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Enablers for change

A mixed-methods study of Lean-based quality improvement in hospitals

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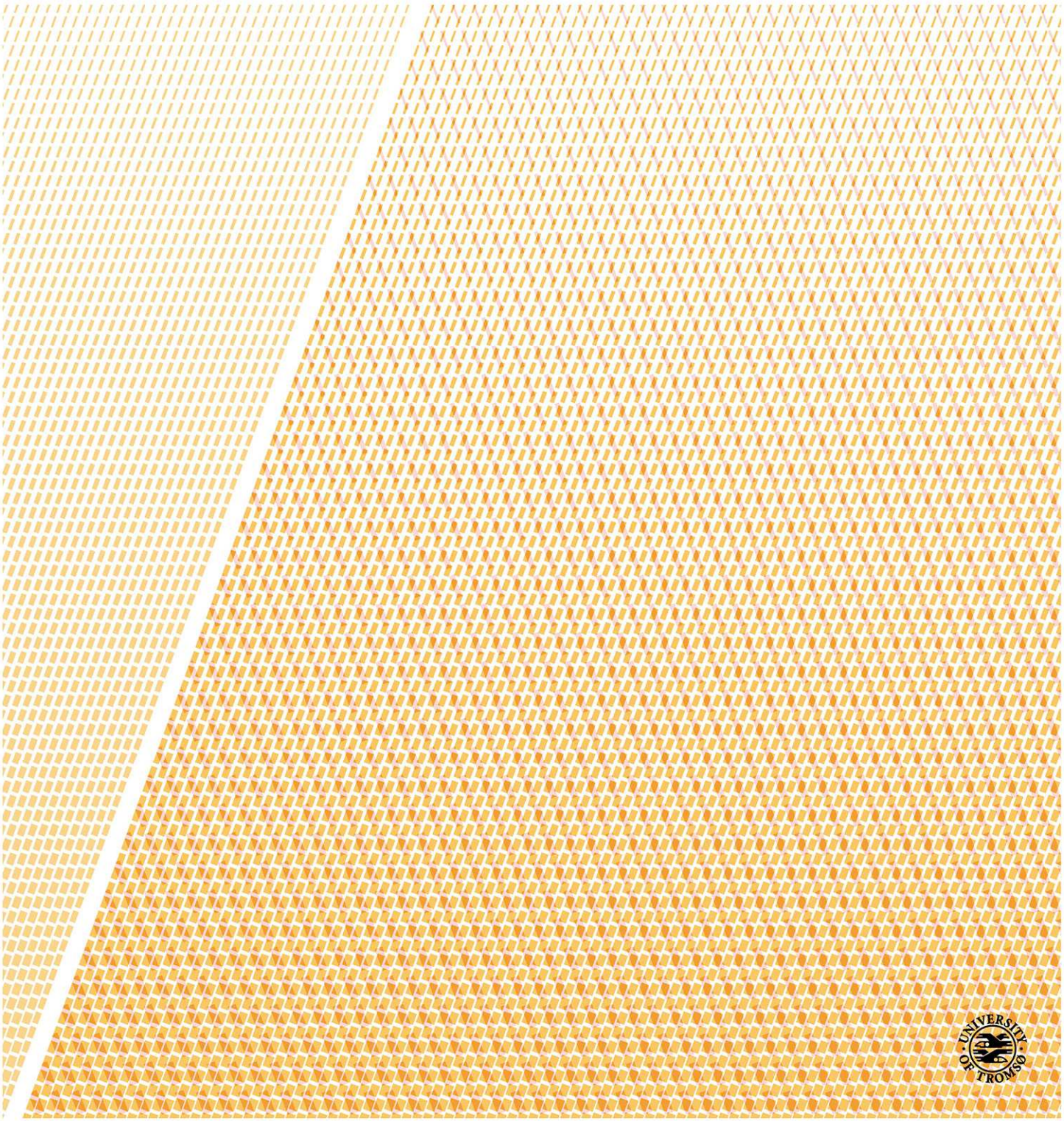
Hege Andersen

A dissertation for the degree of Philosophiae Doctor – December 2015



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Tromsø, December 2015

Hege

List of papers

I. Andersen H, Røvik KA, Ingebrigtsen T. Lean thinking in hospitals: is there a cure for the absence of evidence? A systematic review of reviews. BMJ Open. 2014;4(1):e003873

Appendix

II. Andersen H, Røvik KA. Lost in translation: a case-study of the travel of Lean thinking in a hospital. BMC Health Services Research. 2015;15(1):401

Appendix

III. Andersen H. How to design Lean interventions to enable impact, sustainability and effectiveness. A mixed-method study. Journal of Hospital Administration. 2015;4(5):p18

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1. Introduction – The challenges of health care and the implementation gap

In January 2015, the Norwegian Minister of Health and Care Services gave his annual hospital speech in which he stated improving *patient health services* as his main mission as minister(1). He asked the fundamental question of how we would deliver and manage health care if the patient was to lead decisions therein, and claimed that the answer to this is decisive for the future development of health care, in general, and of hospitals, in particular. His statement adds to the general observation that the role of the patient is changing. Patients' increased access to information, higher education, and new technology affects the way health care is organized and delivered. In the future, patients and their relatives will be involved to a much greater extent in decisions concerning treatment.

Higher expectations are one of the main premises for quality improvement and change. This must be considered as one of the challenges of health care. A greater number of patients and more complicated cases must be treated with less money and fewer hands in the years to come(2). Simultaneously, the public requires improved and documented quality with timely delivery of health services(3). Expectations include a substantial increase in chronic and complex health problems due to a higher average age of the population, increased incidence of lifestyle diseases, and longer life expectancy, among other causes. Simultaneously, we are observing increased governance and accountability, where authorities put pressure on hospitals to meet stringent performance targets, and call for improved efficiency in a context of scarce resources(4). Thus, in the future, hospitals will be required to deliver more health care with fewer resources.

Rapid technological and drug development offers new opportunities in diagnostics and treatment; however, higher complexity, expectations, and expenditures are also parts of this picture. Hospitals have become high-tech companies, based on highly specialized expertise and continuous knowledge acquisition. This challenges hospitals

in many ways, of which ensuring access to qualified health care personnel is among the most important. The medical treatments and patient pathways are correspondingly complex, and dependent on well-functioning multidisciplinary teams and cooperation across professional and organizational borders.

1.1. The implementation gap

There is a considerable and well-documented gap between the health care we provide and the evidence-based health care that should be provided. This is labeled *the implementation gap*(5), or *the quality chasm*(6), as initially introduced by the US Institute of Medicine to describe the gap between the health care services we have and those we could have(6). Studies show that 30 to 40 percent of patients do not receive evidence-based care, and that 20 to 25 percent of the given care is not needed, or is potentially harmful(7). The distance between the knowledge we have of good care and the care we deliver worries policymakers, as well as researchers, around the world.

The quality chasm may even widen over time, concurrently with rising health care costs, uneven distribution of care, new treatment opportunities, expanded expectations among a population that is growing older, and an incipient shortage of health care professionals. The quality chasm cannot be reduced by further stressing the current system of care(8). 'Every system is perfectly designed to get the results it gets', the famous quote of Paul Batalden (IHI), illustrate this. If we keep doing what we have always been doing, we'll keep getting what we've always gotten – an expensive, high-tech, inefficient health care system. The system needs to be redesigned. To achieve better care, we need to know more about quality improvement and factors affecting organizational capacity and capability to change.

To bridge this gap, many hospitals consider management ideas and concepts from the process industry, and quality improvement methods such as Six Sigma, Redesign and Lean thinking. The mantra of these tools are '*work smarter – not harder*', reducing waste from processes, improving quality, and thereby making patient care

flow more smoothly(9, 10). These initiatives are based on the underlying assumption that organizations are made up of linked activities or processes, and that quality improvement can only be achieved by altering such work processes(4).

One relevant example is the introduction of 'clinical pathways' in Norwegian health services, where standardized, time-limited patient pathways have been established for more than 20 cancer diagnoses nationwide in 2015.

All of the university hospitals in Norway have introduced at least one of these quality improvement methods in the last decade, though at very different scales. The University Hospital of North Norway can be viewed as a pioneer, as the first Norwegian hospital that systematically introduced Lean thinking (Lean), and the only one to plan a full-scale implementation of Lean to meet the challenges of health care. Lean has gained extensive popularity in health care, and management has had great expectations regarding its success, despite high observed variance in outcomes and a general lack of proof of Lean's efficiency. The plasticity of Lean may be a prerequisite for its popularity, and at the same time a reason for the high variance in outcomes of Lean interventions. This assumption constitutes the point of departure of my dissertation.

1.2. The rigor–relevance gap

The rigor–relevance gap concerns the growing recognition that findings from scientific studies are frequently found not to be useful to practitioners, and consequently are not implemented(11). Insufficient academic knowledge of organizational problems and their solutions leads to theories and findings not being relevant for organizational practice(12). Practitioners do not read scientific publications, and practice-oriented 'success-factor' studies are no exception. The idea that theory and research are useful for improving organizational practice seems to be challenged by these observations(13).

A possible explanation for this gap is described in Luhmann's system theory(14), where specialized systems develop a specific logic, which boosts their performance via autonomy, self-reference, and operative closure. Assuming that science can be defined as a system, science is also characterized as highly autonomous, self-referential, and self-reproducing(11). Thus, the same also applies to (hospital) organizations as practice systems. Possible consequences of the relationship between science and organizational practice are reduced capacity to communicate with each other, reduced transferability of ideas, and limited opportunity to influence research topics or organizational decisions.

Increased collaboration between researchers and practitioners would produce research that is both scientifically rigorous and relevant to practice. However, from a system theory perspective, these two systems are impossible to merge, due to insurmountable communication barriers(11). The alternative may be bilingualism, in which facilitators of dual competence who are able to apply scientific knowledge in practice and practical knowledge in theory production contribute to bridging the gap. In this way, relevant theory can be viewed through a practice lens and the role of context may be recognized, adapting theory according to the demands of a specific context(12). The latter describes my attitude towards research and my approach in this dissertation. By aiming at bilingualism – that is, being familiar with both the language of the hospital and the language of political science – I aspire to contribute to bridging these gaps.

1.3. Outline of the dissertation

My dissertation is based on three connected studies and three associated scientific papers(15-17). These three studies guide the structure of this dissertation. The papers will be referred to by their Roman numerals. Following this introductory outline of the challenges of health care, Chapter 2 accounts for the study's paramount aim, background and setting. Chapter 3 presents the theoretical framework of my work. In Chapter 4 you will find an overview of the material and

methods used, including designs, instruments and research process, and a paper-specific guidance of data collection and analysis. Here I also describe the specific aims of the three studies. Thereafter, in Chapter 5, I present a synopsis of the results of the three studies. Chapter 6 embraces a discussion of the findings, including possible implications for hospitals' quality improvement work, contributions to the research field, critical reflections and suggestions for future research. The main conclusions are summarized in Chapter 7.

2. Aims of the study – Identifying the how, when, and why of Lean thinking

2.1. Main aim of the dissertation

In my work at the University Hospital of North Norway, I was engaged in the introduction of Lean during the period 2008–2010. By 2012, 17 patient pathways had been improved by incorporating Lean. By observing the implementation, and after an internal evaluation, it became evident that the outcomes of the improvement interventions varied; some achieved lasting success, while others did not alter practice or sustain quality improvements at all(18). These 17 interventions constitute the empirical basis for this study.

After conducting a preliminary literature review, I concluded that the research field could be characterized as immature. Qualitative case studies were showing positive results, but were characterized by methodological shortcomings. Studies based on quantitative approaches had trouble identifying effects of Lean at all, partly caused by theoretical shortcomings. Thus, a severe lack of evidence for Lean efficiency was unveiled, even though Lean has been introduced at hospitals worldwide, accompanied by a 'cottage industry' of how-to guides, training manuals, and conferences on how to revolutionize health care using Lean(19).

The considerable challenges in health care, Lean's popularity regardless of its lack of proven success, and the varying outcomes of Lean interventions at the case hospital attracted my attention. My paramount research question is: *How can we understand, and explain, that some Lean interventions succeed while others do not, within one hospital?* I claim that thorough knowledge of what happens when a change management idea such as Lean encounters practice will contribute to more accurate choices regarding future interventions. The specific research questions for Papers I, II and III are outlined in Chapter 4.1.

2.2. Background and setting

The case hospital went through some major structural changes in 2008, reorganizing more than 70 departments into 10 divisions(20). Lean was chosen as a quality improvement method to support the organizational changes, based on the recognition that the restructured organization lacked an effective tool to execute its strategy. Lean was intended to contribute to improving the patient flow through the hospital's departments and across functional silos and organizational borders. The hospital's board anticipated that Lean would produce quality improvements for the patients, improve the workplace environment, and contribute to the effective management of the hospital.

In the following, all activity based on quality management concepts will be collectively named quality improvement (QI). The reader must bear in mind that Lean and other members of the QI family have many features in common(21), and that the research literature, like organizations, often mixes different QIs. Some would say that Lean is nothing more than "new wine in old bottles"(22). However, the primary concern of this dissertation is quality improvement interventions based on the Lean thinking philosophy.

2.2.1. Lean thinking – The philosophy and the tools

Lean is a well-known philosophy in the QI family. It emerged originally as the *Toyota Production system* (TPS). TPS inspired Womack and Jones to write the book *The machine that changed the world*, wherein Toyota was described as a 'lean' corporation and the idea of Lean as a panacea(23). The idea spread from cars to other mass-production industries, and thereafter to service organizations. Between 1995–2000, it found its way into health care and hospitals; first in the United States, followed by Great Britain and then the Scandinavian countries(24).

A common characteristic of Lean and other QIs is that improvement is seen as cyclic processes of plan, do, study, act (PDSA cycles). Different QIs often contain similar sets

of tools and techniques, and they share a belief in engaging and empowering frontline staff(21). They employ structured problem solving, including statistical methods and monitoring to diagnose problems and oversee improvement(25).

More specifically, Lean is based on five principles – or improvement stages – and seven categories of waste, represented in Figure 1 and Figure 2.

