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UNPACKING PROCESS IMPROVEMENT

IN-DEPTH STUDIES OF HOW LEAN AND CLINICAL PATHWAYS CONTRIBUTE TO THE TIMELINESS OF CARE

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To my parents, Daniele and Paola

ABSTRACT

Introduction: Lean thinking and Clinical Pathways are two process improvement strategies that have gained popularity in health care. They both have the potential to improve the timeliness of care, which is an important goal shared by decisions makers, practitioners, and patients alike. Accounts of both approaches report success in terms of improved process performance but seldom explain how and why they work.

Aim: To clarify how contemporary process improvement efforts, in this case lean thinking and clinical pathways, work in practice and how they relate to performance, particularly the timeliness of care.

Method: The main research strategies were organizational case studies and realistic evaluation, drawing on multiple data collection methods and sources. Study I is a realist review of empirical studies of lean applications in health care. Study II and IV investigate a lean-inspired intervention in seven emergency care services at the Karolinska University Hospital. Study III examines a clinical pathways intervention for hip-fracture care patients at the Danderyd Hospital.

Findings: All articles reviewed in Study I reported positive results from lean interventions, explained by how they enabled staff to: understand processes, organize and design for effectiveness and efficiency, improve error detection, and collaborate to solve problems. Studies II and IV found initial improvement in the timeliness of care across all seven emergency services studied. The most common changes involved matching capacity with demand through modifications in staffing, scheduling and competency levels. Differences were observed regarding the degree of improvement, performance levels, and the sustainability of results. These differences were related to how the services adapted the intervention to the degree of complexity of their care processes and their educational commitments. Learning from daily practice proved a challenge. Study III found that extending improvement efforts beyond the hip-fracture care process resulted in a net reduction in lead time to surgery for all acute surgical orthopaedic patients. Two key improvement mechanisms were involved: more active and centralized planning of surgery and restructuring of how resources were allocated among patient groups.

Discussion: Lean and clinical pathway improvement efforts make inconsistent and inefficient practices in health care visible. Care providers can then use a number of planning activities to address those problems. This can yield improvement in the timeliness of care delivery. While these changes are not unique to lean or clinical pathways, they are triggered by these two approaches. The ability to sustain and continually improve performance depends on adapting the process improvement efforts to the specific context of application and on routines that support learning from daily practice.

Conclusion: Practitioners, managers, and researchers should become aware of the specific characteristics of their particular health care delivery systems when they develop, implement, and evaluate process improvements. Practices that foster learning from daily work, including data-driven improvement, timely feedback loops, and the involvement of managers in problem identification and problem solving may support adaptation and continual improvement.

LIST OF PUBLICATIONS

I. **Mazzocato, P.**, Savage, C., Brommels, M., Aronsson, H., Thor, J. Lean thinking in healthcare: a realist review of the literature. Quality and Safety in Health Care. 2010; 19(5), 376-382.

II. **Mazzocato, P.**, Holden, R. J., Brommels, M., Aronsson, H., Bäckman, U., Elg, M., Thor, J. How does lean work in emergency care? A case study of a lean-inspired intervention at the Astrid Lindgren Children's Hospital, Stockholm, Sweden. BMC Health Services Research. 2012; 12(1), 28.

III. **Mazzocato, P.**, Unbeck, M., Aronsson, H., Elg, M., Sköldenberg, O.G., Thor, J. Revealing the role for resource coordination in improving the timeliness of hip-fracture care: An in-depth case study. Submitted.

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LIST OF TERMS AND ABBREVIATIONS

5S	Short for *Sort*, *Straighten*, *Shine*, *Standardize*, and *Sustain*. Together these five words form a sequential series of activities that eliminate wastes which contribute to errors, defects, and workplace injuries. (Liker, 2004).
Care processes	Consist of the tasks and decisions that converts a sick patient (the "input") with the addition of other resources such as capital, labour, and raw materials into a patient whose health has improved (the "value-added output") (Bohmer, 2009).
Clinical Pathways	The optimal sequencing and timing of activities or interventions (such as consultations, assessments, treatments, nutrition, medications) to be performed, given the resources, knowledge, and evidence available, in order to maximize the quality of care and to minimize delays for a specific diagnostic group (Coffey et al., 1992).
Countermeasures	The "temporary responses to specific problems that will serve until a better approach is found or conditions change" (Spear and Bowen, 1999).
CQI	Continuous Quality Improvement. With roots in statistical process control (SPC), the purpose is to design quality into the process from start (Nicolay et al., 2012).
ED	Emergency Department
ENT	Ear, Nose, and Throat
Flow	Tied to Just-in-Time production. In manufacturing, machines are arranged in the order of processing. In this way, the product "flows" between the machines without interruption (Imai, 1997).
Gyn	Gynaecology
Jidoka	In manufacturing, the principle of detecting defects and then stopping production. Problems are communicated to operators through visual signboards called *andon* (Fujimoto, 1999).
Just-in-time (JIT)	"A system where a customer initiates demand, and the demand is then transmitted backward from the final assembly all the way to raw material, thus ''pulling'' all requirements just when they are required" (Abdulmalek and Rajgopal, 2007).
Kanban replenishment system	This is a signalling system which is used to support just-in-time production (Abdulmalek and Rajgopal, 2007).
Lean	A "strategy for organizing production systems" which was originally developed at The Toyota Motor Corporation (Karlsson and Åhlström, 1996).
LPN	Licensed practical nurse
MD	Medical Doctor
Med	Internal Medicine
OM	Operations Management. The field of knowledge that deals with how to design, plan and control the production and delivery of goods and services to customers (Chase and Jacobs, 2006).
One-piece flow	The movement of products through a process one at a time (Liker, 2004).
Health care operations	The activity (or set of activities) that transform inputs into outputs in order to generate a service that adds value to the individual patient (Vissers and Beech, 2005).

Ped	Paediatrics
Pull	"The previous process produces only as many products as are consumed by the following process" (Imai, 1997, p.xxvii). Related to just-in-time.
RN	Registered nurse
Six Sigma	"A quality improvement methodology focusing on reducing error and process variability" (Nicolay et al., 2012).
SPC	Statistical Process Control is the "philosophy, strategy and set of methods for the ongoing improvement of systems, processes and outcomes, based on learning through data" (Nicolay et al., 2012).
Standard Operating Procedures	The "best" way to do a job which includes the "policies, rules, directives, and procedures" that are established for major operations. They serve as guidelines for employees so they perform their work in a manner which ensures good results (Imai, 1997).
Surg	Surgery
Takt time	The time allocated to produce each part which is determined by "dividing the total production time by the number of [parts] to be produced" (Imai, 1997).
TPS	Toyota Production System. The production system developed at the Toyota Motor Corporation and which has been characterized as "lean".
TQM	Total Quality Management is "the management philosophy to improve continuously the quality of products and processes to meet or exceed customer expectations" (Nicolay et al., 2012).
Value stream	All the actions required to produce a product (or a group of products) that use the same resources (Rother and Shook, 2003).

1 INTRODUCTION

1.1 HEALTH CARE SEEKS SOLUTIONS

The increasing pressure to meet patient expectations within the constraints of limited resources has placed health care managers and clinicians in a difficult position. In looking for solutions to deal with these challenges, many health care organizations have launched improvement programmes which often draw upon methodologies imported from manufacturing, such as Total Quality Management (TQM), Continuous Quality Improvement, Six Sigma, Clinical Pathways, and Lean thinking (lean) (Young et al., 2004, Walshe, 2009, Coffey et al., 1992).

The two approaches studied in this thesis have gained a solid footing in health care. In the past decade, a number of health care organizations have begun to apply lean, a production philosophy developed by Toyota Motor Corporation (TPS, Toyota Production System) (Womack et al., 1990). In Sweden, nine out of ten hospitals claim to have implemented lean to some extent (Weimarsson, 2011). There is the possibility that lean is merely the next trend spreading through hospitals (Walshe, 2009). To determine if this is so or if lean is actually able to deliver on its promises is a question that needs to be explored.

Clinical Pathways is a planning technique, also inspired by manufacturing concepts, which has a longer history of application in health care (Coffey et al., 1992). It emerged prior to lean, when prospective payment of hospital services based on Diagnosis Related Groups (DRG) was introduced in the USA (Keen et al., 2006).

One reason these methodologies have gained popularity is that they can be used to address the problem of waiting times. This problem is commonplace in Emergency Departments (EDs). EDs represent the first contact with a hospital for the majority of patients. EDs' overcrowding and delays in providing patients with the care they need can lead to serious consequences with regard to medical outcomes (Miro et al., 1999, Derlet et al., 2001), medical errors (Derlet and Richards, 2000), as well as the negative impact waiting patients (and the violence that sometimes erupts due to their frustration) have on health care professionals and their work environment (Pearce, 2002, Stirling et al., 2001).

Awareness of the problems caused by lengthy waiting times has reached national policy levels. The UK, Australia, Canada, and New Zealand have all set national targets aimed at reducing unnecessary waiting and improving patient outcomes in EDs (Jones and Schimanski, 2010, Mason et al., 2011). In Sweden, which has one of the world's lowest number of beds per capita, waiting time has also become a major political issue (OECD, 2009). The Swedish Minister of Health and the Swedish Association of Local Authorities and Regions together launched an initiative in 2010, allocating 1 billion SEK from which to reward those county councils which have succeeded in providing their patients with timely care and reducing treatment waiting lists (Swedish Association of Local Authorities and Regions, 2010).

Given the widespread use of lean and clinical pathways, it becomes increasingly pertinent to ask: How might the application of these methodologies help improve acute care, particularly the ability of health care organizations to provide care in a timely manner? To come closer to an answer, it is necessary to address the assumption behind these approaches. Both lean and clinical pathways rest on the same assumption that the key to improvement is to identify, differentiate, and make planned changes to processes in health care.

1.2 MANAGING CARE PROCESSES

Bohmer defines a care process as "the set of tasks and decisions that takes the 'input' of a sick patient (plus some other resources, such as capital, labour, and raw materials) and converts these into a value-added 'output' – namely a patient whose health has improved" (Bohmer, 2009, p. 117). The typical steps in a care process thus include diagnosis, treatment selection, treatment execution, and post treatment monitoring. In other words, care processes are ubiquitous in health care, but they are not always explicitly recognized or actively managed. In fact, they are often poorly managed (Vissers and Beech, 2005, Institute of Medicine (U.S.). Committee on Quality of Health Care in America, 2001, Bohmer, 2009).

The management of processes finds its roots in Operations Management (OM). This is the field of knowledge that, originating in manufacturing and further developed in the service sector, deals with how to design, plan and control the production and delivery of goods and services to customers (Chase and Jacobs, 2006). Health care OM deals with the "analysis, design, planning, and control of all the steps necessary to provide a service to a client," where the most important client is the patient (Vissers and Beech, 2005, p. 3). The term "operations" in the health care context refers to the activity (or set of activities) that transforms inputs into outputs in order to generate a service that adds value to the patient (Vissers and Beech, 2005, p.40).

To illustrate, consider the process that a patient goes through to replace an arthritic hip. There are the activities undertaken by different actors, such as the surgeon, the anaesthetist, and the nurse. There are the resources involved that are often grouped together in units based on the similarity of the type of resources consumed, such as wards, operating theatres, or intensive care units. The final outcome in terms of service delivered to the patient is therefore the result of the set of activities organized in a process (Vissers and Beech, 2005).

1.2.1 Manage processes or units?

Advances in technology and scientific knowledge are drivers behind the ever-increasing specialization of health care as a professional service (Bohmer, 2009). This has led health care services to be organized primarily around specialized functions and units rather than around processes (Vera and Kuntz, 2007, Lega and DePietro, 2005). This, in turn, has led to fragmentation and poor coordination of care processes, with patients suffering unnecessary delays (Walley, 2003, Institute of Medicine (U.S.). Committee on Quality of Health Care in America, 2001, Bohmer, 2009, Glouberman and Mintzberg, 2001).

There are two basic approaches for the management of health care operations (Vissers and Beech, 2005): one approach takes the perspective of the unit; the other approach takes the perspective of the care process. Both perspectives have their advantages and disadvantages.

1.2.1.1 The unit perspective

The unit perspective focuses on managing the total flow of patients served by one unit. The aim is to maximize the efficient use of the available resources. Key efficiency indicators from a unit perspective include the level of resource utilization versus the output achieved, for instance, the number of patients per hour who are scanned in a magnetic resonance imaging machine. The unit perspective tends to reinforce the fragmentation of care processes (Vissers and Beech, 2005). While the component parts of the process may work efficiently, the entire care "journey" may not work smoothly or efficiently from the patient point of view.

The unit perspective suggests that key decision areas involve how to manage capacity in order to achieve high utilization levels of the resources while at the same time avoiding peaks and valleys in the workload that can affect both efficiency and work climate (Vissers and Beech, 2005).

1.2.1.2 The process perspective

In the process perspective, operations are managed with a focus on planning and monitoring efficiency and effectiveness for a defined patient group (Vissers and Beech, 2005). In contrast to the unit perspective, the process perspective focuses on maximizing the service level, particularly the timeliness of care delivery, from the perspective of a specific patient group. Therefore, to address the problem of waiting times, the process perspective on health care deliver needs to be strengthened.

There are two basic approaches by which hospitals can strengthen the process perspective on health care delivery. The organizational structure can be modified to build multidisciplinary departments organized around patient needs with the aim to overcome organisational (disciplinary) boundaries. The other approach is to develop mechanisms to coordinate the activities that form a care processes for a homogeneous patient group (Vos et al., 2011, Vera and Kuntz, 2007, Gemmel et al., 2008). Lean and clinical pathways are often used in health care with the aim to improve coordination of care processes from the perspective of the patient.

The process perspective suggests that key decisions for how to plan operations concern how to coordinate the supply and demand of care services in order to make resources available in a timely manner as patients move through the process. This is referred to as operational coordination. As resources are often not allocated to a specific patient group, but rather to specialties, and are therefore shared between patient groups, a key challenge is how to allocate shared resources both to specialised units and to different patient groups (e.g., how many operating rooms to allocate to the patients in the different specialities). This challenge falls within the realm of structural coordination (Vissers and Beech, 2005).

1.2.2 Designing care processes

Process design deals with how to configure resources in processes in order to deliver a service to a patient (to use the health care context) (Walley, 2003) or, more broadly, to a customer. The design of care processes is influenced by the knowledge available and needed to solve a medical problem in order to relieve human suffering from illness or injury (Bohmer, 2009).

Care processes are problem solving types of processes in which the ability to predict a certain set of steps will depend on the level of knowledge available for how to solve a specific medical problem (Bohmer, 2009). While well-structured, easily recognized problems can be solved in a sequential and standardized manner following pre-specified steps, unstructured or semi-structured problems, that are harder to recognize at the outset, can best be solved in an iterative process of testing and probing (Bohmer, 2009, Bohmer, 2005). In a similar vein, Lillrank and Liukko (2004) categorize care processes as standard, routine, and non-routine, depending on the level of predictability of the input (i.e. how well defined the complaints are) and on the process in relation to the medical outcome (i.e. the extent to which the content and timing of clinical activities can be specified ahead of time in clinical guidelines or protocols for the achievement of predictable medical outcomes). Thus, the predictability of resources used to solve a certain health problem will be greater for standard and routine processes than for non-routine processes.

The level of knowledge available for how to solve a certain health problem influences clinicians' practice. For instance, medical knowledge for how to solve structured problems is often embedded in clinical guidelines and care protocols. This creates demands on the type and level of knowledge, skills, attitudes and training practitioners need to solve a typical problem. Sequential processes can be undertaken by less trained physicians, whereas iterative processes may require higher training levels (Bohmer, 2009). Moreover, variation in staff training and skills can influence the number of iterations needed to solve a particular patient's health problem (Walley et al., 2006b). In other words, a routine process can become a non-routine process for a junior physician, whereas a non-routine process can become a routine process for a more senior physician (Lillrank and Liukko, 2004).

