and Study IV how the QI program evolved and with what outcomes over the study period.

Study I showed that waiting times emerged as a dominant problem identified by teams, and that a strategy combining a bottom-up with a top-down approach to identifying problems enabled management teams to harness staff insights and motivation. Study II demonstrated how facilitators provided a framework and methods’ support for QI efforts and how they continuously adapted the QI approach based on their own learning and participant feedback. Study IV found that 58 % of QI projects (39/67) demonstrated success, a comparatively high proportion. The study also showed that the QI program – and the conditions for its conduct – changed continuously over the study period. The biggest difficulty participants reported was a lack of time for improvement efforts, while reported benefits included an increased ability to see the “bigger picture” and improvements for both patients and employees. In Study III, Statistical Process Control was shown to be a versatile tool, which can enable diverse stakeholders to manage and document change in healthcare and to improve patients’ health.

Establishing QI in a healthcare organization is an evolutionary process involving continuous adaptation to organizational needs, ambitions, and circumstances, as the model developed in this thesis shows. This corresponds with change management theory, which is mostly derived from studies in other industries. The evolutionary aspects need to be taken into account both by practitioners and researchers, when introducing, or evaluating, QI programs, more than has typically been the case.
LIST OF PUBLICATIONS

This thesis is based on the following studies, which will be referred to by their Roman numerals (I-IV):


LIST OF ABBREVIATIONS

CQI Continuous Quality Improvement
EBM Evidence-Based Medicine
HUH The Huddinge University Hospital
IHI The Institute for Healthcare Improvement, Boston, MA, USA
IQD Integrated Quality Development
JCC The Jönköping County Council
PDSA-cycle Plan-Do-Study-Act-cycle, a model for testing changes
QA Quality Assurance
QI Quality Improvement
SPC Statistical Process Control
TQM Total Quality Management
1 PROLOGUE

The research reported in this thesis was inspired by a deceptively simple question: Does quality improvement (QI) work in healthcare? In other words, does application of QI principles and methods enable clinicians and managers to manage and improve healthcare? The answer, as it turns out, was not quite that simple, as I will elaborate on in this thesis.

I became interested in QI – or, really, I was driven into it – for two reasons: My desire to provide good care to my patients, and my experience as a young physician that the healthcare system I found myself working in was not well designed to enable me, or others, to provide such good care. I remember, for instance, working temporarily at a Primary Healthcare Center and one day being asked to see an older woman – although we had never met before – who was coming back to learn about the results of diagnostic tests she had undergone. The tests indicated that she had gastric cancer with a poor prognosis, and now I was asked to let her know. Not only did I lack significant experience of care for her disease, I was also unfamiliar with the local context and how this woman would best be cared for subsequently. Even though it probably did not affect the medical course of her illness, this situation was not professionally satisfying to me, and most certainly could have been a lot better for my patient. I wish my patient had instead received care from a team she knew, or could get to know, and that her care had corresponded with the best knowledge available for this situation. Or I wish I had, at least, had such knowledge available at my fingertips.

Frustrated, I saw a need to improve the state of affairs. Then, I ran into another source of frustration: It turned out to be rather difficult to improve healthcare as a junior physician (and for many others too, I later found out). My suggestions to colleagues and superiors for ways to improve typically met with anything from mild disinterest to outright rejection. The feeling that I needed to strengthen my ability to improve healthcare was brewing inside me.

When I had the opportunity to learn about QI at Harvard School of Public Health, and later at the Institute for Healthcare Improvement, in Boston, I began to be hopeful again. The QI principles and methods resonated with my experience and my values. I felt that this was by far the best approach to addressing the problems I had witnessed in healthcare. Eager to apply QI at home, I encountered the next challenge: Many colleagues were sceptical of QI, and asked for evidence that it really works. That brings us back to the question at the beginning of this prologue. I have spent the past ten years or so thinking and learning about this issue. This thesis reports my research and my understanding of the literature on this topic so far.
2 INTRODUCTION

Quality improvement (QI) represents a leading approach to the inevitable, and often challenging, task of managing organizational change. Before we address the question for this thesis, how QI is established in a healthcare organization, we need to place it in context and discuss the theoretical problem that motivates this research.

First of all, why do we have organizations? Because they help us do things that are important to us. Or, as one of my professors at Harvard put it: we have organizations because we are all mortal. Organizations enable us to do things more quickly and efficiently in the limited time we have than we otherwise could. If we did not have organizations, we would have to do everything on our own, or form new groups of people to collaborate with each time we needed to perform a demanding task. So, organizations help us, through division of labor and routinized, smooth ways of performing recurring tasks. In addition, organizations can house many people who together can accomplish things that individuals alone could not (even if they were immortal). This is very clear, for instance, in the kind of organization where I work: a university hospital. Many procedures there, such as a liver transplant or a hip arthroplasty, and the associated care, require the coordinated actions of several highly skilled individuals. Nobody could do it all alone.

All organizations have a raison d’être, or mission, even if not necessarily explicitly stated, which drives one of the premises indicated above – that change is an inevitable challenge for organizations and their members. Organizations need to manage change to sustain their ability to deliver on their mission, or else they risk to fail and be dissolved. The need for change can come from threats or opportunities, such as new regulation, shifts in the labor market, competition, new disease patterns, scientific advances or technological breakthroughs. For instance, the number of organizations that make and sell typewriters has declined markedly with the advent of personal computers and printers. Typewriter manufacturers either failed or managed to change and adapt to the new situation. In medicine, the shift from surgical treatment for peptic ulcers to predominantly medical treatment is a similar example. A hospital that failed to make that transition would be out of (at least that particular) business today. Most have made the transition, by managing this change one way or another.

Often, however, change is difficult. In fact, organization research has repeatedly shown that failure in change projects is more the rule than the exception. “Indeed, [some observers] claim that nearly two-thirds of change efforts fail. Though this seems a staggeringly high failure rate, studies of particular types of change initiatives do appear to come to similar conclusions.”(2 p. 3) In other words, many attempts at intentional change fail to achieve the intended outcomes. (This is true not only for organizations, of course, but for us as individuals as well.) Consequently, the benefits of opportunities pursued do not materialize, or the threats faced do impact the organization as feared. This explains why change management is a central task in organizations, and a vital branch of organization theory. (1, 4) This also links to a fundamental insight from systems theory, what Berwick calls the “indissoluble bond between improvement and change. Not all change is improvement, but all improvement is change.”(5 p. 619)
If we want to improve performance, as we do in healthcare for reasons we will review in a moment, then we need to manage change successfully. Otherwise, we will not improve our performance. Improvement does not typically happen spontaneously but instead requires intentional change through concerted efforts. As noted initially, QI is one leading approach to undertaking such efforts.

There are many reasons for undertaking improvement and change in healthcare, of course. First, the normative view that healthcare is a good thing, that it provides benefit to patients and to society, at least most, or some, of the time (6). Then, one reason to undertake improvement is to increase the efficiency of the healthcare system, so that it can yield greater benefit to patients under prevailing resource constraints, or stretch the benefits to additional people using the same amount of resources. Another reason to undertake change is to increase the equity of healthcare, so that the benefits are distributed more fairly. Or, we could aim to lower the costs for healthcare and maintain the level of benefit, as attempted during the economic downturn in Sweden in the 1990’s (7). Finally, a significant driver of change aimed at increasing the benefits yielded by healthcare is the potential to improve health outcomes through the application of new scientific knowledge, or of older knowledge that is not applied to its full potential.

Failures to apply the best available knowledge on the effectiveness of medical technologies, or on the most efficient forms for healthcare provision, correspond to lost opportunities to reduce the burden of illness and injury on peoples lives, and thus to inefficient use of scarce resources. For example, one landmark study found that adult Americans, whose healthcare encounters were reviewed using 439 indicators of effective care for 30 serious and common conditions as well as preventive care, received only 55% (range 10% to 79%) of recommended care. (8) In Sweden, an analysis of data from 32,954 patient episodes from 67 hospitals in the national quality register for acute myocardial infarction showed wide variation in the application of recommended diagnostic and therapeutic methods. This variation was shown to correspond to one additional life lost per 20 admissions in hospitals with the lowest, compared to those with the highest, degree of such application (a range in 1-year mortality from 25% to 20%). (9)

2.1 MODELS FOR HEALTHCARE CHANGE

Many theories and models have been developed to explain how change can occur in healthcare (10, 11), in part based on analyses of barriers to successful change. One review observed that “obstacles to change in practice can arise at different stages in the health-care system, at the level of the patient, the individual professional, the health-care team, the health-care organisation, or the wider environment”. (12) Consequently, interventions to facilitate change address one or more of these levels. Different interventions also are informed (at least implicitly) by one or several theories.

Theories and models can be divided into those primarily relating to (A) individual professionals, (B) social interaction and context, and (C) organizational and economic context.(13) Examples include, at level (A): cognitive, educational, and motivation
theories; at level (B), theories on: social learning, social networks, patients’ expectations and needs, professional development, and leadership; at level (C): quality management, organizational learning, complex systems, and economic theory.

This thesis primarily concerns the organizational level (C), although, again, there is overlap between different perspectives. QI efforts, for instance, combine several components, such as “systems thinking” and “small scale testing”. Let us now review the concept of QI, its history and application to healthcare, with a view to then framing the research problem for this thesis.

2.2 APPROACHES TO QUALITY IN HEALTHCARE

Concern for quality is not new to healthcare. Indeed, such concern can be traced back at least to the mid-1800’s, to Ignaz Semmelweis who demonstrated the dramatic reduction of puerperal fever and mortality in the maternity wards as a result of improved hand hygiene at the Allgemeine Krankenhaus teaching hospital in Vienna (14), and to Florence Nightingale who cared for soldiers in the Crimean War of 1854–6. She demonstrated, by way of ingenious data collection including comparisons, that most fatalities at the hospital “were due not to battlefield wounds, but from what today we would call infectious diseases” ((15) p. 317) and that the in-hospital mortality rate decreased from a peak at 43 % to just 2.2 % following her sanitary interventions. Another early student of quality in healthcare was Ernest A. Codman (1869–1940), a surgeon in Boston, MA, USA, who made “a lifelong systematic effort to follow up each of his patients years after treatment and recorded the end results of their care. He recorded diagnostic and treatment errors and linked these errors to outcome in order to make improvements.” ((16) p. 104) He challenged his fellow surgeons to systematically assess and report their actions and outcomes as he did. His challenge was not well received then, and is not universally met even today, nearly a century later.

For much of the 20th century, the emphasis in healthcare was largely on defining and measuring quality, and correcting negative deviations from defined standards of care. This approach – known as Quality Assurance (QA) – is intended to uphold a minimum level of quality. Much important work was done in the QA era to develop methods and principles for assessment of healthcare quality.(17) In 1966, Avedis Donabedian proposed a now classic model for healthcare quality with three dimensions: structure, process, and outcome.(18) Structure refers to the facilities, equipment, staff and procedures available to enable healthcare provision; process refers to the actions that are carried out in healthcare; and outcomes refers to the ultimate “changes in patients’ health status that are attributable to the care received”. ((17) p. 21) Factors in the former two dimensions are viewed as helping or hindering the achievement of desired outcomes.

Palmer discussed three categories of healthcare quality – technical quality, accessibility, and acceptability – and three related concepts – efficacy, effectiveness, and efficiency. These correspond to the six dimensions of quality later proposed by the US Institute of Medicine(6), which also have been prescribed by Swedish authorities(19). See Box 1 for definitions of these central terms.
Box 1. Key concepts of healthcare quality and their definitions

**Technical quality** is “the degree to which providers coordinate judgement, skill, and available technology to improve the health of patients” and includes “the choice of an appropriate item of care and its safe and timely performance”

**Accessibility** is “the ease with which health care can be reached by a beneficiary in the face of financial, geographical, organizational, cultural, and emotional barriers”

**Acceptability** is “the degree to which health care satisfied patients”

**Appropriateness** concerns whether providers “used medical technologies such as tests, procedures and treatments correctly” (whether they did “the right thing”)

**Efficacy** is “the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use” (as assessed in randomized controlled trials)

**Effectiveness** is “the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under average conditions for use” (i.e. in “real life”)

**Efficiency** is “the degree of quality present in a given unit of health care for which a fixed amount of resources is used” (a concept related to both cost and quality of care). This concept can also be inverted so that efficiency is defined as “the amount of resources used to produce a given unit of health care of a fixed degree of quality”. In either case, “greater efficiency means more value for money”

Source: ((17) p. 20)

Towards the end of the 1980’s, a dramatic shift – perhaps a “paradigm shift”, to borrow from Thomas Kuhn – emerged in the way healthcare quality was viewed. A visible marker, and driver, of this shift was the 1989 New England Journal of Medicine article “Sounding Board: Continuous Improvement as an Ideal in Health Care” by Don Berwick (20) (which has been cited over 750 times since). Reflecting on the prevailing way of addressing quality, he found that it “relies on inspection to improve quality. We may call it the Theory of Bad Apples, because those who subscribe to it believe that quality is best achieved by discovering bad apples and removing them from the lot.” This approach leads to unproductive defensiveness, argued Berwick, and gives rise to the “my-apple-is-just-fine-thank-you response” on the part of those under such scrutiny. In contrast, Berwick suggested, the Theory of Continuous Improvement is focused on “understanding and revising the production processes on the basis of data about the processes themselves [to] reduce waste, rework, and complexity.[...] Modern
theories of quality improvement in industry are persuasive largely because they focus on the average producer, not the outlier, and on learning, not defense.” (20) p. 53-4

The meaning of this shift is well captured in the following image:

![Figure 1. “Comparison of Continuous Quality Improvement (CQI) and traditional Quality Assurance (QA). QA focuses only on low-quality outliers and has limited effect on the mean. CQI affects systems of care and thus has potential for greater impact.”](image)

From: (21) p. S61
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Palmer and Adams noted about the experience with QA that “much was learned about quality measurement, but dramatic gains in quality of care did not result”. (17) p. 27

The shift from QA to QI was reflected in a number of articles in 1989-1991. (22-25)

We need next to review what is meant by “quality improvement” and how it has fared when applied in healthcare. QI is an overarching term which has come to encompass many more or less specific approaches to improvement. It includes process orientation, broad participation of employees, leadership commitment, customer orientation, decision-making based on facts, and experimentation in everyday work. (26) Some common terms, and their definitions according to the American Society for Quality, are given in Box 2.

**Box 2. Terms in quality improvement**

**Continuous quality improvement (CQI):** A philosophy and attitude for analyzing capabilities and processes and improving them repeatedly to achieve customer satisfaction.

**Kaizen:** A Japanese term that means gradual unending improvement by doing little things better and setting and achieving increasingly higher standards. Masaaki Imai made the term famous in his book, Kaizen: The Key to Japan’s Competitive Success.

**Lean manufacturing/production:** An initiative focused on eliminating all waste in manufacturing processes. Principles of lean manufacturing include zero waiting time, zero inventory, scheduling (internal customer pull instead of push system), batch to flow (cut batch sizes), line balancing and cutting actual process times. The production systems are
Quality management: The application of a quality management system in managing a process to achieve maximum customer satisfaction at the lowest overall cost to the organization while continuing to improve the process.