Figure 1: The five principles of Lean

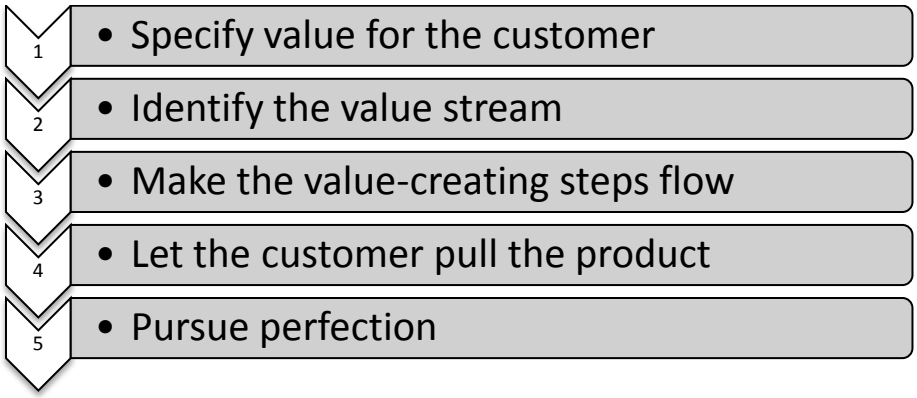
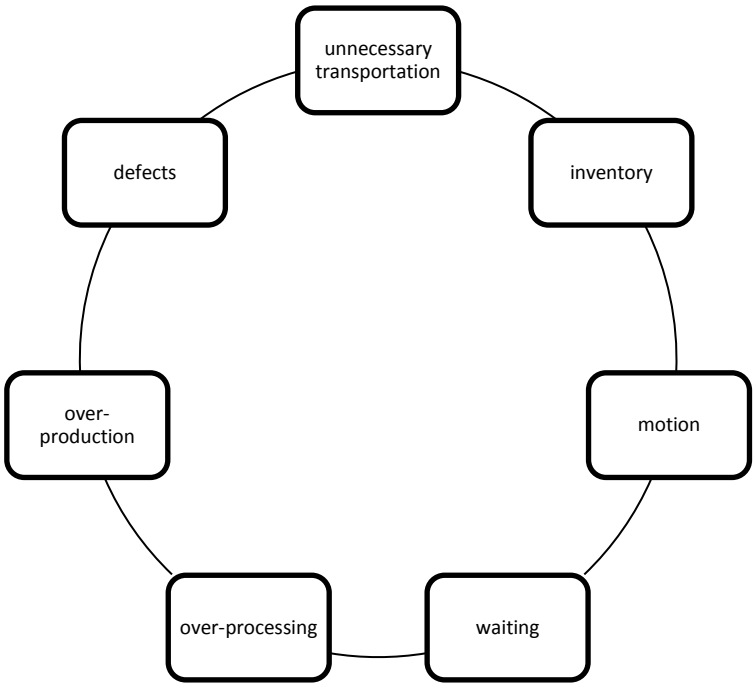


Figure 2: The seven wastes of Lean



Lean's five improvement stages and seven wastes are founded on customer value. Lean includes tools for identifying and removing waste activities from work processes, thereby creating flow in the patient pathways through the hospital. Processes are series of activities that are repeatedly performed in the care of groups of patients, and Lean interventions promote systematic ways of organizing, leading, and improving these processes(26). Improved processes are characterized by customer pull, avoiding queues and batching, and providing what the customer desires(27). Lean's focus on measurement and continuous improvement is expected to facilitate the implementation of more efficient patient processes and ensure sustainability(9, 23).

Originally, Lean was developed as a production philosophy, emphasizing standardization to reduce variation and increase the quality of work processes(28). In practice, Lean is often seen as a toolkit, where tools such as *value stream mapping* (analyzing the current state of a work process and designing a new, improved one) and *5S* (organizing the work-space for efficiency) are applied to improve the quality of health services(29). The simplicity and 'ready-to-use' features of Lean attract management and policymakers across fields and organizational borders to apply these tools domestically. Lean's global popularity is indisputable.

There are also numerous criticisms concerning Lean, especially regarding the fact that Lean increases work intensification and disengagement, standardization, and control ('Taylorism'), and rests on fantasy and exaggeration(19). In Norway, labor unions in particular exhibit skepticism towards the idea that Lean will improve working conditions and further respect for the employee. In effect, 'Lean is mean' is the adequate slogan, rather than 'work smarter not harder', according to Lean opponents.

2.2.2. Lean practiced at the hospital

So, what is expected to occur when implementing Lean in hospitals? Womack and Jones advocated Lean in hospitals, emphasizing involvement by patients and staff. The focus on zero defects, no delay, continuous improvement in care and 'just-in-time' treatment make health care well-suited for Lean(23, 30). In Lean terminology, patient care and treatment processes are chains of production. Multiprofessional improvement teams will map the patients' paths through the hospital, identify valued actions, and eliminate wastes and bottlenecks, thereby creating flow in these paths. Less variation in treatment should occur by means of standardized procedures.

Lean tools will assist employees in understanding processes and identifying and analyzing problems based on a shared understanding(31). Lean provides practical suggestions for improving work flows and work environments. Staff should be motivated, engage in the metrics and take responsibility for patient care, 'working smarter, not harder'. Lean is intended to improve error detection and raise staff awareness, thereby improving process reliability. Unwanted variation in treatment and care should be reduced, and staff members' well-being promoted. The presence of a stable and systematic, team-based approach is anticipated to nurture a culture of continual improvement and learning.

As an important aspect of Lean, the patient is viewed as a customer, presupposing that the patient is aware of the treatments that are offered, as well as the waiting times, possible clinical outcomes, and so on, in advance of treatment. The patient is informed, and can make qualified choices among treatments and hospitals. At a 'Lean hospital', the treatment is expected to be faster, more efficient, and safer. The quality of care should improve, and eventually the mortality rate should be lowered. The hospital is expected to save money, free up space and recourses, and become more effective and efficient. The focus on continuous improvement is expected to ensure sustainability and promote, speed up, and spread QI interventions over time(28).

The case hospital's strategy was a total roll-out of Lean, where improvement initiatives in one department should contribute to speeding up and spreading the approach to other departments(32). A few successful improvement projects were expected to enable spin-offs to other parts of the hospital via 'budding'. Knowledge of Lean was anticipated to spread through the organization, as a focus on bottom-up processes was expected to motivate staff to engage in improvement work. Identified redundant resources were to be redistributed inside the clinic and motivate further action. Successful implementation of improved patient processes would give rise to satisfied patients and staff, who would be the best ambassadors for additional improvement efforts. A step-by-step approach was expected to provide room for adjustments on the way, and ensure that no single department was disproportionately loaded with improvement work. In addition, experience was anticipated to make the projects more efficient and effective over time. In other words, a gradual roll-out was predicted to ensure continuous improvement.

During the project period, it was not possible to initiate independent Lean interventions at the hospital. Standardized procedures for application, project organization, implementation, measurement, and follow up were established. Permanent teaching and training programs for Lean thinking and Lean tools, and rapport- and information-systems, comprised all projects.

As part of the approval process, the local project managers created mandates including success criteria for each intervention. These criteria had to be concrete, quantifiable, and possible to measure, and involved improvement for:

- The patients, via quality improvements to treatment, service, and timely examination, nursing, and rehabilitation.
- The employees, via codetermination, improved working conditions, reduced stress, and additional time to conduct research and development work.
- The hospital, via improved capacity and efficient use of resources.

For measurement purposes, improvement data was collected prior to initialization, after implementation, and then at regular intervals. Specific schemes were developed for this reason.

Five paramount principles were launched for the Lean approach at the case hospital. These were that the improvement work should: be conducted by the staff, emphasize the patient, be anchored in the management, be part of a continuous improvement effort, and not be used as a tool for workforce – or economic – cuts. The campaign was relabeled, from Lean to *The Patient Path Project*, before it was introduced to employees.

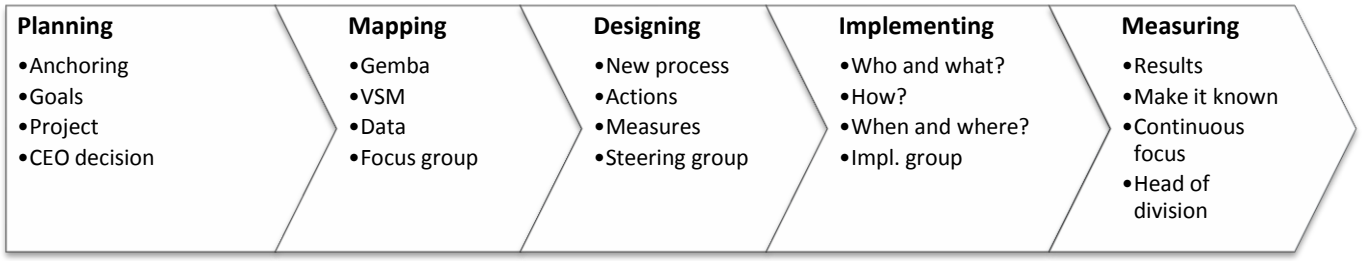
Each Lean intervention was organized as a project, including a steering group, a focus group, and, if necessary, a project and/or implementation group. A department-internal project manager (Lean consultant), who was trained in Lean philosophy and improvement techniques and tools, was responsible for running the project on a day-to-day basis.

The improvement work of each intervention was initiated by 'walking the processes'. The basic Lean term *Gemba* (the place where the work is done) stresses the importance of having detailed knowledge of the process you are intending to improve. The focus group walked the path of the patient, from entering the emergency department, through lab-tests and x-rays, transfer to bed wards, being treated and cared for, being dismissed, and leaving the hospital. The mapping also included collecting data concerning the patient processes at stake.

Based on the data and the walk, the focus group conducted value stream mapping (VSM), which mapped all the steps, waiting, communication, and information involved in the work process. By using the Lean principles and the seven wastes, they thereafter outlined a plan to improve the patient process by reducing waste and promoting flow in the remaining, value-adding steps of the process. The project group then prioritized the improvements, and the steering group made the final decision on which ones should be implemented. Smaller work groups planned the

implementation in detail. The head of each division was responsible for implementation and follow-up of the changes made. The typical phases of a Lean intervention are as described in Figure 3.

Figure 3: The phases of a Lean intervention



From 2008, more than 30 Lean interventions were initiated; by 2012, 17 of these had been implemented. At that time, more than 90 internal consultants and hundreds of employees at the hospital were engaged in Lean-based improvement work. Table 1 lists the 17 intervention subject areas and timeframes, from initiation to implementation.

Table 1: The Lean interventions. Areas and implementation periods

Acute stroke 2008–09	Drug addiction (referrals) 2009–10
Hip and knee surgery 2009–10	Geriatric psychiatry 2009–10
Blood test unit 2009	Drug addiction no-shows 2009–11
Laboratory 2009–10	Acute psychiatry ward 2009–10
Lung cancer 2009	Internal medicine ward 2009–10
Coronary angiography 2010	Multiple sclerosis 2010–11
Sepsis 2009–10	Child psychiatry 2009–10
Triage ED 2010–11	Health research law 2010–11
HR internal service 2009–10	

The Patient Path Project represents the most ambitious and resource-demanding quality improvement campaign in the case hospital's history, which makes it a suitable focus to study the outcomes related to the chosen method, in terms of what Lean is, and when and how Lean works(33). This can also answer questions such as: Is Lean worth the effort? Does it result in improvements? Does it work? And if so, what are the enablers – or barriers – for change?

An internal evaluation (2012) unveiled substantially varying outcomes of Lean interventions(18). Some succeeded, showing continuous improvement and sustainable results, while others faded out and left no traces of improvements. How can we make sense of the fact that interventions based on the same approach, at one single hospital, in a limited period of time, involving the same people and similar patient pathways, have such divergent fates? Why does Lean work sometimes, and not others?

3. Theoretical framework – An urge to cope with change

In this part of the thesis, I will present the status of the research field and theories considered relevant to Lean and QI. This is followed by a description of the theoretical approach applied in my dissertation.

3.1. Status of the research field of QI

After conducting a systematic literature review (2000–2012), I concluded that the available research on QI was immature, characterized by weak study designs and by a publication bias, with few studies discussing possible limitations to the application, design, or potential to generalize the findings(34). Several research articles supported that there was a lack of evidence for Lean's efficiency. A critical review concluded that most of the QI research has been dominated by questions of *what*, describing interventions' effect on a few, selected outcome measures, while not moving beyond to the *how, when,* and *why(35)*. There is a need for theories that link these, incorporating structure, process, and outcome, through inter-organizational studies, multilevel analytic techniques, mixed-method longitudinal studies, enhanced measurement, and expanded data availability.

In addition to the systematic review (see Paper I), I conducted a brief review of more recently published articles (2012–2015) concerning Lean in health care, which indicates minor progress in this field of research in recent years(2, 4, 34, 36-42). The findings can be summed up as follows:

- Enthusiasm about the potential of Lean is widespread in health care(4).
- Evidence of Lean's contribution to improved hospital performance is limited(42), and the results are rather mixed(36, 37).
- Rigorous research to assess Lean's impact on performance is lacking(42), especially in terms of implementation across the hospital(38).
- The fact that hospitals are diverse organizations limits Lean's application(40). Hierarchy, compartmentalization, lack of resources, and a weak link between

QI and strategy represent barriers for success, as do past history and backsliding to old practices.

- Most of the successful Lean interventions can be characterized as small pockets of improvement(4). The possibility to generalize across hospitals is limited(38, 39).
- Among the enablers for Lean success are a holistic approach; a culture of continuous improvement(40); leadership, empowerment and teamwork(2); and communication, training, reward systems and decentralized management(40).
- There is little knowledge regarding which enablers are most critical to success(41).
- Replication of Lean has not increased receptivity to QI(36).
- Embedding the changes made is challenging and demands high-quality data collection and measurement(36).
- Lean has considerable potential to improve organizational performance, but the outcomes are limited by poor application(36).

The lack of evidence regarding Lean interventions compared to the spread of Lean in health care is surprising(28, 43). Underlying this lack of evidence is the fact that QI is a hybrid discipline, involving both the science of social change and clinical research. Traditional health science is built on evidence-based medicine, while QI rests on theories of social change and change management. To put it simply, medicine concerns doing the right things, while QI concerns itself with doing things right(44).