Researchers have argued that manufacturing approaches, such as lean, are better suited for sequential care processes, but less well suited for dealing with the uncertainty that characterizes more iterative types of care process (Bohmer, 2005, Lillrank and Liukko, 2004).

To summarize, health care is delivered to patients through processes. From a patient perspective, the core process is the care process. Nevertheless, care processes are not always explicitly identified nor actively managed. Lean and clinical pathways represent two approaches for how to manage care processes.

1.3 LEAN

1.3.1 Lean in manufacturing

The roots of lean can be found in the Toyota Production System (TPS). After World War II, Toyota experienced a major financial crisis. Looking for a solution to their problems, Toyota managers visited American car companies to study their manufacturing methods. While impressed, they eventually realized that the mass production model, with its large batches and its focus on maximizing economies of scale, was not suitable in their Japanese context. Compared to their American counterparts, Toyota needed to develop a manufacturing system that would enable them to produce a wide variety of models at a low volume per model type, all under heavy financial constraints. At this time, the quality movement with Juran and Deming's 14 principles was gaining popularity in Japan (Deming, 1986). Under these circumstances a number of principles and techniques were developed that focused on reducing costs and eliminating waste (Holweg, 2007, Hines et al., 2004).

By the 1980s, the principles and techniques had paid off. As Japanese automotive companies became more competitive, the US automotive industry saw them as a serious threat. This led to the establishment of voluntary import restrictions in the USA.

A group of researchers participating in the International Motor Vehicle Program (IMVP), primarily based at the Massachusetts Institute of Technology, began to examine the performance gap between Japanese and Western companies. The resulting book, *The Machine that Changed the World,* popularized the term "lean" as a way to describe the Toyota Production System (Womack et al., 1990).

Since then, many scholars have tried to characterize lean production as used by Toyota. This has resulted in many different definitions of what lean is and how it can be achieved (Pettersen, 2009). Therefore lean, lean thinking, and TPS are often used interchangeably.

Liker (2004) describes the "Toyota way" as a long-term philosophy that focuses on adding value to customers. He suggests that a company should begin by asking, "What does the customer want from this process?" By eliminating waste from the production processes, the expectation is that this will lead to lowered costs, shorter lead times, and higher quality (Liker, 2004). In the lean literature, waste is referred to as *muda* (the Japanese word for waste). Sources of muda include: overproduction, waiting, transport, inappropriate processing, unnecessary inventory, unnecessary motion, and defects (Liker, 2004).

Spear and Bowen (1999) emphasize the importance of reducing any source of ambiguity in operations. Operations are designed with a focus on: 1) specifying the content, timing, sequence and outcome of all work; 2) developing unambiguous connections between every customer and supplier; 3) developing a simple and direct pathway for every product. With no ambiguity, waste is removed from production processes, which in turn enables staff to easily detect problems, which are defined as deviations from the "ideal production system". When problems are detected, staff members are empowered to immediately investigate their root causes and then to develop "countermeasures" that

are tested through rapid experimentation before they are implemented. Countermeasures are implemented "until a better approach is found or conditions have changed" (Spear and Bowen, 1999). This will ultimately lead to the development of a "self-improving organization" in which people are responsible for both doing and improving their work.

Fujimoto explains Toyota's success in terms of three capabilities (Fujimoto, 1999). The first, "routinized manufacturing capability," involves a set of "organizational routines that affect the level of manufacturing performance". The second, "routinized learning capability," is "a set of organizational routines that affect the pace of continuous or repetitive performance improvements, as well as recoveries from system interruptions or deterioration"(Fujimoto, 1999, p.17). The learning capability is built on routines for problem identification, routines for problem solving, and routines for solution retention. Solution retention involves the ability to formalize and institutionalize countermeasures that are developed into new standard operating procedures. This provides the stability necessary for individuals to internalize the solutions. The third capability, or "evolutionary learning capability", is the "non routine ability" to integrate new manufacturing and learning routines through different paths (Fujimoto, 1999). Fujimoto describes this as:

> the dynamic capability [that] encompasses making good decisions, learning from mistakes, and grasping the competitive benefits of unintended consequences. Manufacturing companies that survive for decades don't succeed just because they implement the right systems or routines at a certain point in time; they also have a long-term ability to generate effective routines even without prior knowledge of their competitive effects (Fujimoto, 1999, p.5).

Lean is a strategy that encompasses all functions in a company including product development, procurement, manufacturing, and distribution (Karlsson and Åhlström, 1996). At the manufacturing level, several principles and practices are available for how to manage production processes and continually improve them (Karlsson and Åhlström, 1996). Two principles are mentioned by Toyota as the core of TPS: j*ust-in-time* and *jidoka* (Toyota Motor Corporation, 2012). *Just-in-time* involves tools and techniques that allow a company to deliver what is needed, when it is needed, and in the amount needed. This includes moving products through the process in small batches, ideally one-at-a-time (*one-piece flow*). Operations are scheduled according to a *pull system*, with the production of products being pulled by actual customer demand instead of being pushed by a sales forecast. The consumption of an article then creates a demand for replenishment that is communicated up-stream, through what is referred to as a *kanban replenishment system*. To facilitate *flow* in the operations, multifunctional teams are responsible for all tasks that are needed to complete a certain process (Liker, 2004).

Jidoka or "automation with a human touch" is achieved by using equipment that automatically stops when quality problems are detected. This allows one operator to visually monitor (through visual signals referred to as *andon display boards*) and control several machines and processes simultaneously (Toyota Motor Corporation, 2012). The problems detected in the production process are dealt with in different ways, ranging from structured quality circles (small number of employees who continuously perform

improvement activities within the workplace (Imai, 1997)) to less structured ways (Karlsson and Åhlström, 1996). Improvement is decentralized to the level of multi-functional teams but is also supported by vertical information systems that communicate the company's goals to multifunctional teams (Karlsson and Åhlström, 1996).

1.3.2 Lean in health care

Lean health care is a relatively new field. Publication of the first empirical studies have been traced to the year 2002 (Brandao de Souza, 2009). Both Great Britain's National Health Service (NHS) (Jones and Mitchell, 2006) and the Joint Commission Institute in the USA (Zak, 2006) have promoted the use of lean thinking as a strategy that can help health care organizations provide more value to their patients, while at the same time using less resources.

Lean applications have been used to tackle different types of problems such as patient safety (Furman, 2005, Furman and Caplan, 2007, Nelson-Peterson and Leppa, 2007), EDs' overcrowding (Kelly et al., 2007, King et al., 2006), or simply to develop clearer work procedures (Braaten and Bellhouse, 2007). Lean has been used both at the level of the single unit, such as EDs (King et al., 2006, Kelly et al., 2007) and at the level of the whole organization (Ben-Tovim et al., 2008, Ben-Tovim et al., 2007, Harrison and Kimani, 2009).

1.3.2.1 Potential benefits of lean in health care

The first potential benefit of lean health care is that it will help to manage care processes that are centred on patient needs. This begins by defining value from the patient perspective, such as the timeliness of care delivery. The NHS defines value as "...anything that helps treat the patient. Everything else is waste" (Jones and Mitchell, 2006). For flow to occur, all the steps that add value to the patient are linked seamlessly together in a value stream (Jones and Mitchell, 2006, Zak, 2006).

In lean, patient groups are usually identified based on the characteristics of the care process and the constellation of resources that they need. This is referred to as "process streaming" (Walley, 2003). In EDs, patient streams have been identified based on different criteria, such as the likelihood that patients will be admitted or discharged (King et al., 2006, Kelly et al., 2007), or based on the need or lack thereof for further investigation (Walley, 2003). These applications have led to reduced waiting times and length of stay (LOS) for the patients (King et al., 2006, Kelly et al., 2007, Ben-Tovim et al., 2008).

The second potential benefit of lean is that it will ultimately lead to the development of a "self-improving organization" in which people are responsible for both doing and improving their work (Spear and Bowen, 1999, Spear, 2005). The NHS suggests that the development of clear, easily seen, standardized processes through lean creates the foundation for continuous improvement (Jones and Mitchell, 2006). Some articles report that lean contributes to the development of a culture in which all employees are involved in solving problems at the source as a way to continually improve (Braaten and Bellhouse, 2007, Condel et al., 2004, Furman and Caplan, 2007).

1.3.2.2 How has lean worked in health care?

Research in lean health care has been dominated by speculative rather than empirical studies (Brandao de Souza, 2009). A large number of the empirical studies report positive results both when lean is applied to care processes as well as to support processes, such as laboratory services or medications administration (Brandao de Souza, 2009). They focus predominantly on describing how lean was introduced in the specific organization rather than on presenting a critical analysis of how lean has worked and why. Moreover, because this research often lacks statistical analyses of the reported changes in outcomes, it is difficult to determine the effect of lean and link it to specific interventions (DelliFraine et al., 2010).

Some authors have argued that few health care organizations have achieved the level of maturity needed to develop the capability to "self-improve" (Brandao de Souza, 2009, Radnor and Holweg, 2010, Radnor and Walley, 2008, Spear, 2005). Indicative of this is the fact that most applications are "tool-based", and little is done to align lean with the organizational strategy and to develop stable structures for continual problem solving (Radnor and Boaden, 2008).

1.3.1 Clinical Pathways

Like with lean, the origin of clinical pathways can also be traced to manufacturing; specifically to the Critical Path Method. Critical Path is a mathematically based algorithm for planning and coordinating the activities needed to complete large-scale projects with minimal duration (Stevenson, 2005). Critical paths were first introduced in USA following the introduction of Diagnosis Related Groups in the beginning of the 1970s. This introduction led to hospital reimbursement based on standard LOS and costs. Thus, critical paths were used to map care processes and to specify the activities that composed them, with the purpose of reducing variation in practice and thus in cost and lead times (Coffey et al., 1992).

By then, a number of different terms had been introduced that cover a multitude of applications of this methodology: critical pathways, clinical pathways, care paths, chain of care, or diagnostic and therapeutic paths (Luc, 2000). In this thesis, the term clinical pathway is used. These applications do not include the use of formal techniques developed in the industrial sector (Pearson, 1995), but rather focus on providing structured information about the optimal sequencing and timing of activities to be carried out to meet the needs of a specific patient group (Luc, 2000). Thus, clinical pathways can be defined as the "optimal sequencing and timing" of activities or interventions (such as consultations, assessments, treatments, nutrition, medications) to be performed, given the resources and the knowledge available, in order to maximize the quality of care and to minimize delays (Coffey et al., 1992). They aim at achieving coordination along the whole chain of care, often also including pre and post hospitalization interventions. Typically they are developed for high-volume, high-risk, and high-cost diagnoses and procedures (Coffey et al., 1992). In the development of coordinated care processes, clinical pathways define the actual content of the diagnostic and treatment process, with the aim of promoting the use of evidence-based practice (Luc, 2000, van Vliet et al., 2010).

1.3.1.1 How have clinical pathways worked?

One patient group for which clinical pathways have been successfully developed are hip fracture patients (Koval and Cooley, 2005, Choong et al., 2000). The use of clinical pathways have led to reductions in inpatient complications (Neuman et al., 2009) and reduced LOS (Choong et al., 2000, Koval et al., 2004, Hommel et al., 2008, Olsson et al., 2006, Lau et al., 2010).

Several authors have stressed the superficial level of conceptualization of clinical pathways, and the difficulty of disentangling what is actually being implemented (Luc, 2000, Vanhaecht et al., 2006). It is also unclear whether clinical pathways actually result in a better managed care process and, if so, how better coordination of care processes is achieved (Vanhaecht et al., 2009, Keen et al., 2006). This is partly because clinical pathways do not seem to provide clear guidance for how care processes can be organized and managed (Vanhaecht et al., 2006).

1.4 SUMMARY

The enthusiasm with which consultants, managers, and members of the research community have greeted the promises of process improvement through lean and clinical pathways risks leading to uncritical, and unsuccessful, application of these concepts. Therefore, this enthusiasm must be tempered not only by analysing the effects of these approaches on timeliness of care, but also by analysing and understanding the underlying mechanisms.

In the context of this thesis, a clinical pathway is defined as an approach to manage care processes for a diagnosis/patient group, with a focus on eliminating unnecessary delays and supporting the implementation of evidence-based clinical guidelines. Thus, it entails a process view across organizational boundaries. Lean is defined as an approach to manage processes by using a number of tools and principles which focus on eliminating waste from the point of view of the patient. Lean also involves developing a capacity for continual improvement.

Accounts of both approaches report results in terms of improved process performance but seldom explain *how* and *why* they work. Consequently, there is a need to systematically analyse the state-of-the-art as well as how stakeholders in health care comprehend these approaches, methods, and techniques, including how they are applied in their particular contexts.

2 AIM AND SPECIFIC OBJECTIVES

The general aim of this thesis is to clarify how contemporary health care process improvement efforts work in practice and how they relate to performance.

The contribution of the four studies to the general aim is to:

- Critically appraise empirical studies of lean applications in health care in order to identify what about lean thinking works in health care, how, and why (Study I)
- Explain how and why a lean-inspired intervention at a paediatric emergency department influenced waiting time and throughput (Study II)
- To explain, by using hip-fracture care as a case, connections between a clinical pathways intervention and process performance, indicated by the percentage of patients operated within 24 hours and the lead time to surgery (Study III)
- Explain how different emergency services adopt and adapt the same hospital-wide lean-inspired intervention and how this is reflected in waiting time and throughput (Study IV).

2.1.1 Overview of the studies

The four studies consist of one literature review of the empirical applications of lean thinking in health care (Study I) and three empirical studies that investigate process improvement efforts at two Stockholm area hospitals (Studies II, III, and IV). As summarized in Table 1, the improvement efforts investigated differed in their scope and in their approach. Study II and Study IV investigated lean-inspired improvement efforts at the Karolinska University Hospital, which focused on the total emergency patient flow within EDs. Study II is a single case study. Study IV is a multiple case study of the lean intervention in seven emergency services. Study III investigates efforts to improve the hip-fracture care process at the Danderyd Hospital. This clinical pathway-based improvement effort involved several units.

Table 1. Overview of the four studies

Study	Title	Objectives	Setting	Scope of the improvement efforts	Improvement approach used
I	Lean thinking in healthcare: A realist review of the literature	Critically appraise empirical studies of lean applications in health care in order to identify what about lean thinking works in health care, how, and why	Various types of health care organizations	From narrow to wide	Lean thinking
II	How does lean work in emergency care? A case study of a lean-inspired intervention at the Astrid Lindgren Children's hospital, Stockholm, Sweden	Explain how and why a lean-inspired intervention at a paediatric emergency department influenced waiting time and throughput	Paediatric emergency service at the Karolinska University Hospital	Total patient flow within one unit	Lean thinking
III	Revealing the role of resource coordination in improving the timeliness of hip-fracture care: An in-depth case study	To explain, by using hip-fracture care as a case, connections between a clinical pathways intervention and process performance, indicated by the percentage of patients operated within 24 hours and the lead time to surgery	Several units at the Danderyd Hospital	One single care process across multiple hospital units	Clinical pathway
IV	Complexity complicates lean: lessons from seven parallel emergency care services in the same hospital-wide lean program	Explain how different emergency services adopt and adapt the same hospital-wide lean-inspired intervention and how this is reflected in waiting time and throughput	Seven emergency services at the Karolinska University Hospital	Total patient flow within each unit	Lean thinking

3 METHODOLOGY

This chapter begins with a description of the study context, followed by a description of the main research strategies used in the thesis. The research design, data collection and analysis are then presented for each of the four studies.