Reengineering: A breakthrough approach for restructuring an entire organization and its processes. [Also known as Business Process Reengineering, or BPR, where a process is redesigned “from scratch”, this is considered a more radical approach to improvement compared with the more incremental approaches such as CQI and TQM.]

Six Sigma: A method that provides organizations tools to improve the capability of their business processes. This increase in performance and decrease in process variation lead to defect reduction and improvement in profits, employee morale and quality of products or services. Six Sigma quality is a term generally used to indicate a process is well controlled (±6 s from the centerline in a control chart).

Total quality management (TQM): A term coined by the Naval Air Systems Command to describe its Japanese style management approach to quality improvement. Since then, TQM has taken on many meanings. Simply put, it is a management approach to longterm success through customer satisfaction. TQM is based on all members of an organization participating in improving processes, products, services and the culture in which they work. The methods for implementing this approach are found in the teachings of such quality leaders as Philip B. Crosby, W. Edwards Deming, Armand V. Feigenbaum, Kaoru Ishikawa and Joseph M. Juran.

Toyota production system (TPS): The production system developed by Toyota Motor Corp. to provide best quality, lowest cost and shortest lead time through eliminating waste. TPS is based on two pillars: just-in-time and jidohka (Stopping a line automatically when a defective part is detected.) TPS is maintained and improved through iterations of standardized work and kaizen.

Source: American Society for Quality (27)

Different authors emphasize different features as emblematic of QI. This has contributed to confusion over the years, and to difficulties when trying to evaluate QI effectiveness, since there is a great risk of comparing “apples and oranges” when quite different interventions are described with the same labels. Box 3 contains examples of differing views on QI concepts.

**Box 3. Differing views on quality improvement concepts**

“Continuous quality improvement in health care comes in a variety of ‘shapes, colors, and sizes’ and is referred to by many names. Don’t be confused – whether it is called total quality...
management (TQM), continuous quality improvement (CQI), or some other term, TQM/CQI is a structured organizational process for involving personnel in planning and executing a continuous flow of improvements to provide quality health care that meets or exceeds expectations. In this book, the two terms CQI and TQM will be used interchangeably: TQM, referring primarily to industry-based programs, and CQI referring more often to clinical settings. [...] Although CQI comes in a variety of forms and is initiated for a variety of reasons, it does have a set of distinguishing characteristics and functions. These characteristics and functions are often defined as the essence of good management. They include: (1) understanding and adapting to the organization's external environment; (2) empowering clinicians and managers to analyze and improve processes; (3) adopting a norm that customer preferences are the primary determinants of quality and that the term customer includes both the patients and the providers in the process; (4) developing a multidisciplinary approach that goes beyond conventional departmental and professional lines; (5) adopting a planned, articulated philosophy of ongoing change and adaptation; (6) setting up mechanisms to ensure implementation of best practices through planned organizational learning; and (7) providing the motivation for a rational, data-based, cooperative approach to process analysis and change." ((28) p. 3, 5)

Juran discusses three interrelated processes for Quality Management: quality planning, quality control, and quality improvement; the Juran Trilogy. Improvement activities are guided by organizational goals, and gaps identified between current performance and these goals. “Improvement means ‘the organized creation of beneficial change; the attainment of unprecedented levels of performance.’ A synonym is ‘breakthrough.”” ((29) p. 5.3)

“TQM appealed to me at many levels. As a theory of management, it was humane, democratic, and oriented toward learning and education. Perhaps most important of all, however, it seemed to me grounded fundamentally in the scientific method. TQM advocated the application of validated data, sound statistical analysis, and the experimental method to diagnosing and treating problems in the processes that organizations used to produce their products. [...] The fundamental source of the power of TQM lies in [the] simultaneous commitment to the scientific method on the one hand and to applying that method in real world settings on the other. The result is a remarkable blending and interaction of theory and practice”.((30) p. XI-XII, XVIII)

Shortell et al highlight conceptual strengths of CQI, rendered through its “fourfold focus:
1. on determining and meeting the needs of patients or customer
2. on a holistic approach to quality improvement, based on identification of underlying causes of poor performance
3. on fact-based management and scientific methodology, which make it culturally compatible with the values of health care professionals
4. on empowering its practitioners to improve quality on a daily basis”.
((31) p. 605)

They further assert that, to achieve significant organizational improvement, four interrelated dimensions “must be present": a strategic dimension – an organization’s ability to focus on strategically important areas for its QI efforts; a cultural dimension – the underlying beliefs, values, norms and behaviours in an organization that help or hinder QI efforts; a technical
“Quality improvement is a complex and heterogeneous organisational intervention and the names given to different forms or approaches bestow a misleading impression of uniformity on the realities they describe. For example, different total quality management programmes may share little more than the title and basic terminology of total quality management/continuous quality improvement, and can have quite different structures, training, measurement methods, and levels of resource investment.” ((32) p. 85)

“The terms continuous quality improvement (CQI), total quality management (TQM), and quality improvement (QI) are often used interchangeably in North America, although they mean different things to some people. These ideas are defined in at least three ways. One is by the writings of Walter Shewhart, W. Edwards Deming, Joseph Juran, and like-minded thinkers, which concern reducing variation in standard operations processes. A second way defines CQI as a way to answer these three questions: Why do we do what we do? How do we know it works? How can we do it better? The third definition is very similar to the second, promoting customer-mindedness, statistical-mindedness, and organizational transformation.” ((1) p. xxxiii)

“CQI is also described by reference to Deming’s 14 points [...]. Behind these points are a number of assumptions. Production is a process with inherent variation. Understanding the causes of variation and changing the process to reduce variation will result in improved quality. [...] Inspection, fear, quotas, and slogans will not help – education, pride of workmanship, teamwork, participation, and leadership will. All this transformation is intended to better meet the needs and wishes of those we serve. Despite the fact that the active use of CQI methods in health services is less than 20 years old, it is now a worldwide movement.” ((1) p. xxxiv-xxxv)

“Quality improvement (QI) is a management philosophy to improve the level of performance of key processes in the organization. In particular, this approach insists that ‘quality is an organizational problem’ [...], that is, that variation in quality is as much due to the way in which care is organized and coordinated as it is to the competence of the individual caregivers [Ref]. It was developed originally by several industrial quality experts and applied successfully in a variety of industries worldwide [Ref.s]. The principles espoused by these experts differ little but have helped spawn several terms used interchangeably with QI: total quality management (TQM), industrial quality control, and continuous quality improvement (CQI).” ((33) p. 439)

QI development began in the 1920’s in telephone manufacturing with the efforts of Walter Shewhart (34), who developed the control chart – an application of statistics to understand and control variation in production processes (35) – and proposed small-scale testing as an approach to change, which has developed into the PDSA-cycle (for
Plan-Do-Study-Act), a central component in QI. W Edwards Deming, who learned how to apply statistics to process variation from Shewhart, subsequently elaborated Shewhart’s work.(36, 37) Like Deming, Joseph Juran (38, 39) had worked with Shewhart at the Hawthorne plant outside Chicago. Both Deming and Juran disseminated the ideas on QI in Japan, where they evolved further and were applied on a broad basis starting in the 1950’s, fuelling the Japanese industrial revolution. Having fallen out of fashion after World War II in the US, QI methods gained new interest based on the example of the Japanese, both in the US and in Western Europe in the 1970’s and 1980’s.

Towards the end of the 1980’s, the principles of QI found their way into healthcare, first in the US, pioneered in large part by a few leading physicians, personally encouraged by Deming and Juran, including Paul Batalden (40), at the time with the Healthcare Corporation of America, today a professor at Dartmouth Medical School; Don Berwick (20) then at the Harvard Community Health Plan and Harvard University, today CEO of the Institute for Healthcare Improvement (IHI); David Blumenthal (41), then at the Brigham and Women’s Hospital and Harvard University, today Director of the Institute for Health Policy, Massachusetts General Hospital and at Harvard; and Brent James (42) at Intermountain Health Care (IHC) based in Salt Lake City, Utah, where he directs the IHC Institute for Health Care Delivery Research.

Drawing on Deming’s work, Batalden and colleagues applied Deming’s framework of “Profound Knowledge”, later termed “Improvement Knowledge”, to healthcare. (43) This field of knowledge is taken to complement traditional professional knowledge – subject, discipline and values, e.g., in healthcare, knowledge of pharmacology, pediatrics, or nursing – with particular focus on how to enhance the capacity to improve. Improvement knowledge consists of four elements:

1. Knowledge of systems – understanding work processes as part of a larger system of production
2. Knowledge of variation – understanding and controlling variation in production processes, an application known as Analytical statistics (in contrast to Enumerative statistics which is more commonly used in biomedical research)
3. Knowledge of psychology – particularly concerning motivation, workplace design, and change
4. Theory of knowledge – understanding and adapting to how professionals learn from their own practical experience

The application of improvement knowledge is supported by models and tools developed during the TQM/CQI evolution (43), which were synthesized by Nolan et al into a practical “Model for Improvement”. (5, 44) The model consists of three foundational questions for improvement efforts, and the PDSA cycle as a means to test and learn from changes on a small scale, and make appropriate adjustments before wide implementation. The questions are:

1) What are we trying to accomplish?
2) How will we know that a change is an improvement?
3) What changes can we make that will result in improvement?
In Berwick’s words, the “simplicity of [the model] belies its sophistication. [These] four simple steps – set aims, define measurements, find promising ideas for change, and test those ideas in real work settings – challenge the mettle of the best and push against many deeply held assumptions.” ((5) p. 620)

A forerunner in the QI movement in healthcare was the US National Demonstration Project on Quality Improvement in Health Care (NDP), launched in 1987 and hosted by the Harvard Community Health Plan to address the question: “Can the tools of modern quality improvement, with which other industries have achieved breakthroughs in performance, help in health care as well?” ((45) p. xvi) Only eight months in duration, the project brought together 21 healthcare organizations and QI specialists to test QI principles and methods in practice. Using the NDP experience as a foundation for introducing these principles and methods to healthcare, the authors reporting on the project also recognized the limitations inherent in this approach. “The critical reader will notice that the strength of this book – its foundation in real projects in real organizations – is also its weakness. These teams actually existed; they actually struggled with the challenges of adapting these methods to health care and with the resistance to change that awaits any who begin the journey to quality improvement. They did take the first steps and proved that others can, too. But because these are real stories, there are no astounding results to report. How could there be in a project that lasted only eight months? No hospital in these eight months turned around its bottom line. No team reaped million dollar successes. So far as we know, no single life was saved. [...] The glamour in what they did is not in the results achieved – those, we believe, will follow later as commitment and experience grow – but rather in the innovation begun. The first steps were taken by real organizations toward something truly new in an industry that desperately needs new ideas for helping itself.” ((45) p. xviii-xix)

And the rest, as the saying goes, is history.

The movement catalyzed by the NDP led to the 1991 founding of IHI, as a non-profit organization to further promote QI in healthcare. Led since its inception by Don Berwick, the Harvard pediatrician, IHI has grown to become a powerhouse for QI worldwide, through education, training, collaborative improvement efforts, advocacy, and breakthrough improvement demonstration projects. By 2005, nearly 21,000 organizations, spanning 50 countries, had been involved in IHI’s work. (46) A recent example is the “Save 100k Lives” project, which enrolled over 3,000 hospitals to implement six evidence-based interventions to reduce mortality among hospital patients. Under the motto “Some is not a number, soon is not a time”, IHI reported that Campaign participants had increased their application of these interventions and prevented over 122,000 deaths among hospital patients over an 18-month period, ending on June 14, 2006. (47, 48)

The campaign, and the estimates of lives saved, met with widespread interest, but also – and this heralds the research problem addressed in this thesis – with scepticism (some healthy, some perhaps less so). Two independent health services researchers raised a number of both methodological and policy concerns prompted by the Campaign and the associated publicity. Their exchanges with IHI representatives encapsulate many of
the research problems that have accompanied the QI movement since its inception in healthcare. (49, 50) Questioning the estimation of lives saved, the attribution (at least in many media reports) of effects to the Campaign per se, rather than to other, simultaneously influential factors, and the evidence base for some of the interventions, the two sceptics argue that “patients, clinicians, and others ought to know, with scientific integrity, whether quality improvement efforts work. When hyperbolic estimates of benefits are presented as truth, we worry that quality improvement efforts—including the remarkable work of IHI and its partnering organizations, hospitals, and providers—are set back, not enhanced.” (50) p. 631

2.3 ASSESSING THE IMPACT OF QUALITY IMPROVEMENT

Predictably, the emergence of QI, and the optimistic predictions by many proponents that it could help solve central problems in healthcare, prompted efforts to evaluate its actual impact. These efforts, by and large, have resulted in enduring uncertainty about the effectiveness of QI programs; whether they can facilitate organizational change management and performance improvement.

In 1996, for instance, Blumenthal and Epstein concluded that “there is so far no convincing scientific evidence that the application of the techniques of total quality management in health care improves the quality of care in entire institutions or among large numbers of physicians.” ((Blumenthal and Epstein, 1996) p.1329) Similarly, a major textbook on CQI in healthcare noted that “[d]espite widespread enthusiasm for total quality management/continuous quality improvement (TQM/CQI), whether or not it works in health care remain legitimate concerns.” ((51) p. 34) More recently, two other scholars argued that the evidence-base for QI efforts is still frustratingly weak, and that “in sharp contrast to the paradigm of evidence-based medicine, these efforts often proceed on the basis of intuition and anecdotal accounts of successful strategies for changing provider behavior or achieving organizational change.” ((52) p. 138) To better understand these statements, let us now review some key evaluations of healthcare QI efforts.

In 1997, the National Roundtable on Health Care Quality, an initiative of the Institute of Medicine (IOM) of the US National Academy of Sciences, convened a conference of experts to assess the strategies for healthcare QI, and their impact. This led to a consensus statement from the Roundtable on the urgent need to improve quality (53), and to the publication of a number of articles and comments in the Milbank Quarterly. (54)

One of these articles was a “Report card on CQI” based on interviews with QI experts and organizational representatives, aimed at learning lessons from the first decade of CQI application in healthcare. (55) The authors list accomplishments and shortcomings, highlighting for instance the value of educating healthcare staff in applying the scientific method to improve organizational performance; the potential benefits in adopting the principles for Learning organizations; but also that the QI movement “has not had the impact that many advocates and observers hoped for”. (55) p. 635) They comment that the early proponents of CQI were often overly enthusiastic and dogmatic, and that “many physicians were repelled by the evangelism that characterized early
CQI programs. [Suspicious of managers’ motivations,] many physicians quickly concluded that CQI was another form of QA cloaked in a new version of management psychobabble. They tuned it out and went about their business, waiting for the fad to pass.” ((55) p. 640) Seeing several similarities with political campaigns, they note that CQI is “a struggle for the hearts and minds of health professionals. Likewise, health care organizations, particularly academic institutions, consist of multiple departments and divisions, each powerful and each with its own strategy and vision for the future that often diverge from those of the parent organization, resulting in disunity that can paralyze initiatives in the quality arena.” ((55) p. 641-2) Before (correctly) predicting the growth of interest in the value of healthcare, and the necessity therefore of improving the processes of healthcare, as is done in CQI, the authors summarize lessons learned as the CQI movement was maturing. These include the importance of involving physicians early and of using their time effectively; of focusing QI efforts on clinical, patient-oriented issues; and of investing sufficiently in QI.