There is a need to link evidence-based medicine and evidence-based management. Health science needs to take into account the organizational and community contexts(45), while QI research needs theory, refinement of design, and analytics. The observed gap between science and experience in QI is deeply rooted in epistemology, according to Berwick, who introduced the term '*the science of improvement'* in health care(46). QI interventions rely on leadership, context, and

social change. Berwick suggested that evaluating both mechanisms for change and local contexts would improve the evidence and help accelerate QI in health care.

There are three kinds of evidence that should be searched for: *theoretical*, which underpins and explains how and why QI is expected to work; *empirical*, which reveals under which circumstances, settings, or organizational contexts it works best; and *experimental*, providing practical lessons based on the experience of individuals and organizations in using QI methodology(21). This requires more research and greater skepticism regarding Lean.

3.2. Theoretical approaches in QI research

Varying outcomes of Lean interventions indicate that local transformation and context influence success. Lean is not a panacea, in contrast to the impression one may get by reading the success stories. Its nature, as complex, social, and context-dependent, has implications for the theoretical approach, the choice of research method, and the conclusions to be drawn. Studies of Lean interventions are studies of what happens when an idea encounters practice.

A theory is an organized, heuristic, coherent, and systematic set of statements related to specific questions, presented as a meaningful whole(47). It describes what is observed and why it happens. Theory development in QI is necessary to predict interventions; that is, what something is, what purpose it fulfills, and what is supposed to happen as a result(48). Theory warrants explaining why a variation between different sites occurs within a multisite strategy. Lean methodology and research, in its current, multifaceted form, suffers from a lack of articulated theoretical contributions and bases(2, 49). The lack of theory to guide the conduct of empirical studies may also be a reason for the absent evidence(50).

McDonald et al.(47) suggested that implementation research may contribute to reducing the quality chasm, including theories of transfer of knowledge and

behavioral change. They introduced a general hierarchy of theories by which QI researchers are inspired:

- Classical theories of change (diffusion and innovation theory).
- Planned models of change (Berwick's rules for dissemination(46)).
- Mid-range models (Shortell's levels for interventions(51)).
- Social-psychological theories (action theories).
- Organizational theories (rational and institutional models).

Pawson et al. described the nature of interventions themselves as theories (hypothesis underlying the program), active (dependent on the active input of individuals), and undergoing a long journey (a cumulative process)(33). (See sections 2.2.1 and 2.2.2, where I give an account of Lean interventions' program theory – or how it is supposed to work.)

3.2.1. Theoretical frameworks for research on Lean interventions

As a substitute for proof of Lean's effectiveness, there is a growing body of literature on enablers or contingency factors that promote QI(29, 52, 53). There is consensus that characteristics such as management, resources, and culture matter(25, 31), but the current knowledge base lacks specification regarding when and why the different enablers work. There is also little knowledge of which factors are most important, under which conditions, and in which implementation phases(52). Some have even argued that Lean thinking is deliberately vague and open to wide interpretation by opportunistic adopters(19).These observations address the need for a conceptual framework for change, emphasizing context by relating the enablers to interventions' domains and organizations' dimensions of capability.

Several theoretical frameworks have been developed to guide the implementation, reporting, or evaluation of QI interventions and evidence-based clinical practices. Among these are PARISH, ORCA, HRET, RE-AIM and QUERI(54, 55), all of which are in the test phase as valid measurement instruments for practical use. These instruments

have been developed on the basis of research that has identified essential determinants of successful implementation(56, 57); their ambition is to offer an assessment instrument for organizational readiness so that policymakers can assess readiness as part of the preparation for a larger QI effort(58). The underlying assumption is that a better understanding of facilitating factors enables a course of action with prospective outcomes. The aim of these heuristic frameworks is to compare interventions, evaluate them, and thereby set priorities for funding and reimbursement. These frameworks guided my research and study design. However, the lack of practical use of, and experience with, these frameworks makes them insufficient for evaluating real-world interventions at present(42).

3.3. The theoretical approach of the dissertation

This thesis concerns implementation. Implementation is the set of processes or activities that are designed to bring an intervention into use within an organization(59, 60). It represents the critical gateway or transition period between a decision to adopt an intervention and the routine use of the new work processes. An idea such as Lean that is found to be effective has no value (other than symbolically) to a host hospital if it does not translate into quality improvement for the patients, the staff, or the hospital itself. As mentioned initially, there is a profound gap between what is known to be best practice and what is actually done in health care. The outcomes of interventions often exist quite independently of the quality of the content of the idea. Some estimates have indicated that two out of three organizational interventions fail(59).

Implementation research is a large, robust, and growing family of research and theory building which acknowledges that it is not sufficient to know ‘what works’ in order to improve health care and other services. In addition, we need to know more of the events and actions of those who convert the idea into practice(59-63). Without this dimension, large-scale acceleration and spread of QI is impossible.

Implementation processes not only vary in size, but also take different forms, varying from paperwork in file cabinets and manuals on shelves (paper implementation) to actual change with good effects on patients (performance implementation). In addition, implementation processes have several stages, from adoption and program installation to full operation, innovation, and sustainability(60). The intervention itself is only the first step towards improving the quality of health care. Implementing it involves long-term hard work in order to ensure lasting quality improvement.

Durlak and DuPre(62) identified eight different dimensions in the process of implementation:

- Fidelity (the intervention's correspondence to the original program)
- Dosage (quantity, intervention strength)
- Quality (program elements delivered correctly)
- Participant responsiveness (interest)
- Program differentiation (uniqueness compared to other programs)
- Monitoring of control conditions
- Program reach (rate of involvement)
- Adaptation (program modification)

Recent reviews of implementation research have shown that the level of implementation affects the outcomes of interventions as effective implementation is associated with better outcomes(62), and that relevant implementation factors are common across domains(60). Contextual factors must be considered when interventions are implemented. Several implementation theories have been developed to increase the likelihood of successful implementation, based on different combinations of such contextual factors. Damschroder et al.(59) developed a consolidated framework for implementation research, offering verification about what works where and when (CFIR). Corresponding frameworks developed specifically for the QI field, such as QUERI, were mentioned earlier in this chapter (see Chapter 3.2.1.). These frameworks aim to facilitate identification and understanding

of relevant factors for successful implementation. Implementation frameworks, and impact and process theories, can guide the planning and design of implementation. In addition, theory may be employed to develop hypotheses about how various contextual factors and activities can facilitate quality improvement.

There are at least two main schools of implementation theory – one of which is a top-down and the other a bottom-up approach(64). The top-down school views implementation processes as being planned, governed, and controlled by the top management, which delegate the implementation 'down and out' through chains of local, loyal implementers in the organizational hierarchy. The bottom-up school emphasizes anchoring at the executive levels of the organization, where the professional workers are the prime force for implementation, based on their knowledge, significance, and experience. In addition, there is a third approach to implementation, which emphasizes networks consisting of complementary competences, where learning and motivation drives the implementation process forward in a tight, interdependent relationship between the idea and the context.

The slogan of implementation theorists may be simply put like this: Effective ideas for change and management programs must be implemented well to succeed. Thus, to understand more of why Lean does not always work, we have to remove the focus from the core elements of the idea of Lean, to the local adaption and implementation of Lean interventions. Are Lean interventions implemented with maximum fidelity or reinvented to suit local needs? How do these aspects of implementation affect the outcomes?

3.3.1. A translation approach

The top-down, bottom-up, and network schools of implementation theory are partly challenged and partly supplemented by the theory of translation. Translation theory incorporates the 'software', rather than just the material aspects of ideas, and views the host as an active part of the transfer of ideas. These are two good reasons to

introduce translation theory as complementary insights to those of implementation theory.

There is no doubt that Lean can be labeled a management fashion, where the collective beliefs about which management ideas lead to progress are continuously redefined inside the organization(65). Researchers have described the successive rise and fall of a number of QI concepts, in terms of life cycles of fads(19). Today's hot topics include Lean Thinking, Six Sigma and Patient Safety(21). The QI methods and philosophies all have a bell-shaped evolution, with each fad lasting for approximately four years. It has been claimed that this process of 'pseudo-innovation' is driven by methodology developers, as well as by demands and expectations of health care organizations. Progress does not occur if the shared beliefs remain stable for too long(65). At the case hospital, *Organizational Redesign* has been replaced by *Breakthrough Series Collaborative* and in the last decade by *Lean as separate initiatives*.

Fashion theory, which sprung out of neo-institutional theory, strongly emphasizes the supply side of management concepts: the fashion setters, the market, norms of rationality, and socio-psychological and techno-economic forces. The receiver is often treated as passive or imitative, mimicking those whom they consider to be superior in order to strive for conformity(66, 67). Organizational actors look for new ideas in response to their needs or demands from their surroundings(68), and gaps between actual and desired performance are the main drivers of management processes(65). Hospitals' urge for new management ideas is explained by an increased transparency and amplified demands for efficiency and quality improvement from patients, authorities, and society as a whole.

To understand why Lean has spread, and its uptake in hospitals, a stronger focus on the adaptation of management ideas and the host organization's absorptive capacity, and ability to identify, assimilate, and exploit knowledge, is needed(69). External drivers such as consulting firms, management gurus, business mass-media

publications, and business schools are all important in order to understand how Lean management travelled from the automotive industry in Japan to a university hospital in Norway. However, a more dynamic perspective is required to explain the embedding of Lean and the varying outcomes within the hospital.

It is the individuals constituting the host organization that bring the new knowledge into the organization, and that exploit it in terms of products and processes. The fact that absorptive capacity can be seen as a multilevel construct, which functions like a funnel to help organizations meet their specific needs, has been partly ignored in prior research(69). A stronger focus on stakeholders, organizational structures, levels, and processes may reveal the significance of internal knowledge transfer, translation, sharing, interpretation, and spread. In turn, this will contribute to identification of the enablers for change.

Several researchers have recognized the role of internal drivers and pinpointed the misleading passive role that is given to the receiving organizations in fashion theory(22, 70, 71). This links to another variety of neo-institutionalism: the field of translation theory. The theory of organizational translation of practices and ideas focuses on how ideas and various representations of practices travel in time and space(68, 72-76), in contrast with the diffusion model, in which the spreading ideas resemble physical and hardly changeable objects. Inherent in the diffusion approach is also the image of the adopters as passive receivers, and of an active central broadcasting point that provides the energy to the dissemination process. Translation theorists have conceived management ideas as immaterial accounts that are transformed as they spread. The power behind the dissemination does not stem from one single powerful source, but is created by the richness of interpretations the idea triggers in each actor within a network(77).

Latour suggested that the concept of diffusion should be replaced by that of translation, in order to embrace the spread of ‘anything’ by chains of actors who can leave it, modify it, deflect it, betray it, add to it, or appropriate it(74). According to

Czarniawska and colleagues, who introduced the ‘sociology of translation’, translation is the key concept for understanding organizational change(73), as it refers to the process whereby ideas are interpreted, filtered, reformulated, and tailored in particular organizational settings(78).

In translation theory, the host organizations behave as active translators of popular management ideas, copying some aspects and neglecting or altering others. This ‘internal stickiness of organizations’ involves impediments to the transfer of ideas within the organization; that is, the barriers of knowledge(79). There are several factors that influence the transfer of best practices, including the knowledge characteristics, source, recipient, and context. Lack of absorptive capacity, causal ambiguity, and an arduous relationship between the source and the recipient are the most important factors explaining stickiness. The host organization must adapt to the new practices, and to ‘make them fit’ to the local context. The ideas that flow the best are characterized as trustworthy, universal, and relevant; formed as general recipes(80). The popular recipes are claimed to be universal, well-calibrated tools for efficiency, and are linked to central values of modernity, such as rationality, renewal, development, and justice(76).

To gain legitimacy, organizations search for improvement ideas among other organizations they ‘look up to’(72). The ideas that are chosen are believed to be a compelling solution to the host organizations’ problems(76). However, the idea is decoupled from its original state by adapting some structures while simultaneously protecting the host’s own core activities through various buffers. To increase its transferability, it is de-contextualized and highly plastic at departure. Ideas travel, but are not untouched at arrival – they are translated, imitated, edited, and so on, to be contextualized into the host organization. In addition, there is already an established practice in the host organization, which the new idea has to be translated into, entangled with, and adjusted to(28, 81, 82). The idea has to be ‘boiled down’ to make it acceptable to local conventions(70). Watching ideas travel is synonymous with

observing a process of translation, rather than one of reception or rejection(83). A management idea such as Lean is unlikely to survive the translation fully intact(82).

According to Sahlin-Andersson, an intervention's success is not dependent on its origins, but on the process of translation(80, 84). In this process, new meanings are created and ascribed to activities, so that similar ideas are presented in a great variety of ways. Sahlin-Andersson introduced editing rules, or restrictions, for the ways models or ideas are translated, based on social control, conformism, and traditionalism. The first set of rules concern the context, as the idea prototype is disembedded and reembedded. The second set concerns the formulation and labeling of the idea, or the rules of 'telling a good story'. The third set of rules concerns rationality, where cause and effect are clarified to legitimate the idea as serious and true. Editing processes provide room for various actors to pursue their own interests, but, at the same time, problems, since the idea may be so plastic that it becomes difficult to implement(84). Thus, the management support ideas they think will lead to more efficiency, though these may turn out to be something else at the work-floor level(81). There is not one, rational, translator managing the host organization, but rather complex chains of translators(75). Translation is a multilayered process(70).

Røvik listed several blank spots in translation theory in a recently submitted paper concerning knowledge transfer as translation(85). Among these blank spots is the lack of examples of instrumental thinking; that is, how the translated versions of an idea affect the host organization's efficiency. What are the possible connections between organizing and outcomes of translation processes? Røvik also argued that few attempts have been made to make empirically based predictions about how translation processes are most likely to proceed, and about their probable outcomes under various conditions. What are the rules and regularities of translation?

I would like to add a third blank spot, concerning how the host organization manages the tension between allowing local adaptation and retaining control(86). In

translation processes, there is tension between standardization and variation; that is, preserving the core practice but still allowing local adaptation. The plasticity of lean may be a prerequisite for its popularity, and at the same time a reason for high variance in the outcomes of lean interventions. This reasoning will be given more attention during the discussion and conclusion chapters of this dissertation.