3.1 STUDY CONTEXT

The Swedish health care system is financed primarily through taxes levied by the 20 county councils and 290 municipalities (Swedish Association of Local Authorities and Regions, 2012). The National Board of Health and Welfare in Sweden issues national guidelines and quality indicators used for follow-up on the performance of health care providers (The National Board of Health and Welfare, 2009). Health care services are the responsibility of each county council and are predominantly publicly provided, although there has been an increase of publicly and privately funded private health care providers in recent years (Anell, 2005). The Stockholm County Council is the largest county in Sweden, with almost 200 local medical centres and seven emergency hospitals (Stockholm County Council, 2012). To stimulate health care providers to improve access to care, the County Council established financial incentives linked to performance indicators (Stockholm County Council, 2012).

The empirical data in Studies II, III, and IV are based on improvement efforts carried out at two publicly funded and owned hospitals operating within the Stockholm County Council: the Karolinska University Hospital (Study II and Study IV) and the Danderyd Hospital (Study III). Table 2 provides a brief comparison of the two hospitals. Under political and patient pressure to improve access to care, the Karolinska University Hospital and the Danderyd Hospital both initiated organization-wide programmes to improve care processes. These initiatives were launched by the hospital management at each hospital concurrently with the appointments of new Chief Executive Officers (CEOs) (Hansson et al., 2012, Study II).

Table 2. Characteristics of the two hospitals in 2011
(Stockholm County Council, 2012, Karolinska University Hospital, 2012, Danderyd Hospital, 2012)

Hospital	Population served	Employees	Turnover	Inpatient admissions per year	Outpatient visits per year	Patient visits at the ED per year	Number of beds
Karolinska University Hospital	2 million	15,013	14.696 billion SEK[1]	110,000	1,478,700	200,000	1,561
Danderyd Hospital	450,000	3,400	2.867 billion SEK[2]	43,700	407,000	80,000	578

[1] approx. €1.6 billion or $2.3 billion, [2] approx. €320 million or $440 million (Riksbanken average 2011, www.riksbanken.se)

3.1.1 Lean programme at the Karolinska University Hospital

In 2007, hospital management initiated a strategic long-term, lean-inspired programme that they referred to as "flow-work" (Karolinska University Hospital, 2012). The program had some of its roots in process improvement efforts that were initiated in the 1990s (Thor, 2007).

The implementation process was designed and facilitated by the hospital's Strategic Services Development Unit. The overarching goal was to improve care processes (i.e. increase patient value and decrease waste) and working conditions.

Taking a stepwise approach to the patient "journey" in the hospital, improvement efforts initially focused on improving patient flows at the ED. The division of emergency care, which includes 16 emergency services, is responsible for 60% of all hospital admissions. Other units such as, wards and support services, would then naturally become involved in later stages of the improvement efforts. The specific goals for the emergency services were the following: to reduce the average time between patient arrival and initial physician assessment to 40 minutes; to increase the throughput of patients at the ED so that 90% of patients can leave within four hours; and to reduce the number of patients at the ED at 4 PM. In the initial phase, goals were to be met between 8 AM-4 PM on weekdays.

Improvement efforts were organized in a three-phase model: I) Redesign/Test/Learn, II) Implement, and III) Continuously Improve. Phase I was initiated in the autumn of 2007. Multidisciplinary process improvement teams, led by a physician as process leader, were formed to drive the improvement work at each ED service. Each team began by mapping the care process at the ED to identify "non-value adding time" from the patient perspective. All sixteen ED services, guided by a coach from the hospital's Strategic Services Development Unit, used the principles in Table 3 to develop process prototypes, which were to be iteratively tested, evaluated, and refined before they were implemented.

Table 3. Improvement principles used in the lean-inspired programme

Principle	Description of the principle
Visualize	All people involved in the care process should have an overview of what happens, where one's colleagues are, and where the patient is in the care chain
Link patient care activities	The various activities that compose a patient's care process should, if possible, be linked together or even be performed in parallel
Takt (work pace)	Different activities can take different time, but the goal is to decrease the variability in the time to complete each step in the process and to achieve a steady work pace to meet projected demand
First-time quality	By getting things right the first time, quality is improved, and the need for rework is reduced.
Standardize	To the extent possible, patient care processes should be standardized to reduce wasteful patient-to-patient variability
Continual improvement	Processes and practices can be adjusted several times – by testing, evaluating, and trying again, using a scientific approach – before work flows smoothly

The process prototypes involved changes in ways of working, competence, and staffing in order to move from the "current state" characterized by non-value adding time from a patient perspective to an "ideal state" where activities in the care process were better linked (from the perspective of the patient). Each service implemented the process prototypes between April and December 2008 (Phase II). When the goals were achieved and sustained, and the process prototypes had become the new standard procedure at the ED, then Phase III would begin, with the aim of continually improving processes (Study II).

3.1.2 Improving hip-fracture care at the Danderyd Hospital

In early 2008, the Danderyd Hospital management launched an improvement programme initially named "the no-wait hospital" (Hansson et al., 2012). This programme later evolved into a lean programme (Danderyd Hospital, 2012). Although the improvement efforts investigated in Study III were partly inspired by the hospital's overarching lean programme, limited connections were drawn to the hospital's lean programme. The improvement efforts were also grounded on previous work, begun in the 1990s, to improve care of hip-fracture patients (Striem et al., 2003).

This improvement work organizes a care process based on an evidence-based clinical pathway in accordance with the national guidelines that recommend surgery within 24 hours (The National Board of Health and Welfare, 2003). In line with the national guidelines, a related quality indicator, and financial incentives from the Stockholm County Council, the specific aim of the improvement initiative was that 80% of the surgeries for hip-fracture patients would begin within 24 hours of the patients' arrival at the hospital.

3.2 MAIN RESEARCH STRATEGIES

To address the thesis objectives, this thesis used two main research strategies: case study and realistic evaluation. Both approaches can be considered research strategies because they are not limited to the use of a particular method for data collection or analysis (mixed methods are often used). Instead, they represent ways of understanding complex interventions in their context of application. The strategies and the rationale for choosing them are presented next.

3.2.1 Case study

Case study is a comprehensive research strategy that "investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident" (Yin, 2003, p.13). Including the context is of particular importance when the setting is complex and dynamic. The general aim of case study research is to better understand, in depth, the dynamics that are present in a certain setting (Eisenhardt, 1989a). Case study research is useful when the research questions are focused more on the "why" and the "how" than on the "how many" "how often" or the "what" (Eisenhardt, 1989a, Yin, 2003).

Process improvement interventions such as those investigated in this thesis are often complex because they can entail multiple components that interact with one another and with the local context. These interventions are often developed stepwise within their setting of application in response to the needs and expectations of patients, health care professionals, managers, and politicians. Moreover, OM is an applied field where much can be learned from field research (Näslund, 2002, Voss et al., 2002). Thus, the case study approach was deemed appropriate for this research.

3.2.2 Realistic evaluation

Both realistic evaluation and case study aim at describing and understanding outcomes as the product of a complex intervention in a specific context. One difference between the two strategies is in how the interactions are teased out. The underlying assumption of realistic evaluation is that complex social interventions are based on hypotheses and assumptions (called programme theories) that can be defined, followed and evaluated. They require active input from individuals, and they interact with and adapt to different application contexts. In realistic evaluation, the researcher attempts to elucidate the mechanisms by which an intervention triggers a response in the context of application. This interaction can then explain why similar interventions may yield different results (Walshe, 2007, Pawson and Tilley, 1997). Explanations are expressed as C-I-M-O configurations – an intervention (I) in a context (C) triggers a mechanism (M) that generates an outcome (O). The individual components of C-I-M-O are described in Table 4, modified from Denyer, Tranfield, and van Aken (2008).

The term realistic signifies that this is a form of applied research "*not* performed for the benefits of science as such, but pursued in order to inform the thinking of policy makers, practitioners, program participants, and public" (Pawson and Tilley, 1997, p. xiii).

A realistic evaluation approach was deemed appropriate for Study IV because interventions such as lean are complex interventions, because the aim was to understand how lean was implemented and worked in its context of application, and because of the need for empirical studies that inform stakeholders working with process improvement in health care.

Table 4. CIMO logic
(modified from Denyer, Tranfield, and van Aken 2008)

Component	Component description
Context (C)	The surrounding factors that influence an intervention, including four layers: the individual, the interpersonal relationships, the institutional setting and the wider infrastructural system
Interventions (I)	The interventions, by which behaviour can be influenced. The nature of the intervention, and how it is implemented
Mechanisms (M)	The mechanisms that are triggered by the intervention in a certain context and that yield a particular outcome
Outcome (O)	The outcome of the interventions (e.g. performance improvement or cost reduction)

3.2.2.1 Realist review

The realist review approach has gained much popularity in health care management and policy research, as evidenced by the increased number studies that use this method (Greenhalgh et al., 2007, Pawson et al., 2005, Jagosh et al., 2012, Macaulay et al.,

2011). A realist review, which is based on the same principles as realistic evaluation, aims at investigating "how" and "why" management and policy interventions work in relation to the underlying mechanisms and the contexts (Pawson et al., 2005). This contrasts with systematic review that aims at synthesizing the evidence of "what works" and at assessing the overall effect of a clinical treatment through statistical analysis of quantitative data. A realist review approach was used in Study I to come closer to understanding how and why lean worked rather than merely trying to quantify its effects (Pawson et al., 2004).

Systematic and realist reviews follow similar execution steps, but there are some key differences which have been summarized by Pawson et al. (2004) in Table 5. There are two principal differences between systematic and realist reviews: first, a realist review follows a more iterative process; second, they yield different types of data.

Table 5. Design and sequence of traditional systematic review and realist review

Traditional systematic review	Realist review
Identify the review question	Clarify scope of review Identify review question Refine purpose of review Articulate key theories to be explored
Search for primary studies, using clear predefined inclusion and exclusion criteria	Search for relevant evidence, refining inclusion criteria in the light of emerging data
Appraise quality of studies using a predefined and validated critical appraisal checklist, considering relevance to research question and methodological rigour	Appraise quality of studies using judgement to supplement formal checklists, and considering relevance and rigour from a 'fitness for purpose' perspective
Extract standard items of data from all primary studies using a template or matrix	Extract different data from different studies using an eclectic and iterative approach
Synthesize data to obtain effect size and confidence interval and/or transferable themes from qualitative studies	Synthesize data to achieve refinement of programme theory – that is, to determine what works for whom, how and under what circumstances
Make recommendations, especially with reference to whether findings are definitive or whether further research is needed	Make recommendations, especially with reference to contextual issues for particular policymakers at particular times
Disseminate findings and evaluate the extent to which practitioners' behaviour changes in a particular direction	Disseminate findings and evaluate the extent to which existing programmes are adjusted to take account of elements of programme theory revealed by the review

3.3 STUDY DESIGN, DATA COLLECTION, AND ANALYSIS

In the following section, the design and methods for data collection and analysis for Studies I-IV are presented. An overview is in Table 6.

Table 6. Overview of the four studies

Study	Research strategy	Unit of analysis	Quantitative data	Time period covered for quantitative data	Qualitative data	Data analysis
I	Realist review	Descriptions of lean applications in health care	None		Data collected with an abstraction form (Appendix I)	Thematic analysis, articulation of C-I-M-O interactions
II	Single case study	Lean-inspired intervention in one emergency service	Waiting time from triage to first physician assessment[1] Percentage of patients leaving the ED within four hours[1] (throughput)	December 2007-November 2010 (process prototype implemented December 2008)	13 interviews: 4 physicians, 3 nurses, 1 facilitator, 2 administrative staff, 3 managers ~40 hours shadowing staff. Attendance at three improvement meetings ~60 documents	ANOVA and statistical process control charts Case description, triangulation, and explanation building
III	Single case study	Clinical pathway intervention for the treatment of hip-fracture patients	Lead time from arrival to the ED to surgery (hip-fracture patients and other acute surgical orthopaedic inpatients)[2] Percentage of patients operated within 24 hours (hip-fracture patients)[2]	January 2007-December 2011(first changes implemented in September 2009)	19 interviews: 9 physicians, 8 nurses, 2 managers. ~60 hours shadowing staff and patients. Attendance at process improvement meetings during 16 months ~30 documents	Statistical process control charts, independent 2-sample t-test, correlation analysis Case description, triangulation, and explanation building
IV	Multiple case study design and realistic evaluation	Lean-inspired intervention in seven emergency services	Waiting time from triage to first physician assessment[3] Percentage of patients leaving the ED within four hours[3] (throughput)	January 2008-September (process prototypes implemented between April-December 2008)	4 group interviews with members of improvement teams (in total, 9 physicians, 4 nurses, 1 manager)	Statistical process control charts. Case description and articulation of C-I-M-O interactions

[1] Weekly averages data, calculated 8AM - 4PM, Monday-Friday, and collected through hospital administrative systems
[2] Patient data collected through patient administrative systems
[3] Monthly averages data, calculated 8AM - 4PM, Monday-Friday and collected through hospital administrative systems

3.3.1 Study I

Study I is a realist review (Pawson et al., 2005) of the literature which presents empirical data on lean applications in health care. A systematic search of PubMed, Web of Science, and Business Source Premier was performed covering the period January 1998 to February 2008. The database search involved combinations of the following terms: *lean health care, Toyota way, lean thinking, lean manufacturing, Toyota production system, lean service, lean process, lean enterprise, Toyota DNA, lean production, lean health care, lean method,* and *lean principle*. After a first review of the literature, inclusion and exclusion criteria were determined. Articles that reported empirical applications of lean health care in clinical processes were selected for analysis. Articles that did not address lean or health care, that did not include empirical data on applications of lean, that did not concern clinical processes, or that reported hybrid approaches (such as "Lean Six Sigma") were excluded. Reference lists of the retrieved articles were also searched to identify other relevant articles.

Data from the selected articles were extracted with the help of a data abstraction form (Appendix I). The form covered questions on the study design, objectives, setting, the definition of lean used, implementation process, scope of the lean intervention, and reported benefits, barriers, and facilitating factors. The co-authors shared the responsibility for reading and analysing the full text articles. The first author then reviewed all the data abstracted. When something appeared unclear, this author reread the articles. Data were initially collected in an Excel spread sheet and then organized around three main themes (Berg, 2007): context, components of the lean intervention, and outcomes. Data collected for each theme were then inductively coded and organized in tables (Patton and Patton, 2002). A database based on the tables was also created (Microsoft Access; Microsoft, Seattle, Washington) and then used to query the data in search of possible C-I-M-O configurations that could explain how the interaction between the components of the lean interventions and the specific contextual settings yielded the reported results. By analysing these configurations, key mechanisms were articulated to develop a cohesive theory of how lean works in health care.

3.3.2 Study II and Study III

Study II and Study III are single case studies. A single case study design is appropriate to test a theory with a critical case, document an extreme or a unique situation, learn from a representative or typical case, analyse a case that has previously not been accessible to researchers, or study a case at different points in time (Yin, 2003). In designing case studies, the first step is to choose appropriate cases (Yin, 2003). Most importantly, full access was granted to the researchers by the hospitals, a key requirement in organizational research (Gummesson, 2000). The cases were selected because the targeted care processes address many of the common challenges faced by health care today (lack of standardization, fragmentation, and poor coordination between process steps). These challenges were dealt with using approaches consistent with lean or which support the use of a clinical pathway. Thus, the cases were considered typical cases (Yin, 2003) of how lean and clinical pathways are used to improve care processes.