In another article, Shortell et al. review the literature between 1991 and 1997 on clinical application of CQI, recognizing that CQI efforts had been directed to clinical practice (rather than to administrative areas) only for three to four years. (31) Noting many challenges in assessing CQI impact – e.g. difficulties in measuring outcomes; difficulties in ruling out alternative explanations for findings (due to a lack of appropriate controls); and the limited understanding of cause-and-effect relationships for many conditions – they examined 55 studies, predominantly from hospital settings. Three studies used randomized designs, one used a matched comparison group, and the rest were either before-and-after observational studies or cross-sectional studies. While most studies reported favorable results, none of the randomized studies found any impact of CQI. Despite the difficulty of attributing effects to CQI in the majority of studies, due to their designs, the authors conclude that “the early evidence suggests that quality and outcomes of care can be improved and certain efficiencies achieved through the application of CQI to clinical conditions and processes. Particularly important correlates of success appear to be the participation of a nucleus of physicians, feedback to individual practitioners, and a supportive organizational culture for maintaining the gains that are achieved.” (31) p. 604) At the same time, “no evidence has yet emerged of an organization-wide impact on quality” (31) p. 609) although the authors note some prominent examples, such as the “60 ongoing clinical improvement initiatives” at Intermountain Health Care (IHC) in Utah “that are resulting in approximately $30 million of annual savings.” (31) p. 613)

While this review has been cited widely (more than 150 times) including in high profile overviews of methods to promote healthcare change (12, 56), it has important limitations in addition to those already discussed by the authors. One such limitation is the apparent focus exclusively on the US healthcare system. The authors make many comments that are relevant only to the US (which is not surprising given the Roundtable context for the paper). They do not make it clear whether their review also included studies from other countries, nor whether there were lessons to be drawn from, or for, CQI application in healthcare systems elsewhere. QI methods may not be directly transferable across national contexts, and may require adaptation to fit a foreign setting. (57, 58) Another limitation is the apparent diversity of CQI “interventions”
assessed in the included studies. The authors explain, for instance, that among the studies reviewed, “provider training and education were the most common interventions [and that other] common interventions were information dissemination, feedback to staff, guideline/protocol development [ref.s], physician retraining [ref], and feedback from utilization managers or case managers”. These interventions are not necessarily incompatible with CQI, but do they constitute CQI? Just because the authors of the different studies categorized their interventions as CQI (if they did), this does not mean that they all really represented CQI. Another limitation is that we do not know to what extent, i.e. with which breadth and depth these interventions were applied in the study organizations, or for how long.

The reviewers argue that “the two [single site] studies that relied on randomized clinical trials did not show any changes”.((31) p. 599) A closer look at these studies suggests that other interpretations are plausible: One of these two articles, which was not primarily aimed at assessing the effectiveness of TQM, but instead at demonstrating the benefits of experimental data collection methods, describes, as an example, a TQM project to reduce the no-show rate for first appointments in a mental health youth clinic. The QI team devised two alternative changes (which, contrary to the tenets of TQM, were not particularly “customer-oriented”) for how patients could complete required forms prior to the first appointment, and then randomly assigned patients to one of these alternatives or to the usual procedure. In summary, “[n]ot only did the experimental conditions fail to reduce the no-show rate, they also seemed to reduce the likelihood of entry into treatment. [...] On the basis of these results, the team decided to continue using the original admission process.” ((59) p. 689) This could well be viewed as a successful outcome of the TQM project – that these inadequate changes were not implemented but rejected! (Hopefully, the team could design more customer-oriented changes subsequently to address their problem, although that is not reported in the article.)

Moving beyond the Roundtable reports, a cluster randomized trial of CQI to increase the use of 8 preventive services in 44 urban primary care clinics in Minnesota found that the intervention “did not result in clinically important increases in preventive service delivery rates.” ((60) p. 105) The intervention, lasting for 22 months 1994-1996, involved teaching a leader and facilitator from each clinic about a prescribed 7-step CQI model – which apparently did not involve small scale testing using PDSA-cycles – and about prevention systems; it also involved telephone consultations, and ongoing contact throughout the study period. While all 22 intervention clinics established QI teams, participants spent only limited time on QI efforts (team members spent 5 hours per month; facilitators 12 hours), and only “few teams finished even one complete CQI cycle.” This intervention can be criticized for using a highly prescribed focus for participating clinics, rather than allowing for local adaptation and application of CQI for those areas considered to be of greatest local importance, and for not allowing any time for participants to develop experience with CQI before conducting the trial. The question becomes: did the trial assess the effectiveness of CQI, or the extent of implementation of CQI (which mostly appeared rather limited)?

Another ambitious study failed to demonstrate the hypothesized correlation between greater TQM application and positive clinical outcomes or lower costs.(61, 62) It
involved 16 hospitals and over 3000 patients undergoing coronary artery bypass graft (CABG) surgery in 1995-96. A prospective, observational study, it attempted to assess the degree of TQM application, and the type of organizational culture, by way of a 78-item questionnaire which was given to 54 respondents, on average, at each hospital, including clinicians and administrative support staff. While the study found 2- to 4-fold variations in the outcome measures between hospitals, “TQM implementation and a supportive organizational culture, for the most part, [were] not associated with these differences.”

Despite its ambitious design, the study had important limitations: The response rate on the questionnaire ranged from 78% for the support staff to only 43% for surgeons and anesthesiologists. The degree to which even supposedly “High-TQM” hospitals applied TQM was limited. The questionnaire results “indicate that the cultural, technical, structural, and strategic dimensions are not adequately developed and/or aligned in the various study hospitals.” ((61) p.89) The proportion of eligible patients enrolled in the study ranged from 29% to 78% between hospitals. By design, sicker patients were excluded from the study which “compromised the external validity or generalizability of the findings to other CABG patient populations.” ((62) p. 215) The study did not consider trends in the outcome data within the different hospitals. The implicit assumption therefore appears to be that greater TQM application is associated with better absolute levels in study outcomes, rather than with a faster pace of improvement over time from whichever starting point a hospital had. All of this goes to suggest that the study might have underestimated the potential effects of TQM application.

While healthcare QI appears to have originated in the US, attempts ensued within a few years to adapt it to healthcare in other nations, including Mexico, Japan, Australia, the UK, the Netherlands, even Niger (63), and the Nordic countries.(64, 65) An action evaluation conducted between 1995 and 1998 of the early QI efforts at 6 public hospitals in Norway (66, 67) showed, among other things, that while there was evidence that small project teams were able to achieve measurable improvements, “the hospitals only began to work on quality measurement by the end of the third year. Therefore, the evaluators] were not able to report objective measures of changes in quality which were attributable to the programme or projects.” ((66) p. 71) The evaluation also crystallized many lessons learned at the hospitals, and through comparisons of their experiences. For example, most “hospitals underestimated the change in role and the demands on the competence of managers which the quality programmes would bring. They [assumed] that people would be convinced by the ideas in a short course and would go away and change how they behaved without assistance. [Lacking practical QI experience], managers had little support to apply the ideas and had great difficulty translating the ideas into actions.” ((66) p. 66)

2.4 APPROACHES TO EVALUATION

In addition to the uncertainty regarding the effectiveness of QI in healthcare, there is disagreement about how best to evaluate healthcare QI efforts. This disagreement essentially falls along the lines of two dominant paradigms for research; one favors positivism, or objectivity; the other adheres to interpretivism, or subjectivity. (68) Positivists assume that there is one absolute truth which can be revealed by an objective
researcher – through a deductive approach to research, where theoretically derived hypotheses are tested empirically. Interpretivists, on the other hand, believe that there are many plausible and thereby complementary interpretations of phenomena in the world, and that each researcher’s interpretation is partly subjective, dependent on the researcher’s own perspective. In its extreme form, this approach starts free from any theory, makes empirical observations and builds theory inductively. These “paradigms” may also be viewed as extremes on a continuum; many researchers blend aspects of both paradigms into their research approach and place it somewhere closer to the middle of this continuum.

In the case of QI effectiveness, the “positivist” approach is well represented by many of the reviews and evaluations related above (8, 9, 11-13, 31, 52, 56, 59, 60, 62). In a methodology paper, proponents of this view hold that “[t]he same arguments that are used to justify randomised controlled trials of clinical interventions such as drugs are at least as salient to the evaluations of quality improvement interventions.” ((69) p. 48) In contrast, researchers closer to the interpretivist approach, exemplified by the action evaluation of QI in Norwegian hospitals (66, 67), suggest that what is needed is not merely testing whether QI works or not, but rather clarifying “how and why it works—the determinants of effectiveness.” ((32) p. 86) Furthermore, these questions “are certainly not amenable to investigation using the traditional tools of the biomedical health services researcher. Experimental methods like randomised controlled trials will not help. These research questions need to be explored through primarily qualitative methods using techniques such as participant observation and in-depth longitudinal organisational case studies. We also need to develop better theoretical frameworks to explain the results of these studies, from which we can then begin to develop more generalisable and transferable findings.”((32) p. 86)

Along the same lines, Øvretveit and Gustafson discuss quality programs – “the planned activities carried out by an organisation or health system to improve quality” – and conclude that there has been “little independent and systematic research about effectiveness and the conditions for effectiveness” regarding such programs, particularly outside US hospitals. ((70) p. 270) Previous research has “tended to rely on quality specialists or senior managers for information about the programme and its impact, and to survey them once retrospectively. Future studies need to gather data from a wider range of sources and over a longer period of time.” ((70) p. 271)

Similarly, when Greenhalgh et al reviewed the literature on diffusion and implementation of innovations in health service delivery and organization, such as QI programs, they identified the following question:

“By what processes are particular innovations in health service delivery and organization implemented and sustained (or not) in particular contexts and settings, and can these processes be enhanced? This question, which was probably the most serious gap in the literature we uncovered for this review, would benefit from in-depth mixed-methodology studies aimed at building up a rich picture of process and impact.” ((71) p. 620)
There is, actually, some agreement here across the methodological spectrum outlined above, reflected in the comment from two positivist researchers that we need to pay “greater attention to the understanding of why particular interventions work and the factors that augment or interfere with their success in different settings.” ((52) p. 149)

2.5 RATIONALE FOR THE STUDIES

To sum up, organizational change management is essential, but difficult, in healthcare as elsewhere. Many attempts at intentional change fail, thus hampering an organization’s ability to deliver on its mission, and ultimately threatening its very survival. QI is a leading approach to change management.(1-3) Research evaluations have failed to demonstrate that application of QI principles and methods in healthcare organizations consistently facilitates change management and leads to better performance. At first, this could be viewed as indicating that QI does not work in healthcare, although it is important to remember that absence of evidence (of QI effectiveness in this case) does not equal evidence of absence (of such effectiveness).(72) It is perfectly conceivable that QI can be effective; several of the studies cited above suggest that, even if it has perhaps not been convincingly demonstrated (yet). Some argue that the search for such universally applicable evidence is futile: “Conclusive evidence of effectiveness may never be possible. At this stage a more realistic and useful research strategy is to describe a programme and its context and discover factors which are critical for successful implementation”. ((70) p. 274)

In view of the growing awareness that the quality and value of healthcare, and their improvement, are of long-lasting concern (73-79); that no clearly superior approaches to change management and QI in healthcare have emerged; and that the QI methods outlined above retain their conceptual strengths, it is important to further advance our understanding of QI application in healthcare.

As we have seen, there are substantial difficulties in evaluating QI efforts. The apparent failure of QI effectiveness may thus be due, in part, to our limited understanding of what it takes to apply QI fully in healthcare organizations. If we assess the effects of QI based on limited application of its principles and tools, we may draw erroneous conclusions. What looks like limited effect may instead really be a case of limited application.

This problem leads to the question that forms the basis for this thesis: How does an organization begin to apply QI in practice? There are a myriad of decisions and actions that go into establishing QI, and thus many opportunities to “go wrong”. The sum of all these choices and actions over time constitute the degree to which an organization applies QI in practice. Understanding the degree of application is key for assessing the impact of QI.(70) Therefore, this project aims not primarily at demonstrating whether QI causes better performance, but rather at demonstrating how QI is established in a healthcare organization, thus forming the basis for QI effectiveness, in line with the suggestions cited above.(32, 70, 71)
3 AIM AND OBJECTIVES

3.1 GENERAL AIM

To illuminate how systematic quality improvement is established in a healthcare organization, and to thereby add to change management theory and practice.

3.2 SPECIFIC OBJECTIVES

1. To demonstrate how QI efforts in a healthcare organization were initiated, particularly how multiprofessional clinical teams and managers identified and selected problems for subsequent improvement efforts.

2. To explain how QI facilitators, who give methodological support to improvement efforts, acted to help establish systematic QI in a healthcare organization, particularly how they helped clinical teams and managers apply QI principles and tools and how they simultaneously developed their own skills.

3. To systematically review the literature on how Statistical Process Control has been applied to healthcare QI, and to examine the benefits, limitations, barriers and facilitating factors related to such application.

4. To elucidate the evolution and outcomes of a hospital QI program over a five-year period.
4 STUDY DATA, SETTING, AND DESIGNS

The research reported in this thesis draws on two data sets: data collected during the introduction of process management – a method for QI – at the Huddinge University Hospital (HUH) from 1997 through 2001 (studies I, II, IV); and a set of scientific articles reporting empirical data on the application of statistical process control to healthcare QI, identified through a systematic database search covering the period 1966 through June 2004 (Study III).

The introduction of process management – defined at the hospital as “a systematic way to organize, lead and continuously improve the processes of an organization” – provided what is called a “natural experiment”. In 1997, the hospital management initiated improvement efforts in 12 clinical processes at the hospital. By the end of 2001, over 25 processes were involved, 93 improvement projects had been initiated and over 65 of them had been completed or otherwise ended. The HUH (which merged to form the Karolinska University Hospital in 2004, after the study period), was a tertiary care academic medical center, part of the Stockholm County Council publicly funded healthcare system. During the study period it had more than 6000 employees, including some 2500 nurses and 1000 salaried physicians. Caring for approximately 45 000 inpatients annually, it had 800 beds, and its clinicians provided some 500 000 outpatient visits, including in a busy Emergency Department. Care was provided in 50 departments, which were organized into six clinical divisions. The hospital had close ties with Karolinska Institutet; many of its students in the health professions received their clinical training at the hospital and much research was carried out there. In April of 2000, the hospital was incorporated but it remained wholly owned by the County Council.