This tension between standardization and variation is made possible by the interpretative viability of the idea, leaving certain room for interpretation(87). Innovations consist of hardware (material) and software (ideational) components. On the other hand, ideas or concepts often lack a material component, which makes them ambiguous and receptive to local adaptation, resulting in pragmatic behaviors. It also makes such concepts very popular, because all kinds of organizations can recognize their own situation and a solution to their own challenges in the concept. Finally, this interpretative room also entails that it is difficult, if not impossible, to judge the efficacy of a concept per se(87). It is all a question of translation and local application.

More attention should be paid to local application and translation in order to understand the varying outcomes of Lean interventions (43, 88-90). Are there any patterns in the local application of Lean? And, if there are, do some key factors enhance success? My chosen theoretical and methodological approach will illustrate how local stakeholders eventually translate and transform an intervention, and thereby create different versions of Lean and consequently different interventions in different contexts. I believe that in order to understand varying outcomes, one must understand why and how the intervention itself has changed. This implies a shift of attention in QI research: from cause–effect to conditional attributions and to the transformative power of local translation processes (91-93).

In my research, I have explored the travel of Lean within a hospital by identifying local actors' perceptions of Lean through their images of enablers for successful interventions. These attributions represent the characteristics of Lean in practice;

that is, its prevailing version. By conducting a comparative analysis of 17 lean interventions, I search for patterns in the use of Lean. Are there certain local applications or key factors that characterize successful interventions, while others do not?

4. Outline of thesis, material, and methods – In search of evidence

Lean interventions should be regarded as complex and social, which implies that such interventions are not 'magic bullets' that always hit their targets, interdependent of context and local implementation(33). Context is understood as every factor that is not part of the Lean intervention itself(52). Lean interventions are dependent on individuals, and evolve as a cumulative process. Furthermore, the implementation chains are non-linear and fragile, as they are embedded in multiple social systems; they are leaky and prone to be borrowed, reinvented, and adapted to local conditions, so that the same intervention may be delivered in different versions. Finally, Lean interventions are open systems that feed back on themselves, as – due to learning – they change the conditions that made them work in the first place. It would be wrong to consider Lean interventions as simple before–after projects; they may more correctly be labeled as facilitated evolution(52), which should be reflected in the research by including the longitudinal aspects of interventions.

4.1. Description of the study and outline of the thesis

Initially, my approach towards the phenomena under study may be characterized as inductive. An inductive study design is exploratory, seeking new knowledge in areas of scarce prescience. The use of qualitative methods enables collection of data that contributes to a more detailed, nuanced picture of the phenomena, which in this case is varying outcomes of Lean interventions at the case hospital. However, as it progressed, my research turned in a more deductive direction, testing hypotheses based on theory and assumptions emerging from the literature review and conclusions of my previous work. Use of quantitative methods made it possible to test causal coherence and broadened my perspective from the particular features of Lean interventions at the case hospital to the general features of Lean, labeled as enablers for change. In addition to a test of enablers, I have developed a conceptual framework for QI interventions, generated a method for ranking interventions, and

suggested a possible framework for future testing of the implementation of QI interventions.

4.1.1. Paper I

The first article theorized the concept of context by establishing a two-dimensional conceptual framework that acknowledges Lean as a complex social intervention, deployed in different organizational dimensions and domains. The specific aim of this study was to identify contingency factors influencing intended outcomes of Lean interventions via an umbrella review, and to understand when and in which dimensions different factors contribute to QI in hospitals.

4.1.2. Paper II

In the second article, my co-author and I explored the travel of Lean within a Norwegian hospital by identifying local actors' perceptions of Lean through their images of enablers for successful interventions. These enablers were collected through focus group interviews that included managers, internal consultants, and staff. In addition, a survey was conducted to reveal the enablers' relative importance. Through this, it was possible to explore whether the enablers from the literature review (Paper I) were retrieved, and if other, not formerly known, enablers were put to use at the hospital. We applied an analogous conceptual framework as in Paper I, emphasizing the intervention domains to simplify the interpretation.

The specific aim of this study was to answer two main research questions:

- Is Lean translated during its travel within the hospital? If so, where do the translations take place, and who are the translators?
- How is Lean translated? Do such translation processes have any rules and regularities?

Based on these two questions, our ambition was to suggest to what extent varying outcomes could be considered consequences of whether and how Lean was translated.

4.1.3. Paper III

The last article explored how far various organizational designs of Lean interventions affect their success. The specific research question was as follows: How do various organizational designs, improvement targets, resources, and time horizons affect Lean interventions' impact, sustainability, and effectiveness? In addition, I examined whether the applied methods were suitable to test the implementation of QI in hospitals. An experienced Lean panel ranked the impact of 17 Lean interventions on outcome, sustainability, and effectiveness. The aim was to gain increased understanding of which organizational attributes may enhance success. The potential relationship between the interventions' rank and their project organization, targets for improvement, use of resources, and time horizon was analyzed using a linear mixed model. The ranking and analysis were based on quantitative, longitudinal data concerning the 17 Lean interventions before, during, and after implementation, collected from internal quality registries. The variables were chosen on the basis of the identified enablers quoted in Papers I and II, though they were limited by data availability. By utilizing the linear mixed model, I was able to test whether the identified enablers influenced the Lean interventions' success at the case hospital.

4.2. Shortcomings of the prevailing methods of QI research

Lean thinking is applied in health care institutions worldwide(31). Lean and other quite simple, production-oriented ideas can be challenging to adopt within a medical environment, which is characterized by evidence-based practice and highly educated professionals requiring scientific proof in order to take action(94). There is a fast-growing collection of studies trying to meet this demand for proof, by evaluating the effects of QI initiatives.

Initially, I will present a brief reiteration of the research methods' shortcomings. They lack empirical and theoretical coherence, as well as solid conceptual frameworks(95). Further, the strong interaction between the interventions and the context threatens the external validity, and too few studies have tested the effects systems of organizational factors have on quality. Finally, there is conflicting evidence on the outcomes: experimental studies have trouble identifying positive effects, while case studies have mainly reported positive outcomes of Lean initiatives(28, 36, 43, 95, 96).

Qualitative QI studies often include a narrow technical application that has limited organizational reach. Most of them are quite anecdotal, single-case studies. Inappropriate analyses and other methodological limitations undermine their validity(97). Studies of single-unit QI initiatives restrict the possibility to generalize and make comparisons, and limit the transferability. There are also difficulties attached to measuring effects. Improvement in one department can create 'bottlenecks' in others(51). Some reviewers also claim to have observed severe biases, caused by positive storytelling embedded in the culture of QI practitioners. There is a profound gap and tension between the medical approach and the QI methodologies(24).

Randomized controlled trials (RCT) are suggested as an alternative to qualitative case studies. Some QI research has copied methodologies from medical research, experiments, and testing of new drugs and clinical treatments(98, 99). However, most of these studies have not found any significant effects of Lean(43, 49, 94). This may be caused by the limitations of experimental methods, as they depend on fixed protocols that assume unidirectional cause–effect relationships, and try to control the influence of the context. Controlled trials are expensive and time-consuming, and do not take into account the fact that Lean interventions are adaptive, evolve over time, and mutually reinforce one another. Trials are not designed to say why an intervention varies according to the setting, as many features of the settings themselves are excluded(49).

The absence of evidence and weak designs may tempt researchers and policymakers to conclude that QI efforts have no effect on the quality of health care. However, before concluding that the gains of QI are limited, we must ask whether the choice of research method and design is to blame. Could it be that the study designs are correlated to a medical profession-based way of thinking, a kind of institutional logic, which is not congruent with the logic of Lean interventions(45)? Furthermore, is lack of evidence a valid justification for inaction(100)?

The social, complex nature of Lean thinking has implications for the choice of research methods. The literature review illustrates that both qualitative case studies and randomized controlled trials have constraints of their own in the attempt to answer whether Lean works in hospitals(43).

Mixed methods, as an umbrella term, comprise a combination of different methods. A combination of qualitative and quantitative methods can compensate for the drawbacks of single methods, which only partly answer the questions and present rival explanations. Through triangulation, the weaknesses of each method are believed to be compensated by the counter-balancing strengths of others. Among the benefits of mixed methods are converging or collaborating findings, minimizing alternative explanations, and elucidating divergent aspects of a phenomenon(101). Advocates have argued that different methods reciprocally extend one another, that the strengths of each method are capitalized, and that they encompass the richness of social phenomena. This, in addition to a stronger theoretical framing, may better enhance evidence for Lean efficiency.

4.3. Operationalization of core concepts

In the following paragraphs, the core concepts of quality in health care, successful interventions and organizational features will be accounted for.

4.3.1. On quality in health care

To evaluate the success of Lean interventions is ultimately to evaluate the quality of health care. This raises the fundamental question of what quality is, and for whom? Quality is often defined as the degree to which health services increase desired outcomes in accordance with professional knowledge, including six dimensions: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitability(102). In addition, our understanding of quality always reflects the prevailing values and goals of society(103). Choices I make about how to define quality, and for whom, influences the approach, the methods, the assessments and the results of the study. An explicitly declared definition of quality and the interventions' outcomes, and for whom, are therefore most important.

The difficulties of measuring quality are based on the fact that hospital services are multidimensional. The care delivered is affected by the facilities, the organization, competence, and interpersonal relations(104). There will never be a single comprehensive criterion through which to measure the quality of patient care. Outcomes – in terms of recovery, restoration, and survival – have many limits, even though they are frequently used as quality indicators(103). Outcomes can be irrelevant, difficult to measure, and influenced by other factors.

When evaluating the quality of health care, features regarding the structure and process of care should be included in addition to medical outcomes(103). Lack of knowledge concerning the relationships of structures, processes, and outcomes makes it difficult to recommend organizational changes that could improve patient care(105). There are three aims of improvement: better health, better care, and learning, all of which must be improved if a change is to produce real improvement(106). To verify that a change is an improvement, we need to measure the outcome for the patients (health and wellbeing), the staff (learning and job satisfaction), and the hospital (care services and efficiency). Interventions' effects on these three areas are used as a measure of QI in this study.

4.3.2. On successful interventions

This dissertation focuses on the success of interventions. *Effectiveness* is defined by whether the established success criteria are achieved. In addition, the varying range and durability of interventions must be taken into consideration when assessing success(107). Therefore, I added two more aspects of success in the assessment of Lean interventions: impact and sustainability. Some interventions have a wide range and great ambitions, which predict a massive impact on complex patient pathways, while others are bounded to incremental changes in a confined work process. This aspect is labeled *impact* in this study. Finally, some interventions have long-lasting, sustainable results over years, while others 'flop', and the staff returns to previous routines soon after implementation. Here, this assessment of the durability of improvements is labeled *sustainability*. My assumption is that these nuances better illustrate the relationship between the *what, how, when,* and *why* of Lean success.

4.3.3. On organizational features

There is a call for stronger attention to be paid to the organization, and especially organizational context, in order to understand and explain variance in implementation and outcome(108, 109). As a contribution to bridging the implementation gap in health care, Radnor et al.(3) recommended moving away from Lean's tool focus and towards a system-level approach in which Lean is contextualized. The authors suggested that Lean's varying outcomes are a result of organizational and managerial weaknesses, rather than cultural resistance.

Together with findings from the umbrella literature review(34), the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines constitute a framework for the organizational features that are included in this study(110). The SQUIRE guidelines include information regarding the interventions' background, local problem, intended improvement and setting, outcomes, and limitations.

4.4. Design, instruments, and process

This study was initiated by a systematic review of reviews – an umbrella review – which concluded that the research field was immature, and that there was an unfulfilled need for proof that Lean works in hospitals, among managers and health workers. This led to a shift of focus from cause–effect to conditional enablers for Lean interventions. In carrying out the literature review, we learned that there are multiple factors that may facilitate – or hinder – quality improvement. Most hindrances were simply opposites of the enablers(42). We decided to focus on enablers, based on the fact that the literature chiefly pays attention to enablers rather than barriers(24, 31, 49).

The enabling factors were both numerous and vague; thus, it was difficult to use them as guidance for successful implementation. To succeed, one must have 'the right culture, the right people, the right in-house processes and the right tools'(91). The generic requirements of QI were not sufficiently well established: 'to want to do it' is not enough; in addition, one must be able to do it, and know where to make a contribution(111).

To strengthen the utility of these potential enablers for QI, we developed a conceptual framework, comprising dimensions of capability and domains of an intervention. O'Brian and Shortell developed a Continuous Quality Improvement model including four *dimensions of capability* that are necessary for successful implementation(112):

1. Cultural: underlying beliefs, values, norms and behaviors of the organization
2. Technical: competency and training in methods and tools supporting systems
3. Strategic: alignment with the organization's priorities and strategic plans
4. Structural: management systems and structures that facilitate learning and the spread of best practice.

The dimensions are multiplicative, interrelated and equally necessary to accomplish improvement, and in practice, the interplay of dynamic processes is related to the four dimensions.

Walshe(43) differentiated between four domains of interventions: the context (the setting or situation in which the intervention is deployed), the content (the nature or the characteristics of the intervention), the application (the local delivery process), and the outcomes (the results including the maintenance phase). These domains may be understood as stages or phases of the intervention, all of which may be characterized by low or high variance. Walshe's use of the concept of 'context' (setting/situation) must not be confused with the general use of the term in this dissertation and elsewhere, where context is understood as all surrounding factors that are not part of the intervention itself(52, 108).

By combining Shortell's dimensions and Walshe's domains, a two-dimensional framework was developed and applied to describe and better understand the contextual factors encountered in a QI effort (Table 2). The framework incorporates the complex social and organizational context in which Lean interventions are applied.