Study II and Study III utilize an explanatory approach (Yin, 2003). To explain how lean (Study II) and clinical pathway (Study III) applications impact process performance,

multiple sources of evidence (triangulation of data) and multiple methods (triangulation of methods) were used (Yin, 2003). Preliminary theoretical frameworks and data collection and analysis were outlined in case study protocols developed in advance (Yin, 2003). The specific qualitative and quantitative phases of the studies are described below.

3.3.2.1 Quantitative data collection and analysis

Statistical analysis was conducted to identify possible changes in process performance captured by the process indicators that were used to guide and assess improvement efforts (Table 6). All process indicators addressed the timeliness of health care delivery.

In Study II, analysis of variance (ANOVA) was used to compare process performance measures and patient volumes between three groups: 52 weeks prior to implementation changes, 52 weeks directly after implementation, and 52 weeks follow-up. Statistical significance was set at 0.05. Assumptions for normality were checked using normal probability plots (Campbell et al., 2007).

In Study III, an independent 2-sample t-test was performed to compare the percentage of hip-fracture patients operated on within 24 hours one year before and after improvement efforts began. Data were log-transformed to meet the assumptions for normality. Significance was set at 0.05. Correlation analysis of the lead time to surgery for hip-fracture patients versus other acute orthopaedic inpatients was also performed (Campbell et al., 2007).

To overcome the limitations of before-and-after study designs, statistical process control (SPC) charts were used to analyse patterns of performance over time (Amin, 2001, Duclos and Voirin, 2010, Benneyan et al., 2003). Control charts help distinguish between common-cause and special-cause variation. Common-cause variation refers to the natural, inherent and historically stable variation of any system. Whenever such behaviour is present, the system's variation, sometimes considered to be noise, is stable and predictable. Variations of special-cause are characterized as deviations from the natural behaviour of the system such as might be seen following an intervention. New unanticipated, emergent patterns that are not explainable by historical data make the system unpredictable. The distinction between common-cause and special-cause variations makes it possible to detect significant improvements or deterioration of process performance (Montgomery, 2005, Shewhart and Deming, 1986).

Two types of control charts were used in Study II and Study III to assess the process improvement initiatives over time and to detect significant changes. P-chart analysis, where "P" stands for "proportion", was used in Study II and Study III for the binary outcome variables "proportion of patients leaving the ED within 4 hours" and "the proportion of patients operated within 24 hours", respectively. An unequal sample size method was used since the number of patients varied between weeks (Study II) and months (Study III) (Duclos and Voirin, 2010, Benneyan et al., 2003). I-charts, where "I" stands for "individuals", was used in Study II for the outcome variable "waiting time to first physician assessment" (Benneyan et al., 2003). In both Study II and Study III, control limits were set at three standard deviations, or 3σ, from the central line

(Shewhart and Deming, 1986, Montgomery, 2005). In Study II, the central line was calculated based on performance data prior to the lean changes, whereas in Study III, central lines were calculated for the period before and after improvement efforts. This latter approach is used when there are sufficient data points for the new process (Amin, 2001). Two decisions rules were used to detect special-cause variations: any single data point outside the 3σ limits and nine consecutive data points on the same side of the central line (Montgomery, 2005, Duclos and Voirin, 2010). Statistical analyses were performed using MINITAB 16 and IBM SPSS Statistics 19 software.

3.3.2.2 Qualitative data collection and analysis

In both Study II and Study III, qualitative data were collected though interviews, documents, and non-participant observations (see Table 6). Interviews were conducted with key persons on the improvement team, such as coaches and process leaders, who in turn suggested other persons of interest to interview who had insights into daily operations. The interviews were semi-structured (Kvale and Brinkmann, 2009) with a set of questions concerning: patient group and process characteristics; routines for the management of the care process; obstacles to efficient process management; the changes that were planned and implemented; implementation process and knowledge-base for the changes introduced; intended and actual effects of the changes implemented; and contextual factors that may have influenced the implementation process (See Appendix II for an example of the interview guide. Interview questions were modified relative to the position of the interviewee). Each interview lasted about one hour and was digitally recorded.

Non-participant observations (Patton and Patton, 2002) were made by shadowing staff members and patients (see Table 6). Observations focused on understanding how the care process was carried out in practice and how it worked. Observations also included attendance at improvement meetings in order to gain a deeper understanding of how improvement efforts were designed and conducted. Several documents (Yin, 2003) were also collected, including meeting notes and Power Point presentations from improvement meetings, as well as checklists, job descriptions, and care protocols.

Documents were organized in chronological order in an Excel file and analysed in order to reconstruct the implementation process. All interviews were transcribed verbatim. Data collected through interviews, documents, and observations were organized in NVivo 8 software (QSR International Pty Ltd, 2008), and then coded to characterize the care process prior to the improvement efforts and the related challenges, the implementation process, the intervention's components, the actual changes implemented, and their perceived effects. This qualitative data analysis was used to develop case descriptions, which were then iteratively validated by key informants (Yin, 2003).

3.3.2.3 Triangulation and explanation building

Triangulation of data and methods (Yin, 2003) was used as a strategy to develop explanations of how the observed changes in performance were linked to the intervention's components. Qualitative data was triangulated to capture objective data (Voss et al., 2002) on the changes made and on how they influenced operations. A particular focus was on differentiating the changes that had been successfully implemented from

changes that were never implemented, were poorly implemented, or appeared not to influence operations. Qualitative and quantitative results were also triangulated. SPC analysis was used to detect special-cause variations, and qualitative data was used to investigate whether the performance changes occurred in conjunction with when the changes were implemented.

Empirical patterns were compared to relevant theoretical frameworks, which in turn helped to develop plausible and more generalizable explanations of how the intervention's components influenced performance (Yin, 2003). The theoretical framework used in Study II was based on Spear and Bowen's four rules (Spear and Bowen, 1999). In Study III, the theoretical framework focused on coordination of operations (Vissers and Beech, 2005, Malone and Crowston, 1994).

3.3.3 Study IV

Study IV, which builds on the results from Study I and Study II, uses a multiple case study approach (Yin, 2003) to explain how different services at the Karolinska University Hospital were adopted and adapted using the same hospital-wide lean-inspired intervention and how this is reflected in access to care. The advantage of a multiple case study is that it generates a stronger base from which one can develop generalizable knowledge (Yin, 2003, Eisenhardt and Graebner, 2007). Yin (2003) argues that cases for study should be chosen following a "replication logic". Thus, cases should be chosen because they are expected to produce similar results (literal replication) or contrasting results for predictable reasons (theoretical replication) (Yin, 2003).

Seven of 16 possible emergency department services were selected, based on recommendations from the implementers of the lean program and on the research team's preliminary observations. The selection of cases was intended to provide an empirical basis for both literal and theoretical replication (Yin, 2003). The following services were selected: two Paediatrics (Peds-1 and Peds-2), one Internal Medicine (Med), one Surgical (Surg), two Ear-Nose-and Throat (ENT-1 and ENT-2), and one Gynaecology (Gyn).

Data collection and analysis was guided by the realistic evaluation approach taking the following steps (Pawson and Tilley, 1997).

Process performance data (waiting time for first physician assessment and percentage of patients leaving the ED within four hours) were collected as monthly averages (weekdays 08:00-16:00) for the period 2007-2011. Process performance data for each service were analysed using p-charts and i-charts, following the same procedure as in Study II. Control chart analysis was combined with descriptive statistics to compare performance levels before and after implementation of the lean changes at each site, and to compare process performance across the services for the year 2011.

Preliminary programme theories and candidate mechanisms (Appendix IV) were developed based on the results from Study I and Study II. These sought to explain how the lean-inspired hospital programme impacted process performance (process capabil-

ity) and learning capability. The two overarching programme theories are presented below:

Preliminary programme theory 1 (Process capability): Lean is a strategy for how to plan, design, and manage operations in emergency services to achieve continuous patient flow and thereby improve operational performance (e.g. reduce lead and waiting times).

Preliminary programme theory 2 (Learning capability): Lean in emergency services makes processes more explicit and standardized. Staff members become more aware of how things are done and should be done. Deviations from standardized procedures become easier to detect. Stable and systematic approaches to problem solving, including management involvement, can then help staff learn and continually improve.

Health care professionals who were or had been part of the local improvement teams were invited to four realistic evaluation group interviews (three hours each). On two occasions, representatives from several services (one to three from each service) could participate in the same interview session. For the other two sessions, only representatives from one service could participate. The interview sessions were organized in two steps. First, representatives from the services were interviewed following a focused interviewed guide (Yin, 2003) (Appendix III) to collect data on how the hospital's lean programme had been put into practice at each site. Second, each interviewee was asked to individually rate the relevance of each candidate mechanism in their particular service on a scale of 1-4 (considerable, moderate, slight, not at all) (Pawson and Tilley, 1997) (Appendix IV). The team of researchers collected the ratings and then analysed them to identify similarities and discrepancies within and across the services. The researchers then facilitated an open-group discussion based on the data to identify contextual and implementation aspects that could explain the observed patterns.

The transcripts from the group interviews were analysed to develop case descriptions (Yin, 2003) which characterized the context and content of the lean interventions for each case. Case descriptions were reviewed and revised when needed by key informants (professionals who participated in the interviews) for validation (Yin, 2003). The candidate mechanisms were then revised for each case to explain the interactions between the context, the lean intervention, and the outcomes (C-I-M-O configurations). The C-I-M-O configurations developed for each case were then compared across cases to look for evidence of literal replication or theoretical replication. Interviewees were then invited to discuss the revised mechanisms (Pawson and Tilley, 1997, Yin, 2003). The output was then used to refine the programme theories of how lean works in emergency services.

3.4 ETHICAL CONSIDERATIONS

Study I is based entirely on the study and analysis of published scientific articles. The study involves neither information nor actions of a nature that ethical vetting is required according to the Swedish law on ethical vetting of research that involves humans. For all other studies included in this thesis, ethical approval was sought in accordance with

the Swedish law. The Ethical Regional Ethical Review Board at Karolinska Institutet approved the ethical application (Protocol numbers: 2008/623-31 and 2009/1657-31).

Interview participants gave their verbal informed consent. They were told their participation was voluntary and they had the right to withdraw at any time. Interviews were digitally recorded with participants' consent. Data collected were presented in the studies in such a way as to ensure full anonymity.

For observations, the researcher's presence was made known to the members of the organization. When shadowing staff members, the researcher focused on understanding how the work process was organized and managed. The researcher limited her participation to the minimum of what was necessary to allow data collection on the care process. The researcher consulted with staff members on whether her participation might interfere with their work. In Study III, patients were asked for informed, written consent before observations were made.

Quantitative data collected through hospital and patient administrative systems were collected and analysed without use of name or personal number.

4 MAIN FINDINGS

The findings are grouped according to the improvement approach studied, first Study I, Study II and IV (lean) and then Study III (clinical pathway).

4.1 STUDY I

The aim of Study I was to identify what about lean thinking works, how, and why, through a realist review of empirical studies of lean applications in health care. Thirty-three articles which reported lean applications in a wide range of organizational settings, clinical specialties, and health care fields were reviewed. In accordance with the realist review approach, the content of the articles was coded and analysed to characterise the components of the lean interventions reported (I), their outcomes (O), and the mechanisms (M) that triggered the observed outcomes in the particular health care context (C). The identified intervention components and outcomes are described individually below. Subsequently, C-I-M-O configurations are described as an interpretation of how and why reported interventions work.

4.1.1 Components of lean interventions

The lean interventions involved the use of several tools and methods. The different methods were grouped into four general categories of lean components, which are described below.

(1) Methods to understand processes in order to identify and analyse problems
Improvement efforts most often began with process mapping and value stream mapping to create a shared understanding of the targeted process and the related problems. The difference between the two is that the focus of value streaming is on what adds value or represents waste from the patient's point of view. In some cases, these activities led to the specification of an "ideal process".

(2) Methods to organize more effective and/or efficient processes
Process mapping was often followed by the development of changes aimed at achieving more effective and/or efficient processes. Several methods were used, often in combination. The most common methods were process orientation, specification of standard procedures and physical work setting redesign. One-piece continuous flow was found most frequently in laboratories where the specimens were analysed one at a time. When applied to patient flow, staff members were encouraged to complete as much as possible for one patient before attending to the next. A kanban replenishment system was used in diagnostic units to reduce inventory, and in nursing and endoscopy units to achieve just-in-time replenishment of supplies. Process streaming involved splitting up a patient flow into different streams based on similarity of care processes. Two articles presented changes in how staff members worked in the care process (e.g. changes in team composition and multidisciplinary task training).

(3) Methods to improve error detection, relay information to problem solvers, and prevent errors from causing harm

The articles reported various ways to facilitate error detection and to relay information to problem solvers. Visual management was achieved using specific lean tools such as 5S and kanban as well as various other tools. Adherence to standard procedures was addressed by, for example, the introduction of directives and checklists. Procedures for error reporting were also developed. For example, the Virginia Mason Medical Center (VMMC) developed a Patient Safety Alert (PSA) system that requires any staff member who encounters a potentially harmful process or employee to make an immediate report to the patient safety department .

(4) Methods to manage change and solve problems with a scientific approach

The majority of the articles reported the use of multidisciplinary teams involved in problem-solving activities, ranging from *ad hoc* teams created to solve a specific problem to more stable and systematic structures. Only few cases, however, described how managers were involved in rapid, real-time investigations to solve problems that required authority and information beyond that of the front-line staff.

4.1.2 Outcomes

All articles reported that lean interventions yielded favourable experiences and outcomes. The most common areas of improvement included improved service delivery time, reduction of costs or productivity enhancement, and reduction of errors or mistakes. Time and money savings were often reported together. Other reported areas of improvement included patient and staff satisfaction, although for these benefits mainly anecdotal evidence was presented without systematic measurement. In two cases, decreased mortality rates were attributed to lean interventions (Table 7). Notably, only ten articles described the use of explicitly stated and transparent research methods.

Table 7. Reported benefits of lean applications in health care

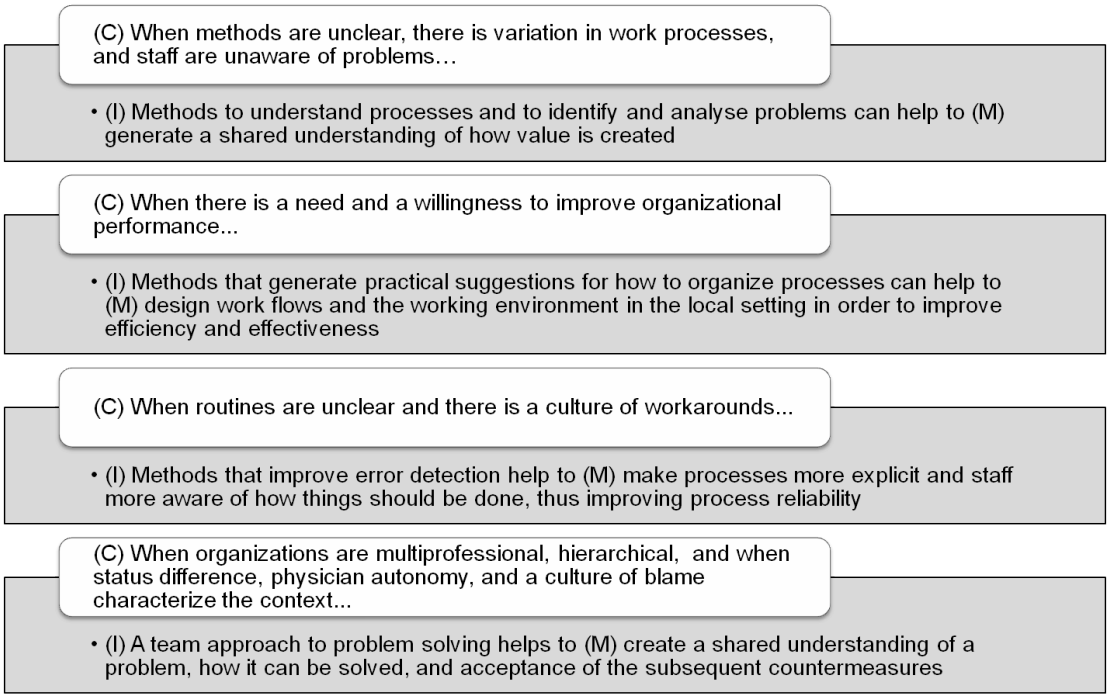
Reported Benefits	No. of Articles (n=33)
Time aspect improvement (e.g. waiting times, lead times, and reduced delays)	24
Cost containment or productivity gains	18
Error and defect reduction and improved process accuracy	13
Staff satisfaction	8
Patient satisfaction	5
Decreased mortality rates	2

4.1.3 C-I-M-O configurations

The reported results were interpreted in terms of the interaction between the components of the interventions and the application contexts. Despite the variety of settings in which lean was used, several common contextual characteristics (C) were identified, including “a need/willingness to improve organizational performance, unclear procedures and staff unaware of problems, workarounds, multiprofessional and hierarchical organizations, status differences, physician autonomy, inconsistent team communication, and a culture of blame” (Study I). Different mechanisms (M) by which lean interventions triggered improvements were identified. Figure 1 summarizes the general

Context-Intervention-Mechanisms configurations that appeared to be linked to improvements.