I had the opportunity, together with colleagues, to both participate in the process management efforts and collect data documenting those efforts with the explicit intent to subsequently use the data for research purposes. This was an observational study of a natural experiment: the actions taken, and the decisions made, by various stakeholders in the process management initiative were guided by the needs and circumstances of the hospital and its employees and managers; not by the researchers. This is in contrast to an experimental study where researchers design and govern the application of the intervention of interest, or to action research, where the researchers and their research findings guide the intervention as it unfolds.

The study of the introduction of process management at HUH was, in this sense, opportunistic. The hospital leadership had decided to make an effort to introduce process management; I was recruited to help with that effort. My interest in adding a research dimension to that effort was received favorably. Given the uncertainty about the effectiveness of QI in healthcare, and perhaps facilitated by the fact that this was a university hospital where research – even if not typically management research – was seen as part of the identity, the idea to evaluate the process management efforts through research was accepted. Consequently, the group of facilitators that I joined arranged to collect data documenting the efforts to introduce process management from the outset.
of the initiative. A guiding design principle was to make data collection part of the regular work, and to make it useful both to the practical efforts at the hospital and to subsequent research efforts. I also discussed research design issues broadly with one of my advisors, although the specific studies did not take shape until later. Our data collection was rather broad, partly because it fit with our practical needs, partly perhaps because we wanted to cast our net wide to enable the pursuit of different future research questions.

In this section, we will take an overview tour of the data and how they were collected. The specific data elements used in the different studies are detailed therein. As part of the efforts to introduce process management, the outcomes of all team efforts were documented electronically. Frequently, for instance, improvement teams used brainstorming to generate ideas – on problems, their causes, or potential solutions – at different stages in their improvement efforts. They wrote down these ideas individually on sticky notes (Post-it®) which they subsequently organized thematically on a white board or a wide paper taped onto a wall. After each meeting, a facilitator, or on rare occasions a team member, dictated all the text from the sticky notes, and their categories. The dictations were transcribed by a medical secretary. The facilitators and team representatives checked these transcriptions for accuracy and made corrections before they were circulated to all stakeholders. The facilitators stored all these electronic documents on a secure hospital server.

Similarly, team members’ evaluations of small-scale tests or implementation efforts, and their quality improvement indicators, were recorded into electronic format. Participants’ evaluations of both difficulties and benefits of the improvement efforts were also collected and recorded. Decisions taken by management teams, with responsibility for different improvement projects, were also documented in this manner. Flow charts, depicting entire processes, or selected parts of them, were likewise documented electronically.

Annual plans, and other overall documents, for the hospital-wide process management initiative were also saved electronically. So were the successive versions of a manual for the improvement efforts that facilitators developed continuously over the study period. Annual reports, phone directories, newsletters and other documents providing background information about the hospital were collected throughout the study period.

The facilitators documented their observations during team meetings, and other significant events or communications, such as key e-mail messages, in electronic progress notes. These were kept in a database (File-Maker®) designed by the lead facilitator. The facilitators usually dictated, or sometimes typed, these progress notes immediately after the conclusion of a team session, although sometimes time did not permit this and notes were written later or even, occasionally, not at all. A medical secretary transcribed the dictations, and the facilitator concerned checked these transcriptions for accuracy and made any changes necessary. The facilitators relied on these progress notes for their ongoing efforts – mirroring how clinicians use progress notes documenting patients' care – to keep track of what had been done at different meetings, commitments made etc. They also used the notes in their periodic evaluations.
of their own work, to identify areas in need of improvement, and sometimes also specific ideas for how to improve.

A typical note from a team session includes the facilitator’s preparations for the meeting, the scene when the meeting got started (the setting, who was present, whether the meeting could start as scheduled or was delayed, and any particular observations), the activities undertaken during the meeting, any particular observations during the meeting (problems, successes, surprises, etc.), the duration and outcome of the meeting, and feedback on the conduct of the meeting from participants.

In addition to these data, which were collected as part of the process management efforts at the hospital, two elements of data were collected more specifically for this research: First, in the course of the first year and a half of the process improvement initiative, I interviewed all the heads of the six clinical divisions at the hospital and the two hospital CEOs who were in charge during this period. The interviews were semi-structured with questions regarding the respondents’ views on the rationale for the process management initiative at the hospital, and the recent history leading up to it, their views on the potential of this initiative, as well as main challenges and barriers to success. I took notes during the interviews, and then documented the interview electronically afterwards. I contacted the respondents afterwards if there was anything from the interview I needed to clarify.

Second, members of the facilitator group at the hospital gathered over a weekend, after the end of the study period, to review and reflect on their efforts and capture lessons learned. These lessons were documented on sticky notes, transcribed into electronic format, shared with all participants, and stored electronically.

For the systematic literature review on the application of statistical process control (SPC) to healthcare QI, we searched for potentially relevant articles in scientific databases. We tested all articles identified against explicit inclusion and exclusion criteria, to arrive at the final set of 57 articles reporting empirical data on SPC application. We extracted data from these articles to answer specific questions in a data abstraction form we developed for this purpose, in the form of verbatim quotes or our own summaries of the article text.

4.1 STUDY DESIGNS

The three studies based on data from the HUH were all observational studies, undertaken within an overall framework of a case study. The overall case study design is chosen because it is “the preferred strategy when ‘how’ or ‘why’ questions are being posed, when the investigator has little control over events, and when the focus is on a contemporary phenomenon within some real-life context”. ((80) p. 1)

To deal with the limits to generalization of knowledge from a single case study, even if extensive and in-depth, the findings are related to other empirical studies regarding the establishment of quality improvement in healthcare, and to organizational theory, particularly change management theory. This makes it possible to generalize to theory, rather than to a defined population (of healthcare organizations, in this case) as is done
in epidemiological research, and to generate hypotheses that can guide further research in the area.

Considering now the designs of studies reported in this thesis more specifically, Study I examined the efforts early on at HUH to initiate 2 improvement projects in each of the 12 clinical processes selected in the first year. We cataloged the efforts undertaken by multi-professional clinical teams and the management teams responsible for each clinical project and categorized the different types of problems identified and prioritized by these teams. We compared the proportions of problems in these categories. Study II and Study IV both used case study designs. The details of these studies will be explained further when they are summarized below.

In Study III, the systematic literature review, we employed principles and methods for systematic reviews (81), to the extent that they were applicable, and, since the data extracted from the articles were of a qualitative nature, we performed thematic analysis (82) and formed categories to describe how SPC has been applied to healthcare QI, according to these articles.

In addition to these four studies that form the basis for this thesis, I attempt to put the introduction of process management at HUH in context here in the thesis summary and to form the overall case study of that introduction, based on these four articles and on additional analyses of the data outlined above. I also attempt, in the remainder of the thesis summary text, to illuminate how systematic quality improvement is established in a healthcare organization, by way of a theoretical model. This model is based on the research reported here, and on my understanding of the literature in the field. In developing this model, I have been guided by advice in the literature on how to develop theory both more generally (83-88), and from case studies specifically (89-91). I do not consider this model to represent a “proven” answer to the research question, but rather to express my best understanding of the topic so far. As such, it needs much further empirical testing and refinement. My hope in developing this model is that it will facilitate understanding and that it can be useful to both practitioners and researchers when introducing and evaluating QI efforts in healthcare, and hence, that it will make a small contribution to both practice and theory.

The logic behind developing a theoretical model in response to the overall research question rests on the premise that case study research is not well suited for generalization to underlying populations, as is done in epidemiological studies. Instead, the appropriate form of generalization from case study research is what Yin terms “analytic generalization”. It is at the level of theory that “the generalization of the case study results will occur. [...] In statistical generalization, an inference is made about a population (or universe) on the basis of empirical data collected about a sample. [Then,] research investigators have ready access to quantitative formulas for determining the confidence with which generalizations can be made, depending mostly on the size and internal variation within the universe and sample. [...] A fatal flaw in doing case studies is to conceive of statistical generalization as the method of generalizing the results of the case study. This is because your cases are not ‘sampling units’ and should not be chosen for this reason.” ((90) p. 32) Recognizing that a common criticism of case study research is that “it is difficult to generalize from one
case to another”, Yin continues to assert that this happens when “analysts fall into the trap of trying to select a ‘representative’ case or set of cases. Yet no set of cases, no matter how large, is likely to deal satisfactorily with the complaint. The problem lies in the very notion of generalizing to other case studies. Instead, an analyst should try to generalize findings to ‘theory’, analogous to the way a [laboratory] scientist generalizes from experimental results to theory. (Note that the scientist does not attempt to select ‘representative’ experiments.)” ((90) p. 38)

4.2 ETHICAL CONSIDERATIONS

Plans for the research reported in this thesis were submitted to the regional board in Stockholm for vetting the ethics of research involving humans (Regionala Etik-prövningsnämnden i Stockholm) in accordance with Swedish law and regulations for research at Karolinska Institutet. The board concluded that this research did not meet the criteria under the law for research that it needs to vet (because it did not involve data deemed to be of a sensitive nature, about individuals), and added that, from its perspective, it had no objections to the research. (Diarienummer: 04-714/5)

The main object under study in this project was the organization – particularly how process management was introduced there – rather than the particular individuals who worked there. While it is the actions and decisions of many individuals that constitute an organization, it was not their individual behavior that was of prime interest here, but instead the organizational phenomena that those actions and decisions represent.

The vast majority of research data from the HUH was initially collected as part of the day-to-day operation of the hospital. The process management efforts were undertaken irrespective of this research initiative. The potential ethical problems in this research, therefore, do not have to do with the process management efforts that employees of the hospital were “subjected” to, but rather with the act of using the data documenting those efforts for research purposes.

One important way to prevent ethical problems is to request informed consent from research participants and keep participation voluntary. (92) This was practiced in the case of the interviews with senior managers at the hospital and for the follow-up session with the group of facilitators. Information was given verbally, and participation in the subsequent interview, or review session, was documented as an expression of informed consent. For the data documenting the process management efforts, approval to use them for this research was obtained from the hospital management and this, in keeping with the guidelines for social science research (93), was deemed sufficient, since the research does not concern issues of a private, or sensitive, nature.

The main ethical concern is any potential embarrassment for members of the organization when data stemming from their efforts are analyzed and used to generate research findings. We have sought to prevent this risk by trying to avoid identifying individual actors when reporting the research. Furthermore, all data have been stored securely in electronic format with password protection, and the data repositories have been reported to the appropriate officer (personuppgiftsombudet) at Karolinska...
Institutet (KI), in accordance with the law on treatment of data concerning individuals (Personuppgiftslagen) and regulations at KI.

The potential ethical concerns are, in our view, outweighed by the benefits of this research, not only to the community of healthcare stakeholders and researchers of healthcare and change management, but also to the employees of HUH who were involved in the process management initiative. This research can potentially help them gain a deepened understanding of their experience at the time and of change management more generally.
## 5 FINDINGS

### 5.1 THE FOUR COMPONENT STUDIES AT A GLANCE

<table>
<thead>
<tr>
<th>Study</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
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<tbody>
<tr>
<td><strong>Research problem/question addressed</strong></td>
<td>How did multi-professional clinical teams and managers collaborate to identify problems and balance local anchoring with strategic priorities?</td>
<td>How did facilitators help clinical teams and managers apply QI principles and tools and how did they simultaneously develop their own skills?</td>
<td>How has Statistical Process Control (SPC) been applied to healthcare QI and with which benefits, limitations, barriers and facilitating factors?</td>
<td>How did a QI program in a Swedish university hospital evolve over a five-year period, and what were its outcomes?</td>
</tr>
<tr>
<td><strong>Study design/methods</strong></td>
<td>Observational study with categorization of problem data</td>
<td>Case study</td>
<td>Systematic literature review with thematic data analysis</td>
<td>Case study</td>
</tr>
<tr>
<td><strong>Main findings</strong></td>
<td>Most problems fell into one of three categories: “information issues”, “poor procedures”, or “waiting times”, with this last category emerging as dominant as problem identification progressed.</td>
<td>They provided a framework and methods’ support for improvement efforts and incorporated participant feedback and lessons from reviewing and reflecting on their own practice.</td>
<td>SPC was applied in a wide range of settings, at diverse levels of organizations and directly by patients, with 97 variables. It helped different actors manage change and improve healthcare.</td>
<td>Of all QI projects, 58 % (39/67) demonstrated success. The QI methodology was continuously adapted to the local context. Lack of time was a barrier, and “seeing the bigger picture” a benefit.</td>
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<tr>
<td><strong>Conclusion - implications</strong></td>
<td>By combining a top-down and a bottom-up approach, management teams harnessed staff insights and motivation, as they selected problems for further improvement efforts.</td>
<td>Facilitators can help busy managers and clinical teams to manage change through QI, contributing to improvement by using a learning approach throughout, including to their own work.</td>
<td>Statistical Process Control is a versatile tool which can enable diverse stakeholders to manage and document change in healthcare and to improve patients’ health.</td>
<td>Comparatively high degree of “success”. The measurement of quality was weak. Reliable measurement is important for the ability to conduct, and evaluate, improvement efforts.</td>
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5.2 THE FOUR STUDIES SUMMARIZED

5.2.1 Study I: Getting going together: can clinical teams and managers collaborate to identify problems and initiate improvement?

**Background:** Among the early challenges when trying to introduce QI are to agree on the aim for improvement efforts and to build momentum. In large organizations, there is a tension between focusing on improvements of local interest, and ensuring that improvement efforts yield strategically important effects. This is usually described as the tension between a “bottom-up”, or grassroots perspective, and a “top-down” approach. Yet, there is limited empirical research elucidating this tension and how it may be managed. We therefore examined how multi-professional teams and management teams responsible for 12 selected clinical processes at HUH in 1997 collaborated to identify problems, and compared the different kinds of problems these stakeholders prioritized.

**Materials and methods:** The efforts to identify problems for subsequent improvement projects were guided by the overall improvement model which QI facilitators helped stakeholders apply at HUH. After flowcharting their respective processes, multi-professional teams brainstormed in two stages to identify potential problems. First, they identified problems they knew or believed that their patients experienced when receiving care. Second, they listed problems they themselves experienced in providing that care. Working with sticky notes on a long paper attached to a wall, team members organized the sticky notes into different categories of problems. They then ranked these problems in order of importance by selecting the top five categories (A). Subsequently, they articulated “problem statements” according to guidelines from the literature (B). They also planned for sample measurement of quality indicators reflecting the selected problems. They presented their findings to their management teams, who, in turn, selected two of the problems for each process. They articulated an assignment for improvement which included a clear aim and a deadline for reaching that aim (C). For this study, we described the approach to problem identification, categorized the data generated at stage A-C, and compared their frequency across teams and stages.

**Findings:** All 12 teams and their managers succeeded in identifying problems according to the QI model. The 12 clinical processes displayed varying degrees of complexity, covering both acute and elective care, both surgical and non-surgical. The distribution of problems, which fell into eight problem categories, was similar across all processes. The majority of problems identified fell into one of three categories: information issues, poor procedures, or waiting times. The proportion of problems changed through the three stages of problem identification; waiting times emerged as the most frequent problem category, with 58% of all problems at stage C falling into this category.