Table 2: Framework for QI interventions' domains and dimensions of capability

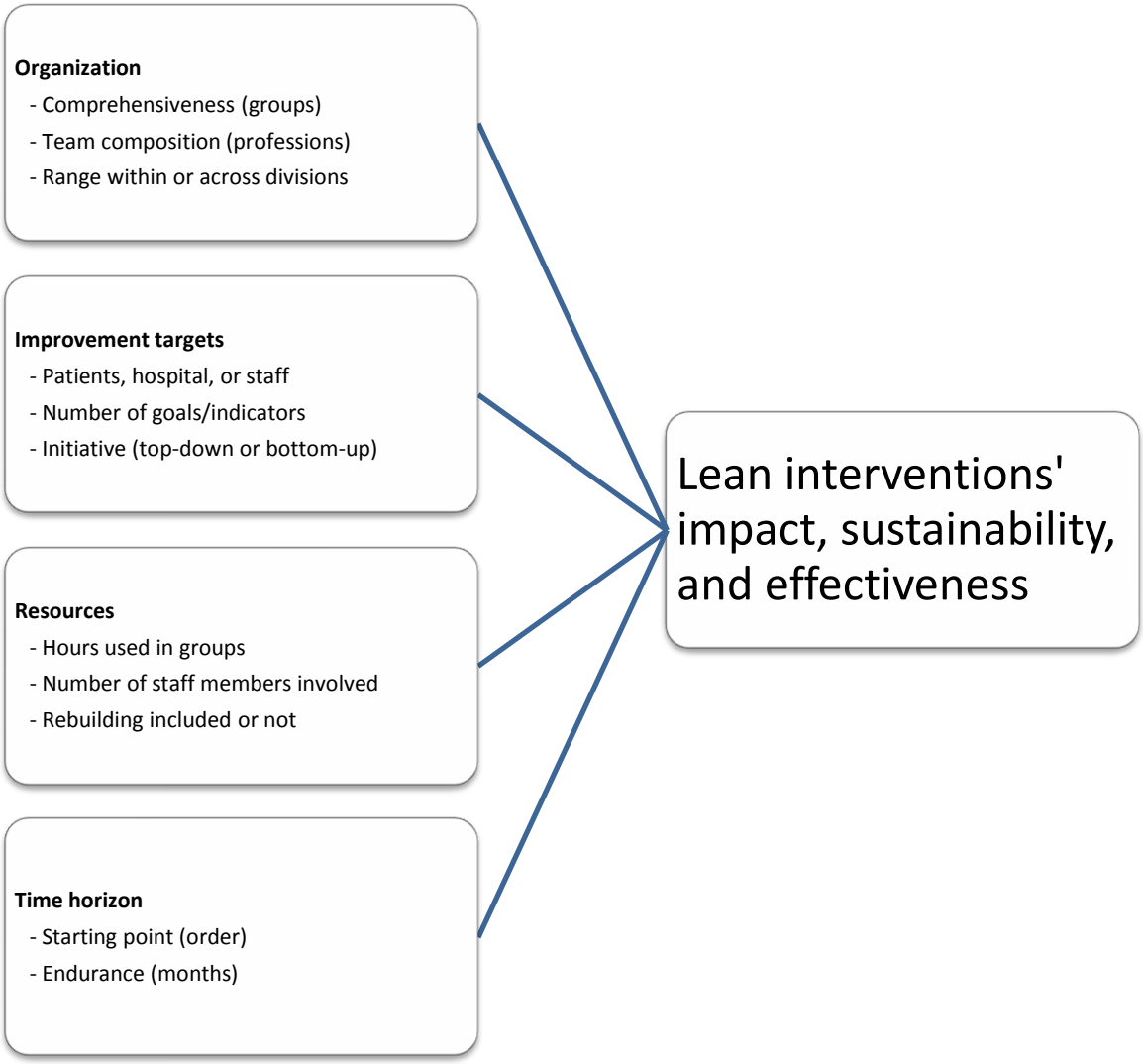
	Domains of the intervention	**Context** Situation and organization	**Content** Characteristics of the intervention	**Application** Local delivery process	**Outcomes** Results and maintenance
Dimensions of capability	Cultural	Underlying beliefs, values, norms and behavior			
	Technical	Training and information-support systems			
	Strategic	Strategic importance and opportunity to change			
	Structural	Mechanisms to facilitate learning and best practices			

The boundaries between the intervention and its surroundings are relatively arbitrary, which challenges a strict distinction between interventions and context. Lean interventions are open systems that feed back on themselves. They may change the conditions that made them work in the first place. This challenge also applies for the categorization of different enablers in one specific dimension and one specific domain, as all enablers constitute parts of situation-dependent cumulative processes.

Subsequently, we identified local enablers for comparison with those identified in the literature. This was done through focus group interviews at three different hierarchical levels, along with a survey, which made it possible to shed light on Lean's travel within a hospital. Local actors' perception of Lean was identified through their images of enablers for successful interventions.

To answer the main question of varying outcomes of Lean interventions, I focused on organizational and contextual variables that are believed to relate to Lean's success. This was done with the aim of contributing to reducing the gap between science and experience, by clarifying some of the relationships between the design, the implementation and the outcomes of Lean interventions. Figure 4 illustrates the chosen research model.

Figure 4: Research model



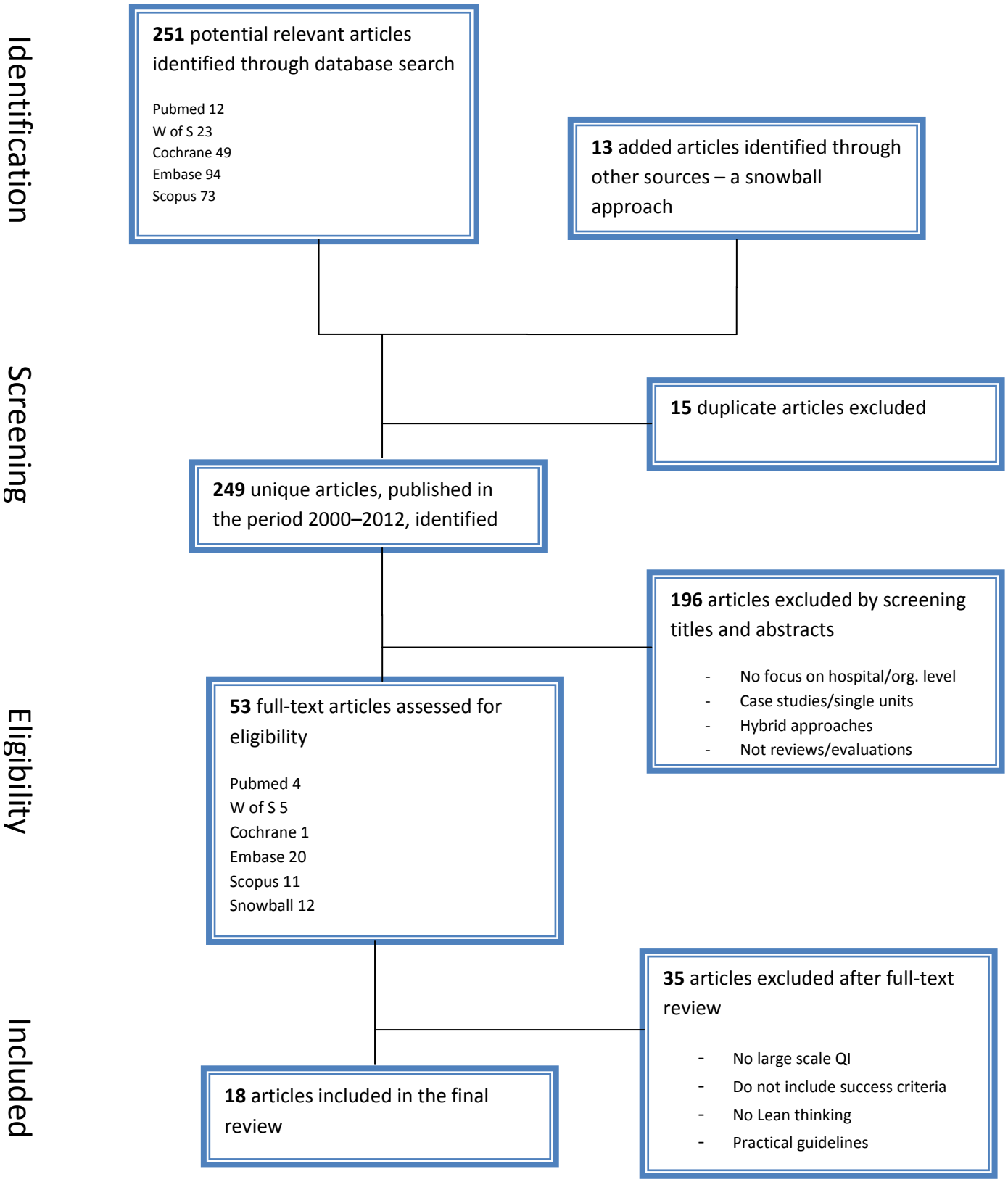
The dependent and independent variables are described more closely in Chapter 4.5.3.

4.5. Data collection, quality and analysis

4.5.1. Paper I

In Paper I, an umbrella review of research on QI in hospitals was conducted. The review only included articles concerning Lean thinking that were published between 2000 and 2012, and it was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines(113). The research strategy is accounted for in Figure 5.

Figure 5: Flow chart of the detailed search strategy



A total of 18 articles met the inclusion criteria; these were searched for any references to enablers, which are defined as contingency factors predicted to promote QI. The articles were systematically analyzed and recorded in a standardized format using feature maps(114). The 149 identified enablers were then assigned to larger categories, resulting in a list of 23 identified enablers for QI in hospitals. Subsequently, these were analyzed and reorganized into a conceptual framework combining four dimensions of capability (cultural, technical, strategic, and structural) and four domains of an intervention (context, content, local application and outcomes)(43, 112). The purpose was to provide a classification of the enablers as emerging in different domains in a multistage process and through different organizational dimensions.

4.5.2. Paper II

Local enablers for Lean interventions were collected through separate, semi-structured focus group interviews including three groups of stakeholders at the case hospital: 8 leaders of steering groups, 14 internal Lean consultants, and 11 members of staff participating in implementation groups. This sample was considered representative of the population. 8 of 10 steering group leaders and 14 of 17 internal consultants attended the focus group. Representatives of the staff were invited by drawing lots from a list including all employees that had participated in Lean improvement work. The total sample of 11 was considered to be sufficient to represent the population. All included participants had first-hand Lean experience during the relevant period (2008–2012), and all of the 17 Lean interventions were represented.

The critical incidence technique (CIT) was utilized for the data collection(115). CIT was introduced to the social sciences by Flanagan (116) in 1954, initially by observing ‘critical incidents’, but over time based more on reports provided by the research subjects, as a substitute for direct observation(117). This qualitative interview

procedure investigates significant processes and perceived outcomes, as identified by the respondent(115).

The participants were asked, in two different ways, to emphasize the incidents that they believed made the most important contributions to the intervention. The questions were: 'Regarding the Lean project you participated in, what would you say were the most significant incidents or processes that contributed to the project's success?' And, 'Regarding the possibility that the project did not succeed, which incidents or processes could have contributed to increased success?' The participants were not familiar with the findings from the literature review.

Subsequently, the identified incidents or processes were defined as enablers for quality improvement. The identified enablers were assigned to 44 larger categories, based on the assumption that broad conclusions increase the study's relevance. I conducted the first systematic classification of the data, consulting my two supervisors on the matter of merging enablers into larger categories. Thereafter, we systematized the enablers according to the four domains of interventions applied in Paper I: the context of the intervention, the content of Lean, local application, and outcomes.

An electronic survey (Questback) was conducted to reveal the relative importance of the enablers. A total of 363 employees registered as participants in Lean projects received an e-mail in which they were asked to confirm that they had participated in Lean projects. Of the 197 that responded, 165 confirmed, and completed the survey. The total number of participants is summarized in Table 3.

Table 3: Study sample and data collection method

Stakeholder group	Focus group interview	Questionnaire	Total number
Steering group Leaders/members	8	40	48
Internal consultants	14	23	37
Implementation staff	11	102	113
Total number	33	165	198

The respondents were asked to point out the three most important enablers within each of the four domains. We made use of the 44 enablers identified in the focus group interviews, and the systematized four categories of enablers. The respondents chose the three enablers in each category they believed was most important for the Lean project's success; that is, the three factors concerning the context, the content, the local application and the outcomes of the project that were the most significant for its success. In addition, they were asked to identify other possible enablers that were not accounted for in the survey.

4.5.3. Paper III

Data concerning the 17 Lean interventions implemented at the case hospital in the period 2008–2012 was selected and collected from internal quality registries on the basis of the research questions, the findings from Papers I and II, and the SQUIRE guidelines(110). SQUIRE is a 19–item checklist for quality improvement reporting and publication, and was applied as such. The checklist emphasizes the background of the intervention and the local problem at stake, among other factors, which helped me to ensure that important nuances of the intervention were collected and reported. The data especially emphasized the success criteria and indicators of each project, followed by their qualitative and quantitative outcomes at three or more measuring points; before, during and after implementation. See Table 4 for details.

Table 4: Data collection of factors describing Lean interventions*

Area under consideration	**Factors**	**Description**
Setting	Initiative	Initiation by management or staff
	Sequence	The numerical order of projects' start-up
	Scope	Comprising one or more departments
Issue	Problem	Description of the problem that needed to be solved
	Purpose	Articulated general purpose of the intervention
Goals and indicators	Success criteria	Outlined goals established by the project
	Indicators	Outcome measures defined by the project
	Focus	The number of success criteria and indicators that were expected to improve the conditions for patients, staff, and hospital efficiency
Intervention	Organization	Use of steering groups, project groups, focus groups and/or implementation groups
	Participants	Number of participants and professions represented
	Initiatives	List of initiatives taken (planned and/or executed)
	Use of time and resources	Number of hours used in meetings, endurance of the project (in months) and any rebuilding
Results	Outcomes	Qualitative and quantitative outcomes due to the given success criteria and indicators at a **minimum of three measuring points** before, during, and/or after implementation
Continuous improvement	Spin-offs	A description of known spin-offs of the project
	Present status	Status as in progress or implemented, based on a judgment by the project management

*All data is gathered in spreadsheets and can be provided upon request.

Data collection was restricted by accessibility to data in the local quality registries, which implies that not all the identified enablers were encompassed in the analysis. The local quality registries were established for purposes other than those pursued in this study, which implies that the data does not necessarily 100 percent fit the definition of each enabler. This point can be exemplified as follows: in order to test the enabler *Customer Focus,* I collected data from all 17 interventions concerning patient-oriented goals and indicators (as distinct from hospital- or staff-oriented goals). In addition, some of the enablers were not suited to operationalization in quantitative terms, and were therefore excluded. The enablers *Realism and Patience* and *Credibility* are examples of this. For these reasons, I chose not to apply the conceptual framework from Papers I and II in Paper III. However, in this dissertation, the framework is applied to juxtapose the findings of Papers I, II, and III (see Table 5, Chapter 5.4).