Figure 1. Context-Intervention-Mechanism configurations that led to improvement



4.2 STUDY II AND STUDY IV

The findings from Study II and Study IV, which investigated the lean-inspired intervention at the Karolinska University Hospital, are presented together here. Study II investigated a paediatric emergency service at the hospital; this same case was also included in the seven emergency services examined in Study IV.

4.2.1 Implementing the lean prototype

For each service, a process team was created, led by a physician in the role of process leader. Each team worked with a coach from the hospital's Strategic Services Development Unit to map the current care processes and to develop an "ideal state" process map. Informed by the lean-inspired principles presented in Table 3, changes to achieve the ideal state were captured in a process prototype. The prototypes focused on five key intervention areas, which are described below, together with the changes suggested by the coaches in each area.

Way of working. Implement teamwork and changes to the physical layout to facilitate work done in parallel and to improve care providers' coordination. Institute nurse and physician flow managers to improve patient flow coordination by assigning patients to care teams.

Competence. Involve the highest competence at the earliest opportunity in the process. A highly competent flow physician such as a senior specialist can better support and supervise a heterogeneous group of junior and rotating physicians in

the initial phases of the diagnostic and treatment processes (e.g., by taking part in the initial physician assessment).

Free staff. Avoid multiple and parallel tasks. Move competing tasks such as telephone consultations or educational activities that cause workflow interruptions out of the ED.

Staffing. Match staffing to typical demand levels.

Continual improvement. Use visual management systems including a "takt board" and a whiteboard to identify and document daily process problems and thereby support continual improvement. The takt board is a computer-based tool to monitor the number of patients assessed by physicians per hour. This is compared to the expected pace calculated based on the average hourly patient inflow rate for that hour plus one standard deviation. In the event of deviations from the expected work pace, a link appears on the screen to enable flow managers to register possible explanations. Stable organizational structures to support continual improvement were developed, including bimonthly process improvement meetings facilitated by the coaches. In these meetings, the coaches fed back performance data. Once a month, meetings were organized between process leaders and the hospital management team (the hospital CEO, directors of the different divisions, the Strategic Services Development Unit, pertinent department chiefs, and first-line managers). The process leader began by presenting performance data and suggesting possible steps for improvement. The management group then decided which plans to implement.

The process prototypes developed by each service were implemented during the period April-December 2008, and then revised in a stepwise manner. Table 8 summarizes the changes that were in place by the end of 2011 when data were collected.

Table 8. Changes implemented by each service (end of 2011)

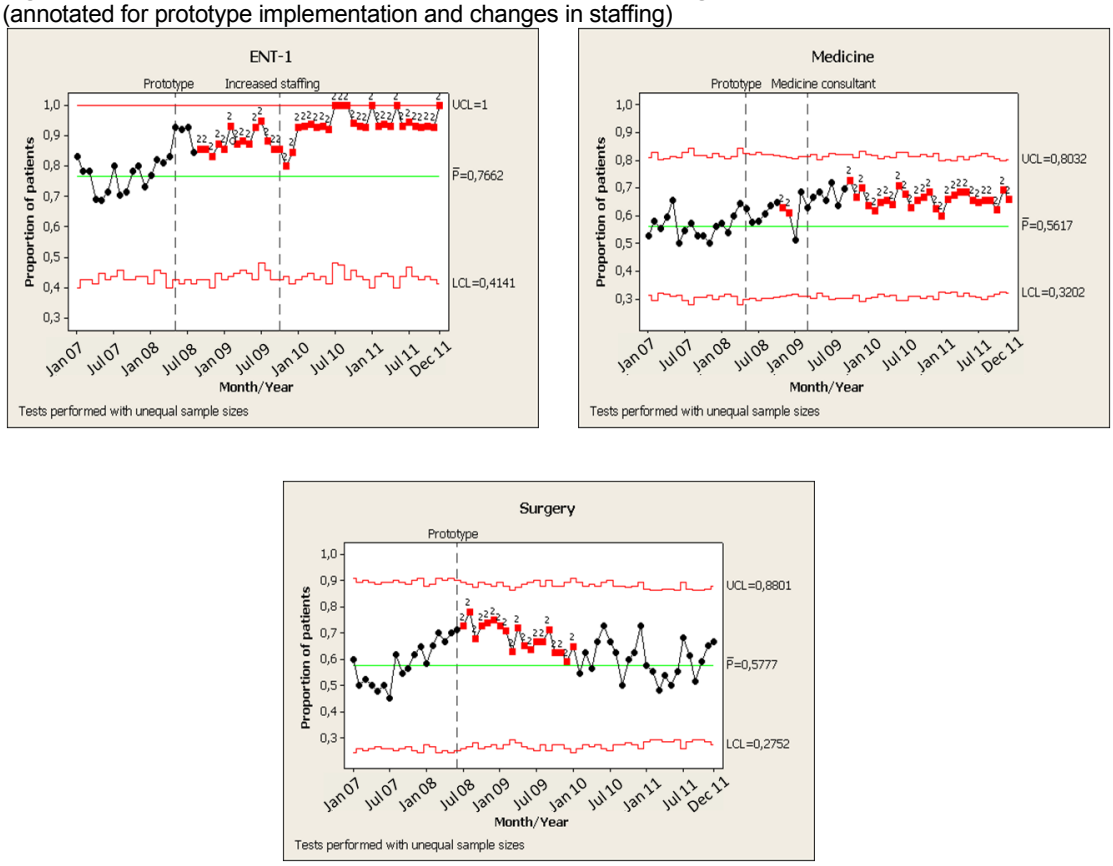
Lean intervention areas	Specific changes	ENT-1	ENT-2	Gyn	Peds-1	Peds-2	Med	Surg
Way of working	Introduce RN/LPN-MD pairs	x	x		x	x	x	x
	Introduce flow nurse role	x			x	x	x	x
	Introduce flow physician role				x	x	x	x
	Move equipment into the patient room			x		x[1]		x
	Eliminate and standardize diagnostic process steps			x			x	
	Develop process changes involving units outside the ED			x			x	x
Competence	Increase competence level of physicians involved in direct patient care		x	x				
	Increase physician competence as flow physician				x	x	x	x[2]
	Replace LPNs with RNs		x			x	x	x
Free staff	Move tasks outside the ED	x						
	Limit non-direct patient care activities to one physician		x	x				
	Schedule one extra consultant specialist during the day-time				x		x	
Staffing	Schedule changes	x	x	x	x	x	x	x
	Increase physician staffing involved in direct patient care	x	x	x		x		
	Increase nurse staffing		x	x	x			
Continual improvement	Tools and practices for continual improvement	x	x	x	x	x	x	x

[1] The computer in the room is used only by two physicians.
[2] An initial lack of senior surgeons at the ER in the flow physician role was temporarily overcome.

4.2.2 Process performance

The SPC analysis performed in Study IV showed that a systematic improvement in performance (percentage of patients discharged within four hours, and waiting time to first physician assessment) occurred in all services, either simultaneously with, or shortly after, the implementation of the lean process prototypes. All services with the exception of Surgery and Peds-2 managed to sustain improvement. Over time, three patterns emerged: large and sustained improvement where targets were met, (ENT-1, ENT-2, and Gynaecology), moderate to large sustained improvement but where targets were not met (Medicine and Peds-1), and an initial improvement which was not sustained (Peds-2 and Surgery). An illustrative sample of the p-charts for the "proportion of patients discharged from the ED within 4 hours" is presented in Figure 2.

Figure 2. Sample of p-charts for proportion of patients discharged from the ED within four hours
(annotated for prototype implementation and changes in staffing)



Tables 9 and 10 present an overview of the process performance before and after the implementation of the prototype as well as the performance levels during 2011. Comparing 2011 performance, only three services (both ENTs and Gynaecology) achieved the throughput target of 90%, and only one service achieved the waiting-time target of 40 minutes (ENT-1).

Table 9. Percentage of patients discharged within four hours

Service	Before prototype implementation (%)	After prototype implementation (%)	Absolute change in percentage points	Relative change (%)	Performance level year 2011 (%)
ENT-1	77	93	16	19	96
ENT-2	73	90	17	23	92
Gynaecology	69	90	21	29	90
Peds-1	66	79	13	19	76
Peds-2	82	85	3	3	79
Medicine	56	65	9	17	66
Surgery	57	64	7	12	58

Table 10. Waiting time to first physician assessment

Service	Before prototype implementation (minutes)	After prototype implementation (minutes)	Absolute change (minutes)	Relative change (%)	Performance level year 2011 (minutes)
ENT-1	112	49	63	56	33
ENT-2	118	58	60	51	49
Gynaecology	141	69	72	51	66
Peds-1	75	56	19	26	60
Peds-2	72	54	18	25	60
Medicine	89	49	40	50	55
Surgery	99	66	33	33	79

4.2.3 Analysis of a paediatric service

In Study II, data collected through interviews and observations were used to examine clinical operations and improvement at Peds-1, before and the year after the implementation of the process prototype. The analysis was informed by Spear and Bowen's (1999) four lean mechanisms (Table 11). The lean intervention contributed to improvements in the process performance as it: increased work standardization, helped to connect care providers who were dependent on one another in their work, enhanced uninterrupted flow, and it empowered staff to investigate problems and develop countermeasures for improvement.

Table 11. Analysis of clinical operations and improvement at a paediatric ED based on four lean principles

Before prototype implementation	Intervention component	Lean mechanism	After prototype implementation
Care providers' roles and responsibilities defined based on spheres of expertise could cause ambiguity about who should do what, when, and how	Specific new job roles (flow manager, team nurse and nurse's aide, and care team physician) with job descriptions. Improvement principles (see Table 3)	Standardize work	A more consistent, standard, and unambiguous way to work
No explicit expectation concerning who should provide a service, to whom, and when. Asynchronous communication	Team-based organization and changes to work station location	Connect people that are dependent on one another	More clear and synchronized connections between care providers in the process
Care providers shared responsibility for all patients at the ED. Could result in the involvement of several care providers in the same patient's care process. No explicit expectation on the timing of care providers' actions	Centralized management of the patient flow by flow managers Team-based organization and changes to work station location Additional specialist scheduled and schedule changes	Create seamless, uninterrupted flow through the process	More adherence to work patterns and timely supervision of junior physicians that enhanced the ability to get the diagnostic and treatment process right from the start Fewer people involved in the same care episode and more direct care process Fewer interruptions in the workflow
Lack of stable tools and practices for continual improvement	Stable structures for continual improvement (team approach to problem solving and coach supervision, and takt board) also involving management (monthly meetings)	Empower staff to investigate problems with the process and to develop, test, and implement countermeasures using a "scientific method"	Team approach to problem solving. Takt board empowered people to make suggestions for improvement that fit the local setting. Monthly management meetings opened up communication between hierarchical levels

Despite the positive results achieved by the paediatric service, some contextual factors prevented additional improvement. These factors were professional autonomy; discomfort with inter-professional collaboration; a mismatch between job tasks, licensing con-

straints, and competences; and the large number of employees not directly involved in improvement work partly due to the large number of rotating staff members.

4.2.4 Cross-case comparison of seven emergency services

The cross-case comparison conducted in Study IV was based on interviews conducted between November 2011 and March 2012.

The comparison showed how operational performance changes (programme theory 1) were related to how the different services adopted and adapted the lean intervention to their local context, particularly the complexity of the care process and the educational commitment of the service. The degree of complexity of the care process was determined by the number of iterations, interactions, and decisions needed to diagnose and solve a problem, as illustrated by the key characteristics presented in Table 12.

Table 12. Characteristics of the care processes

Characteristic	**ENT-1**	**ENT-2**	**Gynaecology**	**Peds-1**	**Peds-2**	**Surgery**	**Medicine**
Percentage of patients referred to radiology services	6.3%	6.2%	2.5%	12.3%	6.5%	30.1%	27.3%
Percentage of patients referred to lab services	14.3%	21.0%	25.4%	21.8%	50.6%	69.4%	82.2%
Average number of patients 08:00 - 16:00	14.4	18.9	16.1	27.0	19.9	25.9	36.6
Percentage of patients admitted per day	4.3%	6.9%	9.9%	15.5%	14.0%	24.5%	39.0%
Average number of admissions per day	0.62	1.30	1.59	4.19	2.79	6.35	14.27
Referral requirement to the ED	Yes	Yes	No	No	No	No	No
Work organization	Physician remains in the examination room	Physician remains in the examination room	Physician remains in the examination room	Physician & patients move between rooms and units	Physician & patients move between rooms and units	Physician & patients move between rooms and units	Physician & patients move between rooms and units
Complexity of care process	Less complex <——————————————————————> More complex						

The most important C-I-M-O configurations identified are presented here. The two ENTs and the Gynaecology service were characterized by lower degrees of complexity in the care process and by a smaller number of staff members working on each shift within a limited physical layout. For the two ENTs, the way of working remained almost unchanged. Thus, the large and sustained improvement in performance, and the achievement of the set goals, appeared mainly due to a better match between capacity and demand. This was achieved by the increased staffing and schedule changes (both ENTs), and by the increased competence of physicians involved in direct patient care (ENT-2). At the same time, both services excluded rotating physicians and students from direct patient care at the ED. At ENT-1, the limited opening hours enabled the development of demand management practices. Table 13 summarizes key C-I-M-O configurations identified at the two ENTs.

Table 13. C-I-M-O configurations for the two ENTs services

Context	Intervention	Mechanism	Outcome
Lower degree of complexity in the care process Limited opening hours (ENT-1)	Increased staffing and schedule changes (both ENTs)	Match capacity with patient demand	Improved and sustained process performance (both ENTs) and achieved one target (ENT-2) or both (ENT-1) targets
	Increased competence of physicians involved in direct patient care (ENT-2). Excluded rotating physicians and students from direct patient care (both ENTs)	Match capacity with patient demand	
	Developed demand management practices (ENT-1)	Match capacity with patient demand	

Gynaecology also improved the match between capacity and demand by making similar changes. In addition, other changes were introduced that improved work process interaction between MDs and midwives, reduced non-value adding steps from a patient perspective, and improved the ability to coordinate care across organizational boundaries. Table 14 summarizes key C-I-M-O configurations identified at the Gynaecology service.