**Discussion:** The types of problems identified appeared “generic” across this diverse set of clinical processes. They fell into the same categories, in similar proportions. The problems reflect difficulties patients experience when they receive healthcare, and clinicians experience when they provide it. Waiting times emerged as the dominant
category, particularly favored by the managers; this is consistent with the emphasis on a process perspective. The model for QI applied here enabled the combination of a bottom-up and top-down approach to problem identification. By choosing between problems proposed by the process teams, managers harnessed the insights and motivation of those “grassroots” while contributing their own view, thereby forming what has been called a “pincer strategy” to QI.

5.2.2 Study II: Learning helpers: How they facilitated improvement and improved facilitation – lessons from a hospitalwide quality improvement initiatives

Background: Given the challenges inherent in applying QI, many organizations employ facilitators who specialize in providing methodological support and in helping stakeholders articulate and achieve their aims. Facilitation can take a variety of forms; it is unclear how QI facilitators operate and how they develop their own skills. To address this and examine what contribution facilitators might make in healthcare QI, we explored how facilitators worked at HUH as QI efforts were established over a five-year period.

Study design and data: This was an in-depth observational case study of the introduction of process management at HUH 1997-2001, with particular emphasis on the work of QI facilitators. Three of these facilitators were also co-authors of the study, providing insiders’ perspectives on the data. The study draws on the electronic documentation of multi-professional improvement team efforts, including over 1000 team sessions; the facilitators manuals and other documentation; the facilitators’ progress notes; and the output of a seminar in 2002 where members of the facilitator group reviewed and reflected on their experience.

Findings: The facilitators designed a model for improvement adapted to the local setting, at the request of the hospital management team, drawing on the QI literature, personal experience, courses and seminars. Their aim was to provide a figurative “shop” where multi-professional teams could come and get support for conducting QI projects. Facilitators emphasized to all stakeholders that 60% of the initiative was aimed at enabling participants to gain a new understanding of daily work and how it may be improved, while 40% was aimed at directly solving complex process problems, signalling the centrality of learning. The article catalogues 10 ways that facilitators helped improvement teams and managers improve and seven ways that they improved their own efforts. For example, facilitators prepared, and guided improvement teams through, the successive steps of a QI project. They set up meeting rooms with all the necessary equipment. They instructed teams in how to brainstorm about causes underlying the problem at hand and how to collect relevant data, etc. They ran team sessions with a view to both achieving the stated objective for each meeting and finishing on time. They took care of documenting the output of the team's efforts. They improved their facilitation through, for example, sitting in on each other's sessions to learn and provide feedback, documenting their own efforts and observations, asking for feedback from participants, reviewing their own experience, and developing a
manual to guide their own efforts. Inspired by the principles for “Learning organizations”, they developed and pursued a shared vision for QI work at the hospital.

**Discussion:** This case study demonstrates how facilitators helped managers and healthcare professionals learn about their own clinical processes and how to manage change in them, while also improving their own efforts through a learning approach. Key lessons learned, and their implications, include: the benefits of a clear division of labor between facilitators and other QI actors, with facilitators providing a framework, infrastructure and methodological support during team meetings; the benefits of specialization whereby facilitators developed substantial experience and skill faster than would have been possible for managers or clinicians; the benefits of facilitators serving as repositories of organizational learning; transferring insights across the organization and different teams; and the centrality of learning. Facilitators may help busy managers and healthcare professionals increase their capacity to manage change in clinical processes.

5.2.3 **Study III: Systematic review: Statistical Process Control**

**application in healthcare improvement**

**Background:** SPC is a key approach to QI. Invented by Shewhart for application in manufacturing, it comes with a set of tools, most notably the control chart. By plotting data mirroring the performance of a process consecutively it visualizes that performance and enables stakeholders to characterize the variation and to make informed decisions about how best to manage it. In light of the prevailing uncertainty about the value of SPC in healthcare QI, we examined the literature on how SPC has been applied in healthcare QI, and the related benefits, limitations, barriers and facilitating factors.

**Study design and data:** Drawing on principles for systematic literature reviews of healthcare QI interventions, we searched for relevant articles in bibliographic databases, covering the period 1966 to June, 2004. The searches yielded 311 potentially relevant references. An initial review of these against our study criteria yielded 100 articles that we obtained in full text version; examination of the full text articles left 57 articles that fit our criteria. We developed a standardized data abstraction form which was used to extract relevant data from the articles. We conducted thematic analysis of these data and produced a number of categories to convey our findings in response to the research objectives.

**Findings:** The majority of articles (45/57) stemmed from SPC application in US health care; only towards the end of the study period did articles from elsewhere appear. SPC was applied in a wide range of settings (predominantly in hospitals), specialties, at diverse levels of organizations and directly by patients, using 97 different variables. The **benefits** included the ability to document the impact of changes in healthcare processes; the ability to identify, understand, and respond to different forms of variation; the ability to predict future process performance; and the empowering properties of SPC application. The **limitations** included that SPC application does not automatically prompt improvement; that cause-and-effect relationships are not always clear; that it is challenging to apply SPC to heterogeneous patient populations; and that
there are challenges in data collection and management. The **barriers** included challenges in understanding how to use SPC; in accessing data; and in constructing the most appropriate charts. The **facilitating factors** included the availability of information technology to facilitate SPC application; the possibility to teach and learn about SPC application; the motivational effects of SPC application; and various techniques for data stratification, risk adjustment etc.

**Discussion:** The review findings indicate that SPC can be a powerful and versatile tool for healthcare change management through QI. SPC helped diverse stakeholders manage and improve healthcare processes. It also helped clinicians and patients understand and improve patients’ health, thereby demonstrating therapeutic properties. To apply SPC correctly is not a trivial task; specialized skill is needed to set it up properly and enable clinicians, patients, managers and other stakeholders to use it to its full potential.

The designs of the included studies were generally weak. Therefore, the findings need to be interpreted with caution, but they can be used to guide more robust evaluative studies of SPC effectiveness in healthcare change management. Until such studies are available, this review offers an extensive overview of how SPC has been applied in healthcare QI according to the literature, including many substantial benefits to healthcare change management and even to the understanding and improvement of patients’ health.

### 5.2.4 Study IV: Evolution and outcomes of a quality improvement program

**Background:** There is enduring uncertainty about the effectiveness of QI programs in healthcare organizations and also about how to best evaluate such effectiveness. There have been calls for studies that not only determine the effectiveness of QI programs, but examine in-depth how they evolve over time and how they contribute, or not, to organizational improvement. This study sought to answer those questions by examining how a QI program was established over a five-year period at HUH.

**Study design and data:** Within a case study design, we examined data from the hospital’s documentation regarding QI projects undertaken in clinical processes during the study period, with particular focus on the degree of goal achievement. We arbitrarily defined goal achievement >50 % along the way towards the aims set out at the beginning of each QI project as a “success”. We cross-tabulated the proportion of projects which demonstrated such success against the year projects started and against the sex of the improvement team leaders. Furthermore, we reviewed data including project plans, facilitators’ manuals and progress notes on how the QI program evolved over time; and summaries of participants’ evaluations of the QI efforts, to build the case description.

**Findings:** Overall, 58 % of projects (39/67) demonstrated success; 3 projects were not completed, and for 5 projects, data was missing. The proportion of success appeared to be highest (75 %, 18/24) for projects started the first year. A greater proportion of projects led by female doctors demonstrated success (91 %, n=11) than projects led by
male doctors (51 %, n=55). The data on QI indicators were generally weak with limited reliability; both the measurement and documentation of these data proved to be challenging. Facilitators at the hospital continuously adapted the improvement program to the local context, for instance by trying to simplify the QI methodology, by going from two simultaneous QI projects initially to one at a time in each clinical process, and by providing feedback on the progress of QI projects (or the lack thereof) to stakeholders. The degree of QI efforts changed over time, with some clinical divisions becoming more active, and some less so. The QI program – and the conditions for its conduct – thus changed continuously over the study period. Participants reported a lack of dedicated time for improvement efforts as their biggest difficulty. Other major challenges included that key team members were missing from meetings, and that managers did not provide enough support for the improvement efforts. The dominant benefits included an increased ability to see the “bigger picture”, improved results for patients and employees, a sense that the QI efforts were effective and that they enabled broad participation among many stakeholders.

**Discussion:** A review of QI project outcomes reported from other settings indicates that the proportion of QI projects with demonstrated success in this case was comparatively high, at 58 %, although it is difficult to compare across studies, due to differences in methodology. Furthermore, the findings should be interpreted with caution due to the measurement limitations. In unison with other studies, this also points to the importance of reliable indicator measurement for the ability to conduct and evaluate QI efforts. The indication here of gender differences in leading and succeeding with improvement efforts warrants further study.

The case demonstrates how the QI program, and the conditions for its conduct, changed over time. The level of activity in the QI program varied across the hospital. To evaluate the effectiveness of such programs, the degree of application of QI methods, in terms of both depth and breadth, ought to be factored in.

### 5.3 PUTTING THE PIECES TOGETHER: HOW QI WAS ESTABLISHED IN THIS CASE

To develop an answer to our overall question of how QI is established in a healthcare organization, the following section will put together the pieces on how QI was established at the HUH based on studies (I, II, IV), complemented by additional analysis of the HUH data and other referenced sources, attempting to provide a more holistic case description. In particular, this will draw on the early interviews with senior officers of the hospital, and on documents from the hospital.

To better understand the decision in 1997 to introduce process management at HUH, it is helpful to briefly review the context and history of the hospital and Swedish healthcare more generally. Like other Western healthcare systems, the Swedish healthcare system experienced a period of substantial growth in the 1960s and 70s, fueled by the expansion of the Swedish economy and the welfare state, and by advances in medical technology.(94) For example, the number of full-time equivalent employees in Swedish healthcare almost tripled between 1960 and the early 1990’s (when it began to decline, in part through lay-offs) from 120 000 to 350 000, going
from 7,000 to 25,000 physicians. During the same period, perinatal mortality declined from 26 to 5 per 1,000 newborns. Mortality related to acute myocardial infarction declined from 40% to 15%.

The HUH was planned during this phase, to provide primarily South-western Stockholm with hospital care, and to carry out medical education and research. Built to highly rationalistic ideals in a symmetrical, square style dominated externally by concrete walls, but also extensively decorated with art, the hospital was inaugurated in 1972. The culture at the hospital has been characterized as modern and open to new ideas, perhaps related to its relative youth compared to other area hospitals. Its brief history also covers several pioneering accomplishments, including Sweden’s first transplantation of the pancreas (1974) and its first bone-marrow transplantation (1975).

As the economic growth in Sweden slowed down (and even turned negative in 1991) the healthcare sector underwent many changes aimed at controlling costs, including the purchaser-provider split introduced in 1992 in the Stockholm County Council. There were many structural organizational changes, including the concentration of tertiary care to the two university hospitals in the County (HUH and the Karolinska hospital), initiated in 1996. The HUH internal structure changed three times between 1992 and 1996, when the hospital was organized in six clinical divisions. While the first two hospital directors served for eight and eleven years, respectively, in the 1990’s the CEOs’ tenures lasted only 2-3 years.

Towards the end of 1996, the hospital CEO asked a senior cardiologist – who had spearheaded dramatic improvements in patient access to the Department of Cardiology – to prepare for a hospital-wide project to introduce process management. This was motivated by an increasing sense that hospital services had to be adapted to better meet the needs and demands of patients and other stakeholders, as patients were increasingly being encouraged and enabled to exercise choice over their healthcare providers. The hospital needed to increase its ability to attract patients and become more “customer oriented”. The CEO also emphasized the need to move from a cumbersome bureaucratic management model to a more efficient approach, inspired by his experience from previous jobs in pharmaceutical companies and smaller hospitals.

This mirrored the trends in Swedish healthcare at the time more generally. As Garpenby observed, “local politicians were anxious to rapidly refute growing criticism of the rigid, inflexible organization which did not allow the population freedom of choice. [Simultaneously], the need arose to make the organization more effective by increasing productivity, thereby shortening queues for elective surgery in particular. Those measures introduced to deal with these problems were, in order of occurrence, increased opportunity for individuals to choose providers both within and between counties, a separation of health care purchasers and providers, and new financial incentives for health care, particularly diagnosis related group (DRG)-inspired per case payment systems [reference to(99)].” In a similar spirit, the Swedish National Board of Health and Welfare issued new regulation in 1996 requiring all healthcare providers to take a systematic approach to quality assessment and improvement (Socialstyrelsens föreskrifter och allmänna råd (SOSFS 1996:24) Kvalitetssystem i hälso- och sjukvården).
There were several forerunners to the process management initiative at HUH, including the improvements at the Department of Cardiology and projects aimed at improving quality and efficiency, such as a project on Multidisciplinary care and development (Tvärvetenskaplig Vård och Utveckling, "TVU 97") and the “Olivia-project” which included consultant-assisted mapping of healthcare processes. Several alternative approaches to quality improvement were considered, including applying QI frameworks such as the Quality-Development-Leadership (QUL, for “Qualitet, Utveckling och Ledarskap”) modelled on the Swedish version of the US Malcolm Baldrige National Quality Award framework. Several healthcare organizations around Sweden applied this model – including the Danderyd Hospital (101), the University Hospital in Linköping (102), and the Jönköping County Council (103). While this model informed efforts also at HUH, it was not adopted in full due to concerns that it was not sufficiently action oriented.

In sum, the initiative to introduce process management did not happen in a vacuum. Instead, it emerged in response to the circumstances both outside the hospital, including politically driven changes, and inside, including the interest among many stakeholders in quality improvement. A key factor was also the availability of an internal expert with a positive track record on QI, the senior cardiologist, who accepted the challenge to set up a project to introduce process management. He recruited two assistants, including the author of this thesis, and they started to plan the year-long project in January 1997. Drawing on the literature on QI and Learning Organizations, e.g. (5, 43-45, 104-106), on QI courses, and on their personal experience as well as experiences from other organizations, they proposed to the hospital management team to put QI ideas and methods into practice directly by initiating improvement projects in 12 clinical processes, evenly distributed across the hospital’s six clinical divisions.

Mindful of the key importance of leadership commitment and support for QI efforts to succeed, the facilitators arranged to brief the hospital management team on the plans and to request such commitment prior to initiating the efforts in practice. Short, perhaps, of complete consensus in favor of the project, the management team members at least did not express any explicit objections to the plans. The project thus started on May 1, 1997. One of the first tasks was for the heads of the clinical divisions to identify two clinical processes each, and to appoint one senior physician in each process to head a multi-professional improvement team.