A method for ranking interventions was generated based on a Likert scale and on three aspects of interventions' overall success: impact on outcome, sustainability of the results, and effectiveness – that is, degree of goal achievement(107). In order to rank the success of the 17 projects, a panel consisting of the 11 most experienced Lean consultants at the hospital was established. Owing to Lean's social and complex nature, a nominal group technique was chosen(118). The panel conducted ranking of the 17 projects based on the collected data (see Table 4). The covariance between the panel's judgment of effectiveness, impact, and sustainability was calculated using correlation coefficients (Pearson's *r*). A univariable and stepwise backward multivariable linear mixed-model regression was applied to analyze associations between the design and the success of interventions.

4.5.4. Approval

In Norway, medical and health service research organizations are regulated by the law of June 20, 2008, no. 44 *Helseforskningsloven*. The law's objective is to promote rigorous and ethical research. Quality assurance as part of the health service is not mandated by the law.

This study is categorized as a QI project, whose aim is not to present new knowledge of health or diseases, but to study the effects of an organizational intervention regarding the quality of the services provided, the staff's work satisfaction, and the overall efficiency at the hospital. Therefore, the abovementioned law does not impact this study, meaning that approval from the Regional Ethical Committee was not necessary, as approval from the Privacy Ombudsman for research at the hospital was sufficient. The Ombudsman's job is to ensure information and personal data are protected. His approval stated that informed consent from the patients was not needed, since the data was collected from ongoing QI work at the hospital, and since the data had been depersonalized before it was handed over to the researcher.

5. Synopsis of the results – A snapshot

A short synopsis of the results from the three parts of the dissertation is presented in this chapter. The three studies constitute separate parts of this dissertation, and will therefore not be repeated here. For detailed information and a complete overview of all the results and conclusions, see the three papers and their appendixes at the end of this dissertation.

5.1. Paper I

The aim of the umbrella review was to identify factors facilitating intended outcomes of Lean interventions, and to understand how and when different enablers contribute to QI in hospitals. Among the 18 reviewed articles included in this study, 149 enablers for Lean interventions were found. These were categorized into 23 extensive classes, which are subsequently presented by frequency. The most frequently identified enablers were as follows (frequency reported in brackets):

- Management: Leadership support, ownership, and commitment (13)
- Supportive culture: Views, norms, and beliefs that support QI (10)
- Accurate data: Robust and timely, evidence-based data as an impetus to change (8)
- Physicians: Clinical leadership and champions' engagement, support, and collaboration (8)
- Teamwork: Multiskilled and multidisciplinary team collaboration, including decision-making (8)
- Training: Accessible, substantial, practical, and relevant training for immediate use (8)

The other identified enablers were: vision (targets and solutions), customer focus (including patients and the workforce), external support (sponsorship), staff involvement (empowerment), resources (capability), communication (patients and staff), alignment (to strategic priorities), IT systems (infrastructure), continuous

improvement (sustainability), system-wide scope (across silos), prior experience, administrative support (practical facilitation), competence (in tools and methods), a holistic approach including everyday improvement, belief in benefits (motivation), local adaptation, and measurement (local audits).

5.2. Paper II

The aim of this study was to examine whether Lean had been translated, along with how, where, and by whom. The findings indicate the extent to which varying outcomes can be considered a consequence of how Lean is translated. All the enablers identified in the literature review, except for the need for external experts, were retrieved at the case hospital. In addition, we identified more than 20 local, supplementary enablers, of which two-thirds were viewed to be among the most important ones for the success of Lean. These were:

- Management-structure support (coordination and continuity)
- Need for change (perceived need, potential for improvement)
- Bottom-up (improvement suggestions from the floor, voluntariness due to initiative)
- Problem, not method, focus (Lean as a meeting place)
- Credibility (no bragging, trustworthiness, no camouflaged dismissals or cuts)
- Internal consultants (project management skills, mentors, and network)
- Few, palpable measures (definite, quick results, visual success stories)
- Realism and patience (distinct mandate, demarcation, small projects, adjustment)

The retrieved enablers assessed as important were: vision, customer focus, teamwork, and a holistic approach. These features describe the characteristics of Lean in use; that is, the prevailing version of Lean.

The management, consultants, and staff had different images of Lean, depending on their hierarchical level. Both the management and consultants gave preference to

their own role, while the staff emphasized the need for decentralized decision-making, clinic-anchoring, and continuity of staff.

5.3. Paper III

The aim of this study was to gain an increased understanding of which organizational attributions may enhance the success of Lean interventions. The panel assessed the effectiveness, impact and sustainability of 17 local Lean interventions. A total of 30 percent of the interventions were assessed as successful, 60 percent were assessed as moderately successful, and 10 percent as unsuccessful. There was a relatively strong correlation between the panel's judgment of sustainability and effectiveness (Pearson's r = 0.83), while the correlation between effectiveness and impact (r = 0.52), and impact and sustainability (r = 0.47) were weaker. The inter-rater reliability varied from 0.10 to 0.36 (RSD).

Comprehensive project organization (β 0.30 (CI 0.18–0.43)), multidisciplinary teams (β 0.16 (0.08–0.24)), improvement for patients (β 0.15 (CI 0.04–0.19)), participation by employee- and safety staff (β 0.25 (CI 0.89–0.41)), and a reach across organizational silos (β -1.39 (CI -1.96– -0.81)) were statistically significant with regard to effectiveness. Participation by employee- and safety staff (β 0.22 (CI 0.07–0.37)) and top management's attendance (β 0.14 (CI 0.10–0.18)), improvement for patients (β 0.13 (CI 0.06–0.20)), and hours used (β 0.01 (CI 0.00–0.01)) were related to the impact on outcome. A reach across organizational silos (β -0.45 (CI -0.75– -0.19)), employee- and safety staff participation (β 0.44 (CI 0.29–0.60)), comprehensive project organization (β 0.22 (CI 0.08–0.36)), and improvement for patients (β 0.18 (CI 0.11–0.26)) were related to sustainability.

5.4. Juxtaposition of the results of Papers I, II, and III

In Table 5, the main results of the three papers are collated. The identified and tested enablers are classified as emerging in different domains of the multistage process of the Lean intervention.

Table 5: Juxtaposition of enablers that matter – Papers I, II, and III

Domains of the intervention	**Context** Situation and organization	**Content** Characteristics of intervention	**Application** Local delivery process	**Outcomes** Results, maintenance
Main findings from the umbrella review (paper I)	Vision Targets of urgency and direction, but realistic, simple and practical solutions External support Expert change agents, networks and sponsorship	Customer focus Patient/workforce value creation Training Accessible, substantial, practical and relevant, for immediate use Resources Available, sufficient and accessible Accurate data Robust and timely, evidence-based	Teamwork Multiskilled and –disciplinary collaboration incl decision-making Physicians Clinical leadership and champions' engagement, support and collaboration Management Leadership support, ownership and commitment Staff involvement Commitment, engagement and empowerment	Supportive culture Views, norms and beliefs supporting QI
Main findings from the focus groups/survey (paper II)	Management structure support Organisational structural support, coordination and continuity Vision Need for change Perceived, potential for change	Customer focus Bottom-up Initiative from the work-floor, voluntariness Problem, not method focus Lean as a meeting place	Teamwork Credibility No bragging, trustworthiness, no camouflaged dismissals or cuts Internal consultants Project management skills, mentors and network	Few, palpable measures Concrete, quick results, visual success-stories Realism and patience Distinct mandate, demarcation, smaller projects, adjustments Holistic approach Lean as an entire value system, embracing everyday improvement
Main findings from the linear mixed model analysis (paper III). Factors related to a) impact b) sustainability c) effectiveness and d) no statistical significant relationship	Comprehensiveness in project design (bc) Use of steering-, project-, work-, or implementation groups Endurance (d) Months from start to implementation	Initiative (d) Made by management (top-down) or staff (bottom-up) Main target area improvement for • Patients (abc) • Hospital efficiency (d) • Staff (d) Rebuilding included? (d) Amount of hours used in work groups (a)	Team composition • Multi-teams (c) • Top-management (ac*) • Employee- and safety representatives (abc) • Physicians (d) Number of participants in work groups (d)	Number of goals and indicators (d) Starting point of each project (d) Organisational range (bc) Within or across divisions

* Negative relationship between top management and effectiveness

6. Discussion – Is there more than one way to skin a cat?

Having access to extensive data covering 17 interventions within one hospital seemed to provide a golden opportunity to conduct systematic comparative analysis. The hospital has implemented many Lean interventions, with varying degrees of success, over the last six years. This gave me relatively easy access to a rich portfolio of comprehensive, longitudinal data. Traditionally, hospitals have applied Lean methods in small parts of the organization, producing only small-scale local gains, or small pockets of improvement(3, 4). In contrast, this was an organization-wide, ambiguous initiative.

There may be disadvantages attached to this choice of study object, which will be discussed in the following. Even so, I claim that through systematic statistical comparison of social interventions, we can generalize, within limits, what works in which context, when, and in what order(119).

Based on the results of the analysis of this dissertation, I make the following conclusions: (1) to achieve successful QI in hospitals, policymakers should invest in time and organize a comprehensive project; (2) the interventions should engage multidisciplinary teams including employee- and safety staff representatives and pursue improvement for the patients across divisions; and (3) refinement of design and analytics contributes to the knowledge of organizational change management, and promotes sound investment in quality improvement.

6.1. Implications

To recapitulate: Lean's plastic nature has implications for the choice of research method and the conclusions to be drawn. The research field is characterized as immature; experimental studies have shown barely any effects of Lean interventions, while qualitative case studies have reported positive effects, but suffered from methodological weaknesses. This has directed researchers away from seeking proof of Lean, redirecting them towards questioning why, how, and when Lean works. This

is also the path I have chosen in this study, with the aim of contributing to the methodological and theoretical shift from cause–effect ('hardware') to conditional characteristics ('software') of successful Lean interventions.

Several recent studies have indicated the conditions for improvement that may influence success, but there are some blank spots in our knowledge of Lean enablers. I especially want to pinpoint two aspects that formed my methodological approach. Firstly, there is a large amount of literature concerning enablers, but less knowledge exists about which conditions are most important (52). The comprehensive literature review we conducted as a part of this study contributes to the science of improvement by reporting the frequency of different enablers. This responds to the claim that future Lean-thinking research needs to evaluate the components that are most critical for interventions' success(89).

Secondly, the identified enablers are unsuitable to guide policymakers' choices in QI efforts, since they are vague, broadly defined, and comprehensive. A successful QI is dependent on knowledge of what to do, and where to make a contribution(91, 111). Our focus group interviews with management, consultants, and hospital staff not only confirm the enablers identified in the literature review, but also supplement the picture by adding both novelty and several nuances to the established knowledge base. Through the development of a conceptual framework, it is possible to locate enablers at the stages and levels in which they are activated. This can guide decision-makers considering QI work in their assessment of the organization's readiness for change(57).

The findings of the focus groups and the survey also need to be commented on with regard to the translation that happens when Lean encounters health care. On its travel within the hospital, different versions of Lean were revealed. We describe the transformative power of translation, where Lean appears in different forms depending on where, when, and who one asks. We believe that translation is part of the explanation for the lack of evidence to support Lean, and that it can be decisive

for outcomes; that is, for Lean's success or failure(93). This insight contributes to future Lean implementation by advising policymakers to recognize the transformative power of translation, and tailor Lean to local circumstances in order to achieve successful interventions accordingly. It is not a question of whether Lean works, but of whether the implementation of Lean works.

So, how should QI interventions be tailored? The multivariable linear mixed-model regression analyzed associations between interventions' different designs and their impact, sustainability, and effectiveness, offering valid knowledge concerning what promotes QI. These findings can advise policymakers on how to better invest in organizational change management.

6.1.1. Reliability

High reliability or reproducibility is of great significance in QI studies, given the immaturity of the field and the need to accelerate and disseminate tools and practices that improve the quality of health care(103). In this study, reproducibility of the findings is made possible by ensuring easily accessible data, which has mainly been published online in open-access journals, in addition to establishing an electronic study database, where I have stored a detailed and systematic description of the collection, registration and analysis of all the included data.

The review was conducted following the *PRISMA* guidelines for reporting reviews and meta-analyses(113). The focus group interviews were guided by the critical incident technique(115) and the COREO checklist(120). Data concerning the 17 Lean interventions was collected based on advice from the SQIRE guidelines. These guidelines were developed to strengthen reliability by minimizing errors. In the univariable and stepwise backward multivariable linear mixed-model regression, the Statistical Package for the Social Sciences (SPSS) software version 22 (IBM Software, NY, USA) was applied.

Another main aspect of reliability is avoiding bias(121). In this study, the risk of bias was reduced in several ways, firstly, via close cooperation with my co-authors in data collection and registration; secondly, by making the research steps as operational and transparent as possible; thirdly, by checking the reliability through repetition of the data collection process of the review, and by separating the panel into two different groups.

I also assessed the inter-rater reliability of the panel members. A relative standard deviation (RSD) of < 15 percent is characterized as low variance; that is, a high degree of inter-rater agreement. The RSD varied from 10 percent to 36 percent among the ranking conducted by the members of the panel. The interventions that show the highest variation in rank involve administrative processes, rather than patient pathways (HR service, health law implementation, triage system). The fact that the inter-rater agreement is low in these cases may have limited the reliability of the findings.

There may be a risk of bias because of my own contribution to the study, as a researcher who analyzed, interpreted, and edited all the data into succinct journal articles. The case hospital is my workplace; as such, I know the people there and the Lean initiative, since I took part in the early stages of its introduction at the hospital. There are advantages and disadvantages related to such a close relationship to the object of study. One obvious benefit is the possibility of applying my own prior, expert knowledge as a resource in the research process. Knowing the organization and the people that constitute the case makes it possible to save time and resources, and to avoid misunderstandings during the research process. Knowing the language and local culture may also reduce the interference an investigator often creates.