Table 14. C-I-M-O configurations for the Gynaecology service

Context	Intervention	Mechanism	Outcome
Lower degree of complexity in the care process	Increased staffing and schedule changes	Match capacity with patient demand	Improved and sustained process performance and achievement of one target.
	Increased competence of physicians involved in direct patient care Trained rotating residents and students as a parallel work process	Match capacity with patient and educational demand	
	Developed demand management practices	Match capacity with patient demand	
	Clarified MD midwives' responsibilities	Improve work process interaction	
	Eliminated and standardized diagnostic process steps	Reduce non-value adding steps from a patient perspective	
	Developed process changes also involving units outside the ED	Improve the ability to coordinate care across organizational boundaries	

Medicine, the two Paediatrics, and Surgery were characterized by more complex care processes. While all services appeared to improve, at least initially, interview data indicated more could be done to improve the processes.

All these services were able to match capacity, through staff increases and/or schedule changes. The two Paediatrics and Surgery, however, felt that more could be done to adapt capacity to daily, weekly, and seasonal demand patterns. All four services increase specialist competence at the ED with the introduction of flow managers. However, unlike ENT-2 and Gynaecology, the competence level of the physicians involved in direct patient care remained unchanged. The heterogeneous group of physicians involved in direct patient care, the high number of care teams per flow physician, and sometimes the absence of flow physicians from the floor limited the ability to improve interaction between more experienced flow physicians and less experienced physicians in the care teams. In contrast, work process interaction was improved between MDs and RN/LPNs after the introduction of a care team approach. Despite the large need for services from other units, only Medicine and Surgery introduced changes that strengthened coordination of care across organizational boundaries. Only Medicine eliminated and standardized steps in the care process, which enabled the reduction of non-value adding steps from a patient perspective. Table 15 summarizes key C-I-M-O configurations identified for these four services.

Table 15. C-I-M-O configurations for the two Paediatrics, Medicine, and Surgery services

Context	Intervention	Mechanism	Outcome
Higher degree of complexity of the care process	Increased staffing and/or schedule changes	Match capacity with patient demand, although only partially for Surgery and the two Paediatrics	Temporarily improved process performance (Surgery, Peds-2) Improved and sustained process performance (Peds-1 and Medicine)
	Increased specialist competence with the introduction of the flow physician role	Partially match capacity with patient and educational demand	
	Introduced RN/LPN-MD pairs	Improve work process interaction	
	Eliminated and standardized diagnostic process steps (Medicine)	Reduce non-value adding steps from a patient perspective	
	Developed process changes also involving units outside the ED (Medicine and Surgery)	Improve the ability to coordinate care across organizational boundaries	

Staff members in all services felt that the lean tools and practices contributed to the identification of non-value adding time, helped them identify and visualize problems in their everyday work, and developed concrete suggestions for improvement. However, the ability to develop a learning capability (Programme theory 2) was restricted by several factors:

- Visual management tools were viewed as deficient either because of their design or because their usage led (inadvertently) to public shaming
- Ideas for improvement were not systematically tested

- There was poor alignment between the problems identified and the solutions implemented
- Feedback systems did not return information to the right people due to the frequent staff rotation
- The structure and organization of the meetings between the process improvement teams and the management team caused process leaders to experience conflicting loyalties while managers felt forced to make spur-of-the moment decisions.

Despite these common challenges, learning may have been facilitated at the two ENTs and at Gynaecology by the way educational activities were integrated into operations (i.e. a larger proportion of stable staff were involved in direct patient care), and by the small unit size which allowed the few staff members working on each shift to interact on a daily basis.

4.3 STUDY III

Study III examined process improvement efforts at the Danderyd Hospital for the purpose of explaining connections between a clinical pathway intervention and process performance, measured as the lead time between arrival at the ED for the start of surgery and the percentage of patients operated on within 24 hours.

In June 2009, a multidisciplinary improvement team composed of health care professionals and managers from the different units involved in the care of hip-fracture patients was created. In August 2009, a consultant orthopaedist, who was employed as the head of the trauma section in the Orthopaedic Department, also became the process leader for the improvement team.

Although the focus of the improvement efforts was mainly on improving the hip-fracture care process, changes were also made to the entire surgical acute orthopaedic patient group. For the hip-fracture care process, the main changes involved the development of a fast track to transfer patients arriving via ambulance directly to the radiology unit (thereby bypassing the ED) the development of specific goals, written standard procedures, and checklists. For the surgical acute orthopaedic flow, the main changes involved the designation of four extra beds on the ward, the creation of a centralized role (usually assigned to the newly appointed head of the trauma unit), clarified routines for surgery planning, and the removal of the acute orthopaedic day-surgery from the Central Surgical Unit to the outpatient unit.

The SPC analysis indicated that systematic improvements in performance (percentage of patients operated on within 24 hours) occurred right after the establishment of the process improvement team. This also coincided with the appointment of the new head of the trauma section and her new role coordinating acute surgery. On average, the percentage of patients operated on within 24 hours increased from 60% to 80% after the intervention. The mean lead-time to surgery for hip-fracture patients decreased from 24.8 hours before the changes to 20.0 hours after the changes (T-value = 7.68 p-value < 0.05). A correlation analysis revealed that the reduced lead-time for hip-fracture pa-

tients coincided with shorter lead times for other acute orthopaedic inpatients (Pearson's r=0.286, p-value < 0.05).

Prior to the clinical pathway intervention, unnecessary delays in the hip-fracture care process were found to be due to poor coordination between the different steps in the care process and to poor coordination in the use of resources shared with other patient groups. Resource coordination was improved by more actively coordinating surgery planning (i.e. operational coordination). The ability to assign higher priority to the hip-fracture patient group was also influenced by structural arrangements involving other patient groups (i.e. structural coordination), such as protecting capacity on the ward and moving acute day-surgeries to the outpatient clinic. These arrangements appeared to be mutually beneficial for both hip-fracture patients and other acute orthopaedic inpatients.

4.4 SUMMARY OF MAIN FINDINGS

Study I found that lean has been applied in a large variety of health care settings and specialties. Lean applications yielded positive results, in particular in time savings, cost containment or productivity gains, and error and defect reductions. Staff members were able to understand and reorganize processes, improve error detection, and collaborate in solving problems. The overwhelmingly positive results and the lack of clear research designs revealed the importance of digging deeper into how lean works in health care.

Study II and Study IV found that the lean intervention yielded initial improvements in waiting time and throughput for all services. In Study II, the lean inspired changes resulted in a better-managed care process. Some challenges were identified including the following: a mismatch between job tasks, licensing constraints, and competence; a perception of being monitored; and discomfort with inter-professional collaboration. Study IV reported on the different performance patterns observed in the seven ED services regarding the degree of improvement, performance levels, and sustainability of results. The sources of these differences can be related to how the services adapted the lean prototypes to their specific context, particularly considering the degree of complexity of the care process and their educational commitments. The interaction between these contextual aspects and the interventions triggered different improvement mechanisms in the services. One mechanism that appeared important for all services was to match capacity (staffing, scheduling, and competence) with demand.

The lean intervention helped staff members to identify non-value adding time, to develop concrete suggestions for improvement, to identify and visualize problems in everyday work, and partly to overcome organizational and hierarchical boundaries. Nevertheless, the ability to develop a full learning capability was restricted by negative feelings related to the design and usage of visual management tools, inefficient feedback systems, poor alignment between problems identified and solutions developed, and the structure and organization of management meetings.

Study III found that extending improvement efforts beyond the hip-fracture care process resulted in a net reduction in lead time to surgery for the entire acute surgical orthopaedic patient flow. This followed a complex intervention, where two key improvement

mechanisms were involved: a more active and centralized surgery planning and the restructuring resources allocation among patient groups.

5 DISCUSSION

Based on the realist review of lean interventions and three empirical case studies, we can now unpack and clarify how contemporary process improvement efforts work in practice and effect performance.

5.1 HOW DOES LEAN CONTRIBUTE TO THE TIMELINESS OF CARE?

The first potential benefit of lean, as identified in the Introduction, is that lean contributes to the ability of staff members to better manage care processes to meet patient needs. For patients seeking acute care, the timeliness of care is important, sometimes vitally so.

Based on the findings, lean contributes by making inconsistent and inefficient practices in health care visible. Informed by this enhanced visibility, care providers can then devise changes to address those problems. The most common of these were changes in planning, particularly regarding staffing and scheduling. These changes resulted in improved timeliness of care delivery.

As an example of this, before lean was introduced, all ED services in Study II and Study IV reported long waiting times due to inadequate staffing levels and a mismatch between daily, weekly, and seasonal demand patterns and scheduling. This mismatch is a typical source of artificial variation in the supply of health care services, that is, the mismatch is a source of variation that is not inherent to the care process, but rather is the result of poor planning (Litvak and Long, 2000, Noon et al., 2003, Walley et al., 2006b, Silvester et al., 2004). Another source of artificial variability was the absence of staff members from the ED, either because they did not want to be there or because they had to go elsewhere to attend to parallel, competing tasks. Such practices caused the loss of usable capacity (Vissers and Beech, 2005).

After lean was introduced, staff members, in particular those on the process improvement teams, developed a better understanding of the mismatch between capacity and demand. A better match was achieved by ensuing changes in staffing scheduling, and by moving competing tasks out of the ED. The latter reduced the unnecessary loss of usable capacity.

The fragmentation of care processes constituted another challenge, as mentioned in the Introduction and confirmed empirically in Study II and Study IV. Increased specialist competence early in the process enabled more active supervision of rotating physicians. A care team approach connected care providers who were dependent on one another and who, before the lean intervention, encountered difficulties in locating each other and in coordinating their work.

In summary, prior to the lean intervention, the ED services studied exhibited challenges that are common in health care processes which are not clearly designed (Bohmer, 2009) and which lack basic stability (Radnor and Walley, 2008). These findings are also mirrored in Study I, in which the organizations tried to overcome unclear procedures, fragmented processes, and limited problem awareness among staff.

5.2 CHALLENGES TO LEAN INTERVENTIONS

The research reported in this thesis revealed a number of challenges related to lean interventions in health care: the complexity of the care process, the educational part of the hospital mission, conflicts with professional identity, as well as sustainability and continuous improvement. Understanding, and addressing, these challenges will be important in achieving greater benefits from application of lean in health care.

5.2.1 Complexity and educational commitment

In Study I, health care was viewed as a single context in order to identify general mechanisms for improvement. However, in Study IV, the impact of contextual differences emerged, particularly the *complexity of the care process* and the *educational commitment*, which in turn resulted in variation in skills and knowledge (i.e. professional variability (Lillrank and Liukko, 2004)). The degree of complexity of the care process was related to the number of interactions and iterations needed to solve a certain health problem.

5.2.1.1 Adaptation to the complexity of the care process

The services characterized by more complex care process were unable to achieve target goals or to sustain improvements. This may corroborate the assertion that manufacturing approaches such as lean are better suited for sequential care processes, but less well suited to dealing with the uncertainty that characterizes more iterative care processes (Bohmer, 2005, Lillrank and Liukko, 2004). Since much of emergency care involves a mix of both sequential and iterative processes, one approach could be to separate sequential processes and iterative processes. In this case, subdividing patients into streams with the help of a flow manager might be a useful approach. The flow manager role, which was implemented in the complex care services, could serve this function. However, this role was not used to stream patients in a systematic way (Study IV).

Complex services that are more dependent on other units might have benefited from a more encompassing lean intervention. However, little evidence was found of changes carried out in collaboration with units outside the EDs. This is a common finding in reports on lean health care. The majority of the improvement efforts reviewed in Study I seldom crossed organizational boundaries, a finding corroborated by others (Brandao de Souza, 2009). In this respect, the way lean is adopted does not differ from other process improvement efforts (Elkhuizen et al., 2006). To avoid the risk of sub-optimization and stagnation of improvement efforts, health care organizations need to move towards a more holistic understanding of the entire process (taking an end-to-end perspective on meeting patients' needs for care) across organizational boundaries (Radnor and Holweg, 2010, Radnor et al., 2012). Nevertheless, such transformations may be hampered by current financing and incentive structures, such as budgets or political targets that do not support an end-to-end view of process improvement (Radnor and Holweg, 2010, Radnor et al., 2012), or by deep-seated traditions (McNulty and Ferlie, 2004).

5.2.1.2 Alignment of competency and complexity of care process

The way the complex services adapted lean was insufficient for dealing with the two types of demand that characterize the services studied. The first type is the care demand from patients. Attempts to address this through scheduling changes were, for instance, hampered by disagreements with union representatives. The second type is the competency/knowledge demand from junior physicians. The services with less complex care processes increased the competency level of their care teams. In contrast, the services with more complex care processes kept the same level of competency in their teams and chose to raise the competency level by introducing a flow physician. The fact that flow physicians became a new bottleneck suggests that these services may benefit from allocating additional senior clinicians to the ED care teams.

The strategies adopted by the services characterized by less complex care processes (ENTs and Gynaecology) enabled them to reduce the variability that arose from heterogeneous training levels among physicians (*i.e. professional variability*). Contrary to the prototype, which called for increased physician competency levels, ENT-1 preserved the tradition of junior doctors as providers of care. This suggests, as supported by the literature (Bohmer, 2009), that when a process is predominantly sequential in nature, and when diagnosis and treatment can be completed within the space of one consultation, it is possible to match patient care demands without raising competency levels.

Figure 3 illustrates the relationships between competency and degree of care process complexity in the emergency services after the implementation of the process prototype (Study IV).

Figure 3. Relationship between competency and degree of care process complexity

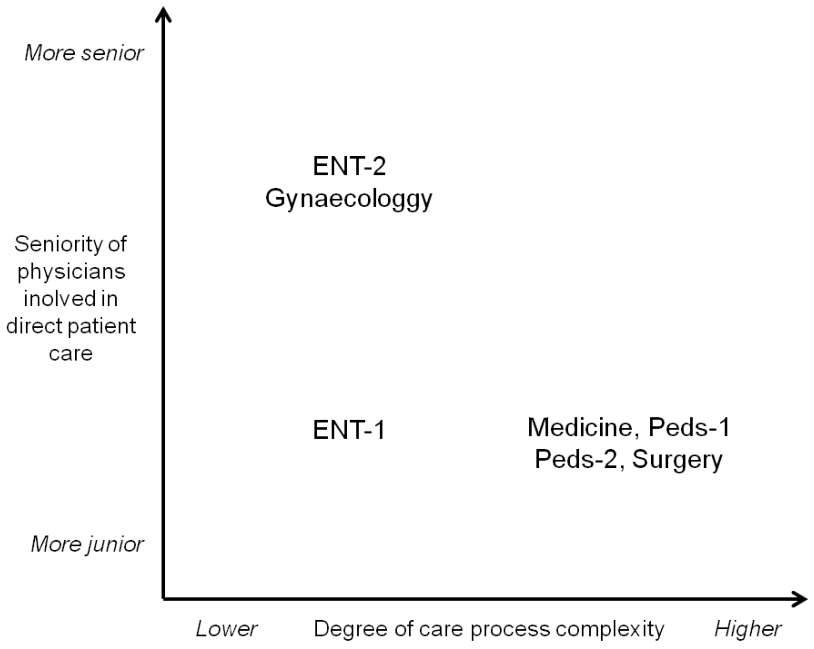


Figure 3 suggests that Medicine, Paediatrics, and Surgery could potentially achieve even better results with a higher degree of alignment between two of the core components of health care delivery systems: the complexity inherent in the care process and

the competency levels of physicians (Bohmer, 2009). Internal medicine has recently begun to address this by adding one more senior physician to the ED care team.