The facilitators met with these physicians, now called “process owners” (even though they did not “own” anything other than the responsibility to assemble and lead a multi-professional team), and advised them to recruit team members covering all the major areas involved in the process. With these teams assembled, the improvement efforts could begin. Following a relatively standard approach to QI, the teams set out to:

1. Describe the patients’ “journeys”, and the related staff tasks, along the processes through flowcharting.
2. Identify, through brainstorming and data collection, problems for both patients and staff in the process.
3. Present problems suited for improvement efforts to the management team of the process to get a QI assignment.
4. Identify, through brainstorming and data collection, causes underlying the selected problem.
5. Generate ideas for practice changes to solve the problem by eliminating the causes and achieve the aims set out in the assignment, through brainstorming, drawing on generic change concepts, e.g. from (44).
6. Develop plans for small-scale testing of the most promising change ideas.
7. Present these plans, and their background, to the management team and get a “go-ahead” for testing.
8. Carry out the tests, collect and evaluate data, and draw lessons for next steps.
9. Develop plans for implementing successful changes.
10. Present implementation plans to the management team and get a “go-ahead” for implementation.
11. Carry out the implementation plans, collect and evaluate data, and draw lessons for next steps.
12. Report on the implementation and the lessons learned to the management team; determine if the team’s assignment had been completed or if additional efforts were needed.

Based in part on previous experience at the hospital, the facilitators avoided extensive teaching of QI principles and methods to team members, in favor of experiential learning, or “learning by doing”. To give some guidance to team members, however they communicated the key ideas in the QI approach by way of images, see figures 2-6.
Figure 2. **A healthcare process** was defined as: “The series of activities that we typically carry out when we provide care for patients that belong to different defined groups.”

Figure 3. **The patient’s journey through functional units**, i.e. Department wards and clinics, each with their own goals, Chiefs, staff, budgets, and organization. The challenge is that no single individual has full knowledge of, or responsibility for, the entire “journey” and that the resulting care risks becoming fragmented and inefficient, through numerous hand-offs.
Figure 4. **Process management**, defined as “A systematic method to organize, lead, and continuously improve the processes in an organization.” To overcome this fragmentation, a process improvement team is assembled with members from all involved professions, led by a physician. Collectively, they have detailed knowledge of the entire process from their daily work in it. A management team is assembled with the concerned Department Chiefs, who have managerial and financial responsibility for the care involved, under the leadership of a Division Head (a member of the hospital’s top management team). Members of the facilitator group provide methodological QI support to the other stakeholders, but do not run or alter the process which remains the responsibility of the process and management teams.

Figure 5. **The Model for improvement** draws on standard QI principles. The Start, Improve, and Control phases include the twelve steps for QI projects outlined above. The four dots (I-IV) represent scheduled meetings between process improvement and management teams.
Figure 6. The “Funnel model” for improvement aims to explain the alternating modes of divergent and convergent thinking throughout a QI project. To generate ideas about process problems, their underlying causes and potential solutions, team members first brainstormed on each issue (divergent thinking) to generate as many ideas as possible, and then selected the top ideas through categorizing and voting/ranking (convergent thinking), further developed through data collection (F for “facts”) and analysis. Finally, change ideas are first tested, and then implemented before ultimate standardization. The asterisks represent meetings between improvement and management teams.
In addition to the emphasis on experiential learning, the QI efforts were designed and facilitated with a view to providing value to stakeholders and, thereby, to building motivation for continuing efforts. For example, as further detailed in Study I, the “pincer strategy” early on combining a bottom-up and a top-down approach to problem identification aimed to yield problems viewed as important by healthcare professionals in the different processes while allowing managers to add their strategic perspective and maintain control over the clinical areas for which they were accountable. As detailed in Study II, the facilitators also attempted to relieve busy managers and healthcare professionals of the many sometimes onerous tasks involved in QI efforts. The goal was to enable them to efficiently allocate their limited time for QI to the content of their clinical processes and to making changes in those processes.

As demonstrated in Studies II and IV, the QI program was continuously adapted throughout the study period, based on participant feedback, new inputs and constraints, and the facilitators’ regular reviews of the efforts. The conditions for the QI program varied considerably over time. In particular, 1999 brought much uncertainty about the future of the QI program. This period overlapped with preparations to incorporate the hospital, a change initiated at the political level which required substantial efforts from many managers (and took effect in April of 2000). The level of activity in QI efforts also varied over time across the hospital; it diverged among clinical divisions towards the end of the study period. Nevertheless, towards the end of 2001, the facilitators received two external awards in recognition of the QI achievements at the hospital. In less than five years, over 90 improvement projects had been initiated, and some 2/3 completed (while others were still under way) with a comparatively high success rate of 58%. Many participants had gained a new understanding of their own work, and how it could be improved to the benefit of both themselves and their patients.
6 DISCUSSION

6.1 A MODEL FOR HOW QI IS ESTABLISHED IN A HEALTHCARE ORGANIZATION

This thesis illuminates how QI was established in a healthcare organization by way of continuous learning and adaptation – combining the insights and motivation of healthcare professionals, harnessed through a bottom-up approach, with managers’ strategic views and accountability, conveyed through a top-down approach – and with the specialized assistance of QI facilitators. While the HUH case revealed weaknesses regarding QI measurement, and the negative implications of that for the conduct and evaluation of QI efforts, Study III demonstrated that SPC is a versatile tool that can help stakeholders manage and document change in healthcare processes.

Although each of the narrower questions addressed in papers I-IV merit their own discussions, the interested reader is referred to those papers for such discussion. The remainder of this thesis will be dedicated to addressing its general aim and the related methodological issues. We begin with the following theoretical model (Figure 7), which draws on Studies (I-IV) and on literature in the field, as further discussed below, and aims to answer the research question: How is systematic QI established in a healthcare organization?

First, some explanatory comments for how to understand the model:

“External pressure” includes regulation that requires QI systems; demands and expectations from purchasers, owners, patients, the general public, referring healthcare professionals and their organizations.

QI ideas, theories, and others’ experiences represent the external sources of QI-knowledge that informs QI thinking and efforts in the organization.

The model presents a sequence of generic steps for how QI is established, with the development and application of indicators adding to the QI application steps. The last two steps in the model can iterate numerous times, in a continuous cycle of potential improvement of the QI efforts and their impact. A failure to adapt the QI efforts to the organization’s needs and situation can lead to the abolition of QI efforts altogether.

Under each step are factors that either strengthen or hamper the establishment of QI in the organization. These factors will be further elaborated in the next section, which discusses each of the steps in the model, with reference to the findings presented above.

Step 1. Perceived need to apply QI, or opportunity to gain from it. The establishment of QI in an organization begins with the perception, ultimately among senior managers (and perhaps sometimes starting with them), that the organization needs to apply QI, or has an opportunity to gain from doing so, to improve its performance, increase the value, reliability and flexibility of its healthcare services, or to otherwise respond to external pressures. This perception also requires some knowledge of QI in the form of ideas, theories, models, and the experience of others.
In the HUH case, this was demonstrated, as we have seen, by the changes in the healthcare sector more generally in Sweden in the 1990’s, including new regulation, increased opportunities for patients (and their healthcare providers responsible for referrals) to choose which healthcare provider to go to, the purchaser-provider split, and DRG-based prospective payment. It was also reflected by the assessments of the top management team that establishing QI through process management was desirable, and possible, given the availability of an internal expert, and that it could potentially help the organization better respond to pressures from outside.
Step 2. Commitment of time & resources to introduce QI in the organization. The establishment of QI in an organization is contingent on the early allocation of time and other resources to take the first steps along the way. Application on a smaller scale may not require this, as when a single clinician or a local team applies QI independent of the rest of the organization, but then it will not really qualify as organizational application of QI. For the organizational establishment of QI, this commitment presumably requires action from the top management of the organization. Such commitment will require a balancing of competing demands on the organization’s scarce resources. It is not obvious that an organization will find commitment to QI worthwhile in the face of competing demands, such as those imposed by pressures to cut costs in the short run.

This step was exemplified in the HUH case by the hospital CEO’s assignment to the senior cardiologist to prepare a hospital-wide project to introduce process management in response to the perceived need to apply QI and opportunities to gain from it. The hospital’s investment was initially limited to less than three full-time equivalents.

Step 3. Preparation and planning for initial application of QI. This step involves planning for how, where, when and to what extent to initially apply QI in the organization. This requires knowledge and skill regarding project planning, the context of the “receiving” organization, and regarding QI methods, principles and tools.

At HUH, this step involved the development of a draft project proposal on how to introduce process management at the hospital. It was based on QI knowledge and others’ experience of QI, as well as on the facilitators’ knowledge of healthcare in general and HUH in particular. The project proposal was presented to the top management team for approval before the project was initiated. The facilitators aimed at experiential learning among stakeholders. By proposing to include 12 clinical processes, with two improvement projects in parallel in each, they aimed at achieving a critical mass to generate sufficient learning (even if some projects were never completed, although this was not the case in the first year).

Step 4. Development and use of indicators to guide and evaluate QI efforts. As indicated in Study IV, it is essential to have solid performance indicators to guide, and evaluate, QI efforts.

This step proved to be a major challenge in the HUH case, where QI indicators were generally weak and of limited reliability. Study III demonstrates how SPC can be a powerful and useful tool for indicator measurement, display, and analysis. Although some indicators could be of a general nature, e.g. “the number of patients per day who wait more than 2 hours to be seen by a doctor in the Emergency Department”, most indicators will be developed once a particular problem has been selected as a focus for improvement efforts. More general indicators could be developed and used at the hospital level, as intended with the application of an organization-wide Balanced Scorecard (107). Such measures could mirror the impact (or lack thereof) of one or several local improvement projects at the organization level. At the same time, specific indicators are needed for each improvement project, in response to the second question in Nolan’s Model for Improvement: How will we know that a change results in
improvement? This justifies that this step feeds into steps 5-6, rather than being part of step 3 in the model, since developing this latter form of indicators can only happen after specific improvement projects have been conceived.

Step 5. Initial application of QI: generation of early experience, effects & outcomes. This step is where “the rubber hits the ground” and improvement efforts actually get underway. QI principles and tools do not make much difference to an organization until they are applied in practice. Conducting QI projects, which involve both concerned managers and healthcare professionals, is one approach to such application.

While there are several alternative routes to QI in healthcare, such as applying QI frameworks like the Swedish QUL, it is ultimately when efforts are made to change daily work that QI will make a difference, as encapsulated in Berwick’s observation that “all improvement is change” ((5) p. 619). Such efforts require participation of stakeholders who have essential knowledge of this daily work, and of managers who control it, and are held accountable for it. The approach to QI can be more or less easy to follow for these stakeholders, in part depending on how well it fits with local circumstances, and on how well the QI methods and tools are applied. Participants, and perhaps some non-participant observers, in the organization will begin to gain experience from these QI efforts and their impact.

At HUH, the plans from step 3 were put to action in the first year-long QI project, starting on May 1, 1997. There was a strong, and explicit, emphasis on gaining experience and on learning from it – “learning by doing”. Key stakeholders were involved through the combination of bottom-up and top-down approaches in a pincer strategy, as discussed in Study I. The facilitators provided the QI framework, the “shop” for improvement efforts, and methods’ support, as detailed in Study II. The outcomes of improvement projects were highlighted at the end of the project, and participants’ experiences were systematically solicited and reviewed. This demonstrated that while most projects succeeded in meeting their goals, and the methods support was helpful, there had been problems related to getting enough time for QI efforts, a lack of support from managers, and difficulties with indicator development and measurement.

Step 6. Adaptation of QI to the local situation; spread to achieve strategic breadth and depth of QI. This step is essential to the establishment of QI – and arguably one that has been overlooked in many evaluations of QI effectiveness – in that it represents the stage where a QI program can be adapted to the local circumstances. While some of this adaptation can, or should, occur during the initial planning (step 3), it is only here, after there are actual local experiences to draw upon, that effective adaptation can take place. If initial application of QI started on a limited scale, in line with the QI principle to test changes on a small scale before full-blown implementation, then this step is where the organization can adapt the depth and breadth of its QI efforts to fit its strategic needs or ambitions and local circumstances. In other words, QI efforts can be adapted to correspond to how much improvement the organization needs, or aspires, to achieve, and to how much QI work it can sustain. This will be reflected in the amount
of resources – including dedicated time for participants – that are allocated to further application of QI.

The depth of QI application refers to the degree to which QI principles and tools are applied. For instance, provision of only brief training to team members in QI tools and principles, for subsequent use without further support, would yield a relatively shallow application of QI, whereas extensive QI training and/or on-going support by QI specialists (such as QI facilitators) would enable greater depth of application. The breadth of QI application refers to the share of the entire organization that is involved in, or affected by, QI efforts. This can range from the efforts of a lone clinician to active QI efforts across all areas and clinical operations of a healthcare organization.

The facilitators at HUH adapted the QI methodology continuously based on participant feedback and their own reviews of the QI efforts, as detailed in Study II and IV. The “Consolidation phase” in late 1999 represented an attempt to spread the QI efforts to what was considered a more strategically relevant scope, or breadth, of clinical processes. The divergence in the level of QI activity between clinical divisions at HUH towards the end of the study period indicates that such spread was uneven across the organization (Study IV). This may have been due, in part, as speculated in Study IV, on a perceived failure of the QI program to address concerns of financially accountable managers. Furthermore, the finding from all three participant evaluations that a lack of dedicated time for QI efforts was a leading difficulty, signal that sufficient resources were not allocated to those efforts.

Step 7. Demonstration of improved performance; increased value, reliability and flexibility. Such effects are the ultimate rationale for QI efforts. Without demonstration of such effects, there is a risk that scarce organizational resources (including the time and efforts of participants) have been wasted on QI efforts, or that a perception arises that the QI efforts have been in vain. It is important for the continued commitment to QI efforts that positive impact can be shown. Ultimately, such impact should be strategically important to the organization and its external stakeholders, as a consequence of proper adaptation in Step 6. Note here the arrow going back from Step 7 to Step 6, indicating the possibility of iteratively cycling between adaptation of QI efforts, continued application, and demonstration of impact. This suggests that QI efforts can be a long-lasting concern, as indicated by the common term continuous quality improvement, CQI. On the other hand, if the adaptation of QI efforts to local circumstances does not succeed, if improvement is not demonstrated for other reasons, or if sufficient resources are not allocated (perhaps due to competing demands on them), QI efforts are likely to decline or be abandoned altogether.

At this point, we need to clarify some of the terms used here. Improved performance can mean either higher quality, lower cost, or both. This is equal to higher efficiency, and greater value, of healthcare services. Reliability is a concept that has gained in prominence with the emergence of patient safety concerns and efforts to improve such safety. Reliability is defined as “failure-free operation over time.” ((108) p. 3) and is measured as “the inverse of the system’s failure rate.” (p. 1) Flexibility can be seen as the capacity in an organization to adapt to changing circumstances, and the speed with which such adaptation is achieved.(109) The American Society for Quality suggests
that organizational processes are evaluated in terms of their: 1) Effectiveness, 2) Efficiency, and 3) Adaptability. (110)

While facilitators at HUH assembled data on the outcomes of improvement projects a couple of times (in April of 1998 and 1999, and possibly additional times), and shared these overviews with hospital management and with participants, these outcomes were perhaps not disseminated so widely within and outside the organization. As discussed in Study IV, the hospital did not capitalize consistently on (or reward) the early successes, e.g. regarding waiting time reductions. As also shown in Study IV, the indicator measurements were insufficient. This, again, underscores the importance of having good indicator measurements which can enable stakeholders to demonstrate, and evaluate, the impact of QI efforts on organizational performance.