Because I know the case hospital quite well, there was a risk of oversimplification of the description of the interventions and the local context (assuming that others know what I know). It was also a risk that my view of the interventions' success would color the research and its conclusions. I took several precautions to prevent this kind of

bias. I had to ensure a sufficient distance to the case study by leaving my job as patient path coordinator in 2010. In addition, I challenged myself to always wear 'critical spectacles' when I studied, analyzed, and reported my findings. My supervisor, among other 'outsiders', has read all the drafts, and was asked especially to bear this risk of bias in mind. In addition, by using two experienced groups to rank the interventions' success based on qualified judgments and solid, identical documentation, my personal interference with the study object was reduced. However, the risk of investigator bias or Hawthorne effects cannot be completely ruled out.

My PhD was financed by the regional health authorities, Helse Nord RHF, through their research program in collaboration with the University of Tromsø. The University Hospital of North Norway is governed by Helse Nord RHF. Thus, there may be a risk of financial constraints connected to my research. However, the regional health authorities are not my employer as a researcher, and the project cannot be characterized as contract research. Furthermore, Helse Nord RHF did not choose or influence the research question by any means, and no future usage of the results has been promised to this institution. Except for electronic annual reports, there was no contact between Helse Nord RHF and me during the research period. I therefore consider the research and researcher's distance from the financial institution to be satisfactory.

6.1.2. Validity

There are two primary kinds of validity that need to be considered: external and internal. External validity is understood as applicability beyond the hospital at hand. Low external validity in QI research represents a major barrier for the spread of successful QI interventions from one organization to another. Common views of whether the findings from one organization are applicable to another may be even more critical in health care. To prevent harm, no new clinical practice is introduced without previous comprehensive, long-lasting testing (RCTs). The evidence-based

culture of medicine challenges social scientists to apply the most robust design possible to maximize external validity(122).

Case studies rely on analytical generalization, in which the researcher aims to generalize the results to theory in the same way that results from experiments are generalized to theory(121). The findings of my comparative analysis represent theory, as the enablers are related to Lean success. The systematic comparison across cases makes it possible to generalize, within limits(119). Findings from multiple cases are considered more compelling, and thereby more robust than singe cases are(121). Nevertheless, the degree of applicability to other contexts must be documented and made plausible by the author.

The external validity may be confined by the number of cases included. In research, there will always be a trade-off between sample size, time, and resources. This study includes longitudinal data from the 17 Lean interventions implemented at the case hospital in the period between 2008 and 2012, which is a considerable sample and time range in the field of QI. If more interventions were to be included, the results from the study would be correspondingly postponed. However, the chosen study methods will always reflect the circumstances – that is, the particular needs, available resources, and purpose of the study(122). Under these conditions, we should use the most robust design possible, thereby trying to minimize bias and maximize the applicability of the findings.

Internal validity is defined as the extent to which we are able to say that no other variables caused the result. High internal validity ensures that the conclusions of a dissertation actually reflect the object of the study. As reliability is mostly an empirical question, validity is in addition based on subjective and theoretical judgments.

My findings rest on theory; that is, on assumptions of causal relationships between organizational features and the success or failure of Lean interventions. Through the indicated relationships and interdependencies of variables, there is always a risk of

spurious effects(121). My findings indicate that some organizational features relate to Lean's success, but it is impossible to rule out the possibility that a third, unknown variable intervened, and may have caused the effect. An unlimited amount of contextual conditions may affect Lean interventions' outcomes. By shedding light on some, others are neglected; this is why the choice of variables – a choice based on evidence and experience – is so important. The conclusions from systematic literature reviews (gathered through our umbrella review) and reputable international guidelines directed the choice of variables in this study.

Regression analysis rests on certain classical assumptions, such as that the sample is representative of the population, and that the independent variables have been measured without error and are linearly independent of each other. The linear mixed model only estimates relationships, and the conclusions were drawn based on an arbitrary cut-off at five percent to indicate statistical significance, which should not be confused with the size or importance of an effect.

The internal validity of this study was strengthened by the use of mixed methods and multiple sources of evidence (that is, data triangulation). As data was collected from multiple sources when examining the varying outcomes of Lean interventions, the conclusions are more robust. The possible problems of construct validity are also reduced by triangulation, as the phenomena under study are measured in multiple ways. Focus group interviews, a survey, and a panel were employed, in addition to a comprehensive literature review and reading of internal and archival documents at the case hospital. Finally, the expert panel's ranking of the 17 Lean projects was examined in order to verify via regression analysis whether there was a potential relationship between their outcomes and the way they were organized, their targets, their use of time, and other resources. This data was collected from internal quality registries and hospital databases, from which I created a case study database. All respondents, including participants of the focus groups and the panel, and the respondents of the survey, were asked to review the relevant article drafts in order to

rule out any possible misunderstandings or other errors in the author's reporting of the data.

6.2. Contribution to the research field

My contribution to the research field relates to the how, when, and why, rather than to the what, of QI. This work rests on a belief that we have to incorporate structure, process, and outcome in order to understand, and explain, why Lean works – and fails – in health care. Research that adds new knowledge of organizational characteristics, and contextual factors that advance improvement, make it possible to give more definite and precise recommendations to accelerate and spread QI in health care.

This dissertation provides a conceptual framework that represents an analytical and practical tool for further understanding and assessment of variation in the outcome of Lean interventions. The framework emphasizes the importance of context by relating enablers to dimensions of organizational capability and stages of change in the model. We concluded that the characteristics of Lean and the local application should be given more attention, in addition to the organization's cultural and strategic capability. Our findings may contribute to reducing the gap between theory and practice, through a shift in focus from cause–effect to conditional characteristics of efficient organization-wide quality improvements.

We identified 23 interrelated enablers for Lean in the umbrella review, summing up the major findings regarding facilitators for Lean interventions in health care over the latest decade. Unfortunately, the enablers are characterized by vagueness, and as broad and comprehensive determinants that need further specification and practical content in order to guide future effective QI in health care organizations(53). Ranking the 23 enablers by frequency contributes to our knowledge of which components are most critical to Lean's success(89). Additionally, we conducted a survey to cross-check the validity of the identified enablers in one specific hospital, finding that all reviewed enablers, except one, were among the local enablers for Lean's success.

Furthermore, we explored the travel of the idea of Lean within a hospital, emphasizing how local interpretation at three different hierarchical levels of the hospital led to the emergence of various versions of Lean. The argument for this approach is that to understand variations in outcomes of Lean interventions, one must first understand why and how the intervention itself changes. This implies another shift, this time from conditional features to the transformative power of local translation processes.

Especially important in the interpretation of our study is the fact that the respondents were invited to identify local enablers of Lean – that is, the content of the versions of Lean that was developed and applied at the local level – and how these versions eventually relate to the outcomes. This approach provides a window into the local translations of Lean, in terms of the extent to which, how, and why the idea is transformed.

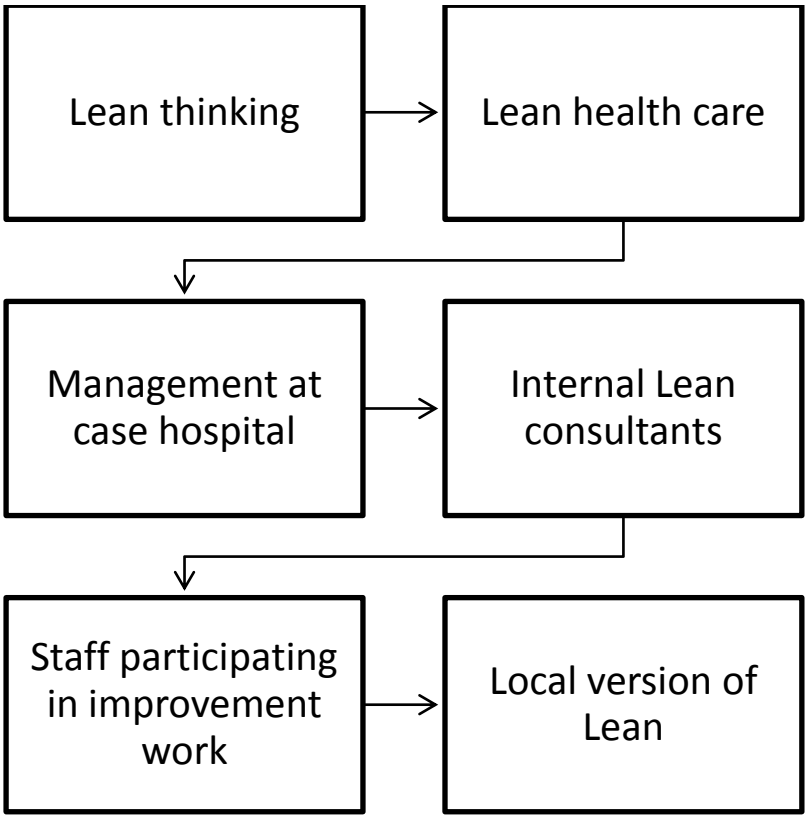
Possible translation rules and regularities are deduced by comparing and analyzing the findings from the literature review, the focus groups, and the survey, making it possible to draw tentative conclusions in relation to whether varying outcomes are a matter of translation. Neither the principles nor the logics are claimed to be results of the analysis. The principles are deduced as characteristics of how Lean is translated to a local version, while the interrelated logics of local translation are introduced as theoretical constructs; that is, conceptual abstractions of phenomena that cannot be directly observed, or abstract statements for categories of observations(123).

These rules and regularities (the practical, the pragmatic, and the skeptical principle), as well as the three logics of translation (translation as a funnel, a wash-out, or a conscious sell-in) add to the field of translation theory, as constructs are the foundation of theory. Constructs are a necessary, but insufficient, condition for theory(123). In this way, our constructs contribute to the research field and future theory building.

I claim that the constructs may also be valid in organizations other than the case hospital, supported by a synthesis of implementation research showing that relevant implementation factors are common across domains(60).

Our conclusion that Lean – when introduced by management, taught and communicated by internal consultants, and applied by staff in practical improvement work – is transformed and translated more than once on its way through the hospital is a contribution to moving the research field of QI in the direction of organizational theory. These findings reflect neo-institutional theory's emphasis on how ideas travel, driven by prophets, followed by disciples, and criticized by revisionists(87, 124). The host organization cannot be portrayed as a naive and unreflective follower. Not many researchers in QI, if any, had touched upon the ideas of this theoretical field at the time the study was conducted. The travel of Lean into and within the hospital can be illustrated as shown in Figure 6.

Figure 6: The travel of lean into and within the hospital



Recently, other studies have supported this course; for example, McCann et al.(19) paid attention to the details of how Lean is sold in the hospital and how staff buy, use, ignore, or reject Lean principles. This work hopefully leads to a tighter – and demanded – coupling between the science of QI and organizational theories(109). I believe that introducing the insight from translation theory to the research field contributes to explaining the lack of evidence in support of Lean(24, 28, 51). Observations of translation processes, which shed light on Lean's plastic nature, have implications that should guide future choices of research methods.

Outcomes may depend on the extent to which, and in what way, Lean is tailored to meet local needs. Local factors, such as the need for credibility, anchoring, realism and patience, are most important for local improvements. On its way through the hospital the idea of Lean is translated, so that it eventually represents something different to the staff than it did to the top management that introduced it. The idea of Lean is partly 'washed out', or edited, by management during their sell-in, and is partly lost in translation via a funnel effect. We claim that translation is a considerable part of the explanation for the varying outcomes of Lean interventions within and among hospitals. The plasticity of lean may be a prerequisite for its popularity, and at the same time a reason for the high variance in outcomes of lean interventions. Careful adaptation to local conditions has also been recommended by other recent studies(40).

Another contribution to the research field is the comparative study of 17 Lean interventions. There are few extant comparative studies, quantitative studies, and studies covering an entire hospital organization, that include multiple Lean interventions. In addition, the data collection for this thesis is comprehensive, and includes longitudinal data, measuring process outcomes before, during, and after the project period (from 2008 until 2012). Longitudinal studies are highly recommended to increase our knowledge of how to succeed in QI.

Inspired by Raab(107), I developed a method for ranking interventions, as an attempt to solve the classic dilemma of 'how to compare apples and pears'. By applying the ranking tool and drawing on solid documentation, the panel ranked 17 interventions with different applications. This method offers some nuance to a simple success-or-failure classification, as it includes impact, sustainability, and effectiveness, and provides qualified judgments rather than judgments based on intuition. Other researchers could benefit from a further development of this tool for ranking interventions.

A univariable and stepwise backward multivariable linear mixed-model regression was applied to analyze associations between the interventions' different organization, targets, resources, and time horizon, and the 17 interventions' impact, sustainability, and effectiveness. A number of previous studies have explored single Lean interventions, and some have studied hospital-wide Lean initiatives; to my knowledge, this is the first study to systematically assess a broad range of organizational factors, the way that they are designed and carried out, and their relationship to successful Lean initiatives over time. Future design and analysis refinement will contribute to the knowledge of change management and promote sound investment in QI.

A mixed-methods approach, including both qualitative and quantitative methods, allows for a more comprehensive picture of Lean interventions. My research may contribute to implementation theory, QI research methods, and the 'readiness' tradition. My findings may also guide policymakers on how to better invest in organizational change management; that is, how to organize their interventions to increase the probability of success. Subsequently, this may lead to more efficient and sustainable QI in hospitals.

6.3. Critical reflections

In the search for answers to my initial question – Why do some Lean interventions succeed while others do not? – I soon realized that Lean interventions' social,

complex, and context-dependent nature makes it hard to draw any solid conclusions on the matter. Sometimes Lean works, and sometimes it does not. Lean is not a panacea or a magic bullet, or a one-size-fits-all approach: Lean requires local tailoring and modification. At the same time, the program should be delivered correctly and by fidelity(62). If everything becomes Lean, then Lean becomes nothing(19). This tension between fidelity and local adaptation is a blank spot in translation theory(86). Lean's plastic nature has implications for both the choice of research method and the conclusions to be drawn, and the research field is influenced by this fact(125). It can be tricky to maneuver in this field, and my research probably suffers from some of the same shortcomings faced by the research field as a whole.