5.2.1.3 Lean as a challenge to educational commitment

The services approached their educational commitments in three different ways:

- Exclude rotating physicians and students from direct patient care (the two ENTs) while increasing the competence of physicians involved in direct patient care (ENT-2)
- Invest in a two-week training period for rotating residents and students as a parallel process while increasing the competence level of physicians involved in direct patient care (Gynaecology)
- Increase specialist competence at the ED to enable more active supervision of rotating and junior physicians and students (Medicine, Surgery, and the two Paediatric services)

Excluding rotating physicians and students from direct patient care helped in developing fast, uninterrupted flows. However, the missed educational opportunities were a cause for concern according to interview data. One promising approach may be the one developed by Gynaecology, which invested in a two-week training period for new physicians that enabled them to contribute to ED care while also acquiring skills for their future practice.

5.2.2 Professional identity

A common practice in lean is that of multi-functional teams (Karlsson and Åhlström, 1996). However, in Study I only two articles were found that reported changes to team composition (Kelly et al., 2007) or multidisciplinary task training (Shannon et al., 2006). Åhlström (2004) has described how the development of flexible teams with interchangeable tasks can be hampered by professional licensure issues. This was mirrored by observations in Study II, where some RNs and LPNs expressed frustration about the mismatch between their job tasks and perceived professional skills that followed the introduction of the RN/LPN-MD pairs. RNs were forced to perform tasks that were below their professional qualification; LPNs could not perform all the tasks requested by physicians.

These findings suggest that job design implications of lean applications in health care require more research, as noted by others (Young and McClean, 2008, Proudlove et al., 2008, Holden, 2011).

5.2.3 Sustainability and continuous improvement

The lack of sustainability or continual improvement observed in some of the services (Study IV), reinforces the point that few health care organizations have achieved the level of maturity needed to develop into "self-improving" organizations (Spear, 2005, Brandao de Souza, 2009, Radnor and Holweg, 2010, Radnor and Walley, 2008). This has been attributed to the fact that most lean applications are more partial, and "tool-based", rather than instances of "full-implementation"(Radnor and Walley, 2008). One

possible explanation for this shortcoming was identified in Study I, where few organizations reported stable structures for continual improvement involving management.

The organization-wide lean-inspired initiative in Study II and Study IV can, in many respects, be viewed as an example of full implementation. Several structures were established to support continual improvement. For instance, the regular meetings between the process improvement team and the hospital management team initially enabled improvement teams to develop solutions that would otherwise have been beyond the reach of the improvement team. Despite this, several challenges emerged in the studies:

- Feedback systems that do not return information to the right staff and with little real-time problem solving
- Poor alignment between problems identified and solutions implemented
- Little understanding of cause-effect relationships
- Gaming and lack of commitment

These challenges can explain the difficulties encountered by health care services to sustain gains and continually improve. Below, the challenges, as well as some of the approaches that can be developed to address these, are discussed in further detail.

Feedback systems that do not return information to the right staff and with little real-time problem solving

The type of improvement routines developed, and the large staff rotation in some ED services, made it difficult to return information to the people affected by the problem and to conduct real-time problem solving. Other authors have reported similar challenges and have attributed them to the following: staff members' lack of familiarity with workarounds and the absence of a culture for solving problems at the source (Braaten and Bellhouse, 2007); time scarcity that hampers real-time problem solving (Ballé and Régnier, 2007, Shannon et al., 2006, Raab et al., 2006, Raab et al., 2007); clinicians' lack of experience from working with problem-solving techniques (Harrison and Kimani, 2009). The importance of real-time problem solving was illustrated in Study I in the analysis of the Allegheny General Hospital (Shannon et al., 2006) and the Virginia Mason Medical Center (Furman and Caplan, 2007, Nelson-Peterson and Leppa, 2007). These cases suggest that real-time root cause analysis and problem solving can help view mistakes as an opportunity for learning and a move away from a culture of blame.

In the services studied, Gynaecology developed a unique approach to meet these challenges. Regular monthly process improvement meetings were replaced with informal ad-hoc meetings that were convened when and where problems were identified. This may have been facilitated by the smaller number of people on each shift, working within a small space, and with a more stable staff group. Ad-hoc meetings may help to move from a "push" to a "pull" approach to improvement, where employees pull improvement actions rather than having them pushed from above.

Experiences from manufacturing suggest that re-organizing work around multi-functional teams increases employees' understanding of the process, which in turn increases their commitment to improvement work (Karlsson and Åhlström, 1996). This might explain why the ad-hoc team approach developed in the Gynaecology service. Using care teams was part of the prototype; however, in Gynaecology fixed teams were aban-

doned in favour of the entire shift forming one cohesive, multi-professional team. This team became responsible for their own improvements.

Poor alignment between problems identified and solutions implemented
Improvement team members expressed frustration that the solutions they developed were not implemented. This was partly due to disagreements with union representatives or the way managers prioritized resource allocation. This mismatch may relate to heterogeneous views of what "value" actually is, partly due to involvement of multiple stakeholders (Radnor and Holweg, 2010, Young and McClean, 2008, Radnor et al., 2012).

Another explanation may relate to the choice of excluding middle managers from the problem identification and problem-solving efforts. This forced them to become accountable for changes they were not familiar with, and unable to influence. The lean literature proposes a new role for managers, with managers involved in root cause problem solving by being on the floor, observing processes and asking questions (Mann, 2009, Spear and Bowen, 1999). A similar approach is in use at Virginia Mason Medical Center, where the vice president and the medical managers have made a commitment to go to the floor, observe problems, and perform a root cause analysis within 24 hours to 1 week from when staff has signalled there is a problem (Furman and Caplan, 2007).

Little understanding of cause-effect relationship
Despite an explicit intention to adopt a scientific approach to continual improvement, solutions for improvement were commonly implemented or rejected based on the opinions and personal experiences of staff and coaches. While experience is a valuable source of information, Brandao de Souza and Pidd (2011) suggest that an initial qualitative approach to improvement could be strengthened by adding a more quantitative approach.

Gaming and lack of commitment
A few isolated episodes of gaming such as data manipulation and false reporting were found. While not widespread enough to challenge the quantitative data, these problems raise questions about the suitability of measuring and managing performance with metrics that are not clearly aligned with the values of health care staffThis may also explain why improvement tools were used repeatedly but with limited engagement.

Waring and Bishop (2010) found similar patterns in an operating department in the NHS. In their study, clinicians evidenced symbolic compliance with the new ways of working because they felt it did not contribute to improved service delivery (Waring and Bishop, 2010). Therefore, process changes should be better legitimized in the health care context if changes in practice are to occur (McNulty and Ferlie, 2004, McNulty and Ferlie, 2002). Recent experiences from the Productive Ward programmes in the NHS (Morrow et al., 2012) confirm that narrowing improvement efforts to productivity measures is a hindrance to professionals' engagement.

5.3 CLINICAL PATHWAYS AND LEAN

In both lean and the clinical pathway interventions, inconsistent practices became visible and allowed improvement teams to develop solutions. But they differed in some key ways. Despite the fact that the clinical pathway intervention occurred in the context of a hospital with widespread lean activity it was difficult to identify crossover effects from lean. What the hip-fracture process succeeded in achieving was to cross unit boundaries, which the lean applications did not do initially (although that was an intention for the longer term).

Both the lean and clinical pathway interventions focused on care processes. The difference, however, was that in the clinical pathway intervention, the national guidelines were the starting point from which the care process activities were planned. This would suggest that clinical pathway interventions can contribute to lean by integrating evidence-based medicine in the design of the care process. Indeed, Van Vliet (2010) successfully developed an approach for a cataract pathway where health care professionals defined the content of the clinical activities and then lean was applied to organize the process. However, previous research conducted at the same hospital as in Study II and Study IV, found a hip-fracture pathway was not integrated in the lean effort, but instead withered (Löfgren et al., 2012). This suggests that, while these two approaches share similarities and can be complementary they can also be challenging to integrate in practice.

Both the clinical pathway and lean interventions involved the establishment of two new roles: the acute care coordinator (clinical pathway) and the flow manger (lean). Both roles are related to operational coordination. The clinical pathway coordinator worked actively to coordinate the supply and demand of services. The flow manager role was originally intended to increase competency early in the process. In practice, the role evolved into one of supervision of junior doctors. In one service, the flow manager role was similar to the clinical pathway coordinator, assigning patients to care teams based on the competence and the capacity available. If streaming is one of the lean tools that can be applied in services with more complex care processes, the flow manager as coordinator may take on that task of streaming.

5.4 IMPROVING PROCESS IMPROVEMENT

This thesis shows that more can be done to improve care processes. A better way to understand what can be done emerges when we relate the health care process improvement efforts described in this thesis to Fujimoto's (1999) three capabilities framework.

In health care, Fujimoto's first capability (routinized manufacturing capability) can be translated as care process capability. This includes organizational routines that affect care process performance. This thesis demonstrates how such capability was enhanced (e.g. efforts to match capacity and demand – in terms of staffing, scheduling, and competence level – and the introduction of new roles to coordinate supply and demand using the acute orthopaedic coordinator). To further improve, the changes implemented need to be better aligned with the complexity of the care processes. Adding resources may have been motivated by inadequate staffing levels. However, given the perennial pressure to contain costs, simply adding resources may be an unsustainable practice.

Fujimoto's second capability (routinized learning capability) includes routines for problem identification and solving as well as solution retention. In all the studies in this thesis, improvement efforts enabled staff to *identify problems* through the use of process mapping, improvement meetings, and visual management tools. *Problem solving* was successful in the sense that the organizations were able to implement changes that led to improvement. However, the routines for problem solving were limited by, for example, feedback systems that did not send information to the right staff, limited real-time problem solving, little understanding of cause-effect relationships, poor alignment between problems identified and solutions implemented, in part because not all managers were actively involved in the efforts. Problem solving appeared to be particularly challenging in the more complex care processes that seem to require more complex solutions and more adaptation. *Solution retention* is the ability to formalise and institutionalize countermeasures and develop them into new, standard operating procedures. When this fails, process improvement becomes transient and vulnerable. For instance, Surgery's inability to ensure specialist competence on the ED floor may explain performance deterioration. Or, the fact that the coordinator function in Study III appeared to be dependent on one person reveals a fragile practice.

Fujimoto's third capability (evolutionary learning capability) is of particular importance in health care given the demands created by new technologies and innovations, all of which can disrupt standardized care processes (Christensen et al., 2009). While the thesis studies did not focus on this capability, such non-routine innovative learning and creation of new routines may be what health care needs.

5.5 METHODOLOGICAL CONSIDERATIONS

In this section, I will reflect on the choices made during this research journey and their implications for validity and reliability. Yin (2003) distinguishes between construct validity, internal validity, external validity, and reliability. Construct validity concerns the establishment of correct operational measures for the concepts studied. Internal validity, which depends on how well the study is designed and conducted, concerns the ability to establish causal relationships. External validity concerns how well the study's findings are generalizable. Reliability is the ability to demonstrate how the study was conducted – the extent to which study procedures, if replicated in similar situations, would yield consistent findings.

Rationale for choosing the case study methodology. One reason for choosing the case study approach was that I as a researcher had no control over the process improvement efforts (Voss et al., 2002, McCutcheon and Meredith, 1993). The case study approach can capture the contingencies of the studied systems (Stuart et al., 2002), such as how contextual factors influenced lean applications in Study IV. Moreover, the case study method made it possible to investigate both the human and physical aspects of operations (Dreyer et al., 1998, Voss et al., 2002). For example, it was possible to explore challenges related to the unexpected development of new roles such as care team nurses and flow physicians (Study II and Study IV).

The experience of being out in the "real world" (Voss et al., 2002) was enriching; it gave me a deeper understanding of the challenges and possibilities that characterize health care operations. This understanding and the possibility to redirect data collection in response to unexpected findings or events contributed to the development of a more faithful representation of events based on direct observation, thereby strengthening the internal validity. This was further confirmed through participant validation.

Choice of cases. The case study approach can be a very time consuming research strategy due to the use of multiple data sources and methods (Stuart et al., 2002). To identify and gain access to adequate cases can also take time and require a prolonged data collection period, particularly if the cases selected turn out to provide less empirical ground than expected (Stuart et al., 2002). This challenge was encountered during the early phases of this research, when initial data collection at a hospital site revealed that little change had occurred. In the attempt to stay focused while being flexible (Stuart et al., 2002), new cases were added to this thesis research. In Study IV, the decision to study cases retrospectively, covering a case history of four years, allowed for a more "controlled choice of cases" (Voss et al., 2002), that is, a selection of cases already known to show different patterns of performance. This variation increased the prospects of identifying instructive empirical patterns.

Were we able to select cases where the improvement efforts truly exemplified textbook definitions of lean and CP? Perhaps not. Answering the question, "Is this lean?" or "Is this a clinical pathway?" was outside the main focus of this thesis. Instead, the cases were chosen because they represented real-world efforts to improve patient processes with inspiration from lean or clinical pathways.

Choice of performance data. The choice of process performance measures has implications for construct validity. Such measures should mirror whether process performance improved or not. The measures were chosen based on the indicators used in the improvement work. This choice facilitated data collection and enabled the collection of performance data over several years. This in turn allowed for time series analysis, which are preferred to "before and after designs", where results can be distorted by the natural variation that characterizes health care processes (Walley et al., 2006a).

Nevertheless, two limitations of the quantitative measures in particular are worth highlighting. First, performance measures were merely limited to time aspects of health care delivery. This prevented the research from capturing effects on other dimensions of care delivery quality. For instance, anecdotal evidence revealed that increased competence and staffing had a positive impact on both patient and staff satisfaction, which was in line with the hospital's rationale for use of the lean programme. Second, previous research has found that the four-hour target in EDs is associated with an increase in the discharge of patients within the last 20 minutes of that time span, rather than the discharge of patients across the four hours (Mason et al., 2011). This raises the question of whether the performance measure "percentage of patients discharged within four hours" may be linked to a focus on achieving targets rather than on managing processes better?

Choice of methods for data collection. The use of single case studies (Study II and Study III) enabled in-depth field research involving multiple data sources (data triangulation) and multiple methods (triangulation of methods). This strengthens construct validity (Yin, 2003, Voss et al., 2002). To strengthen external validity the single cases were complemented with a multiple case design (Study IV). While the multiple case study (Study IV) involved less extensive field research, several tactics were adopted to strengthen the quality of the data collected. Based on a pre-understanding of the lean programme at the Karolinska University Hospital and the findings from Study II, a novel approach to data collection developed, built upon realistic evaluation (Pawson and Tilley, 1997). The structured group interviews (Appendix III) enabled the researchers to gain key information on how the lean programme was put into practice in each service. These structured interviews were complemented with group interviews that specifically aimed at testing candidate mechanisms (Appendix IV). The interviews thus served to confirm, falsify, and refine the candidate mechanisms in light of the stakeholders' experience and understanding (Pawson and Tilley, 1997). Data collection was strengthened through the participation of multiple investigators at each interview (Voss et al., 2002).