6.2 HOW THIS MODEL RELATES TO OTHER SETTINGS AND THEORIES

This section is intended to answer questions about how the model presented above relates to the experiences from QI application in other healthcare settings, and to the change management literature more generally. Does this model fit with experiences gained elsewhere? In what ways does it not fit? How does it relate to existing theory on organizational change management? The answers to these questions will provide insight into the relevance of the model, and to how widely it may apply. This section also, then, sets the stage for discussing the implications of the findings and the model presented in this thesis.

The National Demonstration Project (NDP) on QI in Health Care started from the insight that “Almost no one is happy with the health care system. It costs too much; it excludes too many; it fails too often; and it knows too little about its own effectiveness.” ((45) p. xv) One way out of the challenges for American medicine, the NDP investigators suggested, was “to learn and to apply the methods of modern quality management as their primary operating strategy [based on] the evidence of extraordinary turnarounds in other industries in the past two decades”. (P. xvi) This discussion mirrors Step 1 in the model: a perception that QI, which until then had only been applied outside of healthcare, offered an opportunity to deal with challenges and external pressure. Like in the HUH case, the NDP aimed at experiential learning. The 21 participating organizations all initiated QI projects, with the assistance of external QI experts. Given the fact that the NDP lasted only eight months, it is not surprising that it did not cover all steps on the way to establishing QI in the host organizations (and that was not the purpose of the NDP). The NDP report provided many valuable methodological tips – many of which were used at HUH – and concluded that “the concepts and tools of industrial quality improvement can be used to improve the quality of processes in the health care industry.” (p. 219) Had the work continued, the NDP teams’ experiences could have fed into Step 6 in the model. A further limitation of the NDP, from our point of view here, is that each organization only conducted one pilot project; and that most projects were not clinical. Nevertheless, Steps 1-5 in the model proposed here are compatible with the experiences reported from the NDP.

In a parallel book, which is more prescriptive than empirical (proposing 128 “action steps” for managers), Gaucher and Coffey draw heavily on the writings of Deming,
Juran and other quality pioneers, while also conveying their early experiences of QI at the University of Michigan Hospitals, Ann Arbor, Michigan (USA). Of relevance to our model here, they assert (without empirical or other reference) that QI efforts require awareness of pressures from the external environment and that they “must be tailored to each organization, to make sure that it fits and will work in the existing culture.” ((111) p. 98) They preface a step-wise approach to QI efforts by noting that quality “is not a ‘quick fix’ or just another program; it takes from five to ten years to fully implement a quality process.” (p. 99) They offer an example of a “Total Quality Process” from their own organization covering a 2 ½-year period that includes the formation of multi-professional QI-teams and reporting of outcomes of QI projects, to lay the foundation for “Continuous Improvement”. Although it is unclear to what extent they undertake, or foresee, adaptation of their QI approach, the example is compatible with the model presented here (except, then, for Step 6).

The evaluation of the quality journeys of six Norwegian hospitals in the mid-1990’s (67) includes a description and analysis of QI efforts at the Haukeland University Hospital (Haukeland for short here) in Bergen, which is comparable to the HUH. Haukeland, a regional teaching hospital affiliated with the Bergen University Medical School, had 1100 beds and 4400 employees, and was organized in 7 clinical divisions including typical tertiary healthcare subspecialties. While the general principles for QI were similar between Haukeland and HUH, the former program was more top-down in style, driven by the hospital CEO, and relied heavily in the first years on the advice and support from an outside QI-consultant. The main activity of the program was extensive training in QI principles and methods; relatively less emphasis was reported on conducting practical QI projects. In contrast, the HUH approach involved “learning-by-doing” through concrete QI projects. The Haukeland program met with fierce resistance from many doctors, including Department Heads. There was limited objective evidence of improvements achieved, partly because of lacking measurement and reporting of QI indicators, even after several years. Drawing lessons for others, hospital representatives and the researchers advised: “Do not try to cover a large hospital all at once – start in a few departments and then spread the ideas. The resources are better used if concentrated in different departments at stages. The lessons and successes can be used to revise the programme and to better introduce it elsewhere.” (P. 91) This suggestion supports Step 6 in the model presented here, a step that appears to not have been as prominent at Haukeland as at HUH.

Øvretveit performed a cross-case analysis in 17 dimensions of these six hospitals’ QI efforts. (66) The analysis highlighted that the role and contribution of middle managers are key and that a “quality programme will not get far without [their] active leadership” (p. 64). It further highlighted the importance of measurement: the hospitals “recognized how the absence of measures and of other data was hindering the programme and projects: it made it difficult to assess progress, decide which changes or types of project had been the most effective, or decide which problems were highest priority.” (P. 72)

Based on the evaluation, and their experiences (both successes and disappointments), the hospitals agreed on eleven recommendations for QI efforts ((66) p. 78-9), including:

- Get Department Heads to lead quality
• Do not fight resistance to QI, but work with it to be able to learn from it and strengthen the QI program
• Do not rely on a training program to develop staff and managers – help them apply ideas in practice instead
• Get doctors involved
• Develop skills to design and use quality measures.

Øvretveit also suggests a general model with phases and transitions which QI programs tend to go through (p. 81-2):

Phase 1: Formulation of a proposal for a QI program.
TRANSITION 1: Top management decides to introduce the program.
Phase 2: Education in QI.
Phase 3: Projects to make changes and improve quality.
TRANSITION 2: After about 2 years, top management reviews progress and decides to spread the successful parts of the program.
Phase 4: Decline or spreading – depending on the success of the decision above.
Phase 5: Routinization, i.e. QI is integrated into ordinary operations, or acceleration, i.e. the program gains further momentum.
TRANSITION 3: After about 4 years, the situation in the previous transition is repeated.
Phase 6: Again, the program is either integrated, or it more markedly transforms management and professional practices, or else it declines altogether.

The model presented in this thesis appears to relate to these suggestions in the following way: Phase 1 & Transition 1 mirror Steps 1-3 in the thesis model; Phase 2 is less emphasized in the model; Phase 3 mirrors Step 5; the remaining Phases and Transitions essentially mirror Steps 6-7.

Building on the analysis, Øvretveit proposes an Integrated Quality Development (IQD) approach. It draws on TQM and blends in lessons from the six cases and public healthcare elsewhere, and is conveyed through several frameworks and models. One framework coordinates four sub-programmes intended to develop professionals, managers, the organization, and the patient’s role, and thereby the care experienced by patients. The IQD approach relies on teams working in QI projects, assuming a systems and process view of care, developing and applying QI measures. While the IQD contains everything included in the model presented in this thesis, it does not explicitly address the issue of how QI is established in an organization; but the thesis model is generally compatible with the IQD.

The rationale for the emphasis on training managers and healthcare professionals in QI reported in the Norwegian cases was to enable them to understand their own work and how to improve it in new ways. In the HUH case, the same objective was addressed primarily through experiential learning. Such an approach draws on the theories for how professionals tend to learn through reflection, both in, and on, action: do a task, observe how it goes, reflect on what happened, learn and use the insights gained to manage the task (better) next time around.(112-116) This links to the field of organizational learning, which concerns the learning that takes place within the social
structures of organizations. This field was popularized by the writings of Peter Senge (106) and, as previously noted, influenced the QI efforts at HUH.

Research on the quality journey of the Jönköping County Council (JCC) healthcare system offers additional points of reference, both empirical and theoretical, for the model presented here. The journey started with the need to respond to the financial crisis in the early 1990’s. (118) There has been an incremental expansion of the QI program, drawing heavily on QI theory and close collaboration with the IHI. (103) This corresponds to Step 1 in the thesis model. Committed leadership is a prominent feature of the program; mirroring Step 2 and driving the entire QI program – the JCC now views “quality as the business strategy”. Also prominent is the emphasis on continuous trial, learning, and adaptation of the approach, compatible with Steps 2, 5 & 6 in the thesis model. The QI efforts and the related learning and adaptation are supported by a dedicated unit, Qulturum. (119) The QI program combines top-down and bottom-up approaches. The aim is to achieve improvement with both depth and breadth. QI is guided by 5 strategic priorities, widely communicated throughout the JCC.

The main limitations of the JCC QI program concern insufficient measurement of QI indicators – pointing, again, to the importance of Step 4 in the thesis model – and variable commitment among physicians. (118) “Despite the undoubtable spread of QI/QM culture, the extensive and effective learning, and consistent work in many departments, Jönköping County Council still has little improvement data that would be credible to many researchers or clinicians.” ((118) p. 76) This finding led Øvretveit and Staines to propose the following generalization, “that there is an initial phase in which the health care system needs to build a quality infrastructure. After this phase, some process improvements may start to show. If these are sustained, outcomes improvement will start to show.” (P. 80) The investigators continue to hypothesize that there is an “investment threshold” to establishing a QI program. The investment goes into "building infrastructure for QI: awareness, leadership will and commitment, the political process of freeing up resources for QI, training staff, building culture, setting up indicators and datacollection systems, and testing QI tools. During this period (possibly even 10 years in the case of Jönköping), no correlation can be shown between patient results and QI work. The impression is similar to being in a zone of noise, where signal is covered by noise. This could be due to too few measures or to infrastructure building taking all the energy.” (P. 80-1)

The model presented in this thesis is in agreement with these suggestions. In effect, what Øvretveit and Staines indicate is that the JCC has not fully reached Step 7 in the thesis model (at a systems level, although many QI projects have demonstrated success), despite extensive and impressive QI efforts for more than a decade. As the investigators conclude: “This case illustrates how much energy, resources, dedication, and consistency are needed to achieve measurably better patient outcomes in some departments. It also illustrates how much is still needed to reach systemwide outcomes improvements.” (P. 82)

The thesis model corresponds well with contemporary change management theory, the branch of organization theory of relevance here. There, change is viewed as a learning process. Approaches to change need “to be matched to environmental conditions and
organisational constraints”. (2) p. 331) Since contemporary change management theory is derived mostly from studies outside of healthcare, the thesis model validates such theory also in the healthcare setting studied here.

6.3 METHODOLOGICAL CONSIDERATIONS

This sections aims at adding to the methodology discussions already offered in the separate studies (I-IV), not repeating them. We will begin by discussing the two data sets and how they were collected, as described in chapter 4 above.

As noted initially, the HUH research (Studies I, II, IV) represents an opportunistic observational study of a natural experiment. Most of the data were collected as part of the hospital’s process management initiative, which was run by the hospital, not by outside researchers. This brings both advantages and disadvantages. The advantages include that data were being collected because they were needed for practical purposes in the QI efforts. This should, in theory at least, increase the accuracy and completeness of the data collection. The facilitators furthermore sought to make the data useful for both practical and subsequent research purposes which should serve to increase data quality. There were no additional efforts required of anyone generating or documenting these data because of the research plans; data were collected the ways they were irrespective of those plans. On the other hand, the facilitator group members, in particular, were mindful of the plans for subsequent research which probably contributed to a higher degree of motivation in collecting and documenting data than would have been the case without any such plans. As Solodky et al. observed: “Psychological theory suggests that partners are better data collectors than subjects.” (120) p. AS 19) The accuracy of the data collected was also strengthened by the way that transcripts of dictations were checked against the original sticky notes by the involved facilitator, and validated by review of the involved team members. Similarly, the facilitators reviewed transcriptions of their progress notes, to ensure their accuracy.

The disadvantages of data collection being a part of the hospital’s process management initiative include that it may have failed to capture data of relevance to this research (but not to the QI efforts in practice), although few such instances have become apparent in this research, apart from the weakness of measurement of QI indicators noted above. Also, the fact that participants collected data on their own efforts, for subsequent research, raises the possibility of bias – conscious or not. It is not clear, however, in which direction such bias would operate, nor how. It may, in theory, have been tempting to fail to document instances that made the person documenting the data “look stupid”, or to favor data perceived as “socially desirable” (a term used for surveys and interviews connoting the risk that respondents modify their responses to “please” the researcher or to “look good”). (121) The fact that the research questions were not specified from the outset, and were finalized after the end of the data collection period, should have reduced the likelihood that data collection was somehow influenced to yield particular answers. Instead, the research questions were developed pragmatically to “fit” with the available data, in light of the research problem identified. For instance, we were not able to carry out quasi-experimental research based on these data, and instead focused on the “how” questions specified in Chapter 3, which could be meaningfully addressed through a case study analysis of the available data.
The fact that as a researcher, I was also intimately involved in the organizational change efforts under study can prompt similar questions about objectivity and neutrality, but it is, arguably, an asset in the research reported here. The justification for such a role is that it simultaneously offers access and understanding of the context for the issue under study, without which this study would be much more difficult, if not impossible, to perform. In the words of Gummesson: “Access refers to the opportunities available to find empirical data (real-world data) and information”; what he calls the management researcher’s “Number 1 Challenge”. ((122) p. 11) Organizational research depends on understanding of context because “organisational behaviour can only be understood in context.”((123) p.25)

When analyzing the data, I benefited accordingly. I believe that I have been able to “read between the lines” in the data. Reading accounts of various sessions I had attended frequently brought memories back to me of the situation – the room, the people, even sometimes the atmosphere – in ways that reach beyond what I can articulate. This raises, of course, the possibility too, that I have “misread between the lines” and added meanings not actually justified by the data. This is one reason to interpret this kind of research with a certain degree of caution. Ways to balance this kind of risk, which we employed, include triangulation, using multiple data sources and having multiple researchers review the material.(124) In line with the arguments above, I think it would have been much more difficult – perhaps prohibitively so – for someone who had not been part of the process management initiative to interpret and analyze the data.

In a similar vein, we noted in Study III, that our reading of the 57 SPC articles was informed by our understanding of QI in general, and of SPC in particular, as well as of healthcare. Having background experience in both areas, as most of us did, was helpful for interpreting and analyzing the SPC data.

This leads us now into a consideration of the research methodology. As stated by Yin, the case study design is useful for studies of how a phenomenon of interest evolves over time, in a particular “real world” context, in situations over which the researcher has limited control. (80, 90) Case studies allow, and are strengthened by, the combination of multiple data collection methods, spanning both qualitative and quantitative data, as exemplified in this thesis. Thus, “the case study’s unique strength is its ability to deal with a full variety of evidence – documents, artefacts, interviews, and observations”. ((90) p. 8)

Could not an experimental design have been used to evaluate the effectiveness of the QI program in the HUH case? This would imply that the QI program could be randomly allocated to one organization, among a population of comparable organizations, where others would serve as controls not receiving the “intervention”. But part of a QI program, as suggested by the model presented in the previous section, is the will and strategic assessment among members of the organization, on whether to allocate resources to QI in the first place and then to on how to guide the QI efforts. It would be difficult to assign such motivation and management decisions randomly to one organization. It would also be difficult to prevent other “control” organizations
from developing some QI approach if they did have such motivation. (121) What we have done, here, is a non-experimental comparison of the HUH case with QI efforts in other settings, drawing on accounts in the literature.