This study's point of departure was observed variance in Lean interventions' efficiency at a Norwegian university hospital. The possibility to generalize the findings may be limited by the way health care is organized and financed in Norway – even though most of Europe has a fairly similar system – and by the fact that only one hospital was studied, even though the data includes a comprehensive, longitudinal set of 17 interventions.

If more hospitals were to be included, new methodological difficulties would arise. The complexity of hospital organizations complicates benchmarking against other hospitals. In the articles, I account for the hospital's size by the number of beds and employees, which should make it possible, within limits, to compare it to similar-sized hospitals.

The study's validity may be confined by the number of cases included. There will always be a trade-off between sample size, time, resources, and scope of the research project. If more interventions were to be included, the dissertation would be correspondingly delayed. Initially, I considered including patient pathways at the hospital that had not been through any Lean interventions, in order to compare 'leanificated' pathways with 'unleanificated' ones, but the samples' methodological challenges were extensive and could not be solved within the scope of this

dissertation. However, it would be interesting to investigate whether and how the 'leanificated' pathways influence the 'unleanificated' ones. Do patient pathways become Lean-infected, and does QI spread without any special efforts being made? If that is the case, there are several dimensions of Lean success and enablers that we would have to add to future QI studies.

In Paper II, our ambition was to show that the idea of Lean in translated on its travel through the hospital, with the claim that translation leads to different versions of Lean interventions that subsequently stimulate varying outcomes. Our data documented that there were varying outcomes of the 17 interventions, and that local actors' perceptions of enablers differed from those identified by literature reviews. In other words, the data documented that enablers for Lean at the case hospital differed from the enablers in health care as such. This argument presupposes that enablers mirror Lean in practice, as the sum of enablers represent the 'recipe' of how to make successful Lean interventions. The enablers functions as substitutes for exact, well defined parts of Lean, as Lean, like other management ideas, unfortunately lacks this refinement, or 'hardware'. The three principles of translation characterize the content of this transformation.

In the same paper, we also showed how the local actors' perceptions of enablers differed, and illustrated the ideas' travel through the hospitals' management and the internal consultants, ending up at the work floor. We categorized our observations according to three logics of translation, as theoretical constructs, which are necessary, but insufficient, conditions for theory. We interpreted that the observed translation led to different versions of Lean. However, we did not collect data covering processes of translation, or data showing which characteristics different local versions of Lean had. Processes of translation were not the subject of this study, but we suggested future research on this topic. The need for research connecting characteristics and outcomes of different local versions of Lean were acknowledged, and experimentally complied with in the mixed-model study (Paper III). However, a

deficiency of process data and a lack of exhaustive data on all aspects of the 17 interventions inhibited the possibility of claiming that varying versions of Lean interventions lead to varying outcomes.

The analysis and conclusions are delimited by the accessibility of data and by the hospital's choice of Lean outcome measures to be process-oriented rather than clinical. Alternative outcome measures could be related to the health care providers' performance (adherence to recommended practice), patient outcome (as quality of life or mortality), surrogate outcomes (as readmissions), or organizational outcomes (such as resource use or sustainability)(25). Consequently, the conclusions are limited in two ways; by the chosen definition of quality and by constraints of the available and measurable data.

Ultimately, the quality of care should be measured by the patients' own experiences. Studies and practice both show that Lean often focuses on internal efficiency and cost control, and not on the value of services provided to patients(3). There is a lack of appropriate methods to measure patients' evaluations, and when patients are asked how they find the quality of care they are generally very positive, regardless of whether the changes made involved real improvement. Therefore, the measurements of quality are limited to surrogate measures, such as overall time spent in care; that is, process-oriented measures.

There may be some loose ends that I have not noticed while conducting my work. There are indeed other organizational features that contribute to Lean's success or failure, even though they are not included here. However, the use of mixed methods and triangulation in the data-collection process strengthens my belief that some of the most important aspects of Lean implementation in hospitals are addressed in this study. Ultimately, there will always be a question of interpretation – and rival explanations will always exist for the observed phenomena. There may be confounding or underlying trends that explain varying outcomes. For example, a lack

of impact from a lean intervention may reflect implementation failure rather than genuine Lean ineffectiveness.

The boundaries between the intervention and the context are rather blurry, and the implementation does not take place in a vacuum(39); Lean interventions consist of multiple, reciprocally interacting elements. The limited number of cases in this study limits the ability to quantify how different variables interact and which variables most influence the ability to achieve success. The relationship between cause and effect is not linear in real life (only in statistics), and it is not possible to control the 'interference' of context. Small effects and causality based on observed data can provide misleading results. Even if results are not statistically significant, it cannot be assumed that they have no effect. In addition, as situation-dependent cumulative processes, Lean interventions evolve over time; they feed back on themselves in ways that may change the conditions that made them work initially. These characteristics limit the possibility of drawing solid conclusions of what works, when, and how. In addition, we cannot rule out the possibility that the observed changes would have happened anyway, regardless of the Lean intervention, or that any other QI method would have gained the same results. It may also be the case that the observed changes are not improvements. Therefore, all conclusions must be presented with caution.

Finally, the shortcomings of Lean that are described by researchers, as in this dissertation, may not be imputed to Lean thinking as a philosophy, but rather to the tools included under the Lean umbrella. The Lean philosophy puts a strong emphasis on people; that is, 'we build people, not only cars'(9). The philosophy also includes respect, a long-term approach, and building a learning organization and culture. Earlier on, I discussed the fact that tools are easier to transfer than philosophy, and that in this case the hospital has in fact translated the former, but not the latter. Authors before me have warned of the consequences of a tool-based approach,

where the essence of Lean is easily lost in translation(4). Thus, perhaps Lean is not to blame for the fluctuating outcomes, because 'it is not Lean that we are doing'.

6.4. Future research and follow-up work

The lack of evidence for Lean interventions is surprising, given the popularity of Lean in health care and elsewhere(28, 43). There are three kinds of evidence that should be searched for: *theoretical*, which underpins and explains how and why QI is expected to work; *empirical*, which reveals under which settings it works best; and *experimental*, providing practical lessons based on experience(21). This requires more research and greater skepticism regarding Lean thinking(108, 109).

Theoretical contributions to the understanding of how Lean is supposed to work are scarce, which has implications for the QI research field. As noted earlier, the need for theory development is crucial to predict the outcome of interventions(48) and to guide sound investments in change management. There is a need for theories that link structure, process, and outcome in order to enable better outcomes of QI initiatives.

I recommend that future research contribute to further specification of the enablers for Lean, including how they interact, intervene, and are interdependent of one another. The main emphasis at present is on possible barriers and enablers for the adaption of Lean, which are unfortunately still characterized by vagueness and a lack of specification. Even though the enablers identified in the literature were supplemented by local, context-specific enablers, there is still a lack of specificity. Broad and general facilitators make it difficult to advise policymakers to arrange and equip the organization in an optimal way for QI work.

Grounded in theory, empirical studies should aim at identifying the settings under which Lean works best, and subsequently, how to ensure sustainability. This requires longitudinal studies. Lean interventions often bring great outcomes, but we know little about the sustainability of these outcomes. If Lean interventions are to be

successful, they must involve continuous improvement; that is, they must not only maintain the improvement of work processes, but also continue to improve these processes over time. Few studies have included a longitudinal aspect; thus, we have only limited knowledge of what makes some improvements last while others vanish. Therefore, we do not know much about how to make a Lean intervention succeed.

The fact that the concept of Lean is characterized by interpretative viability makes it impossible to judge the efficacy of Lean per se. No research will be able to prove definitively whether Lean works – it is all about the local application. I therefore recommend more research on patterns and key factors for successful translation and implementation.

Experimental studies are scarce in QI; this is partly because of the social nature of Lean, as I have discussed earlier. However, the Lean thinking philosophy is grounded in the idea that improvements should be developed by experiments. The Deming's well-known PSDA wheel illustrates the principles of Plan, Do, Study, Act(126), where a planned improvement is tested, evaluated, and (if necessary) adjusted prior to implementation. This PDSA process ensures that the changes made signify real improvements, rather than mere changes. Testing provides practical lessons based on experience.

My methodological choices and developments represent frameworks for follow-up work, by which hospital QI interventions can be tested. Consequently, more work on this subject can ensure more accurate advice on how to better invest in QI and organizational change management.

7. Main conclusions – Is there a cure for the lack of evidence?

The findings from this study contribute to reducing the gap between the health services we ought to provide and the health services we do provide, by shedding light on conditional attributions of successful Lean interventions. The status of the research field and the nature of Lean guide us to shift the focus from whether Lean interventions work to why, when, and how they work. The aim of this dissertation was to better understand the varying outcomes of Lean interventions, within the context of a single hospital.

The umbrella review showed that characteristics of Lean thinking and Lean's local application should be given more attention, in addition to the host organization's cultural and strategic capability (organizational readiness for QI). The most frequently mentioned enablers for Lean in hospitals were: management engagement, cultural support, accurate data, training, teamwork, and physician and staff involvement. Altogether, this coincides with this dissertation's argument that more attention should be given to the influence of context when attempting to explain why some interventions succeed while others fail.

A conceptual framework that incorporates the complex social and organizational context of interventions was developed for the identification and analysis of enablers for Lean. The framework differentiates between four dimensions and four domains, making it possible to see where and when different enablers are activated. In total, the enablers represent a theory; that is, a picture of what, where, and how Lean is anticipated to work in hospitals.

A common argument for a context approach is that outcomes vary because contexts also vary. To explain why outcomes of Lean interventions vary in seemingly similar contexts, we chose a slightly different approach; that is, explaining the transformative power of local translation processes. Varying outcomes are explained by changes in the intervention itself. Managements', consultants', and staff members' perceptions of enablers for Lean interventions represent the prevailing version of Lean within the

hospital. Two out of three of the most important enablers were local ones that had not been identified in the umbrella review. Among these were structural support from the management, palpable measures, a bottom-up approach, credibility, realism, and patience. The translation of Lean was guided by three principles for translation: practical, pragmatic, and skeptical. We found that the further the idea travels within the organization, the more practical, pragmatic, and skeptical the prevailing version of Lean becomes.

We found that management, consultants, and staff each preferred different enablers, and that the enablers' relative importance diverged. This indicates that there is more than one local version of Lean, and that Lean is transformed and translated more than once on its way through the hospital. Assuming that the enablers identified by the review mirror Lean in health care, then only the consultants can be said to have stayed true to Lean.

While three principles (practical, pragmatic, and skeptical) were deduced as characteristics of how Lean was translated, three interrelated logics of translation were introduced as theoretical constructs to categorize the observed translation. These were the logic of translation as a funnel, as a partial copying (wash-out), and as a conscious sell-in of the least controversial parts of Lean. We argue that different translation processes bring about work-floor versions of Lean that diverge from the original Lean approach. In other words: translation makes a difference.

Firstly, these conclusions shed light on the problems of measuring effects and provide evidence regarding outcomes of Lean. Put bluntly, Lean is not Lean; rather, it is usually numerous materialized versions of Lean, which complicates measuring effects. Translations make a considerable contribution towards explaining the lack of evidence for Lean. Secondly, the way translations are performed can be decisive for Lean interventions' outcomes. Outcomes will depend on the way Lean is tailored to meet local contextual needs while balancing the local circumstances, the need to stay true to the Lean philosophy, and the core elements of the methodology.

The data analysis from the 17 initially implemented Lean interventions assessed how varying designs, resources, established targets, and time horizons affected Lean's success, thereby increasing our understanding of how organizational features relate to success. Based on a scaling tool for ranking interventions, an experienced Lean panel ranked the 17 interventions by their impact on outcome, sustainability, and effectiveness. Correlation between impact, sustainability, and effectiveness was measured using correlation coefficients, which showed a distinct correlation between interventions' sustainability and effectiveness.

A total of 30 percent of the interventions were assessed as significantly successful, 60 percent as moderately successful, and 10 percent as minimally successful.

A univariable and stepwise backward multivariable linear mixed-model regression was applied to analyze associations between the interventions' different organization, targets, resources, and time horizons, and the 17 interventions' impact, sustainability, and effectiveness.

The comprehensive project design utilizing steering, project, focus, and implementation groups related to both sustainability and effectiveness in this study, as did improvements across divisions. Furthermore, the broad, multidisciplinary team composition related to both the comprehensive design and improvement across divisions, as it impacted the interventions' success. However, there was no statistically significant relationship between success and the participation of physicians, as is often argued. The context heavily influences the process design, and a broad representation of all professions concerned seems to be more important than the physicians' isolated representation. Projects with considerable participation of employee and safety representatives were related to high impact, sustainability, and effectiveness. This was also the case for top-management representation concerning impact, but there was a negative effect regarding effectiveness; that is, the more top-management, the lower the ranking of the interventions. This is surprising, and should be given further attention in future research, especially

because leadership is among the most attributed factors for Lean in the literature, and because top-level organizational commitment is viewed as a necessity for true improvement.

Interventions that were dominated by improvements for patients were the only statistically significant independent variable concerning improvement targets. It may be that improvements for patients trigger willingness and motivation for change among health care workers, more than efficiency and better work environments. There was no statistically significant relation between top-down or bottom-up initiatives and success in this study. Likewise, there were no relations between the number of goals, the number of indicators, and the interventions' success, even though Lean management books suggest that a few, palpable goals enable QI.

There was a statistically significant relationship between the impact on the outcome of the interventions in this study and the hours spent in work-groups. This was not the case regarding the number of participants and the resources used for rebuilding, even though the literature commonly states that successful Lean interventions require considerable investment in resources, time, and effort. These findings imply that the composition of work groups, including multiple professions, is more important than the number of participants per se.

The starting point and duration of each project, from initiation to implementation, did not relate to the success of the interventions, although one might expect that experience and learning would lead to better results over time. The first interventions were successful, those in the middle showed moderate success, and the later ones attained greater success. One explanation for this observation may be that external consultants guided the first interventions, and when these experts left, the hospital needed to build up internal competence and experience to attain similar success again.

Knowledge and awareness of the translation that occurs when an idea encounters practice may contribute to more accurate choices, implementation, and operation of

Lean-improved patient pathways. Our findings also add to the knowledge base of enablers for the implementation of reform ideas in organizations. Policymakers are recommended to tailor future implementation of QI interventions to fit the local context, which will eventually affect the outcome of care.

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Paper I, Paper II and Paper III