Building explanations and generalizing from case studies. Several tactics were used in the single case studies (Study II and Study III) to identify and explain connections between the lean or clinical pathway interventions and changes in process performance, (i.e. to strengthen reliability and internal validity) (Yin, 2003). These tactics included organizing qualitative data in an Excel file and in an NVivo database and triangulation of data in order to develop in-depth case descriptions. These descriptions were then reviewed by key informants, and empirical data was compared with relevant theoretical frameworks. Nevertheless, explanation building was challenged by the fact that the lean and clinical pathway interventions entailed multiple changes often implemented concurrently. In the multiple case study (Study IV), explanation building started with the analysis of each case (Voss et al., 2002), to yield C-I-M-O configurations for each case. This step was followed by a cross-case comparison to look for evidence of both literal (the same explanation in multiple cases with the same outcomes) and theoretical replication (the inability to find the same explanation in cases with different outcomes) (Yin, 2003). The complexity of the interactions identified within each case was, nevertheless, a challenge to such replication. The explanations developed in this research could be strengthened by the application of other approaches, such as action research, that allow researchers to gain an understanding of health care delivery systems as a result of trying to change them (Starbuck et al., 2008).

On being an observer. With popular innovations like lean, there is a risk of a "pro-innovation" bias, where "the researcher may become an advocate, not an observer" (Voss et al., 2002). To reduce this risk in Study IV, multiple investigators participated in all interviews and conducted the analysis, which strengthened the data interpretation (Eisenhardt, 1989b, Voss et al., 2002). In all studies, interviews were recorded and transcribed verbatim, thereby increasing the data reliability and reducing the risk of recall bias. Key persons involved in the improvement efforts were included in the research team in order to better understand and analyse the improvement efforts. Therefore, to counterbalance the risk of a "pro-innovation" bias, the analysis of case data was first

conducted by those researchers not involved in the improvement work. They then discussed the analysis with the rest of the team.

6 CONCLUSION

Lean-inspired and clinical pathway-related process improvement efforts make inconsistent and inefficient practices in health care more visible. Care providers can then develop changes in planning activities to address those problems. This can yield improvement in the timeliness of care delivery. While these changes are not unique to lean or clinical pathways, they can be triggered by these two approaches.

The variation in process performance and sustainability of results observed indicate that process improvement efforts such as lean should be carefully adapted to the complexity of the care process and to the educational commitment of health care organizations.
This suggests that practitioners, managers, and researchers should carefully consider the specific characteristics of their health care delivery systems when they design, implement, and evaluate process improvements. Ultimately, the ability to adapt lean to the particular context of application depends on the development of practices that effectively support learning from daily processes.

6.1 FUTURE RESEARCH

Some questions that merit further research include:

- How can process improvement interventions be designed to better match complex care processes?
- How can educational activities be effectively integrated in efficient care processes?
- What are the effects of lean applications on value for patients, work design, quality of care, patient outcomes, and staff and patient satisfaction?
- How can problem solving and solution retention be fostered in process improvement efforts?
- How does the process by which lean is implemented affect practice and performance?
- Which targets can be used beyond time measures and which relate to the specific context of health care?
- How can evidence-based practice be integrated into lean improvement efforts?

6.2 IMPLICATIONS FOR PRACTICE

Health care organizations interested in improving care processes need to consider the following:

- Understanding the degree of complexity inherent in the targeted care process is of importance for successful adaptation of process improvement strategies
- Acknowledging and dealing with the two types of demand in health care services: care demand from patients and knowledge demand from junior and rotating staff
- Developing practices that foster learning from daily work, including data-driven improvement, timely feedback loops, and the involvement of managers in problem identification and problem solving.

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APPENDIX I: DATA ABSTRACTION FORM (STUDY I)

1. Article reference
2. What is the study design? Empirical study (case study or others) Tutorial with illustrative case study Tutorial paper
3. Study objectives?
4. **What are the references concerning lean theory?** (This might help define the content of the intervention). **How is lean being defined?**
5. How was the implementation process carried out? Describe the main steps/actions that were taken to implement lean.
5.1 What was the motivation for the introduction of lean?
5.2 How was value defined/identified from a patient perspective?
5.3 Who was the change agent, and which other actors were involved?
5.4 How was lean knowledge acquired?
5.5 Which lean tools were used? Flow/continuous flow, stop the production (andon), cell, 5S (sort, set in order, shine, standardize, sustain), 5 why analysis, *kaizen* (small incremental improvements), *kanban* (visual signalling to pull production), PDSA, poka-joke (inexpensive robust device that alerts when an error occurs), pull, standard, *takt* (synchronize production to maintain balanced flow), value stream map, etc.
5.6 How long did the improvement intervention take?
5.7 Was it a top-down or a bottom-up initiative, or both at different times?
6. Is it the introduction of lean in a certain unit/department part of a bigger project involving the rest of the organization, or is it an isolated initiative (one unit, department, one single process)**?**
7. Which of those two approaches do you think is the prevailing one in the implementation of lean theory? Is it the improvement of a specific process in a short term perspective (mostly focusing on the adoption of certain lean tools for the improvement of specific processes), or the full implementation of the philosophy (a more holistic approach embedding the principles of lean and making a broad use of tools). **a) Process improvement** (in some cases this is referred to as "kaizen events"). **b) Full implementation** (this implies long term commitment to the lean philosophy, the development of a culture of continuously solving problems, and the development of a learning organization).
8. Reported benefits?
9. Which barriers and limitations to lean implementation were reported?
10. Which factors or conditions facilitated the implementation of lean?
11. What type of organizational setting does this implementation occur in? (Hospital setting? In-patient, or out-patient, or both? Non-hospital specialty care clinic? Primary care setting?)
12. In which country?
13. In which clinical specialty?
14. **What is the unit of analysis?** (single clinic, unit/department, division, organization, or

network)
15. To which variables has lean been applied? (Waiting time, inpatient time, etc)
16. Do you think the article follows the "rigor" criterion? (Does the particular inference drawn by the original researcher have sufficient weight to make a methodologically credible contribution to the test of the intervention theory?)
17. OTHER CONSIDERATIONS, in particular issues or principles that can contribute to the development of a "theory" about lean implementation in heath care.

APPENDIX II: EXAMPLE INTERVIEW GUIDE (STUDY III)

Inledning [Introduction]

1. Skulle du kunna berätta vem du är, ditt yrke, var du jobbar (enhet/klinik), hur länge Du funnits i denna verksamhet samt vilka dina arbetsuppgifter/ansvarsområden är.

Patient gruppen och processen [Patient group and process]

2. Vilken roll har Du i vården av patienter med (misstänkt) höftfraktur?
3. Vilka andra patientgrupper jobbar ni med?

Rutiner [Routines]

4. Hur tar ni på Danderyds sjukhus (och på er klinik) hand om patienter med misstänkt höftfraktur?
5. Hur vet du och andra som tar hand om höftfrakturpatienter vem som gör vad?
6. Hur samverkar andra kliniker med er när ni ta hand om höftfrakturpatienter?
7. Vilka mål har ni kring vården för patienter som har drabbats av höftfraktur?

Problematiken med patient gruppen och processen [Challenges related to the the management of the care process]

8. Vilka utmaningar/svårigheter ser du när det gäller att nå de uppställda målen?
9. Var blir det fördröjningar i processen och vad beror det på?
10. Hur samarbetar andra kliniker med er i syfte att uppnå målen för vården av höftfrakturpatienter (24 timmars mål, men även andra mål)?
11. Kan Du nämna andra faktorer/saker i din omgivning som hindrar dig från att genomföra ditt jobb på ett effektivt sätt?

Intervention [Process and content of the intervention]

12. Vad gör ni för att hantera de hinder som finns idag för att nå målen för patienter med höftfraktur?
13. Vilka åtgärder (formaliserade åtgärder, samt informella improviserade lösningar) har vidtagits och när (under det senaste året, sedan 24 timmars målet infördes)?
14. Hur genomfördes åtgärderna? (särskild metod, särskilda projekt)
15. Vilken (typ av) kunskap har legat till grund för utvecklingsarbetet?
16. Vilka resultat förväntas och hur följs dem upp?

Resultat [Results]

17. Genomfördes förändringar som planerat?
18. Vad anser du fungerar bättre, eller sämre idag?
19. Vilka resultat har förändringarna medfört för patienterna och er som tar hand om patienterna?

Intervention och kontext [Contextual factors influencing the intervention]

20. Hur har de lokala/avdelningens förutsättningar varit? På vilket sätt har dessa påverkat förloppet (= implementering av det nya arbetssättet)?

21. Hur har nyckelaktörerna (t ex cheferna, ledarna, dem i processgrupen) arbetat med/påverkat omgivningen?
22. Vilka ”yttre” faktorer/händelser har påverkat processen? När och på vilket sätt har de påverkats?
23. Sammanfattningsvis – vilka faktorer/ omständigheter ser du har stöttat respektive hindrat utvecklingsarbetet? Ange 2-3 st.

Avslutning [Closing]

24. Utifrån din erfarenhet, vad tycker du man behöver ta tag i framöver för att förbättra vården för höftfrakturpatienter?
25. Om du blickar framåt – vilka är för Er de största utmaningarna?
26. Finns det någonting annat som du skulle vilja berätta för mig som jag inte har frågat dig om?
27. Kommer du på någon annan som jag skulle kunna intervjua?

APPENDIX III: INTERVIEW GUIDE (STUDY IV)

Implementering av flödesarbetet

1. Vilka var med i processgruppen från början (fanns det läkare, ssk, usk), samt vem var SVU facilitator?
    a. Hur har konstellationen i processgruppen förändrats under tiden?
    b. Har SVU facilitator byts ut under tiden? I sådant fall, när och med vem?
2. Vad visade processkartläggningen?
    a. Hur såg processen ut innan flödesarbetet? Hur jobbade man på akuten?
    b. Var hittade ni mest onyttig tid?
    c. Hur mycket onyttig tid hittade ni uppskattningsvis?
3. Vilka av sjukhusets mål var aktuella för er?
4. Vad kom ni fram till var dem största orsakerna till ovan nämnd onyttig tid?
    a. Arbetsätt, kompetens, personalen inte fredad, bemanning, eller annat?

Innehåll i flödesarbetet

5. Vilka är de största skillnader i arbetssättet före och efter flödesarbetet?
    a. Har man infört flödesläkare, flödes-ssk, och vårdlag?
    b. Vilka ingår i vårdlag och hur jobbar man i vårdlag?
    c. Hur många vårdlag finns det per flödesläkare?
6. Hur har kompetensen på akuten förändrats?
7. Vilka är de största skillnader i hur personalen är fredad före och efter flödesarbetet?
    d. Hur har man definierat att ”vara fredad” på er akutmottagning?
    e. Vem har blivit fredad och hur har man lyckats freda personalen?
8. Vilka är de största skillnader i bemanningen och schemaläggningen före och efter flödesarbetet?
    f. Hur har bemanningen förändrats för läkare, ssk, och usk?
    g. Hur har schemaläggningen förändrats för läkare, ssk, och usk?
9. I vilken fas i förbättringsarbetet befinner ni er nu?
10. Vilka är er största utmaningar för att komma vidare?

APPENDIX IV: CANDIDATE MECHANISMS (STUDY IV)

Individuellt: Nedan finns en lista med olika påstående. Ange med ett poäng från 1 till 4 till vilken utsträckning du anser (subjektiv bedömning) att dessa påståenden stämmer överens med hur flödesarbetet har fungerat i praktiken på ditt akutflöde:

1. inte alls
2. i viss utsträckning
3. i ganska stor utsträckning
4. i högsta grad

Påstående som beskriver hur flödesarbetet har bidragit till att minska onyttig tid och därmed förbättrat kvalitet, effektivitet, och arbetsmiljö på akuten.	**Poäng 1-4**
1. Flödesarbetet (t.ex. prototypen, nya roller som flödesläkare och flödesssk, arbetsbeskrivningar, flödesprinciper) har bidragit till att göra vårdprocessen mer tydlig till innehåll och utförande, samt minska osäkerheten kring vem som ska göra vad och när.	
2. Flödesarbetet (t.ex. vårdlag, vårdlagsrum) har bidragit till att länka människor som är beroende av varandra i sitt arbete, och därmed gjort att medarbetare (läkare, ssk, usk) är mer lätt tillgängliga för varandra.	
3. Flödesarbetet (t.ex. vårdlag, vårdlagsrum) har bidragit till att individerna kan jobba mer parallellt, dvs jobba samtidigt kring samma patient.	
4. Flödesarbetet (t.ex. flödesläkare, flödes ssk, och arbetet i vårdlag) har bidragit till att skapa en enklare och oavbruten vårdprocess.	
5. Flödesarbetet (t.ex. flödesläkare, flödes ssk, och arbetet i vårdlag) har bidragit till att få en bättre överblick över vad som händer på akuten.	
6. Flödesarbetet (t.ex. flödesläkare, flödes ssk, och arbetet i vårdlag) har bidragit till att få en bättre överblick över var ens arbetskamrater är och var ens patient befinner sig i vårdkedjan.	
7. Flödesarbetet (t.ex. specialist som flödesläkare) har bidragit till att öka kompetensen på akuten och därmed ökat förmågan att ge rätt behandling/handläggning från början.	
8. Flödesarbetet (t.ex. specialist som flödesläkare) har bidragit till att specialisten är mer lätt tillgänglig för mindre erfarna läkare.	
9. Flödesarbetet har bidragit till ett bättre samarbete med avdelningen kring inläggning av patienter.	
10. Flödesarbetet har bidragit till att bemanningen och schemaläggningen är planerat för att matcha efterfrågan.	
11. Flödesarbetet (t.ex. vårdlag) har bidragit till att jämna ut arbetsbelastning mellan olika medarbetare (läkare, specialisten, ssk, usk).	
12. Flödesarbetet har bidragit till att förbättra arbetsmiljö på akuten.	

13. Flödesarbetet har bidragit till att minska stressnivån på akuten.	
Påstående som förklarar hur flödesarbetet har bidragit till ständiga förbättringar, samt lärande.	
14. Flödesarbetet (t.ex. process kartläggningen och prototypen) har bidragit till att identifiera onyttig tid på akuten.	
15. Flödesarbetet (t.ex. takttavlan, whiteboard) har bidragit till att synliggöra hur processen fungerar i vardagen samt synliggöra problem, och därmed ökat förståelse för hur verksamheten fungerar.	
16. Flödesarbetet (t.ex. takttavlan, eller whiteboard) har bidragit till att synliggöra problem i vardagen och därmed lett till att medarbetaren kan delta i förbättringsarbetet genom att komma med förslag på hur verksamheten kan förbättras.	
17. Flödesarbetet (t.ex. mål, mätning, processgruppen, test i liten skala) har bidragit till att driva förändringar med en systematisk ansats: åtgärderna utvecklas, testas, och eventuellt implementeras.	
18. Flödesarbetet (t.ex. processmöten, whiteboard) har bidragit till att göra medarbetare delaktiga i förbättringsarbetet och därmed ökat acceptans för de åtgärderna som vidtas.	
19. Flödesarbetet (t.ex. processkartläggning, förbättringsprinciper och möten i processgruppen) har bidragit till att generera konkreta förslag för hur man kan organisera arbetet på vår akutmottagning.	
20. Flödesarbetet (t.ex. processkartläggning, förbättringsprinciper och möten i processgruppen) har bidragit till att generera förslag för hur man kan organisera arbetet som är anpassade till just för vår akutmottagning.	
21. Flödesarbetet (t.ex. ledningsbeslutmöte) öppnade upp nya kommunikationsvägar genom sjukhusets hierarki som bidrog till att man kunde få igenom och implementera åtgärder som annars skulle ha varit omöjliga.	
22. Flödesarbetet (t.ex. ledningsbeslutmöte) öppnade upp nya kommunikationsvägar genom sjukhusets hierarki som bidrog till att man kunde vidta åtgärderna som främjade ett processtänkande snarare en ett ”kliniktänkande” – utgå från patientens resa genom vården och de behov som dyker upp.	
23. Flödesarbetet (t.ex. mål, mätetal, och prototypen) har bidragit till att skapa en gemensam bild hos alla medarbetare av vart man är på väg.	