A significant form of data collection in the case study was participant observation. With roots in anthropological field research, this is – as the term implies – when one or several researchers “engage in the daily life of the group or setting under study. They watch, listen and record what happens in the everyday interactions, involving themselves in ongoing activities”. (125) p. 45) This is what the facilitators did in the HUH QI efforts. Given that several facilitators, including myself, also engaged in the research concerning those efforts, does the approach not qualify as action research? No. A distinctive difference between these two approaches is that action research “involves opportunistic planned interventions in real time situations and a study of those interventions as they occur, which in turn informs further interventions.” (126) p. 674) While parts of this definition apply also to the HUH case study research, that research was not used to inform the conduct of the QI program, and it was observational, rather than interventionist. As stated before, as researchers, we had limited control over the decisions and actions taken at the hospital. The HUH QI program was not a research intervention; it was a natural experiment in which we were participant observers. To complicate the distinction further, however, QI efforts – such as those studied here – share many features with action research, in that both involve a “participatory process [which is] educative and empowering, involving a dynamic approach in which problem identification, planning, action and evaluation are interlinked.” (127) p. 11, “A definition of action research”)

Nevertheless, the literature on action research, particularly on doing research in one’s own organization, offers insights that apply also to the case study research discussed here. Issues particular to this situation include the pre-understanding of context and phenomena of interest prior to initiation of a research project; role duality when being both a member of the organization and a researcher studying the same organization; and the frequent need to manage organizational politics in these dual roles. (126) Being an insider to the organization offers valuable pre-understanding and contacts, although it may also lead the researcher to assume “too much” about what is going on in certain situations, and it can impose certain barriers that would not apply to a researcher from outside, such as the ability to access certain people, groups, or settings. Role duality can involve having “to deal with the dilemma of writing a report on what you have found, and dealing with the aftermath with superiors and colleagues, if you do, on the one hand, and doctoring your report to keep your job, on the other.” (128) p. 51)

Pre-understanding – the understanding of an issue that a researcher brings to a study of that issue – is important, since it enables, but also restricts, the learning that can result from such study. (122, 129) There is, argue Alvesson and Sköldberg, “in interpretation always an irreducible moment of reshaping, of subjective creativity with its point of departure in the researcher’s already pre-existing frames of reference. The researcher is never tabula rasa.” (129) p. 68) So, what pre-understanding did I bring upon entering this research?
My perspective was that of a junior physician – steeped in the biomedical research tradition that dominates medical school – who had become increasingly concerned about, and fascinated by, how (healthcare) organizations function, and how their members manage change. My perspective was also influenced by my management studies at Harvard prior to the research project. Although based at a medical university, my research has more of a social science character than a natural science one, in that it concerns how human beings collaborate in an organization to achieve intentional change, notwithstanding that such change often aims to increase the use of biomedical technologies which are founded on research closer to the natural science paradigm. As indicated in the Prologue, I saw QI as a promising approach to addressing many of the problems I had encountered in healthcare, personally or through the literature. While I certainly entered this research with a positive attitude towards QI, I was, and am, genuinely interested in understanding whether and how it works, and can be enhanced, with the ultimate hope to improve healthcare, including the working conditions for those who take care of patients, and thereby to improve human health.

Pressed on whether he favored quantitative or qualitative research methods, Gummesson responded that he was “neither a priori for nor against any methods. They should be used where they are appropriate. If they are not suitable, it is hardly scientific to provide one-sided support for one or another research method, although one-sidedness is not unusual in research circles.” ((122) p. 3) For the research questions addressed in the HUH process management initiative, the case study method has, arguably, been suitable. The SPC literature (Study III) review blended features common to systematic reviews in the positivist paradigm with interpretive data analysis and synthesis, given the qualitative nature of the data at hand.

### 6.4 LIMITATIONS AND STRENGTHS

A limitation of this thesis is that it is draws on studies of just one case, even if extensive and in-depth. As argued by Yin (90) and others (89, 91), even a single case can provide important knowledge of a phenomenon of interest, and allow for generalization to theory, especially when informed also by reference to other literature. At this point, it is difficult, however, to determine how widely the model presented here applies. It seems feasible that it could apply to hospitals similar to the HUH in Sweden, and perhaps in other publicly funded healthcare systems. Whether, or how, it might apply in other settings, such as non-hospital healthcare settings, or the competitive and pluralistic US healthcare setting, or low-resource countries, is harder to tell. Additional research is warranted to further develop our understanding of these issues in such settings.

Other limitations of this research include the lack of economic data, both on the costs of the QI efforts, and on the financial impact of the improvements achieved. Furthermore, this research has not been related to the empirical literature from other sectors regarding the establishment of QI in organizations, but has been limited to the microcosm of healthcare organizations.

The strengths of this research include it solid grounding in empirical data, the longitudinal and in-depth study of QI efforts at HUH benefiting from an insider’s view achieved through participant observation, in line with recommendations in the
The bulk of the data was collected continuously as the QI efforts unfolded, rather than retrospectively, as is often the situation in other studies. In addition, the SPC literature review covered a large and diverse body of empirical literature.

6.5 EVIDENCE-BASED MANAGEMENT?

As noted in the Introduction, there is uncertainty not only about the effectiveness of QI programs, but also about how to evaluate such effectiveness. This relates, in part, to the differing assumptions of different researchers and their disciplines. This can lead to clashes or misunderstanding. In healthcare, the effectiveness of clinical interventions is assessed on the basis of evidence from experimental or observational epidemiological studies, as called for in 1972 by Archie Cochrane, forming what has become the paradigm of Evidence-Based Medicine (EBM). Central to this paradigm is the view that there is a hierarchy of evidence (of effectiveness); some evidence is stronger, and more reliable, than other evidence. The research design largely determines the strength of the evidence. Randomized Controlled Trials, and systematic reviews of such studies, are considered the Gold Standard for evaluating the effectiveness of therapeutic interventions. “In health care, doctors have long argued that management methods and organizational changes should be evaluated, and the pressure to do so increases as doctors themselves are expected to practice [EBM]”. This seems reasonable. The trouble is, however, that it is not easy to evaluate the effectiveness of these management methods, including, as we have seen, QI programs. The EBM hierarchy of evidence does not fit as neatly here, because the research designs underpinning it are not well suited, or feasible, for these kinds of issues, as argued by proponents of a realist view. Realism is a methodological orientation which “seeks to unpack the mechanism of how complex programmes work (or why they fail) in particular contexts and settings.”

Interestingly, the EBM paradigm turns out to have a strong appeal also outside of healthcare. In the management field there is, in fact, a growing interest in the notion of Evidence-Based Management even if at times cautious and tentative. Given the origins of EBM, it is perhaps less surprising that there is also a movement to promote Evidence-Based Healthcare Management. Arguing that it is possible, and important, to pursue such management practices, Walshe and Rundall caution that “the implementation of evidence-based practice in health care management is unlikely simply to follow the established clinical model”. One of the challenges stems from the fact that management research, not least in healthcare, is still in the early phases of maturation. As noted by three leading organizational theorists, in “addition to their relative youth, interdisciplinarity, and fragmentation, management and organization scholarship are challenged to develop knowledge in the image of science while also contributing to practice and policy making. This challenge has proven formidable”. Nevertheless, the movement is gaining momentum as reflected in a recent call for the necessity of combining EBM and EBMgt (for “Management”) to advance the quality of healthcare.
The research reported in this thesis hopefully makes one modest contribution to such developments, by demonstrating how a QI program is established in a healthcare organization, emphasizing that it is an evolutionary process that takes time and requires adaptation to achieve a good fit between QI principles and tools, on the one hand, and the host organization’s needs, ambitions and circumstances on the other.

While reporting here on research to illuminate how QI is established in a healthcare organization, it is worth noting that this type of question can be addressed in other ways. Non-fiction prose, for instance, as exemplified by the insightful essays on quality and safety in healthcare by Harvard surgeon Atul Gawande (143, 144), which represent a form of journalistic, and partly autobiographical, inquiry. As a final note in this section, then: what makes the work reported here a form of research rather than, say, journalism? Some hallmarks are the explicit approach to framing the problem (as a “research problem”) and to data collection; the explicit use of research methods; the explicit reflection on that use, and the attempt to link the work both internally from the initial question all the way to the conclusion, and externally to the wider research literature.

6.6 NOTES ON BEING A PRACTITIONER RESEARCHER

The model, for me, of a practitioner researcher is the multifaceted role many of my clinical colleagues inhabit, where they combine, to varying degrees, clinical practice with research and teaching, and sometimes also management responsibility. I consider this one of the assets of the medical profession – the close ties between these different domains.

I have had the privilege to combine the role as researcher with the role of being a QI practitioner in a hospital, working in close collaboration with both clinicians and managers. So for me, the practice part has entailed supporting QI efforts, including process management, EBM and patient safety efforts. While I have not been seeing patients, I view my work as helping those who do take care of patients to improve their work, thereby helping patients as well.

It has been valuable to alternate between theory and practice – what I have learned from research, I have been able to relate to the real world. I have also benefited in my role at the hospital from being exposed to research-based knowledge. For me, theory and practice have been mutually reinforcing. I agree with others that this can be a model for the future, even though it will not be easy: “Integrating EBM and EBMgt also requires practitioners who are aware of and able to draw on evidence from both. Few physicians read management studies; few managers read clinical studies; and few persons read all relevant studies within their own field.” ((142) p 674)

The obvious challenge of being a practitioner-researcher is that it takes time. This helps explain why this thesis has taken over 10 years to complete. A potentially negative consequence of this is that the data risks becoming out-dated. A potential solution is to allocate some time exclusively for research efforts.
7 CONCLUSIONS AND IMPLICATIONS

As we have seen in the HUH case, as well as in our literature review of SPC application and the discussion above, quality improvement methods and principles cannot just be retrieved – by researchers nor by organizational leaders or members – “off the shelf”, “installed” and then applied optimally from day one. Instead, this thesis argues that a QI program is established through an evolutionary process that involves continuous adaptation, as illustrated in the thesis model (Figure 7). Such adaptation can be guided by systematic evaluation and reflection – learning – to continuously improve the fit between the QI program and organizational needs, ambitions and circumstances.

For practicing managers and clinicians, this implies that they are well advised, if intent on initiating a QI program in their organization, to prepare for such continuous adaptation. While early successes, as demonstrated in the HUH case, are possible, they do not guarantee continued success. If participating clinicians and managers do not experience that their QI efforts “pay off”, or that they have acquired the necessary preconditions – including time to carry out the QI efforts – their capability to achieve improvement may wither over time. Such “pay off” may mean, for clinicians, improved clinical outcomes (as illustrated by Mertens et al(145) and others in our SPC review) for patients and smoother operations, and perhaps a respite from campaigns to cut costs, while for managers it may mean assistance in managing those areas that they are held accountable for.

For researchers interested in evaluating the effectiveness of QI, our findings imply that to assess the effectiveness of QI, we need to first assess in some manner the “maturity” of QI efforts in the organization and the extent to which QI methods are applied – both in terms of breadth and depth. This includes the extent to which QI efforts have been adapted to the host organization, the extent to which the organization is actually applying these methods – and this should be assessed through evidence beyond statements from key stakeholders who may, consciously or not, tend to paint too rosy a picture of reality, due to social desirability issues.

By “breadth of application of QI methods”, we mean the extent to which the entire organization is engaged in applying QI methods. In the HUH case, the extent narrowed over time, as the QI efforts mostly occurred in two out of six divisions, whereas they all were equally involved initially. By “depth of application of QI methods”, we mean the extent to which such methods – perhaps the “active ingredients” in QI, as Ovretveit puts it (58) – are applied in an organization. Superficial application might mean providing a brief training for clinicians in QI methods, and then asking them to carry out QI efforts on their own without additional support. In the HUH case, facilitators with specialized training, skill and experience assisted clinical teams and managers to apply, and understand, core QI methods by designing and running meetings.

The evaluations and trials of QI reviewed in the Introduction (31, 60-62) arguably failed to take sufficient account of the evolutionary nature of QI establishment in a healthcare organization. Therefore, they were at risk of lumping together organizations that actually applied QI deeply and broadly with those that only applied QI shallowly.
and narrowly. This is tantamount to comparing apples and oranges, and (although some investigators claim to have succeeded with such comparisons (146, 147)) this makes these studies prone to underestimating the true effectiveness of QI. Considering, again, that absence of evidence does not equal evidence of absence (72) it is still plausible that QI can be effective. Future assessments of QI effectiveness thus should take greater account of the depth and breadth of QI application.

It may not be possible to ever generate evidence of QI program effectiveness with the same degree of certainty that is possible when evaluating clinical interventions. Does this mean that managers and clinicians should shy away from these methods? No. Such a point of view “is founded on a fundamental misunderstanding of the place of experimental methods in investigating and understanding complex social interventions”. ((148) p. 57) Going back to the principles of the EBM movement; the idea is to use the best evidence available to inform our decisions. (132) In the case of QI programs, such evidence will come from an accumulation of evaluations, as exemplified in this thesis, in many different contexts. Over time, it should be possible to tease out which the “active ingredients” in QI programs are, and how managers and clinicians best can adapt them to their local contexts, contributing to the evolution, and dissemination in practice, of Evidence-Based Healthcare Management (71, 138, 142) and thereby to improvements in organizational performance and human health.
8 EPILOGUE

Over ten years have passed since I joined the process management initiative at Huddinge. I have had ample opportunity to study, and reflect upon, QI application in healthcare. The field has continued to evolve. So, what is my thinking at this point, on the deceptively simple question I posed in the prologue – does QI work in healthcare? The answer, as noted initially, was not quite that simple. It goes something like this: Yes, QI can work in healthcare, but its effectiveness is not guaranteed and it is highly dependent on how well the application of its principles and tools is adapted to each particular situation.

The woman with newly diagnosed gastric cancer, whose encounter with me I related in the prologue, could have received better care than she did, I believe, if the system of care in which I was an uneasy cog at that point, had been steeped in QI and thereby designed to truly meet the needs of its patients.

It has been sobering to observe that although the QI program at Huddinge was comparatively successful, both in my own view and by objective assessment, it nevertheless was discontinued in 2004, three years after the end of the study period reported in this thesis. During those years, as I understand it, the QI efforts continued to evolve and exhibited an even higher degree of goal achievement than that reported in the first five years, although the QI efforts were more unevenly distributed across the hospital. While exploring why this happened is beyond the scope of this thesis, it is noteworthy that the QI program’s demise coincided with the merger between Huddinge and its Northern neighbor to form the Karolinska University Hospital, and the related urgent efforts to cut costs. Without full insight into the cause-and-effect relationships, one can at least draw the conclusion that a QI program, even if successful on many counts, is never guaranteed to last.

At the time of this writing, the management at Karolinska University Hospital has decided to re-establish hospital-wide QI efforts. It will be interesting to see how the lessons learned so far, including those developed through this research, will play out in this new situation.
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## References


